AWARD NUMBER: W81XWH-12-1-0619

TITLE: Building a Family Systems Model to Promote Adherence to PTSD Treatment

PRINCIPAL INVESTIGATOR: Laura A. Meis, PhD

CONTRACTING ORGANIZATION: University of Minnesota **Minneapolis, MN 55455-2070**

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Despite the success of evidence-ba	ased psychotherapies	(EBTs) for PTSD. o	nlv half of pa	atients recover, and 1 in 5 will drop		
out of treatment altogether. One central and underutilized resource in keeping Veterans' in treatment and helping them to gain						
the most from these treatments is Veterans' families, yet evidence-based strategies for how to best utilize families in						
treatment have yet to be established. We will survey approximately 378 Veterans and 185 of their significant others before						
and after participation an EBT for PTSD across three VAs (Minneapolis, Palo Alto, and Phoenix). Data collection for these						
surveys is ongoing. We will then conduct in-depth interviews with Veterans who attended an EBT yet still suffer with PTSD,						
their significant others, and their providers, to identify how to help Veterans get the most out of treatment. Findings will provide						
the evidence-base for when, how, and why family involvement can improve adherence to EBTs for PTSD and treatment						
outcomes. By studying Veterans and their families as they participate in EBTs for PTSD, we will develop a comprehensive and						
family-focused understanding of why some service members do not finish treatment and why those who do sometimes fail to						
fully recover. From these findings, we will develop guidelines for providers, outlining how to involve the families in EBTs for						
PTSD, and an initial protocol for a family-centered intervention to improve adherence to EBTs for PTSD.						
15. SUBJECT TERMS						
PTSD, couples, family, psychoth	erapy					
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1. INTRODUCTION:

Evidence-based psychotherapies (EBTs) for posttraumatic stress disorder (PTSD) result in clinically significant symptom relief for many patients and are recommended as first-line treatments by the VA/DOD Clinical Practice Guideline. Despite the success of these interventions, only half of patients receiving them can be expected to recover, and 1 in 5 will drop out of treatment altogether. One central and underutilized resource for maximizing treatment gains is family. PTSD has dramatic negative impacts on social and family relationships, and distress in these relationships predicts negative treatment outcomes. Veterans express strong interest in family-involved PTSD care and multiple organizations, including the VA and DoD, recommend prioritizing family involvement in the treatment of PTSD. Our long term objective is to build evidence-based strategies for how to involve families in EBTs for PTSD to improve treatment outcomes. In order to build these strategies, we must first observe service members and their families as they naturally participate in EBTs as delivered in real-world settings to identify when and how to intervene. The goal of this project is to develop a family-systems model for understanding adherence to EBTs for PTSD and to identify preliminary strategies for family involvement adherence and outcomes.

2. KEYWORDS:

PTSD, evidence based psychotherapy, family, psychotherapy adherence

3. ACCOMPLISHMENTS: The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

The major goals of the project include, 1) To determine the influence of family on treatment adherence among service members referred to EBTs for PTSD, 2) To evaluate a family-systems model of mechanisms of treatment adherence, 3) To obtain an in-depth understanding of the experiences of patients who adhere less to treatment through qualitative, open-ended interviews.

This report covers 9/30/14 through 9/29/15 (Months 25-36 in the statement of work). Below is a list of milestones and planned periods of completion for each milestone (in study months: "Mo.") and our progress towards those goals, as of this time.

- <u>Milestone 3</u>: Complete Time 1 Survey Data Collection for Objective 1 and 2; <u>Planned period of</u> <u>completion</u>: Mo. 12-26; We are 100% complete for Time 1 data collection (465 Veterans enrolled of the 378 target; 246 support persons of the 185 targeted – oversampling was intentional to address challenges discussed below)
- <u>Milestone 4</u>: Complete Qualitative Interview Data Collection for Objective 3; <u>Planned period of completion</u>: Mo. 5-25; We are 100% complete for Veterans' interviews (66 interviews complete)
- <u>Milestone 5:</u> Complete Time 2 Survey Data Collection for Objective 1 and 2; <u>Planned period of completion</u>: Mo. 7-29; We are 100% complete for Time 2 data collection (288 Veterans surveyed of the 265 target; 177 support persons of the 130 target oversampling was intentional to address challenges discussed below)
- <u>Milestone 6</u>: Create Survey Data Set for Objective 1 and 2; <u>Planned period of completion</u>: Mo. 10-28; Time 1 datasets are complete. Time 1 data is scanned, computer syntax has been written, and data cleaning processing is underway (50% complete)
- <u>Milestone 7</u>: Prepare Qualitative Interview Data for Analysis for Objective 3; <u>Planned period of completion</u>: Mo. 18-25; Transcription is 80% complete and de-identification of interview data is 50% complete.
- <u>Milestone 8</u>: Complete Data Analysis for Objectives 1 and 2; <u>Planned period of completion</u>: Mo. 27-31; Due to delays in data collection described in prior reports and below, we requested and were granted a no cost extension in order to complete this Milestone in the upcoming No Cost Extension period (through 9/30/16); This milestone is 30% complete.
- <u>Milestone 9</u>: Complete Data Analysis for Objectives 3; <u>Planned period of completion</u>: Mo. 22-29; Due to delays in data collection described in prior reports and below, we requested and were grant a no cost extension to complete this Milestone; This milestone is 20% complete.
- <u>Milestone 10</u>: Identify Intervention Targets and Strategies; <u>Planned period of completion</u>: Mo. 27-31); Due to delays in data collection described in prior reports and below, we requested and were grant a no cost extension to complete this Milestone; This milestone is 20% complete.
- <u>Milestone 11</u>: Dissemination Activities/Products and Deliverables; <u>Planned period of completion</u>: Mos. 24-36). Similarly, progress towards this Milestone has also be delayed. We have begun presenting preliminary findings at scientific meetings and in recent MOMRP In Progress Review.

What was accomplished under these goals?

The third year of the grant was largely devoted to data collection and monitoring response rates. We have completed Time 1 and Time 2 survey data collection and completed qualitative interviews. The specific objectives of this period are outlined above in the Milestones review. As discussed in prior Quarterly and Annual Reports, data collection was extended to reach our enrollment goals. We had identified problems with the rate of referrals from one study site during 2012-2013. As a result, we requested a site addition (Charleston VA) and revised our statement of work to extend the time devoted to Time 1 data collection. Additional delay was created by unique features of processes at the Charleston VA. Clinic processes led to greater rates of Veterans disagreeing with the treatment plan after study enrollment. We extended data collection to ensure enough participants were enrolled, who agreed with the treatment plan, to address our primary aims. Experience with post-treatment survey administration (Time 2) also demonstrated that some individuals were not finished with treatment within four months. For those who are not finished with treatment, we delayed administration of their Time 2 survey until treatment is complete (typically administering Time 2 surveys four to six months after Time 1). Consequently, Time 2 survey administration to Veterans and their Support has recently ended of the grant period. Consequently, we requested and were grant a no-cost extension to allow our study team to finalize processing of this data, completion of our final datasets, completion of our final data analysis, and completion of final tasks (i.e., identification of family intervention targets and strategies). Data sets are being cleaned and finalized and preliminary data analysis has begun.

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

How were the results disseminated to communities of interest?

Final data analyses are not complete. We have presented preliminary findings at the annual meeting of the International Society of Traumatic Stress Studies (see citations below) and at an In Progress Review on 9/11/15.

Meis, L. A., Spoont, M. R., Erbes, C. R., Polusny, M. A., Noorbaloochi, S., Hagel Campbell, E., M., Bangerter, A. K., Eftekhari, A. Kattar, K., A., & Tuerk, P., W. (November, 2014). Can families help shape veteran's opinions of and response to evidence based treatments for PTSD? Poster presentation at the 30th annual meeting of the International Society of Traumatic Stress Studies, Miami, Florida.

ABSTRACT: We examined the role of family beliefs and family involvement in understanding Veteran's beliefs about and response to Prolonged Exposure (PE)/Cognitive Processing Therapy (CPT) for PTSD. Data collection is ongoing. We surveyed 246 Veterans and 137 of their family members as they began PE/CPT and again 4 months later (Projected N by conference=362 Veterans;190 family). We conducted preliminary multiple regressions with the 72 Veterans who discussed their treatment with family. *Results*: Veterans reporting any therapist-to-family contact experienced greater self-efficacy in completing PE/CPT (B = .23, p < .045), perceived PE/CPT as more important (B = .41, p = .001), and were more likely to attend an adequate dose of PE/CPT (OR: 4.20, p = .027). Veterans whose family members felt PE/CPT was more important were more motivated for treatment (B = .43, p < .001), expressed greater self-efficacy for PE/CPT completion (B = .29, p = .017), and perceived treatment as more important (B = .41, p = .001). Contrary to expectations, relationship strain was not uniquely associated with the outcomes examined. *Conclusions*: Preliminary results paint a complex picture of the role of family in predicting adherence to evidence based treatments for PTSD and in understanding the Veteran's own perceptions of EBTs for PTSD.

Meis, L. A., Spoont, M. R., Erbes, C. R., Polusny, M. A., Noorbaloochi, S., Hagel Campbell, E., M., Bangerter, A. K., Eftekhari, A. Kattar, K., A., & Tuerk, P., W. (November, 2014). The Role of individual beliefs and family involvement in understanding Veterans' commitment to evidence based treatments for PTSD. Poster presentation at the 30th annual meeting of the International Society of Traumatic Stress Studies, Miami, Florida.

ABSTRACT: We examined if beliefs about Prolonged Exposure (PE)/Cognitive Processing Therapy (CPT), therapeutic alliance, and family involvement in care predicted Veterans' adherence to and perceived importance of PE/CPT. Data collection is ongoing. We surveyed 246 Veterans and 137 of their family members as they began PE/CPT, coded patient records, and surveyed them again 4 months later (Projected N by conference=362 Veterans;190 family). We conducted preliminary multiple regressions with 131 Veterans, controlling for baseline PTSD. Homework compliance was greater among those with stronger therapeutic alliances (β =.38;p=.004) and family who were unaware of PE/CPT engagement (β =-.23;p=.031); associations with self-efficacy (β =.26;p=.098) and treatment fit

 $(\beta=.33; p<.075)$ approached significance. Veterans felt CPT/PE was more important when they had greater self-efficacy to complete it ($\beta=.71; p<.001$); associations with family awareness of PE/CPT approached significance ($\beta=.08; p=.098$). No predictors uniquely predicted CPT/PE completion. Final analyses will examine the larger sample through multilevel modeling. *Conclusions*: Preliminary analyses suggest that self-efficacy to complete an CPT/PE, therapeutic alliance, and disclosure of CPT/PE engagement are important predictors of commitment to evidence based treatments for PTSD.

In Progress Review

FINDINGS PRESENTED: Data analyses are ongoing, but preliminary findings indicate Veterans' perceptions of their families substantially influence Veterans' attendance and treatment completion. When controlling for baseline symptoms and other covariates, we found that Veterans who had simply told a family member about their treatment were nearly 8 times more likely to complete at least a minimal dose of therapy (8 sessions; OR = 7.1, p < .001). Additionally, if families encouraged Veterans to face things they have avoided, Veterans were 3 times more likely to reach this minimal dose (OR=2.8; p=.037). Finally, when families encouraged Veterans to quit, Veterans were nearly 13 times more likely to quit treatment before session 8 (OR = 12.8; p = .008). Raw proportions indicate 80% of Veterans who were encouraged to quit, did so prior to attending 8 sessions, while 39% of those who were not encouraged to quit ended treatment early.

Families likely affect Veterans' attendance by 1) influencing Veterans' opinions about trauma-focused psychotherapy and 2) influencing Veterans' willingness to attend, regardless of their own ambivalence about the treatment. Using the same series of controls, we found that Veterans whose families' encouraged them to confront avoided tasks were more likely to find EBPs credible, and subsequently attended more treatment sessions (bootstrapped indirect effect: $\beta = .08$, p < .05). Family perceptions of EBPs also directly predicted future session attendance, even after accounting for Veterans' own beliefs about credibility ($\beta = .33$, p = .043). In fact, we found a significant interaction between Veteran and family perceptions of treatment credibility ($\beta = .66$, p = .017). When families were strongly invested in the credibility of the EBP, Veterans' own opinions about the treatment mattered less to whether or not they stayed in treatment. This suggests that when families feel strongly about treatment's credibility, Veterans may consider their own beliefs about the treatment less in deciding whether or not to complete treatment, perhaps to please their family members.

We found that while 70% of Veterans entering EBPs (and 94% of their family members) expressed interest in family-inclusion in Veteran care, only 17% of providers had any contact with Veterans' families. Among participants with interest in family-involvement in care, most felt family inclusion could make treatment more effective (98% Veterans, 99% family members) and family members were more interested in direct (attending with Veteran) than in indirect participation (support groups; 91% vs 74%, t[156]=6.51, p < .001). These findings highlight the frequency with which providers are missing opportunities to enlist ready and willing family members in helping Veterans get the most from their PTSD care.

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

Over the next year, we will complete data cleaning and preparation and our final analyses. We will use these findings identify intervention targets for involving family in evidence based treatments for PTSD, based on data analysis and team feedback.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

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

Data processing is ongoing. Nothing to Report.

What was the impact on other disciplines?

Data processing is ongoing. Nothing to Report.

What was the impact on technology transfer?

Data processing is ongoing. Nothing to Report.

What was the impact on society beyond science and technology?

Data processing is ongoing. Nothing to Report.

5. CHANGES/PROBLEMS: The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change

Nothing to Report.

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

As discussed above, we have taken several steps over the course of the grant to address problems with low rates of referrals from a study site. These solutions have allowed us to meet our study enrollment goals, but have delayed data processing. Currently, all data is collected and is being processed and analyzed. Over the course of our no-cost extension period, we will complete our final analyses. No problems are currently anticipated.

Changes that had a significant impact on expenditures

Nothing to Report.

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals.

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

- **6. PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."
- **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.

Meis, L. A., Spoont, M. R., Erbes, C. R., Polusny, M. A., Noorbaloochi, S., Hagel Campbell, E., M., Bangerter, A. K., Eftekhari, A. Kattar, K., A., & Tuerk, P., W. (November, 2014). Can families help shape veteran's opinions of and response to evidence based treatments for PTSD? Poster presentation at the 30th annual meeting of the International Society of Traumatic Stress Studies, Miami, Florida.

Meis, L. A., Spoont, M. R., Erbes, C. R., Polusny, M. A., Noorbaloochi, S., Hagel Campbell, E., M., Bangerter, A. K., Eftekhari, A. Kattar, K., A., & Tuerk, P., W. (November, 2014). The Role of individual beliefs and family involvement in understanding Veterans' commitment to evidence based treatments for PTSD. Poster presentation at the 30th annual meeting of the International Society of Traumatic Stress Studies, Miami, Florida.

• Website(s) or other Internet site(s)

Nothing to Report.

• Technologies or techniques

Nothing to Report.

• Inventions, patent applications, and/or licenses

Not applicable.

• Other Products

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Laura Meis Project Role: Principal Investigator No change

Name: Afsoon Eftekhari Project Role: Site Investigator (Palo Alto site) No change

Name: Karen Kattar Project Role: Site Investigator (Phoenix site) No change

Name: Peter Tuerk Project Role: Site Investigator (Charleston site) No change

Name: Martina Radic Project Role: Research Assistant (Charleston site) Nearest person month worked: 6 Contribution to Project: Dr. Radic assisted with study activities at the Charleston site and performed administrative and study tasks, such as site IRB submissions, data pulls and data entry.

Name: Tina Velasquez Project Role: Project Coordinator Nearest person month worked: 8 Contribution to Project: Ms. Velasquez has managed and coordinated project activities across all sites and has performed such tasks liaison between staff at all sites and with respective companies, study administrative tasks, recruitment, project management, IRB, database management and design, data entry and verification, transcription, etc. Funding Support: DoD

Name: Kimberly Stewart Project Role: Project Coordinator Nearest person month worked: 2 Contribution to Project: Ms. Stewart took over after Ms. Velasquez left the project this spring. Ms. Stewart has managed and coordinated project activities across all sites and has performed such tasks liaison between staff at all sites and with respective companies, study administrative tasks, recruitment, project management, IRB, database management and design, data entry and verification, transcription, etc. Funding Support: DoD

Name: Melissa Polusny Project Role: Co-Investigator (MN site) No change Name: Christopher Erbes Project Role: Co-Investigator (MN site) No change

Name: Michele Spoont Project Role: Co-Investigator (MN site) No change

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.

<u>Organization Name</u>: Minneapolis VA Health Care System <u>Location of Organization</u>: Minneapolis, MN

Partner's contribution to the project (identify one or more)

- Study activities take place at the Minneapolis VA and Minneapolis investigators are located at the Minneapolis VA
- Facilities (e.g., project staff use the partner's facilities for project activities) Organization Name: Phoenix VA

Location of Organization: Phoenix, AZ

<u>Partner's contribution to the project</u> (identify one or more)

• Study activities take place at the Phoenix VA and Phoenix investigators are located at the Phoenix VA

• Facilities (e.g., project staff use the partner's facilities for project activities) Organization Name: Palo Alto VA

<u>Organization Name</u>: Palo Alto VA

Location of Organization: Palo Alto, AZ

<u>Partner's contribution to the project</u> (identify one or more)

- Study activities take place at the Palo Alto VA and Palo Alto investigators are located at the Palo Alto VA
- *Facilities (e.g., project staff use the partner's facilities for project activities)*

Organization Name: Charleston VA

Location of Organization: Palo Alto, AZ

Partner's contribution to the project (identify one or more)

- Study activities take place at Charleston VA and investigators are located at the Palo Alto VA
- Facilities (e.g., project staff use the partner's facilities for project activities)

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <u>https://ers.amedd.army.mil</u> for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on <u>https://www.usamraa.army.mil</u>) should be updated and submitted with attachments.

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

None.