

AD _____

Award Number: W81XWH-10-2-0074

TITLE: PTSD and Substance Abuse

PRINCIPAL INVESTIGATOR: Dr. Lisa Najavits

CONTRACTING ORGANIZATION: Treatment Innovations, LLC
Newton Centre, MA 02459

REPORT DATE: August 2011

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

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-08-2011		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 1 AUG 2010 - 31 JUL 2011	
4. TITLE AND SUBTITLE PTSD and Substance Abuse				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-10-2-0074	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr. Lisa Najavits E-Mail: info@seekingsafety.org				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Treatment Innovations, LLC Newton Centre, MA 02459				8. PERFORMING ORGANIZATION REPORT NUMBER	
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 Substance use disorders (SUD) and Posttraumatic stress disorder (PTSD) are some of the most prominent psychiatric disorders among Service Members (SMs), including the Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) cohort. These disorders sometimes go untreated due to SMs lack of awareness, access to care, or stigma about accessing care. Seeking Safety (SS) has been established as an effective model for co-occurring SUD/PTSD. The purpose of this study is to evaluate the SS manual and Adherence Scale for implementation in a military setting. We have not started to collect data and do not have any research findings to report.					
15. SUBJECT TERMS PTSD, Substance Use Disorder, Seeking Safety					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 9	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	8
Reportable Outcomes.....	8
Conclusion.....	9
References.....	9
Appendices.....	9

INTRODUCTION

Substance use disorders (SUD) and Posttraumatic stress disorder (PTSD) are some of the most prominent psychiatric disorders among Service Members (SMs), including the Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) cohort. These disorders sometimes go untreated due to SMs lack of awareness, access to care, or stigma about accessing care. Seeking Safety (SS) has been established as an effective model for co-occurring SUD/PTSD. The purpose of this study is to evaluate the SS manual and Adherence Scale for implementation in a military setting. We hypothesize that the Seeking Safety manual and Adherence Scale can be successfully used in the military setting, with “success” defined as 80% or higher satisfaction and feasibility on this project by at least 80% of participants.

BODY

In order to best describe the research accomplishments associated with each task outlined in the approved Statement of Work, we include the approved Statement of Work for the first 12 months of this project in italics below. Following each task listed in the Statement of Work, we provide a description of our progress on that task.

STATEMENT OF WORK

Task 1: Study startup (months 1-6)
Apply for human subjects approval at each site

This has been completed. We completed the administrative review, the scientific review and the IRB review at Walter Reed Army Medical Center (WRAMC). The IRB determined that this study was a Quality Improvement Project rather than a research project. Since both Fort Jackson and Tripler are under the oversight of the WRAMC IRB, they also agreed that this was a Quality Improvement Project. We are currently awaiting approval from the Human Research Protections Office (HRPO) that this is a Quality Improvement Project. As a Quality Improvement Project we would still be conducting the study with the same scientific goals as originally planned. As soon as we receive official approval from HRPO we can begin data collection on this project. Note that this study start-up has taken longer than the original estimated time due to numerous repeated requests by the WRAMC IRB for resubmissions of the application, as well the loss of two sites originally planned for the study (Portsmouth Naval Hospital and Air Force) due to our points-of-contact at these sites leaving.) However, the PI was able to engage two new sites Fort Jackson and Tripler Army Medical Center, which will allow us to complete the project as planned in terms of recruitment goals.

Establish regular conference calls with sites

We have established regular calls with each site to discuss progress on the project and ongoing tasks that need to be completed. We are also organizing consultation calls with a Seeking Safety senior trainer for each of the sites to speak with twice per month for the first two months of the study, followed by ongoing monthly calls. These calls will allow the clinicians at each site to ask any questions regarding administering the Seeking Safety Therapy and also to discuss any problems clinicians are having adhering to the SS protocol.

Train staff as needed

We hired and trained a project director for the study (Dr. Nicole Capezza). We also hired a research assistant (John Lung, BS). Associate investigators have been identified at each military site and have been trained by the site PI on the study goals and objectives. The associate investigators will assist the site PI with recruitment efforts, data collection, and other tasks. We are working with each site to identify a research assistant. Research assistants have been located for both WRAMC and Fort Jackson. Tripler is working with us to identify possible candidates from within their site. We will begin training the onsite RAs within the next few weeks.

In addition, Dr. Rebecca Beardsley, our site PI at Tripler Army Medical Center, has been receiving training on PTSD/SUD treatment via monthly conference calls with Lisa Najavits and others.

Develop data entry procedures for on-going data entry

We identified an electronic method of data collection that is acceptable to the military sites' IRBs (using Adobe Acrobat). This allows us to eliminate hand entered data entry procedures, as all measures for patients, clinicians and study staff will be filled out via computer and saved electronically. We created all of the study assessments in Adobe (see Appendix A for the Baseline measures to be used. As many of the measures overlap at the Time 2 and Time 3 follow-up we will not include them here, but can provide them on request).

Set up systems for tracking data progress

We have created various tracking logs using Excel for both clinicians and clients. For clinicians we have created logs to track completion of assessments, sessions of Seeking Safety that have been conducted, and we have developed a flow chart for clinicians to use to help them follow the study protocol and complete all study assessments. For clients, we have created a log to track completed assessments and when follow-up assessments are due. These logs will be kept up to date by the onsite Research Assistant and will be checked for accuracy by the Project Director.

Set up standard operating procedures

We are working with each site to develop standard operating procedures. We are working with the PIs and AIs on how best to collect the data needed for the study and to implement the SS program with the least disruption to their facilities. This is a continuous task as we encounter new questions or topics from a site regarding how to handle a given situation regarding data collection and other procedural issues.

Begin the initial Delphi procedure with our consultant team (which does not require IRB approval)

We have not started the Delphi procedure. As stated above in the Statement of Work, we could start this procedure prior to IRB approval; however, we decided to wait for the IRB approval before beginning this procedure to ensure that we have the complete and final list of study consultants before we begin to implement this aspect of the project. The Delphi Method utilizes interviews with experts to gain information on a give topic. For our purposes it is best that we have the complete list of consultants in place before we begin the process of interviewing and assigned chapters of the Seeking Safety Manual for the experts to review. As

detailed below, we are awaiting final approval to begin the study from the Human Research Protection Office.

However, related to the Delphi method, we have created a General Feedback log to be completed by clinicians, site PIs, and site AIs so that they have a place to record any comments they have regarding conducting the SS therapy (see Appendix B).

Task 2: Adapt the SS manual and adherence scale for military use (months 6-22)

Months 7-8: obtain T1 assessment on the first half of the sample of clients and clinicians; then provide them with SS materials.

Months 9-10: create the initial draft of the military SS monograph and adherence scale (based on feedback obtained in prior months).

Months 10-11: Obtain T2 assessment from first half of sample.

Months 11-13: obtain T1 assessment from the second half of the sample; and continue Delphi procedure with consultants.

Due to IRB delays we have not been able to achieve these goals in the expected timeframe above. We have been working with our military sites and in particular with WRAMC since September 2010 to complete the necessary forms for the review process (forms included, the Human Research Protocol Application, Patient Consent Form, Clinician Consent Form, HIPPA Authorization Form, among other forms). We received approval from the administrative review and then proceeded to the scientific review at WRAMC. We had substantial delays on the scientific review. Dr. Lande (the on-site PI) had to present to the committee on three occasions following revisions to the protocol each time. He completed the third (and final) scientific review meeting on April 19, 2011. The protocol was then sent to the human subjects review at WRAMC. The determination of the IRB at WRAMC was that this project was a Quality Improvement Project and not a Research Project. Since both Fort Jackson and Tripler are under the oversight of the WRAMC IRB, they also agreed that this was a Quality Improvement Project. We are currently awaiting approval from the Human Research Protections Office (HRPO) that this is a Quality Improvement Project. Once we receive approval, we can begin data collection on this project.

Below we include a list of other progress we have made on the study (i.e., tasks we have completed that were not listed on the Statement of Work).

Conducted Seeking Safety Trainings at Each Military Site

- Dr. Kevin Reeder, a senior trainer on Seeking Safety and a veteran himself, conducted the training at Walter Reed Army Medical Center on May 13, 2011
- Dr. Martha Schmitz, a senior trainer, conducted the training at Tripler Army Medical Center on May 26, 2011.
- Dr. Reeder conducted the training at Fort Jackson on June 20, 2011.

Located a New Study Site

- We have identified one additional military site that could potentially agree to participate in this study. We have been in contact with Dr. Anthony Dekker at Fort Belvoir, and have tentative plans for Fort Belvoir to participate and if so, will schedule the onsite Seeking Safety Training for early September. They are also working on identifying the site PI and AIs that will work on the study, and we have discussed the IRB procedure at this location. They are awaiting information

regarding the structure of their IRB system at the new facility that will be opening on August 10, 2011.

Scientific Achievements

- Dr. Najavits presented on this study at the Feb 1-2, 2011 DoD conference in Fredericksburg, MD.
- Dr. Najavits presented a two-hour training on Seeking Safety on March 21, 2011 at the VA/DoD Continuum of Care: Battlefield Healthcare Summit in Washington DC.
- Dr. Najavits is now collaborating with Valerie Standler, PhD, another DoD investigator, on a paper on dissociation, PTSD, and substance use disorder, using DoD Naval Health research data.
- Dr. Najavits presented at the national conference, "Complexities and Challenges of PTSD and TBI" to be held in Boston on Friday, Saturday, and Sunday, July 15-17, 2011 in Boston,
- Dr. Najavits presented on July 18, 2011 in Irvine, CA on Seeking Safety at the Institute of Medicine *Prevention, Diagnosis, Treatment and Management of Substance Use Disorders in the U.S. Armed Forces*.

List of articles completed since the beginning of the grant period

1. Norman, S.B., Wilkins, K.J., Tapert, S.F., Lang, A.J., Najavits, L.M. (2010). A pilot study of Seeking Safety therapy with OEF/OIF Veterans. *Journal of Psychoactive Drugs*.
2. Najavits, LM, Kivlahan, D, Kosten, T (2010). A national survey of clinicians' views of evidence-based therapies. *Addiction Research and Theory*.
3. Najavits, LM, Norman, SD, Kivlahan, D, Kosten, T (2010). Improving PTSD/substance abuse treatment in VA: A survey of providers. *American Journal on Addictions*.
4. Najavits, LM (2010). Treatment utilization of pathological gamblers with and without PTSD. *Journal of Gambling Studies*.
5. Najavits, LM (2010). Treatments for PTSD and pathological gambling: What do patients want? *Journal of Gambling Studies*.
6. Brady, LC, Najavits, LM, Fallot, R, Heckman, J, Touissant, D, Veysey, B (2010). Does criminal involvement matter? A study of women with co-occurring disorders in a multisite national trial. *Mental Health and Substance Abuse: Dual Diagnosis*.
7. Najavits, LM, Johnson, KM, Meyer, T. (in press). Pathological gambling and posttraumatic stress disorder: A study of the co-morbidity versus each alone. *Journal of Gambling Studies*.
8. Najavits, L. M. and M. Walsh (in press). Dissociation, PTSD, and substance abuse: An empirical study, *Journal of Trauma and Dissociation*.
9. Peller, A. J., Najavits, L. M., Nelson, S., LaBrie, R. A., Shaffer, H.J. (in press). PTSD Among a Treatment Sample of Repeat DUI Offenders.

10. Capezza, N., & Najavits, L. M. (under review). Trauma counseling in substance abuse treatment facilities: Rates and characteristics of over 10,000 programs. Psychiatric Services.
11. Miller, N. L., & Najavits, L. M. (in press). Creating trauma-informed correctional care: A balance of goals and environment. *European Journal of Psychotraumatology*,
12. Najavits, L.M., & Cottler, L. (in press). Treatment Improvement Protocol: Trauma and substance abuse. Washington, DC: Center for Substance Abuse Treatment / Department of Health and Human Services.
13. Najavits, L.M. (in press). Proximal influences on addiction. In H.J. Shaffer, D. LaPlante & S. Nelson (Eds.), *American Psychological Association's addiction syndrome handbook*. Washington, DC: American Psychological Association.
14. Najavits, L.M., Highley, J., Dolan, S., Fee, F. (in press). Substance use disorder, PTSD, and traumatic brain injury. In J. Vasterling, R. Bryant, T. Keane (Eds). *PTSD and Mild Traumatic Brain Injury*. New York: Guilford Press.
15. Najavits, L.M. (2010). Trauma-Informed Care. In D. Smelson (Ed.). *The MISSION-Veteran Treatment Manual*.
16. Najavits, L.M. (in press). PTSD / substance use disorder comorbidity treatment: Principles and practices in real-world settings. *Toward an Integrated Approach to Trauma Focused Therapy: Placing Evidence-Based Interventions in an Expanded Psychological Context*. B. McMackin, Keane, T., Newman, E., Fogler, J. Washington, DC, American Psychological Association Press.

KEY RESEARCH ACCOMPLISHMENTS:

Details are provided above; requested bulleted list with key accomplishments is here:

- Hired and trained key personnel (including the Project Director, on-site Associate Investigators)
- Completed administrative, scientific, and IRB review at Walter Reed Army Medical Center (Tripler and Ft. Jackson are under the supervision of WRAMC IRB)
- Forms submitted to the Human Research Protections Office at the DoD
- Conducted Seeking Safety trainings at each military site
- Developed an efficient data collection method using Adobe forms
- Created a tracking system using excel logs
- Located two new study sites (Tripler, Fort Jackson) to replace two that dropped (Portsmouth Naval, and Air Force) ; and have potential for another to add at Ft. Belvoir
- Dr. Najavits has had a strong record of publications and presentations relevant to the project content (e.g., PTSD, SUD)

REPORTABLE OUTCOMES

Not applicable. We have not collected any data at this stage of the project.

CONCLUSION

We do not yet have study conclusions or summaries of the results. This is our first annual report and not the final report for the project and thus we do not yet have the requested results.

REFERENCES

Not applicable

APPENDICES

Not applicable