

Award Number: W81XWH-12-1-0614

TITLE: In-Home Exposure Therapy for Veterans with PTSD

PRINCIPAL INVESTIGATOR: Leslie Morland, PsyD

CONTRACTING ORGANIZATION: Veterans Medical Research
Foundation San Diego, CA 92161

REPORT DATE: October 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

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1. REPORT DATE Oct 2018		2. REPORT TYPE Annual		3. DATES COVERED 30 Sept 2017 – 29 Sept 2018	
4. TITLE AND SUBTITLE In-Home Exposure Therapy for Veterans with PTSD				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-12-1-0614	
6. AUTHOR(S) Leslie Morland, PsyD E-Mail: Leslie.Morland@va.gov				5c. PROGRAM ELEMENT NUMBER	
				5d. PROJECT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Veterans Medical Research Foundation 3350 La Jolla Village Drive (151A) San Diego, CA 92161				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				8. PERFORMING ORGANIZATION REPORT NUMBER	
				10. SPONSOR/MONITOR'S ACRONYM(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This is a randomized control trial study that implements prolonged exposure therapy (PE) to military Veterans. We recruited 175 Veterans to participate in the study. Our goal is to compare PE conducted in three different ways: (1) PE that is office-based telehealth (OBT; Veterans come to the clinic to meet with the therapist using videoconferencing technology), (2) PE delivered via home -based telehealth (HBT; Veterans stay at home and meet with the therapist using the computer and video cameras), and (3) PE delivered in home, in person (IHIP; the therapist comes to the Veterans' homes for treatment). We aim to investigate whether symptoms of PTSD, depression, and anxiety get better (less severe) after the treatment and six months later. We will also see if there are differences in the three ways we will be providing the therapy. We hypothesize that the IHIP approach, compared to the other two approaches, will be more effective at reducing the PTSD symptoms experienced by these Veterans because it will help Veterans attend each session and complete the therapy "homework" assigned by the therapists (such as doing feared activities around the house or the neighborhood). We have been referred 900 Veterans. Of the 900 referred, including 736 males (82%) and 164 females (18%), with 180 Veterans participating in the study. 175 Veterans (97% of those enrolled) were randomized while 5 (3%) were pilot subjects. Of the 175 randomized participants, 95 (54%) have completed therapy and 80 (46%) have dropped out of therapy.					
15. SUBJECT TERMS PTSD, Telemedicine, Psychotherapy					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	UU	8	19b. TELEPHONE NUMBER (include area code)

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INTRODUCTION:

This research study provides a type of exposure therapy, called prolonged exposure therapy (PE) to military Veterans. We have successfully recruited **175** Veterans (our target sample size) to participate in the study. Our goals are unchanged since last report: we aim to compare PE conducted in three different ways: (1) PE that is office-based telehealth (OBT; Veterans come to the clinic to meet with the therapist over telehealth), (2) PE delivered via home-based telehealth (HBT; Veterans stay at home and meet with the therapist using the computer and video cameras), and (3) PE delivered in home, in person (IHIP; the therapist comes to the Veterans' homes for treatment). We will be checking to see if symptoms of PTSD, depression, and anxiety get better (less severe) after the treatment and six months later. We will also see if there are differences in the three ways we will be providing the PE therapy. We hypothesize that the IHIP approach, compared to the other two approaches, will be more effective at reducing the PTSD symptoms experienced by these Veterans because it will help Veterans attend each session and complete the therapy "homework" assigned by the therapists (such as doing feared activities around the house or the neighborhood). However, the delivery of IHIP may cost more than the delivery of PE via the other modalities. We expect that the treatment, conducted in all three ways, will reduce the distress caused by PTSD symptoms in most of the participants, which will help to improve the lives of Veterans, their families, and society. The findings of this study will also benefit military Veterans and Active Duty military personnel by investigating new ways for treating PTSD so that the most effective treatments can be made widely available. We will also learn the best ways to manage urgent situations, such as a physical or emotional crisis, that occur when providing treatment in homes and through home based video technology.

BODY:

Our focus in the past year (01 Oct 2017 – 30 Sept 2018) has been to accomplish the tasks outlined in the Statement of Work (SOW) under Task 2, and to complete all assignments outlined under Task 3. Namely, we have completed all treatment and all follow-up assessments for participants. Over the course of the past year, we have also created, implemented, and completed a sub-project to follow-up with participants who prematurely dropped out from study treatment. All individuals who dropped out from treatment were mailed a letter asking if they would be interested in discussing their reasons for dropping from the study. Of all 80 dropout participants, 22 individuals were reconsented and had a one-time qualitative interview to discuss their motivations for dropping from treatment. Ms. Wells has completed conducting qualitative interviews with this subportion of veterans who dropped out of therapy to better understand veterans' reasons for prematurely discontinuing treatment across delivery modalities. She has completed all transcription and coding of patient transcripts; she continues to complete data analysis. The study is presently closed to recruitment.

Assessment clinicians have completed administering IRB approved informed consent and finished all comprehensive baseline assessments with potential participants and have completed all follow-up. The study database is complete, data entry is complete, as is quality control procedures overseen by the local project data manager.

We continue to meet monthly with the parallel study examining home based CPT lead by Drs. Resick and Peterson with the plan to compare and potentially collapse findings as feasible and when ready to do so.

At the date of publication for our previous annual report in October of 2017 we had been referred 900 Veterans. This number has not changed since this report as recruitment efforts have finished. The 900 referred to the study include 736 men (82%) and 164 women (18%). Of the 900 referred, 180 Veterans (20%) were enrolled in the study. Five Veterans (3% of those enrolled) were enrolled in the pilot study and were not randomized. Of the five Veterans in the pilot study, three have completed the study (therapy through the 6-month

follow-up), and two have completed treatment through the 4-month assessment. Neither of those two, however, responded to staff requests to complete the 6-month assessment. Of the 180 enrolled, 175 Veterans (97% of those enrolled) are enrolled in the full study. These pilot sessions helped us refine our procedures for recruitment, telephone screening, consent, assessment, the VTC modality, and treatment. We presented some anecdotes from this study at ISTSS in November of 2015 and we have one manuscript underway. based on Veterans report of preferences for care (see full reference below)

Of the five enrolled in the pilot study, 4 (80%) are male, and 1 (20%) is female. All five (100%) pilot subjects identify as Caucasian. Of the 175 additional Veterans enrolled in the larger study, 132 (75%) are male and 43 (25%) are female. The racial/ethnic information for the 175 randomized Veterans is as follows: 48 (27%) identify as Hispanic or Latino, 115 (66%) Not Hispanic or Latino, and 12 (7%) declined to answer. The racial information is as follows: 71 (41%) identify as Caucasian, 50 (29%) African American, 14 (8%) Asian, 4 (2%) Native Hawaiian or Pacific Islander, 5 (3%) American Indian or Alaskan Native, 17 (10%) Other, and 14 (8%) declined to answer.

Of the 900 referred, 720 (80% of the total referred) were not enrolled. Of those not enrolled, 25 (3%) Veterans were either on hold after phone screen or in the process of being contacted, but will no longer be contacted since the target sample is met for the study. Efforts to refer these Veterans to a different service will be made. Additional 113 Veterans (16%) were not enrolled into the study because they were unreachable by phone (no response after 6 voice messages); 251 (35%) were ineligible for study inclusion after completing the phone screen; 265 Veterans (37%) were not interested in joining the study; 41 Veterans (6%) were eligible after the phone screen, but contact was lost before baseline assessment could be scheduled; 24 (3%) were initially eligible at phone screen, but found ineligible for study eligibility criteria through the baseline assessment; one individual expressed no longer being interested in participating in the study at the baseline assessment after being found eligible in the phone screen.

The randomization breakdown for the 175 Veterans enrolled into PE treatment is as follows: 58 (33%) were randomized to receive In-Home, In- Person (IHIP); 59 (34%) were randomized to receive Office Based Telehealth (OBT); and 58 (33%) were randomized to receive Home Based Telehealth (HBT).

Of the 175 randomized participants, 95 (54%) have completed therapy, and 80 (46%) have dropped out of therapy. The 80 who dropped out included 18 (22.5%) who reported that they did not like the therapy, 12 (15%) who stopped attending their therapy sessions for unknown reasons and did not respond to phone calls and letters from study personnel, 9 (11%) whose primary health concern was not PTSD, 12 (15%) who had scheduling difficulties arise and were no longer able to attend therapy sessions, 6 (7.5%) who moved outside of radius during treatment, 2 (2.5%) who were randomized but became unreachable before beginning therapy, 6 (7.5%) who had severe health concerns arise during treatment, and 15 (19%) who cited other reasons.

Of the 175 who were randomized, 66 (38%) are out of the follow-up phase and have completed all follow-up assessments; 71 (40%) are out of the follow-up phase and have completed at least one follow-up assessments; 30 (17%) are out of the follow-up phase and did not complete any follow-up assessment; and 8 (5%) dropped out of the study by explicitly stating that they did not want to complete any follow-up assessment.

Finally, we have begun Task 4 of the SOW. Specifically, now that data entry and cleaning has been completed and all fidelity is complete, main outcome analyses are underway. The study team works primarily to analyze and disseminate study findings. Further, The PI, co-investigators, and other research study staff will continue to work on publishing articles related to this project and to present at national scientific conferences. Additionally, the project PI will continue collaborations with the parallel in-home study (CPT; Co-PIs Drs. Peterson and Resick) and will specifically work to develop a shared repository in the last phase of the study, which will include both study databases.

KEY RESEARCH ACCOMPLISHMENTS:

We obtained a no-cost extension for the project to complete dissemination efforts.

All enrollment and recruitment efforts have been completed because the target study sample has been recruited.

We have obtained VA San Diego IRB and R&D Approval to conduct our study (IRB #H130390). HRPO has provided initial approval (and most recent re-approval in October 2018).

We have completed a sub-project investigating veteran motivation for dropping out of treatment. This data will also be utilized by student Stephanie Wells for her doctoral dissertation.

We have purchased equipment and supplies for the project, prepared paperwork, including all research dissemination efforts.

All treatment and assessment fidelity was completed.

Data analyses for all phases and components of study has begun and are underway. Specifically, all data has been cleaned and is currently be analyzed. All efforts are now being placed toward data analysis and dissemination efforts. The PI, co-investigators, and other research study staff will continue to work on publishing articles related to this project and to present at national scientific conferences.

REPORTABLE OUTCOMES:

Publication/presentations:

- Morland, L. A., Wells, S.Y., & Grubbs, K. (2018, November). *Home-based delivery of PE therapy: Clinical efficacy of Service Modalities*. Symposium to be presented at the 52nd annual Association for Behavioral and Cognitive Therapies (ABCT), Washington D.C
- Wickramasinghe, I.A., Bosch, J., Jaime, K., Morland, Martinez Ceren, P., Morland, L.A. (2018, November). Examining the impact of childhood trauma on PTSD symptoms and psychosocial functioning in a sample of male veterans. Poster to be presented at the 34th annual International Society for Traumatic Stress Studies (ISTSS), Washington DC.
- Sohn, M., Gutierrez Chavez, M., Wells, S. Y., Armstrong, M. R., Golshan, S., & Morland, L. A. (2018, November). Differences in clinical presentation of high trauma-related guilt group and low trauma-related guilt group in a sample of veterans with posttraumatic stress disorder. Poster session to be presented at the 34th annual convention of the International Society for Traumatic Stress Studies (ISTSS), Washington, D.C

- Wells, S. Y., Grubbs, K., Glassman, L. H., Sohn, M., Savage, U., Chatfield, M., Wickramasinghe, I., Golshan, S., & Morland, L. A. (2017, November). Examining dropout from prolonged exposure in a veteran sample. Oral presentation at the 33rd Annual International Society for Traumatic Stress Studies (ISTSS), Chicago, IL.
- Morland, L. A., Wells, S. Y., Sohn, M., Savage, U., Glassman, L. H., Grubbs, K., Golshan, S., Thorp, S. R., & Acierno, R. (2017, October). What do veterans want? Understanding veteran's preferences for PTSD treatment delivery. Oral presentation at the 2nd Annual San Antonio Combat PTSD Conference, San Antonio, TX.
- Morland, L. A., Wells, S. Y., Howard, I. C., Mikhael, T., Savage, U., Tunze, C. A., Sohn, M., Walter, K. H., & Thorp, S. R. (2015, November). Preliminary findings from a study of home-based psychotherapy for posttraumatic stress disorder. Poster presented at the 31st Annual International Society for Traumatic Stress Studies (ISTSS), New Orleans, LA.
- Morland, L. A., Poizner, J. M., Williams, K. E., Masino, T. T., & Thorp, S. R. (2015). Home-based clinical video teleconferencing care: Clinical considerations and future directions. *International Review of Psychiatry*, 27(6), 504-512.

Patents and licenses applied for and/or issued;

- None

Degrees obtained that are supported by this award;

- Not in the past year, however, in the previous year student Stephanie Wells obtained her Masters of Science in Clinical Psychology from the San Diego State University/University of California San Diego Joint Doctoral Program in Clinical Psychology from the support provided by this award.

Development of cell lines, tissue, or serum repositories;

- N/A

Informatics such as databases and animal models, etc.;

- An Access Database has been created for use of the present study data entry.

Funding applied for based on work supported by this award;

- Not in the past year, however, in the previous year, the Frank W. Putnam trauma Research Scholar award was awarded to help fund student Stephanie Wells' dissertation project which involved conducting qualitative interviews with participants following their completion of this study to better understand why Veterans prematurely dropped out of therapy

Employment or research opportunities applied for and/or received based on experience/training supported by this award.

- None

CHALLENGES:

Our previous challenges from the VA Choice program, as well as the federal government hiring freeze did not affect the present study within the last year due to completion of study recruitment. However, we did still face a few challenges. Specifically, this study faced the unanticipated interruptions to VA-wide technology available to Veterans. Specifically, the VA nationwide has completed the nation-wide transition from Jabber, a secure video teleconferencing tool commonly used by the VA, to a new video teleconferencing system (i.e., Virtual Medical Room [VMR]). Though the transition to VMR did remove some of the problems experienced (nationwide) by Veterans who used Jabber, the rollout was not seamless and resulted in multiple connection issues, often resulting in dropped connections to a point of therapy sessions not being completed and needing to be rescheduled. However, as more

issues with VMR continued to be resolved, these issues diminished throughout the remaining sessions with the final active participants.

It is also worth noting that this study continued to be directly impacted by San Diego VA Healthcare System infrastructure over the course of the past year. Particularly, this VA continues to work to improve the infrastructure of the Veterans and their healthcare experience, which includes more accessible and plentiful parking for Veterans to come to the primary VA Medical Center campus in La Jolla, CA. Specifically, the VA has significantly reduced the amount of available parking not only for VA staff and providers, but for patients as well. Veterans are required to come to the VA for their clinical assessments and if they were randomized to the OBT condition. Unfortunately, Veterans reported that they chose to not attend therapy sessions and post assessments because of parking difficulties. These barriers to seeking and remaining in care provide additional support that research on home-based and telehealth modalities is needed and timely.

CONCLUSION

At the end of year 6 of this study, we have enrolled and completed study participation for 100% of the study's sample size (N=175). Specifically, we have completed all study therapy and post-assessments. Further, an additional sub-project, qualitative interviews for individuals who dropped out from treatment early, was also completed; this project is currently in the data analysis phase. Our database has been cleaned, study fidelity is complete, and is currently being used for all dissemination efforts. Specifically, the main outcome paper for this study is expected to be submitted for peer-review by the end of the calendar year. Additionally, the data from this study will be used to publish on additional outcomes from study participation. We are on track to complete all required components of our last Task for this trial in our final year.

REFERENCES:

Morland, L. A., Wells, S. Y., Glassman, L. H., Grubbs, K., Savage, U., Thorp, S. R., & Acierno, R. (under review). What do Veterans Want? Veterans' preferences for PTSD treatment delivery modality.

APPENDICES:

None