

Award Number: W81XWH-12-1-0614

TITLE: In-Home Exposure Therapy for Veterans with PTSD

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REPORT DATE: October 2017

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 October 2017		2. REPORT TYPE Annual		3. DATES COVERED 30 Sept 2016 – 29 Sept 2017	
4. TITLE AND SUBTITLE In-Home Exposure Therapy for Veterans with PTSD			5a. CONTRACT NUMBER		
			5b. GRANT NUMBER W81XWH-12-1-0614		
			5c. PROGRAM ELEMENT NUMBER		
6. AUTHOR(S) Leslie Morland, Psyd E-Mail: Leslie.Morland@va.gov			5d. PROJECT NUMBER		
			5e. TASK NUMBER		
			5f. WORK UNIT NUMBER		
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Veterans Medical Research Foundation 3350 La Jolla Village Drive (151A) San Diego, CA 92161			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 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, 7 (4%) are currently in prolonged exposure therapy, 86 (49%) have completed therapy and 82 (47%) 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 (30 Sept 2016 – 10 Oct 2017) has been to accomplish the tasks outlined in the new Statement of Work (SOW) under Tasks 2. Namely, we have now completed all recruitment efforts, though participants are still in therapy and are actively being contacted for post-treatment assessments. Over the course of the past year, we have worked with multiple clinic sites, met with clinical staff and San Diego VA Veterans to introduce the project, established liaisons, and generated referrals. The study staff had been actively receiving referrals and scheduling interviews. These recruitment strategies are no longer necessary and are not being pursued as of 10 Oct, 2017.

Assessment clinicians have completed administering IRB approved informed consent and finished all comprehensive baseline assessments with potential participants. However, these assessment clinicians continue to engage in assessments at post-treatment and follow-up. We have used the randomization scheme developed by the study statistician to randomize eligible participants to therapy. CAPS-5 assessment fidelity procedures continue to be underway, per study protocol.

Our treatment clinicians are providing the manual-guided evidence-based PE PTSD intervention. PE fidelity procedures continue to be underway, per study protocol.

We continue to engage in weekly in-person research meetings with our local study personnel. Our foremost concern is safety, and we will have ongoing discussions about ways to maximize safety of Veterans and therapists in all three conditions. We meet bi-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.

The study database is complete and the project coordinator is overseeing data entry and quality control conducted by research assistant and study staff. We are using the study database to enter study data collected at different assessment and treatment time points. All data inputting is occurring in real time with rigorous quality control procedures in place.

We have completed five pilot subjects. 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)

For the full project sample, we have been referred 900 Veterans. Of the 900 referred, 736 are males (82%) and 164 are females (18%).

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; 1 expressed no longer being interested in participating in the study at the baseline assessment after being found eligible in the phone screen.

A total of 180 Veterans (20% of the total referred) were enrolled in the study. Out of those enrolled, 5 Veterans (3%) were non-randomly assigned to the treatment arms as pilot subjects, and 175 (97%) Veterans were randomized to the treatment arms as study subjects.

Of the 175 who were randomized, 132 (75%) are male and 43 (25%) are female. The racial/ethnic information for the 175 randomized Veterans is as follows: 50 (29%) identify as African American, 14 (8%) identify as Asian, 71 (41%) identify as Caucasian, 5 (3%) identify as American Indian or Alaskan Native, 4 (2%) identify as Native Hawaiian or Other Pacific Islander, 14 (8%) declined to answer, and 17 (10%) reported "Other".

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, 7 (4%) are currently enrolled in PE therapy, 86 (49%) have completed therapy, and 82 (47%) have dropped out of therapy. The 82 who dropped out included 19 (23%) who reported that they did not like the therapy, 18 (22%) who stopped attending their therapy sessions for unknown reasons and did not respond to phone calls and letters from study personnel, 12 (15%) who had scheduling difficulties arise and were no longer able to attend therapy sessions, 6 (7%) who moved outside of radius during treatment, 2 (2%) who were randomized but became unreachable before beginning therapy, 9 (11%) who had severe health concerns arise during treatment, and 16 (20%) who cited other reasons.

Of the 175 who were randomized, 7 (4%) are currently enrolled in PE therapy; 11 (6%) are out of PE treatment and in the follow-up phase of the study (post through 6 month); 63 (36%) are out of the follow-up phase and have completed all follow-up assessments; 62 (35%) are out of the follow-up phase and have completed at least one follow-up assessments; 27 (15%) are out

of the follow-up phase and did not complete any follow-up assessment; and 5 (3%) dropped out of the study by explicitly stating that they did not want to complete any follow-up assessment.

The randomization breakdown for the 175 Veterans enrolled into PE treatment is as follows: 58 (33.1%) were randomized to receive In-Home, In-Person (IHIP); 59 (33.7%) were randomized to receive Office Based Telehealth (OBT); and 58 (33.1%) were randomized to receive Home Based Telehealth (HBT).

KEY RESEARCH ACCOMPLISHMENTS:

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 September 2017).

We have hired all personnel, and have completed training with all personnel. Due to a reduced staff in this last phase of the study we now have two part-time clinicians who offer PE treatment for this study.

We continue to consult with national experts about in-home provision of care (through teleconferencing and in-person).

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

Data analyses for baseline treatment preference data are underway. We are in the process of all data cleaning, as well as double data entry. Data will continue to be collected as participants are still in therapy and are active in the post-assessment phases. CAPS-5 and PE treatment fidelity are on track to be completed by the end of data collection. Given that the database will be cleaned, we can devote more resources to dissemination efforts when data collection and fidelity are completed.

REPORTABLE OUTCOMES:

Publication/presentations:

- 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;
 - o None
- degrees obtained that are supported by this award;
 - o 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;
 - o N/A
- informatics such as databases and animal models, etc.;
 - o An Access Database has been created for use of the present study data entry.
- funding applied for based on work supported by this award;
 - o Awarded the Frank W. Putnam trauma Research Scholar award to help fund student Stephanie Wells's dissertation project which will involve 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.
 - o None

CHALLENGES:

In this past year of this study we faced several challenges. First, we continued to be significantly impacted by the **VA Choice program**, which is a VA program that has been temporarily implemented to address the access issue and the inability of the VA to meet the demands of patient care. In most cases, this VA Choice program resulted in rerouting many new Veterans seeking care into the community rather than through VA San Diego PTSD clinics. This significantly reduced referrals for all studies across the VA over the past 12 months. Although our study did continue to make screening and randomization our top priority, we were significantly delayed in reaching our target sample size due to Veterans receiving care in the community rather than through the VA. Although the VA Choice program required some reworking throughout the study and some Veterans returned to the VA for their mental health care, the impacts of such a program, continued to negatively impact recruitment and enrollment. Although the VA Choice program did impact recruitment over the past 12 months, it is likely that the impact of VA Choice on future research efforts will be attenuated due to a reorganization of the VA Choice program.

Moreover, this study was indirectly impacted by the hiring freeze in the federal government during this last fiscal year. Due to the stoppage of hiring and the slow rehiring process, PTSD community-based clinics where we recruit from did not have the staff resources to adequately provide access to services in a timely manner and Veterans were referred to VA Choice. Subsequently, stoppage of hiring resulted in an abrupt decline in provider referrals and drastically hindered our previous projections to complete recruitment in the first half of the fiscal year. Additionally, we continued to face local competition with San Diego VA PTSD research. Given that it is reasonable that some Veterans are skeptical of receiving mental health care via a research study, the Veteran pool that were open to research participation were offered multiple other studies that focused on specific traumas (e.g., military sexual assault) and other studies which were shorter in length. These factors may have made them attractive for potential participants to enroll in. However, with Veterans returning to the VA system as a result of changes in the VA Choice program, as well as intense hiring efforts by the VA to accommodate the high demand for mental health, we were able to successfully complete recruitment.

We also have faced staffing challenges for the clinicians and assessors for this study. Though we were able to retain a part-time assessor for this study, the funding for therapists was no longer available, as all allotted funds were expended; this is a direct result of the study continuing longer than it was anticipated due to the disruptions to referrals in the previous fiscal years. Additionally, this study faced the unanticipated interruptions to VA-wide technology available to Veterans. Specifically, the VA nationwide is in the midst of transitioning 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 new 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, we are more content with the efforts made by the VA in the last month to improve VMR for Veterans and resolve the issues referenced above.

It is also worth noting that this study was 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 the initial baseline assessment or therapy sessions because of parking difficulties. Study staff attempted to remedy concerns by meeting with local VA management personnel. 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 5 of this study we have enrolled 100% of the projected sample size (N=175), but continue to have the final 18 study participants (10%) in treatment and follow-up. The anticipated completion date (i.e., final in-person 6-month follow-up) will be no later than the Summer of 2018. We anticipate a much more seamless finish of this study in the coming months. Our database is in the process of being cleaned and all fidelity is on track to be completed by the end of data collection; therefore, we will be prepared to publish the main outcomes immediately following the completion of the final assessments.

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