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TITLE: Implementation of Prolonged Exposure in the Army: Is Consultation Necessary for Effective Dissemination?

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14. ABSTRACT
The dramatic increase in the number of active duty soldiers identified with PTSD has produced an urgent need to train military mental health providers in how to effectively deliver short-term, efficacious, evidence-based treatments (EBTs) for PTSD. Prolonged exposure (PE) has gained the most empirical evidence for its efficacy and has many characteristics that render it an excellent candidate for dissemination: it is effective with a wide range of PTSD sufferers, it is relatively easy to learn and deliver, and it is preferred by patients over some other treatments. Research indicates that case consultation after participation in a workshop plays an important role in training mental health professionals to successfully implementing EBTs. However, consultation requires a greater investment of resources than a one-time workshop. Thus, it is critical to determine whether consultation increases the success of disseminating and implementing long-term sustainability of PE services.

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INTRODUCTION

Prolonged exposure (PE) therapy for PTSD has many characteristics that render it an excellent candidate for dissemination: it is effective with a wide range of PTSD sufferers, it is relatively easy to learn and deliver, and it is preferred by patients over some other treatments. Research indicates that case consultation after participation in a workshop plays an important role in training mental health professionals to successfully implementing EBTs. However, consultation requires a greater investment of resources than a one-time workshop. Thus, it is critical to determine whether consultation increases the success of disseminating and implementing PE services in routine clinical care. This study will examine how we can successfully disseminate and implement EBTs for PTSD in the Army by comparing two PE training models: Standard PE training (workshop only) and Extended PE training (workshop plus consultation). Approximately 35 mental health therapists in each of three medium- to large-sized domestic Army installations will be randomly assigned to either implement Standard PE training or Extended PE training. We hypothesize that compared to Standard training, the Extended PE training will lead to: 1) Greater frequency and higher quality of PE delivery; and 2 Superior patient response to treatment 3) Higher provider self-efficacy and positive attitudes towards PE.

BODY

The following tasks have been completed during the second year of the project.

Preparation and Revision of the Research Proposal for IRB and HRPO Approval: On September 20, 2013, IRB approval was obtained from the University of Pennsylvania. The study protocol and consent forms for Ft. Carson were subsequently submitted to the MAMC IRB. MAMC IRB's scientific review of the protocol was completed on December 11, 2013. The protocol was disapproved and it was recommended that the study be re-submitted as educational research (i.e., eliminating collection of data on patient outcomes). Telephone conferences were conducted to discuss the disapproval and strategize the best approach to re-submission. Drs. Foa, McLean, Zandberg, Peterson, and Young-McCaughan prepared a letter of request for IRB reconsideration of the decision to disapprove the study. This letter responded to each of the stated reasons for disapproval. Specifically, the letter clarified the intent of the study and the rationale for including patient data, addressed concerns about statistical power, and addressed the concern about undue

influence on potential participants by commanders serving as site PIs. The letter of request for IRB reconsideration was submitted to MAMC. Drs. Foa, Peterson, and Young-McCaughan attended the MAMC IRB review meeting on March 12, 2014 to further support the protocol and address IRB questions/concerns. Revisions to the protocol and site specific addendum were initiated following the March 12, 2014 IRB meeting and were submitted to the MAMC IRB on April 2, 2014. Following the recommendations of the Madigan IRB, changes made to the protocol were also submitted as amendments to the Penn IRB and were approved on April 22, 2014.

The study protocol and all supporting documents were submitted to HRPO for final study approval on April 25, 2014. Per communication with the Deputy Director of the HRPO (Dr. Sharon Evans) on May 19, it was determined that UTHSCSA IRB approval would be required in order for HRPO to issue approval. A request for non-human research determination was submitted to UTHSCSA on June 12, 2014 and approved on June 17, 2014. The IRB determined the project activities performed at UTHSCSA do not qualify as human research and do not require IRB approval. The UTHSCSA IRB determination of non-human subject research was submitted to HRPO on June 18, 2014. A protocol amendment clarifying that UTHSCSA will not be receiving PHI was received by HRPO on August 1, 2014. At the request of HRPO, language concerning UTHSCSA receiving de-identified data was removed from the consent forms, and an amendment was submitted to the Penn IRB and approved on August 7, 2014; it was subsequently forwarded to the MAMC IRB for review on August 10, 2014, and approved by the MAMC IRB on September 4, 2014. The corresponding Fort Carson Site amendment was submitted to the MAMC IRB on August 8, 2014 and approved on September 4, 2014. Following MAMC approval, the study protocol and consent documents were re-submitted to HRPO for final approval of the study, which was granted on September 10, 2014.

Per request of the DOD, the primary outcome measure for the study was changed from the PSSI to the CAPS. An amendment to the Penn IRB was completed and submitted on June 19, 2014. Approval was obtained on July 18, 2014, and the amendment was submitted to the MAMC IRB and HRPO. The MAMC IRB approved the amendment by August 1, 2014.

Hiring and Training of Project Staff: From September 2013-2014, hiring efforts have continued and all but one position (BOA at Ft. Carson) has been filled. See below for specifics:

Hiring: In September 2013, Dr. Mrudula Raparla was offered the position of Project Coordinator at Ft. Bliss, and accepted the position with a start date of October 1, 2013. At the University of Pennsylvania, a post-doctoral fellow, Dr. Laurie Zandberg, was hired and trained by Drs. Foa and McLean to help with coordination of the study. A research assistant (RA) at the University of Pennsylvania, Allison Chernov, was trained to assist with the study at this time. In September 2013, Sally Curtis and Kristen Butcher were offered the RA positions at Ft. Carson and Ft. Campbell respectively and their start date was October 7, 2013. Katherine Ledlie was offered the therapist position and her start date was November 6, 2013. In November 2013, Jan Bestwick and Leslie Buck were offered Behavioral Outcome Assessor (BOA) positions at Ft. Bliss, and Lori-Ann Landry was offered a BOA position at Ft. Carson. Their start date was December 2, 2013. Rachell Jones was offered the position of RA at Ft. Bliss and her start date was December 9, 2013. Tina Fanello was offered the BOA position at Ft. Carson and her start date was January 21, 2014. Viola Raschke was offered and accepted the position of BOA at Ft. Campbell, and began on February 18, 2014. Thomas Fearing was offered and accepted the position of Therapist-Provider at Ft. Bliss, and began on March 24, 2014. Kelly Nypaver was also offered the position of BOA at Ft. Campbell; she accepted and began on April 1, 2014. Jean Hinkebein, Psy.D. was hired for the position of Therapist Provider, and started on June 23, 2014.

Staff Attrition: Tina Fanello resigned from the position of BOA at Ft. Carson and recruitment was re-initiated for this position. Nicole Peak, Ph.D. was offered and accepted the position, and began on May 27, 2014. On June 27, 2014, Allison Chernov departed from the University of Pennsylvania team. A new RA, Jody Zhong, was hired to assist with the study at Penn, and started on July 14, 2014. Dr. Allison Hancock stepped down from the Project Coordinator position at Ft. Carson on August 22, 2014. Ms. Lori-Ann Landry became the new Project Coordinator on September 1, 2014. Efforts are currently being made by the Geneva Foundation to hire an additional BOA at Ft. Carson, who will provide assistance to the two current BOAs and also assist Ms. Sally Curtis with RA duties. Thomas Fearing resigned from the Therapist-Provider position at Ft. Bliss, and candidates to fill the position were subsequently reviewed. An

offer was made on September 12, 2014 to Dr. Martin Ancona, who accepted and will start on October 13, 2014.

Staff Trainings: All hired Behavioral Outcome Assessors traveled to the University of Pennsylvania and completed a two-day training workshop (May 29-30, 2014) on study assessment procedures conducted by Drs. Capaldi, Mclean, and Zandberg. A plan for training the Behavioral Outcome Assessors (BOAs) at all three military sites was created in collaboration with Brian Marx, Ph.D. at the National Center for PTSD. The BOAs completed CAPS training and recorded mock-patient interviews to send to colleagues of Dr. Marx at the VA Boston Health System for review on July 28, 2014. Feedback from the CAPS trainers was received by the BOAs in mid-September 2014. Three out of six of the BOAs were asked to complete a second round of interviews. All newly hired staff have completed hospital in processing, CITI, and IRB trainings.

Administrative Tasks: From April 1, 2013 onward, one-hour weekly telephone conference calls have been conducted with Drs. Foa, McLean, Zandberg and Jody Zhong at Penn, Drs. Peterson and Young-McCaughan at UTSHCA, Miranda Bethay at the Geneva Foundation, and the on-site project coordinators: Dr. Mrudula Raparla at Ft. Bliss, Dr. Jennifer Deluzio at Ft. Campbell, and Dr. Allison Hancock (August 2013-2014)/Ms. Lori-Ann Landry (August 2014-present) at Ft. Carson. Conferences calls have focused on obtaining IRB approval, responding to IRB concerns, hiring remaining study staff, and developing detailed standard operating procedures (SOPs) for conduct of the study. Weekly research meetings have also been held between Drs. Foa, McLean, and Zandberg at the University of Pennsylvania to prepare for the start of the study.

In August 2013, Drs. Mintz and Aguilar, in collaboration with Drs. Foa and McLean, developed procedures for data collection and a plan for database development. Procedures for data collection and database preparations were initiated in November 2013. Ft. Carson and Ft. Bliss each submitted a Data Share Agreement to receive access to the Behavioral Health Data Platform (BHDP) to Lieutenant Colonel Brown, the manager of the BHDP for the U.S. Army Medical Department on July 28, 2014. Approval is pending.

Development of a PE supervisor's application began in November 2013 in collaboration with Drs. Kenneth Ruggiero, Alyssa Rheingold, and April Borkman at The Medical University of South Carolina. Four conference calls have been conducted to determine application content, structure, and presentation; and weekly meetings have been held at Penn to develop application content.

Over twenty detailed standard operating procedures (SOPs) were developed by study staff at each military site to standardize all recruitment, consenting, and assessment procedures, and continue to be revised and finalized by staff at each site.

Requests to change the provider template at each of the military sites were submitted. Providers at both Ft. Campbell and Ft. Carson have been granted three 90-minute slots to use for the study by site leadership. Providers in the extended condition at Ft. Bliss have been granted two 90-minute slots and one hour for study-related training by site leadership.

Dates for two consecutive 4-day workshops to train providers in PE have been scheduled at Ft. Carson. The first workshop will take place from January 6 to 9, 2015, and the second workshop will take place from January 12 to 15, 2015. Provider recruitment was initiated 9/19/2014.

Problem Areas

The MAMC IRB's initial disapproval of the study protocol at the December 2013 scientific review meeting was unexpected. However, on March 12, 2014 the MAMC IRB agreed to rescind its rejection of the study protocol and review a re-submission, which was subsequently approved.

The HRPO request for IRB approval at UTHSCSA received on May 19, 2014 also created unexpected delays in the study timeline. Approval has since been obtained from UTHSCSA (on June 17, 2014) and HRPO (on September 3, 2014).

Drs. Foa, Mclean, and Zandberg have continued to work with collaborators at Geneva to expedite the hiring process and ensure all remaining study personnel are hired in a timely fashion.

KEY RESEARCH ACCOMPLISHMENTS

- Final approval for study received from HRPO.
- Hired key study staff, including BOAs, Research Coordinators, and RAs for each site.
- Provider recruitment initiated at Ft. Carson.

REPORTABLE OUTCOMES

To date, there are no reportable outcomes, as HRPO approval has just been received and participant recruitment has not yet commenced.

CONCLUSION

Accessibility of effective PTSD treatment is an extremely relevant issue for the military and for our national public health in general. The proposed research will help identify the most effective PE training model while ensuring sustainability of implementation and maintenance of treatment quality and adherence. This study constitutes a key step towards the ultimate goal of increased access to evidence-based treatment among soldiers suffering from PTSD and related problems. The results will inform EBT dissemination efforts in the military as well as the public sector.

REFERENCES

None.

APPENDICES

HRPO approval notice (see below).

Zimbra

A-17558, HRPO Approval Memorandum (Proposal Log Number 11077005, Award Number W81XWH-12-2-0116) (UNCLASSIFIED)

From : Sharon A CIV USARMY MEDCOM USAMRMC Evans (US) <sharon.a.evans17.civ@mail.mil>

Wed, Sep 10, 2014 08:05 AM

1 attachment

Subject : A-17558, HRPO Approval Memorandum (Proposal Log Number 11077005, Award Number W81XWH-12-2-0116) (UNCLASSIFIED)

To : 'Edna Foa' <foa@mail.med.upenn.edu>, Jeremy C CIV USARMY MEDCOM EACH Francis (US) <jeremy.c.francis4.civ@mail.mil>

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Classification: UNCLASSIFIED
Caveats: NONE

SUBJECT: Initial Approval for the Protocol, "Implementation of Prolonged Exposure in the Army: Is Consultation Necessary for Effective Dissemination?," Submitted by Jeremy C. Francis, MD, Evans Army Community Hospital, Fort Carson, Colorado, in Support of the Proposal, "Implementation of Prolonged Exposure in the Army: Is Consultation Necessary for Effective Dissemination?," Submitted by Edna B. Foa, PhD, University of Pennsylvania, Philadelphia, Pennsylvania, Proposal Log Number 11077005, Award Number W81XWH-12-2-0116, HRPO Log Number A-17558

1. The subject protocol was approved by the Madigan Army Medical Center (MAMC) Institutional Review Board (IRB) on 4 September 2014. The Evans Army Community Hospital (EACH) site specific addendum (dated 7 August 2014) was approved by the MAMC IRB on 4 September 2014. The University of Pennsylvania IRB approved the protocol on 8 August 2014. This protocol was reviewed by the US Army Medical

Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) and found to comply with applicable DOD, US Army, and USAMRMC human subjects protection requirements.

2. This no greater than minimal risk study is approved for the enrollment of 120 mental health providers and 500 treatment seeking patients across three military treatment facilities. The current approval pertains only to the EACH site; 40 providers and 170 patients are approved for enrollment at the EACH.

3. The Principal Investigator has a duty and responsibility to foster open and honest communication with research subjects. The USAMRMC strongly encourages the Principal Investigator to provide subjects with a copy of the research protocol, if requested, with proprietary and personal information redacted as needed.

4. The following are reporting requirements and responsibilities of the Principal Investigator to the HRPO. Failure to comply could result in suspension of funding.

a. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The USAMRMC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e. would prompt additional scientific review), or a change that could potentially increase risks to subjects.

b. All unanticipated problems involving risk to subjects or others must be promptly reported by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), or by facsimile (301-619-7803) to the HRPO. A complete written report will follow the initial notification. In addition to the methods above, the complete report can be sent to the US Army Medical Research and Materiel Command, ATTN: MCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.

c. Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies will be promptly reported to the USAMRMC ORP HRPO.

d. Events or protocol reports received by the HRPO that do not meet reporting requirements identified within this memorandum will be included in the HRPO study file but will not be acknowledged.

e. A copy of the continuing review approval notifications by the MAMC and the

University of Pennsylvania IRBs must be submitted to the HRPO as soon as possible after receipt of approval. According to our records, it appears the next continuing review by the MAMC IRB is due no later than 8 April 2015 and the next continuing review by the University of Pennsylvania IRB is due no later than 18 August 2015. Please note that the HRPO conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.

f. The final study report submitted to the MAMC and the University of Pennsylvania IRBs, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

g. The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research; the issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any regulatory agencies including legal or medical actions; and any instances of serious or continuing noncompliance with the regulations or requirements must be reported immediately to the HRPO.

5. Please note: The USAMRMC ORP HRPO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

6. Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer/Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.

7. The HRPO point of contact for this study is Karen M. Eaton, MS, Human Subjects Protection Scientist, at 301-619-9268/karen.m.eaton.ctr@mail.mil.

SHARON A. EVANS, PhD, CIP
Deputy Director, Human Research Protection Office
Office of Research Protections
US Army Medical Research and Materiel Command

Note: The official copy of this memo is housed with the protocol file at the Office of Research Protections, Human Research Protection Office, 810 Schreider Street, Fort

Detrick, MD 21702-5000. Signed copies will be provided upon request.

Classification: UNCLASSIFIED
Caveats: NONE