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14. ABSTRACT

The purpose of this 4 year, randomized trial and comparative effectiveness study is to design, implement and evaluate a cost effective, web based self paced training program to provide skills-oriented continuing education for mental health professionals. The objective is to learn *whether novel, internet-based training methods, with or without web-centered supervision, may provide an effective means to train increasing numbers of mental health providers in relevant, evidence-based clinical skills*. The study will launch during the first quarter of the second year grant cycle. There are no research findings to date.

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INTRODUCTION

Psychologically-based treatments and cognitive behavioral therapy (CBT) interventions have been shown to be effective in alleviating symptoms of Post-Traumatic Stress Disorder (PTSD) and related psychological health problem in Veterans and military personnel who suffer from these problems. To meet the increased service of Veterans with PTSD, new training methods need to be developed which are: 1) evidence-based, and *2)* effective in modifying and sustaining changes in provider behavior. Methods of training/implementation must also be scalable, and feasible for delivery to large numbers of providers in cost-effective ways. Internet-based training is a promising new approach for meeting this need, but has received little systematic evaluation to date. Noting the urgency and high priority of this issue, Fairburn and Cooper (2011) have advocated strongly for the development of novel, internet-based training methods and innovative research designs to test the effectiveness of these new training methods. Our current program of research is aimed to address these needs.

The broad objective of our research is to design, implement and evaluate scalable and cost-effective new methods for training of mental health clinicians providing treatment services to veterans with PTSD. The randomized controlled trial (RCT) design is briefly as follows: eligible clinicians in the community and VHA will be randomly assigned in equal numbers to three parallel intervention condition: a) Web-based training plus web-centered supervision; b) Web-based training alone; and c) a written manual control group. An equal number of clinician trainees from VHA (N=219) and the community (N=219) will be recruited and enrolled in the study over an 18-month period according to a randomized, stratified 24-week design. Comprehensive assessments will be performed at baseline (T0), completion of training (T1), and at 3 month follow-up (T2). Participants randomized to the consultation condition will be exposed to a newly developed web-centered form of learning consultation. Measures of compliance and completion will assess adherence to protocol. Training effectiveness will be evaluated by means of a combination of objective (SPE) and self-report measures.

The primary and secondary aims of the study are as follows:

Primary Aim: To compare an enhanced, internet-based training intervention combined with novel web-centered supervision, internet-based training intervention without web-centered supervision and a written manual control with regard to improvements in two CBT-based skill areas (behavioral task assignment and case conceptualization). We hypothesize that enhanced, internet-based training in conjunction with web-centered supervision will result in superior skills acquisition compared to internet training alone and that internet training alone will result in superior CBT skills than a written manual control.

Secondary Aim #1: To compare improvements in knowledge and attitudes following internet-based training with or without web-centered supervision and the written manual control. We hypothesize that web-centered supervision will lead to greater improvements in CBT knowledge and perceived self-efficacy compared to internet-based training without supervision or a written manual condition. We hypothesize similarly that internet-based training will be associated with improved outcomes in CBT knowledge and attitudes compared to a written manual control.

Secondary Aim #2: To compare improvements in skills acquisition in knowledge and attitudes following training in clinicians recruited from VHA mental health treatment settings compared to those providing services in civilian community-based clinics. We hypothesize that comparable improvements will be achieved in the trainees from civilian community-based clinics compared to clinicians recruited from VHA centers.

Secondary Aim #3: To determine whether clinician implementation of skills assessed by means of a novel, objective measure of skills (i.e., standardized patient). We hypothesize that

that comparable improvements will be achieved in the trainees from civilian community-based clinics compared to clinicians recruited from VHA centers.

Secondary Aim #4: To assess the relative efficiency of training, as measured by total time required for training in each condition, in addition to self-reported level of burden for clinicians. We hypothesize that internet-based training with or without web-centered supervision will be associated with increased time investment and burden relative to training-as-usual, but that absolute levels of burden will be low in the web training conditions.

Our study will be the first of its kind to systematically compare web-based training interventions across treatment settings and provider groups (VHA vs Non-VHA).The study will also be unique in: 1) developing and testing of new web-enhanced training modules and a novel web-centered supervision model recently proposed by Fairburn & Cooper (2011); 2) development and implementation of a new patient-reported measure of clinician skill and competency; and 3) assessment of post-training maintenance of skills beyond the training period. Our focus on broad-based, generic CBT skills rather than more narrowly focused protocol-based skills is another innovative aspect of our proposed study. Finally, the use of standardized patient methodology for assessing outcomes of training, and planned comparisons with self-report and knowledge-based assessment, is another novel feature of our proposed study.

If successful, the study will promote a better standard of care for psychological health of Veterans and their families by evaluating technical feasibility of two training models in evidence-based skills for PTSD treatment providers and measuring their outcomes and effectiveness. If successful, the study will provide experimental support for broad implementation of these enhanced new training methods across a variety of treatment settings.

BODY

This section describes the accomplishments associated with each task outlined in the approved Statement of Work (SOW). As stated in our SOW, the major tasks to be accomplished in year 1 were:

1. Develop and Finalize Study Protocol and Measures

   A. Eligibility criteria, exclusion criteria, screening protocol

      i. During the first year of this project, the team finalized the eligibility criteria, exclusion criteria and screening protocol.

      ii. Screening protocol is currently being prepared for programming.

   B. Sample frame, web contact methods, email lists identified

      i. During the first year of the project, the team has secured its two primary recruitment strategies (VA networks of clinicians and recruitment via Give An Hour), and have also identified other existing email lists of potential participants, including collaboration with VA initiatives, professional organizations and community based groups.

         a. Email lists include: VHA mental health clinicians that have participated in the "clinical training program" at the National Center for PTSD in the past, VHA mental health clinicians who have not participated in the "clinical training program" at the NCPTSD, team leaders at the Vet Centers in the United States, and a registry of community practitioners who have agreed to volunteering pro bono to serve the needs of veterans (Give an Hour). A large number (6800) community clinicians participate in the latter registry and our

study has arranged access to this recruitment pool. Additionally, as a backup recruitment strategy we have compiled a listing of other VA organizations and professional organizations that can assist in recruitment.

b. Postcards have been created to be disseminated at conferences and other mental health events to enhance recruitment activities in addition to the pre-defined email lists.

c. Informative/"Save the Date" postcards have been created to be disseminated at conferences, other mental health events, and/or to eligible clinicians to enhance recruitment activities and allow interested individuals the opportunity to pre-register for the study by visiting a website where they can enter their information and be contacted for future participation with the training.

C. Standardized Patient Interviews scripted and pre-tested

i. A standardized patient interview script has been created for assessing clinical skills prior to and following the training. This is being pre-tested currently.

ii. A transcription service has been identified and contracted for creating transcriptions from all standardized patient interviews, and is currently providing satisfactory new pilot transcripts for the finalizing of our second rating scale.

iii. Three pilot raters have been hired and began working on the standardized patient development in September, 2013.

iv. New actors and raters have been identified for the study, and additional personnel will be hired in the upcoming month.

D. Knowledge and attitude questionnaires have been developed for the study, which are currently undergoing pre-testing. Other measures are being finalized based on findings from the first study (Ruzek et al., 2012).

E. Consent form drafted, human subjects protocol finalized

i. During the first year of this project, the web based consent form was created. The consent form and protocol has been approved by both Stanford and NERI IRBs. The terms of the study will be clearly defined with an "accept" or "decline" participation button. Those who accept will progress to the next phase of the study. Those who decline will be thanked for their time. All consent activities will occur through a secure web site.

F. VHA/NERI IRB approvals and USAMRMC HRPO human subject protocol approval

i. The Protocol, Recruitment materials, Informed Consent documents, applicable applications were initially approved by the Stanford IRB (NCPTSD) on March 15th, 2013 and the Research and Development Committee on March 20, 2013. Materials were approved by and New England Research Institutes, Inc (NERI) IRB on May 6, 2013. Materials for our testing of knowledge items was reviewed and approved by the Stanford IRB on June 19th, 2014 and the NERI IRB on June 20th, 2013 to comply with the DoD requirements.

ii. The 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. This approval was dated July 2, 2013.

2. Develop and Finalize Web-based, CBT Training Materials

A. Develop and pre-test CBT instructional modules and materials

i. During the first year, NCPTSD staff co-led the content development modules. All design elements have been developed and completed. Module content for the video clip development has been finalized, including filming for videos and final cut review. The BTA web interface is ready for use, and web programming of content for the chain analysis/case formulation module is on schedule for completion in October, 2013.

B. Develop case material and demonstrations

i. During the first year of this project, the team developed multiple case portrayals for use in the video simulation interviews. All video simulation interviews are complete and are being programmed into the chain analysis web-based interface.

C. Prepare web-based supervision manual and materials

i. During the first year of this project, the team created a manual and materials for the web-based supervision.

ii. This manual is currently being reviewed by content expert Brett Litz, Ph.D. for final feedback.

D. Training content complete, reviewed by CBT expert consultants

i. A team of carefully selected expert content consultants, including Christopher Fairburn, MD, Amy Naugle, Ph.D., Gareth Holmen, Ph.D., and Brett T. Litz, Ph.D., was assembled. These individuals were invited to serve as special consultants to the project based upon their extensive experience and knowledge in these content areas.

E. Pilot test all study procedures and materials (prior to programming)

i. Pilot testing of the knowledge items is in its final stages. Knowledge items were developed this year through a combination of blueprinting and concept mapping approaches. This process identified key concepts and to generate specific knowledge assessment items. Team and expert consultant review resulted in a final set of 50 pilot items. An online survey was programmed for the piloting of these items, and 110 surveys were collected for three target groups: VA clinicians, community practitioners, and cognitive behavioral therapy experts. The surveys collected both qualitative and quantitative data. This dataset is currently being cleaned and analyzed according to our study protocol. Final items will be available at randomization.

3. Develop, Pre-Test and Finalize Web Site and Instructional Program

A. VHA web host programmers provide specification and guidance to web programmers and database programmers

i. The team has collaborated with NERI to determine integration requirements for in the future hosting the web-based training program on an NCPTSD server. There are no anticipated issues with hosting the program with the National Center for PTSD. The site will be compliant with and fully tested for 508 compliance

requirements.

B. PTSD training material completed. All web training modules have been completed and are being beta tested currently.

C. Web programming specifications completed

i. During the first year of this project, the web programming specifications were identified, content was finalized and web programming activities were initiated. Web programming including all interactive elements is on schedule for completion in October.

D. Web program transferred to VHA intranet server

i. Web programming has not yet been transferred to the VHA server as initially planned. This site will be hosted externally until the study recruitment is completed, at which time it will be loaded and tested on the VHA NCPTSD server.

4. Develop Data Management System

A. Flow chart all study steps, web data collection and database requirements

i. During the first year of this project, a design was created to show the steps in data collection to plan for programming of the DM system.

B. Develop web-based data forms for all research measures

i. During the first year of this project, the team has begun the creation of web-based data forms.

C. Program the database including project data entry forms

i. During this period, the team conducted initial programming activities of forms in preparation for the pilot. These activities will be ongoing over the next two months, with completion by launch in the first quarter of the second year grant cycle.

D. Program web usage statistics reports

i. An analysis plan has been developed for selection and validation of knowledge items. These reports will be beta tested prior to initiation of the study.

E. Program reports to monitor project operations and outcomes

i. The project's team members at NERI will be using an electronic case report from systems, eCOS, to store the data forms. The reports will be created to assist with monitoring project operations. Plans have been initiated in this project year, and implementation will be undertaken in the next project year.

5. Major Task Milestone

A. Program automatic email reminders/interaction with web participants

i. During the first year of this project, the email reminder process has been reviewed and is an ongoing part of the data management activities.

B. Beta test all programmed pieces and interactivity with web course

i. Beta testing will be completed by launch, the first quarter of the second year grant

cycle. This will be conducted to ensure that there are no interactivity errors with the web course of the evaluation materials.

6. Prepare Standardized Patient Rating Protocol

A. Develop and Pre-test Standardized Patient (SP) Rating Guide

i. Standardized patient case materials have been developed and are in pre-testing phase.

ii. New rating scales have been developed and are being pre-tested currently. Rating scales are currently undergoing rigorous review and improvement for clarity of language, structure, and inter rater reliability.

B. Study raters and actors have been engaged for the study

Pilot raters have been hired and rating scales are currently undergoing rigorous review and improvement for clarity of language, structure, and inter rater reliability. Main study rater and actor positions have been posted and are currently being reviewed and interviewed.

C. Training procedures have been developed and pre-tested.

Full drafts of training materials have been created and will be finalized once the rating scales are final.

KEY RESEARCH ACCOMPLISHMENTS

- Hiring and training of project staff
- Establishment of ongoing communication system and decision-making processes with partnering institution NERI
- Prepared and finalized research protocol
- Draft knowledge and skills assessment measures and initiate pilot testing
- Obtained all relevant approvals for study protocol, informed consent forms, and recruitment materials
- Developed online training materials
- Provided expert feedback and input on web programming activities
- Authored content on web programming activities
- Hired three new part-time Standardized Patient Raters
- Trained three new part-time Standardized Patient Raters
- Conducted Initial rating sessions with Standardized Patient team to develop rating scales
- Setup contract with Viva Transcription, a voice-to-text transcription service
- Ordered and inventoried audio and recording equipment for standardized patient and clinician phone calls
- Developed and setup scheduling system for standardized patients and participants to utilize

- Provided therapy expertise and acting resources for video filming project
- Developed study assessment methods and materials
- Pre-testing of study assessment methods currently underway
- Pilot testing was initiated

During the next performance period, Year 2, the team will focus on the following activities:

1. Initiate Recruitment Activities and Secure Adequate Enrollment: Based on our established plan for recruitment, the team will develop a data system for screening, consenting and tracking study participants. We will initiate recruitment and in subsequent months adjust our efforts based on rates of enrollment, such that we will have consistent enrollment during the period in which participants will be in enrolled (i.e., the first 18 months of the study).
2. Develop Data Management System: The team will continue to work on development of web based data forms for all research measures and programming the database to include project data entry forms.
3. Launch of web-based training program: Completion of web programming for training program, including installation of all video elements (currently being reviewed and undergoing final edit). Launch of site for study is planned for the first quarter of the second year grant cycle.
4. Complete planning and implementation of email reminders/interaction with web participants: Email reminders are anticipated to be programmed by, the first quarter of the second year grant cycle.
5. Standardized Patient Rating Scales: Pre-testing of interviews and standardized patient rating scales are in process and scheduled for completion in Q5, 2013.
6. CE/CME Accreditation: As study participants cannot be compensated for their time with anything of monetary value, CE/CMEs will be issued for completion of the web-based training. CE/CME accreditation and related activities are in process.

To date there have been no risks or unanticipated issues associated with this project that have impeded its performance.

REPORTABLE OUTCOMES

To date, there are no reportable outcomes.

CONCLUSION

This training program will focus on development of evidence-based CBT skills to improve skills in providers treating Veterans and active duty military and to effectively engage patients in the treatment process. This innovative study will add new knowledge to our understanding of skills dissemination in PTSD provider care. We will test the hypotheses of the study in a rigorous, experimental design, and will assess outcomes of new web-based training modules and consultation methods. This study will provide data to assist researchers, military leaders, and

treatment providers to better understand practical and theoretical implications for future training of mental health providers in the VAH and other health systems.

All major milestones were met in the first 12 months of grant activity.

REFERENCES

Bradley, R., Greene, J., Russ, E., Dutra, L., & Westen, D. (2005). A multidimensional meta-analysis of psychotherapy for PTSD. *The American Journal of Psychiatry, 162*(2), 214-227.

Fairburn, C. G., & Cooper, Z. (2011). Therapist competence, therapy quality, and therapist training. *Behaviour Research and Therapy, 49*, 373-378.

Meichenbaum, D. (1985). *Stress inoculation training*. New York: Pergamon Press.

Monson, C. M., Schnurr, P. P., Resick, P. A., Friedman, M. J., Young-Xu, Y., & Stevens, S. P. (2006). Cognitive processing therapy for veterans with military-related posttraumatic stress disorder. *Journal of Consulting and Clinical Psychology, 74*, 898-907.

Ruzek, J. I., Friedman, M. J., & Murray, S. (2005). Toward a knowledge management system for posttraumatic stress disorder treatment in veterans healthcare. *Psychiatric Annals, 35*(11), 911-920.

Ruzek, J. I., & Rosen, R. C. (2009). Disseminating evidence-based treatments for PTSD in organizational settings: A high priority focus area. *Behaviour Research and Therapy, 47*, 980-989.

Ruzek, J. I., Rosen, R. C., Marceau, L., Larson, M. J., Garvert, D. W., Smith, L., & Stoddard, A. (2012). Online self-administered training for post-traumatic stress disorder treatment providers: design and methods for a randomized, prospective intervention study. *Implement Sci, 7*, 43. doi: 10.1186/1748-5908-7-43

Schnurr, P. P., Friedman, M. J., Engel, C. C., Foa, E. B., Shea, M. T., Chow, B. K., . . . Bernardy, N. (2007). Cognitive behavioral therapy for posttraumatic stress disorder in women: a randomized controlled trial. *JAMA, 297*(8), 820-830.

Shafran, R., Clark, D. M., Ehlers, A., Garety, P. A., Salkovskis, P. M., Fairburn, C. G., . . . Wilson, G. T. (2009). Mind the gap: Improving the dissemination of CBT. *Behaviour Research and Therapy, 47*, 902-909.

Shapiro, F. (2001). *Eye movement desensitization and reprocessing (EMDR): Basic principles, protocols, and procedures (2nd ed.)* (2nd ed.). New York: Guilford Press.

van der Kolk, B. A., Spinazzola, J., Blaustein, M. E., Hopper, J. W., Hopper, E. K., Korn, D. L., & Simpson, W. B. (2007). A randomized clinical trial of eye movement desensitization and reprocessing (EMDR), fluoxetine, and pill placebo in the treatment of posttraumatic stress disorder: Treatment effects and long-term maintenance. *The Journal of Clinical Psychiatry, 68*, 37-46.

APPENDICES

None.

SUPPORTNG DATA

None.