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TITLE: Dissemination of Evidence-Based CBT Intervention
Components: Online Self-Administered Training for Providers
Treating Military Deployment-Related PTSD

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14. ABSTRACT The purpose of this study is to design, implement and evaluate a web-based, self-paced training program to provide skills-oriented continuing education for mental health professionals. It is intended to reach a broad range of mental health providers presenting content that is highly relevant and easy to access. The program incorporates interactivity, practice, and modeling of three effective cognitive-behavioral skills components: goal-setting, motivation enhancement, and behavioral task assignment - as applied to treatment for Veterans with Posttraumatic Stress Disorder (PTSD). A randomized design will be used in which 120 participants will be randomly assigned to one of three conditions: (i) web-based training plus consultation, (ii) web-based training without consultation, and (iii) training as usual. The effectiveness of training will be evaluated by means of simulated patient interview assessment of core skills (primary outcome) and on-line questionnaire assessment of knowledge, perceived self-efficacy in skills use, and self-reported skills application with PTSD patients (secondary outcomes). This report summarizes project accomplishments during the first year, including development of the project team and protocol, content and evaluation materials, design of the web-based					
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Introduction

The purpose of this study is to develop, implement and evaluate a web-based, self-paced training program to provide skill-improvement oriented continuing education for mental health professionals. It is intended to reach a broad range of VA health professionals presenting content that is highly relevant and easy to access for practitioners. It follows adult learning principles and incorporates interactivity, practice, and modeling of effective treatment for Posttraumatic Stress Disorder (PTSD). Overall, the current study is designed to demonstrate in a randomized, controlled design that web-based CBT training is a cost-effective means for developing relevant clinical skills in VHA providers responsible for the clinical care of veterans with symptoms of PTSD. The specific hypotheses to be evaluated are:

1. Web-based training will increase clinician skill in core CBT techniques compared to usual training exposure (control).
2. Web-based training followed by expert group consultation will increase clinician skill in core CBT techniques compared to web-based training alone and usual training exposure (control).
3. Web-based training will increase clinician knowledge, attitudes and self-efficacy in evidence-based counseling practices with PTSD patients.
4. Training effects will be mediated by participant engagement in training, as measured by modules completed and expert group consultation sessions attended.

Body

This section of the report shall describe the research accomplishments associated with each task outlined in the approved Statement of Work.

1. Prepare Training Content

- a. *Prepare PTSD and revise CBT case and instructional material all modules*
 - i. Content development for the three training modules (Motivational Interviewing, Goal-Setting, and Behavioral Task Assignment) was completed during the first year of the project. A team of carefully-selected expert content developers was assembled, comprised of the project investigators, in addition to Amy Naugle, Ph.D., Jennifer Sharpe Potter, Ph.D., J. Gayle Beck, Ph.D., and Brett T. Litz, Ph.D. These latter individuals were invited to serve as special consultants to the project based on their extensive experience and knowledge in the specific content areas.
- b. *Prepare case material to be introduced*

- i. During the first year of this project we developed the character “Robert”, a Vietnam Era Veteran with PTSD, which is the character the simulated patients will be portraying. Detailed background was created for this character.
- c. *Prepare expert group supervisor manual and materials*
 - i. During the first year of this project we created and finalized a manual and materials for the simulated patients.
 - ii. During the second year of this project we have finalized a manual and materials for the consultant procedures for the consultation sessions.
- d. *Training content complete, reviewed by VHA CBT experts*
 - i. During the first year of this project we finalized the training content that will be placed on the web for training purposes. Furthermore, the training modules were reviewed by VHA CBT experts at the National Center for PTSD in Menlo Park, CA and Boston, MA, as well as by qualified study staff.

2. Prepare Research Protocol

- a. Eligibility criteria, exclusion criteria, screening protocol refined
 - i. During the first year of the study we finalized the eligibility criteria (must be a full-time VHA mental health clinician that works primarily with PTSD patients), and exclusion criteria (does not deliver treatment in their daily practice, is not a VHA mental health clinician, and those that have participated in the Beck’s CBT training for depression, as this training is closely related to the web training program).
- b. Sample frame, web contact methods, email lists identified
 - i. During the first year of the study we identified potential participants as well as created several email lists of potential participants
 - 1. Email lists included: VHA mental health clinicians that have participated in the “Clinical Training Program” at the National Center for PTSD, team leaders at each Vet Center in the United States, and the National Mentor Program in PTSD.
 - 2. Announcements were made on national phone calls and presentations to appropriate audience members.
 - 3. Postcards were created and disseminated at conferences and other mental health events. See Figure 1.
- c. Simulated patient interview specified and scripted

- i. In Year 1 a manual was created for the simulated patient interview process. This manual includes detailed characteristics of “Robert”, a precise script for instructions during the simulated patient interview, mandatory statements to be said during interview for evaluation purposes by the simulated patient, a draft of decision rules for the simulated patient if they are presented certain situations in the interview, and finally, a detailed set of procedures for the simulated patient interview.
- d. Research measures modified to reflect PTSD CBT focus
 - i. The training modules were developed in Year 1 to reflect PTSD and CBT focus. All examples on the training modules pertain to patients with PTSD.
- e. Consent form drafted, human subjects protocol finalized
 - i. During the first year of the study the web-based consent form was created. The terms of the study were clearly defined with an „accept” participation button. Those who chose accept moved to the next phase of the study (the consent form was approved by both the Stanford and NERI IRBs). .
- f. NERI/VHA IRB approvals and USAMRMC HRPO human subject protocol approval
 - i. During the first year of the study the protocol was approved by the Stanford and NERI IRBs, VA Research and Development, and finally by USAMRMC HRPO. During the second year of study a continuing review was approved by the Stanford and NERI IRBs and VA Research and Development.
- g. Pilot test all study procedures and materials (prior to programming)
 - i. Repeated simulations of the simulated patient interview were performed and evaluated to assure that procedures were consistently executed. Furthermore, repeated beta testing of the web-based materials was conducted by the study team in Year 1 of the study.

3. Produce Web Site and Instructional Program

- a. VHA web host programmers provide specification and guidance to web programmers and database programmers.
 - i. We have obtained VHA web host programming instructions and have implemented them in the construction of our web-based training program. Currently, the web-based training program will not be on a VHA server as updates are currently being performed for this server which will not allow our program to be uploaded in a timely manner to execute the study. The website is hosted on the server where it is being developed currently. The site was

programmed with the intention and ability to transport the site to another server and plans are to discuss the ultimate hosting location and URL during the final study year.

- b. PTSD case material completed
 - i. During the first year of this project we developed the character “Robert”, a Vietnam Era Veteran with PTSD, which is the character the simulated patients will be portraying. Detailed background was created for this character.
- c. Web programming specifications completed
 - i. During the first year of this project web-programming specifications were identified and completed.
- d. Web modules are programmed
 - i. During the first year of this project programming was completed to host the web training program and online evaluation materials.
- e. Web program transferred to VHA intranet server
 - i. During development and based on meetings with web programmers from the Central Office it was determined that the aspects of the VHA intranet server were under development which could impact programming and hosting of the PTSD for CBT site. It was determined that the best course of action was to host the site on the server where it was developed during the study. During the final year of the study and after data collection is completed we will discuss the possibility of transferring the web program to VHA intranet server.
- f. Beta test and modify the working web program
 - i. Both the web training modules, study screener, consent, and the evaluation materials were beta tested and used in Year 2 of the study.

4. Develop Study-specific Data Management System

- a. Flow chart all study steps, web data collection and database requirements
 - i. During the first year of this project a flow chart of all study steps was created. Simultaneously study staff evaluated web data collection and database requirements and relayed this information to the web programmers. See Figure 2 for flow chart.
- b. Develop web-based data forms for all research measures
 - i. During the first year of the project we have developed all web-based data forms for all research measures. This process was performed parallel to the development of the research measures.

- c. Program the database including project data entry forms
 - i. During the first year of the project the database for project data was successfully programmed, was beta tested, and implemented in Year 2.
- d. Program web usage statistics reports
 - i. During the first year of the project usage statistics reports were created and programmed by study staff. These reports were beta tested and implemented in Year 2.
- e. Program reports to monitor project operations and minimize drop out
 - i. Using the data management system on the NERI server numerous reports to monitor project operations and recruitment were created. These reports are updated as information is entered into the site, making project operations more efficiently monitored.
- f. Program automatic email reminders/interaction with web participants
 - i. During the first year of the study we have created automated emails in conjunction with the programming of the usage reports and the monitoring system for project operations. Separate emails are created for participants in each of the three treatment groups of this study. Furthermore, automated email templates have been created as reminders of key timepoints during scheduling of simulated patient interviews and the consultation sessions.
- g. Beta test all programmed pieces and interactivity with web course
 - i. Betas testing of all programmed pieces were performed and completed in Year 2 to assure that there are no interactivity errors with the web course or the evaluation materials.
- h. Ongoing monitoring of study process
 - i. Study recruitment began in Year 2 in October of 2009. Study recruitment was completed by July 31 of 2010.

5. Prepare Expert Rating Protocol

- a. Modify CBT Rating Guide to reflect web course objectives and PTSD core skills
 - i. The CBT Rating Guide for the simulated patient interviews were completed in Year 2.
- b. CBT advisors comment on Rating Guide and methods
 - i. CBT advisors have been identified to help with the construction and evaluation of the Rating Guide.
- c. Train independent study raters until 100% concordance

- i. Raters have been recruited and trained according to a detailed training manual. Based on the development of the rating system, training sessions conducted, and available literature we have a 70% expectation of concordance, given the complexity of the Rating Guide to reflect the web course objectives and PTSD core skills.
- d. Perform blinded independent ratings ($n = 120 * 2 = 240$) and re-ratings
 - i. During the recruitment period 168 participants were recruited for this study. We have recruited more than the required 120 participants in anticipation of attrition and due to the high volume of interest during recruitment. A random sample of 20% of the simulated patient interviews will be rated by multiple raters to assess reliability of the rating system. Ratings of interviews began in July of 2010 and are estimated to be completed by January of 2011.

6. Data Collection, Intervention, and Simulated Patients (SP) Interviews

- a. Web screening of potential clinician applicants, estimated screenings 200
 - i. During the first year of the project a web screening tool was created. During Y02, this screener was implemented.
- b. Schedule and carry out SP baseline interviews with eligible clinicians, $n = 120$
 - i. Recruitment for this study began in October of 2009. We have exceeded the goal of 120 participants and have closed recruitment with 168 participants enrolled.
- c. Random assignment of participant with completed SP interview by statistician to web-course, web-course+supervision, or control ($n = 120$)
 - i. Random assignment of participant with completed simulated patient interview has been programmed to randomly assign to treatment groups based on experience to assure that clinical experience is balanced among all three treatment groups. Recruitment was completed in Year 2.
- d. Participants complete assigned condition
 - i. Web course participants complete instructions (6 weeks scheduled)
 - 1. Recruitment began and was concluded in Year 2.
 - ii. Web course+supervision completed (12 weeks scheduled)
 - 1. Recruitment began and was concluded in Year 2.
 - iii. Control condition completed (12 weeks scheduled)
 - 1. Recruitment began and was concluded in Year 2.
- e. Schedule and carry out post-training SP Interviews (Goal is 80% follow-up rate)

- i. Recruitment for this study concluded on July 31 of 2010. At this report, not all participants have had the opportunity to complete their post-training SP Interviews based on the study timeline.
- f. Clinicians in training conditions submit Counseling session Forms (CSF) and receive individualized graphic feedback ($n = 120 * 3+ = 360+$)
 - i. A “CBT Session Checklist” has been created for participants in the consultation treatment group to monitor the use of learned skills in current practice. All groups will be asked about skill usage during the midpoint and final study evaluations.

7. Analyses and Evaluation

- a. Monitor data collection rates and data quality
 - i. Programming has been completed to monitor data collection rates and data quality. Furthermore, a graphical report was created at the end of each month during recruitment to monitor recruitment progress compared to the rate we will need to recruit at to complete recruitment by the end of the year 2010.
- b. Create interim and final analytic data sets and basic frequencies for PI’s and study investigators
 - i. Data collection remains in process at the end of Year 2. Interim data sets and basic frequencies for PI’s and study investigators are currently available.
- c. Author and co-author evaluation findings, project reports to funding source, VHA administrators and other stake-holders, scientific papers for the PTSD mental health community
 - i. Data collection is in process as expected at the end of this reporting period. Interim data sets and basic frequencies for PI’s and study investigators are currently available. The Statistical Analysis Plan is under development, and data cleaning activities are planned to begin after data collection is completed in October 2011. Manuscript planning is underway and methodological papers are currently under preparation. The main results paper is under discussion and will be the initial data paper produced on the study.
- d. Host periodic discussion, solicit written comments on evaluation findings to identify strengths and potential barriers for bringing program to scale, within and outside the VHA

- i. Project PI disseminated the study procedures and design at the Military Health Conference in Kansas City, August of 2009.
- ii. Poster presentation on Simulated Patient Interview development and process at World Congress of Behavioral and Cognitive Therapies in Boston, June of 2010.

Key Research Accomplishments

- Prepared training content
- Prepared research protocol
- Produced web site and instructional program
- Developed study-specific data management system
- Prepared expert rating protocol

Reportable Outcomes

- Project PI disseminated the study procedures and design at the Military Health Conference in Kansas City, August of 2009.
- Poster presentation on Simulated Patient Interview development and process at World Congress of Behavioral and Cognitive Therapies in Boston, June of 2010.

Conclusion

Data collection has not been completed at this time, study conclusions are not available at this time. The work planned for year 3 of the study is summarized as follows:

- 1) Complete Data Collection: Enrollment was completed in July, 2010. All active study participants will continue through the study protocol. The last participants enrolled are estimated to complete data collection October 31, 2010.
- 2) Complete Rating, Reliability Re-Rating, and Quality Control (double data entry): The assessment form for the main study outcome was completed during the second year of the project. Raters were trained in July, 2010, and a process for reliability was developed. Rating has begun using the assessment form and all forms will be data-entered into the data management system upon completion of programming. All data entry will occur in the third year of the project.
- 3) Data Cleaning: Data cleaning will occur in the third year of the project when data collection and data entry have been completed. The data management system has a procedure in

place for double data entry of forms to protect against data entry errors. Missing data will be identified and confirmed and any other outstanding data issues will be resolved.

- 4) Analysis: The statistical analysis plan is under discussion and will be developed during the first quarter of Y03. Once completed data cleaning and analysis for the main results paper will begin immediately.
- 5) IRB Annual Review: In the third year the study will submit an Annual Continuing Review Report to the NERI and Stanford IRBs.
- 6) Manuscript Development: Plans for manuscripts have already begun and will be continued in the third year. There are immediate plans to develop several manuscripts about study design and processes that do not require data. A manuscript will be prepared using the main study outcomes upon completion of analyses of these data. Manuscripts based on additional data and secondary outcomes will be considered. Current manuscripts are underway on three topics: main results, simulated patient interview methods, and telephone consultation methods.

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Figure 1: Recruitment Postcards

Post Traumatic Stress Disorder A Continuing Education Course in CBT for PTSD



Online Training in CBT Skills for PTSD Treatment:
Research Project Launching in September 2009

Visit our website to sign up and we will contact you when enrollment begins.
<http://study.neriscience.com/ptsd/intro>

Useful Training!
• CEUs • Self-paced • Interactive
• Focused on 3 key components of CBT

To be eligible you must be:

- A Mental Health Clinician
- A Full time VHA or Vet Center employee
- A Clinician who treats veterans with PTSD
- Able to use the web at work or at home
- Willing to consent to the research study

- Your employment *will not be affected* in any way regardless of whether or not you participate.
- Your individual information will be kept strictly confidential.

For more information contact: **Project PI:**
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For general information about participants rights, contact 866-680-2960.

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Figure 2: Diagrammatic Representation of Evaluation Design.

