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TITLE: Randomized, Controlled Trial of CBT Training for PTSD Providers

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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 <i>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.</i> 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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Table of Contents

KEYWORDS	4
INTRODUCTION	4
BODY	6
KEY RESEARCH ACCOMPLISHMENTS	10
REPORTABLE OUTCOMES	12
PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS	12
INVENTIONS, PATENTS, AND LICENSES	13
OTHER ACHIEVEMENTS	13
CONCLUSION	14
REFERENCES	15

KEYWORDS

Post-traumatic stress disorder, mental health, training, technology, chain analysis, behavioral task assignment, standardized patient, consultation

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=207) and the community (N=207) 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

RECRUITMENT/STUDY LAUNCH

Below are our invitation, registration, and data collection statistics. As of September 29, 2015:

The study launched its recruitment efforts on March 6, 2014 and concluded enrollment on April 15 2015. The recruitment method of working within VA, Give an Hour, and other community partnerships was successful. We exceeded our recruitment goal by 6, closing recruitment with a total of 209 VA and 211 community clinicians enrolled in the study.

As of September 29, 2015, we have secured the following:

Registration Statistics

1609 registrants

Screener Statistics

Out of 1609 registrants...

998 participants screened eligible (62%)

68 participants screened ineligible (4%)

543 participants did not complete the screen (34%)

Consent Statistics

Out of 998 participants screened eligible...

856 participants consented (86%)

142 participants did not consent (14%)

Pre-test Statistics

Out of 856 participants consented...

613 participants completed the Pre-Test (72% of those who have consented)

243 participants did not completed the Pre-Test (28% of those who have consented)

Standardized Patient 1 Statistics

Out of 613 participants who completed the pre-test...

420 participants completed the SP1 (69% of those who have completed the pre-test)

192 participants did not completed the SP1 (31% of those who have completed the pre-test)

Randomization Statistics

Out of 420 participants who completed the SP1...

420 participants were randomized

- 30 participants were randomized but have decided to not partake in the study (Early Termination)

Standardized Patient 2 Statistics

Out of 420 participants who were randomized...

246 participants completed the SP2 (59% of those randomized)

174 participants did not complete the SP2 (41% of those who have been randomized)

Post-test Statistics

Out of 420 participants who were randomized...

219 participants completed the Post-test (52% of those randomized)

201 participants did not complete the Post-test (48% of those randomized)

Follow-up Statistics

Out of the 420 participants who were randomized ...

147 participants completed the Follow-up (35% of those randomized)

273 participants have not completed the Follow-up (65% of those who have been randomized)

Standardized Patient 3 Statistics

Out of 420 participants who were randomized...

163 participants completed the SP3 (39% of those randomized)

257 participants did not complete the SP3 (61% of those randomized)

WEB & VIDEO DEVELOPMENT

- The Behavioral Task Assignment and Chain Analysis modules are currently in use and functioning properly.
- All materials approved for continuing education credits
- The Chain Analysis module are hosted as part of the study website with Behavioral Task Assignment for purposes of this research project. This site will be hosted until the study recruitment is completed, and remain open through December 31, 2015. Participants in the control group (written materials) who have completed their participation time window have been offered free guest access to the site through December 31.
- On September 16, 2015 the team began collaborating with NERI to determine integration requirements for future hosting of the web-based training program on VHA servers.
- While there are no anticipated issues with hosting the program with the National Center for PTSD, the project will be complex and involve the following:
 - Two separate VHA training interfaces (one for VHA employees and one for community-based clinicians).
 - 508 requirements for all sites.
 - SCORM compliance for all sites

- Reprogramming of some training modules into languages useable by VHA servers.
- Securing CEU accreditation for the courses on web servers for psychology, social work, psychiatry, counseling, and nursing.
- Web programming has not yet been transferred to the VHA server. This site will be hosted externally through December 31st.

STUDY MEASURES

Standardized Patient Measures

- A standardized patient interview script was created and finalized for assessing clinical skills prior to and following the training.
- A transcription service was identified and contracted for creating transcriptions from all standardized patient interviews, and is currently providing satisfactory transcripts
- An actor training manual was finalized and used in the training of 5 actors who play the role of the Veteran with PTSD in the standardized patient design.
- The standardized patient measures for both modules of Behavior Task Assignment and Chain Analysis were finalized.
- Two teams of 5 raters were launched to rate the transcripts for clinician performance on Chain Analysis and Behavioral Task Assignment
 - Raters were hired and trained
 - Raters were required to pass “gold standard” transcripts scored by the core research team
 - Satisfactory team inter-rater reliability was secured during training and prior to beginning official ratings
- Ratings of the transcripts began, and inter-rater reliability statistics were conducted at strategic intervals during the process to confirm the usability of the measures; both measures achieved satisfactory IRRs.
 - Both full-team and individual IRRs were calculated, such that potential problem raters could be identified
 - Raters received rapid retraining in any cases where issues with inter-rater reliability arose.
- Teams have made steady progress, with both teams rating 75% of the total transcripts as of September 29, 2015. The Teams will conclude all ratings in the upcoming months, after which data analysis on our primary measure can begin.
- Zafra Cooper, a global expert in online CBT training for clinicians has been active as a pro bono consultant to the project’s metrics work group, attending biweekly meetings and contributing input.

Knowledge Items

- Knowledge items were finalized and programmed into the data management system

Other Measures

- Other measures were finalized based on findings from the first study (Ruzek et al., 2012).
- A newly published, standardized measure for clinician attitudes toward online training (Becker & Jensen-Doss, 2014) was identified and incorporated into data collection.

LEARNING CONSULTATION

- 4 Learning consultants were hired after an extensive, national job search of top-level clinicians familiar with cognitive behavioral therapy and the VA.
- Learning consultant training was completed.
- All learning consultants provided consultation sessions to participants randomized into the web-based training + consultation arm of the study.
- Consultation concluded on June 11, 2015
- The team enhanced the informal debriefing of the learning consultant team (4 staff) by formally collecting data on our learning consultation debriefing sessions; this will create rich data that will help inform the design of the learning consultation model.
 - The consultant interview protocol was finalized in August 2015.
 - Stanford IRB approval was secured in August 2015
 - What is gleaned from the consultant debriefing sessions will add to the participant survey data we collect and help inform future use of the consultation model if it proves to be effective. It is our intention to publish these findings in a secondary paper as part of the overall project.
- Debriefing of the learning consultants will conclude by early 2016.
- A learning consultation team of the Co-PI, program manager, and two research assistants will guide the mixed-method coding, analysis, and synthesis of the three consultation data sources (participant survey, consultant interviews, and session tracking forms)

INSTITUTIONAL REVIEW BOARD

- The current protocol and materials were submitted and approved by the Stanford IRB on January 6, 2015 and previously submitted to/approved by the US Army Medical Research and Materiel Command HRPO on March 22, 2013.
- Recruitment letter was updated and submitted for approval to the IRB. It was approved June 20, 2014.
- Analysis of learning consultation debriefing data was approved in August 2015.

CE/CME ACCREDITATION

- Continuing education accreditation was secured previously for the four national professional organizations (psychology, psychiatry, social work, and nursing) outlined in the proposal.

PERSONNEL

- A new research assistant was hired for the project's operations team.
- A team of 5 actors was hired and trained to serve as standardized patient simulators.
 - Before serving in the actor roll, all actors passed our qualifying procedures for working with actual participants (i.e., completed 3 consecutive mock-interviews successfully).
 - All current actors began participant interviews, which will be completed by early 2016.
- Two teams of five raters were hired and trained to rate the standardized patient protocol. Ratings are 75% complete for both measures and will conclude in December 2015.
- Four learning consultants were hired in the prior year and have worked on the project for the duration of the consultation period.

DATA MANAGEMENT SYSTEM

- A master tracking system at NCPTSD was created to manage participant outreach and track participant progress. The system was tested and deployed for all recruitment/enrollment activities.
- The research team utilized NERI case reports from its data system, eCOS, to store the data forms. The reports will be created to assist with monitoring project operations. The team began using this system during this project year, and will continue to do so for the duration of the data collection period.
- A scheduling interface was identified and two pages were built for standardized patient interview and learning consultation scheduling.
- The transcription service website was integrated into our master tracking system to ensure that all standardized patient interviews are logged and move through the system properly.

KEY RESEARCH ACCOMPLISHMENTS

- Finalization of research protocol
- Formal launch of recruitment in March 2014
- Networked with 12 additional veteran mental health organizations to expand recruitment efforts for community clinicians
- Hiring and training of project staff
- Completed piloting and finalization of knowledge items
- All data collection forms were finalized, programmed, and tested in the data management system
- Obtained all relevant approvals for study protocol, informed consent forms, and recruitment materials
- Finalized and launched online training materials
- Trained all newly hired staff
- Ongoing rating sessions with Standardized Patient team to develop rating scales
- Developed and setup scheduling system for standardized patients and participants to utilize
- IRB approval has been sought and obtained for all necessary modifications, and continuing review approval was obtained
- Developed and setup scheduling system for learning consultants and participants to utilize
- Developed study assessment methods and materials
- Ongoing communication and training with actors, raters, and learning consultants as needed
- Recruitment goals were exceeded with a final randomization number of N = 420.

To date there have been no risks associated with this project that have impeded its performance. While we did close recruitment slightly later than planned, we were able to recruit an additional 6 participants in the process. During the Year 4 next performance period the team will focus on the following activities:

1. Complete participant data collection; conclude follow-up interviews and surveys for all remaining participants who have yet to do so by October 28, 2015.
2. Complete all independent ratings of standardized patient interviews.

3. Conduct final analyses on inter-rater reliability using all full-team ratings
4. Conduct final analyses of actor fidelity measure.
5. Complete learning consultant interviews and qualitatively code results.
6. Transfer both training modules to VHA servers
7. Complete baseline data analysis
8. Publish paper based on baseline data
9. Qualitatively code learning consultation interviews and quantitatively clean and analyze datasets for learning consultation.
10. Publish paper based on learning consultation
11. Review and consider opportunities to re-contact participants who consented in the study to be re-contacted in order to strengthen the interpretation of study findings
12. Analyze main results of the study
13. Write paper based on results.
14. Work with NERI, VHA web hosting sites, five professional accrediting bodies, and other VHA departments to design, secure 508 and SCORM compliance, test, and disseminate the trainings on VHA supported sites for both VHA and community providers.
15. Convene advisory meeting and project review – During Year 4, the team will review study achievements and lessons learned.

REPORTABLE OUTCOMES

To date, there are no reportable outcomes

PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS

Co-I Dr. Rosen (New England Research Institutes) presented an update on the project to CDMRP leadership at the MOMRP meeting in Ft. Detrick on September 11, 2015. The project update was well received and no concerns were raised regarding timelines or completion of the project.

All presentations to date:

Title	Presenter	Conference Dates
A Randomized Control Trial of Online Training for PTSD	Alie, G. & Graham, B.C.	April 2013
Actor Fidelity and Training for Standardized Patient use in Clinical Research	Jordan, K.R. & Graham, B.C.	April 2014
Web-centered Consultation for Online Training in PTSD Treatment: A Scalable Approach to Skill-building	Sardarian, S. & Graham, B.C.	April 2014
Individual and Organizational Factors in Dissemination and Implementation of Skills following an Online Training for Clinicians Treating PTSD	Graham, B.C., Ruzek, J. & Lee, J. E.	May 1 – May 3, 2014
Randomized, Controlled Trial of CBT Training for PTSD Providers: Project OUTFIT	Ruzek, J. & Rosen, R.	August 5 – August 6, 2014
Project OUTFIT: Online User Training for Intervention in Trauma	Graham, B.C. & Ruzek, J.	April 28, 2015
The Role of Organizational and Provider Factors in Community Interventions Across Diverse Systems.	Graham, B.C.	June 1, 2015
Randomized, Controlled Trial of CBT Training for PTSD Providers: Project OUTFIT	R. Rosen	September 11, 2015
Improving the Efficiency of Standardized Patient Assessment of Clinician Fidelity: A Comparison of Automated Actor-based and Manual Clinician-based Ratings	Graham, B.C.	September 25 – September 26, 2015

INVENTIONS, PATENTS, AND LICENSES

To date, there are no inventions, patents, or licenses.

OTHER ACHIEVEMENTS

Graham, B. Clinical Research Loan Repayment Award, National Institutes of Health (2015-2017).

CONCLUSION

This training program focuses on development of evidence-based CBT skills to improve skills in providers treating Veterans and active duty military 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 are testing the hypotheses of the study in a rigorous, experimental design, and will assess outcomes of new web-based training modules and consultation methods. To date, the project is on schedule and recruitment efforts have proven successful for both VA and community clinicians. All major milestones were met in Year 3.

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 VHA and other health systems.

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Randomized, Controlled Trial of CBT Training for PTSD Providers Period of Performance

PT110249

W81XWH-12-1-0531



PI: Joseph Ruzek, PhD Org: Palo Alto Veterans Institute for Research

Award Amount: \$2,464,704

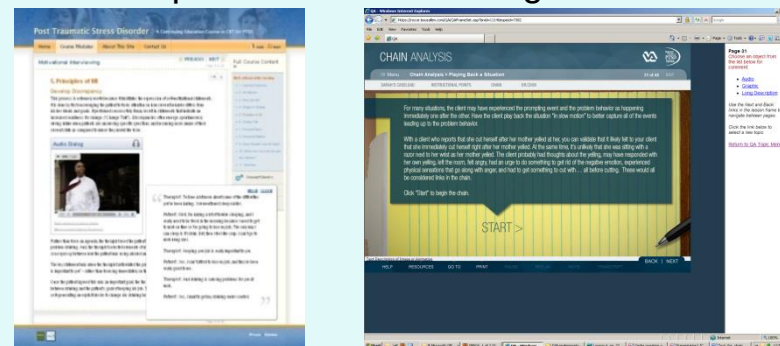
Primary and Secondary Aims

- **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 materials-only control with regard to improvements in CBT skills.
- **Secondary Aim #1:** To compare improvements in knowledge and attitudes following internet-based training with or without web-centered supervision and a written materials-only 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.
- **Secondary Aim #3:** To determine whether clinician implementation of skills assessed by means of a novel, patient-based measure of clinician skills implementation and effectiveness is predictive of changes in an objective (i.e., standardized patient) measure of skills.
- **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.

Approach

These aims will be accomplished by systematically comparing web-based training interventions across treatment settings and provider groups (VHA vs Non-VHA). Other unique qualities of this study include developing and testing new web-enhanced training modules and a novel web-centered supervision model, the development and implementation of a new patient-reported measure of clinician skill and competency and lastly, assessment of post-training maintenance of skills beyond the training period. This study focuses on the broadly applicable CBT skill areas of Behavioral Task Assignment and Chain Analysis. If successful, the study will promote a better standard of care for the psychological health of Veterans and their families.

Examples of Online Training Modules



To date, the Chain Analysis and Behavioral Task Assignment online training modules are in use and functioning properly, and participants are moving through the training and data collection process. Recent accomplishments include exceeding our recruitment goals (209 VA, 211 community), establishing interrater reliability on both rating teams, and concluding learning consultation sessions.

Timeline and Cost

Activities	CY 12-13	CY 13-14	CY 14-5	CY 15-6
Develop content and web based training/Pilot				
Recruitment/Enrollment				
Conduct training interventions and outcome assessments				
Data analysis, manuscript preparation, dissemination				
Estimated Total Budget (\$K)	322	1,074	767	301

Goals/Milestones

CY12-13 Goal – Design training modules and survey instruments

- ☒ PTSD training material completed
- ☒ Web modules programmed
- ☒ Study instruments completed or on time for completion

CY13-14 Goals – Initiate data collection

- ☒ Begin recruitment of participants through established VA and Give an Hour networks
- ☒ Begin phone supervision in the web-centered supervision condition

CY14-15 Goal –

- ☒ Continue data collection
- ☒ Assemble rater teams for standardized patient ratings
- ☒ Complete recruitment of remaining participants

CY15-16 Goal

- ☐ Transfer of web-based modules to VHA servers
- ☐ Coding, analysis, and syntheses of learning consultation data. Writing of results and dissemination
- ☐ Analysis of baseline data, writing of results, and dissemination
- ☐ Analysis of main findings, writing of results, and dissemination
- ☐ Disseminate modules via VHA servers

Comments/Challenges/Issues/Concerns

- No problems to date

Budget Expenditure to Date

Projected Expenditure: \$2,163,943

Actual Expenditure: \$785,813

Updated: 10/20/2015