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

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13. SUPPLEMENTARY NOTES

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 research findings of the study can be found below and in the forthcoming manuscripts.

15. SUBJECT TERMS
There are no risks associated with participation.

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INTRODUCTION

The primary aim of this research is 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). Using a randomized, controlled trial in 420 mental health providers in the VHA and Community, the study evaluated training effectiveness by comparing skills acquisition, the primary outcome measure for this study, across three groups: 1) web-based training; 2) web-based training with telephone consultation; and 3) no-training control group. Skills acquisition was measured using standardized patient (SP) assessments. 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.

KEYWORDS

Behavioral Task Assignment (BTA)
Chain Analysis (CA)
Cognitive behavioral therapy (CBT)
Post-Traumatic Stress Disorder (PTSD)
Randomized controlled trial (RCT)
Standardized Patient (SP)

BODY/ACCOMPLISHMENTS

This section of the report will describe the research accomplishments associated with each task outlined in the approved Statement of Work (SOW).

Year 1:

1. Develop Web-based Training Materials

   a. *Develop and pre-test CBT instructional modules and materials*

      i. During the first year, the content development modules were designed, developed and completed. Module content for the video clip development was finalized, including filming and final cut review.

   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. They were in the process of being pre-tested prior to finalization.

   c. *Prepare web-based supervision manual and materials*

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

   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. These individuals were invited to serve as special

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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 was initiated with > 50 completed surveys collected and both qualitative and quantitative data collected. A combination of blueprinting and concept mapping approaches were used to identify key concepts and to generate specific knowledge assessment items. The assessment items were pre-tested according to our study protocol and final items were later available at randomization.

2. <u>Develop and Finalize Study Protocol and Measures</u>

    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.

    b. *Sample frame, web contact methods, email lists identified*

        i. During the first year of the project, the team identified potential participants as well as identified existing email lists of participants through collaboration with community based groups.

            1. 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) of community clinicians participate in this registry and our study has arranged access to this recruitment pool.

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

    c. *Standardized Patient Interviews scripted and pre-tested*

        i. A standardized patient interview script was created for assessing clinical skills prior to and following the training. It was being pre-tested during year 1. Actors and interviewers were identified for the study.

    d. *Research measures and instruments developed and pre-tested*

        i. Knowledge and attitude questionnaires were developed for the study and were undergoing pre-testing during year 1. Other measures were 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 was approved by both NERI and the Stanford IRBs. The terms of the study were clearly defined with an

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"accept" or "decline" participation button. All consent activities occurred through a secure web site.

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

        i. The Protocol, Recruitment materials, Informed Consent documents, applicable applications were approved by the Stanford IRB on March 15, 2013 and with VA R&D. Revised Consent forms (version 4) were approved by the Stanford IRB on June 19, 2013 to comply with the DoD requirements. 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 9, 2013.

3. <u>Develop, Pre-Test and Finalize Web Site and Instructional Program</u>

    a. *VHA web host programmers provide specification and guidance to web programmers and database programmers*

        i. The NERI team collaborated with the VHA NCPTSD to determine integration requirements for ultimately hosting the of the programmed in the construction of our web-based training program on an NCPTSD server. The site is compliant with and fully tested for 508 compliance requirements.

    b. *PTSD training material completed. All web training modules were completed and beta tested.*

    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.

4. <u>Develop Data Management System</u>

    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 NERI team started the creation of web-based data forms.

    c. *Program the database including project data entry forms*

        i. During this period, the NERI team conducted initial programming activities of forms in preparation for the pilot.

    d. *Program web usage statistics reports*

        i. An analysis plan was developed for selection and validation of knowledge items.

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e. *Program automatic email reminders/interaction with web participants*

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

5. <u>Prepare Standardized Patient Rating Protocol</u>

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

      i. Standardized patient case materials were developed and pre-tested during year 1.

      ii. New rating scales were developed and pre-tested during year 1.

   b. *Training procedures were developed and pre-tested.*

Year 2:

1. <u>Develop and Finalize Study Protocol and Measures</u>
   a. *Web programming specifications were completed*
   b. *Web modules were programmed*
   c. *Beta testing of web program occurred*

2. <u>Develop Data Management System</u>
   a. *Programming of the database including project data entry forms was completed*
   b. *Programming of reports was completed*
   c. *Beta testing of all programmed pieces and interactivity was conducted*
   d. *Ongoing monitoring of study process*
      i. During the second year of this project, the team actively monitored data collection, data management, and the study process. We developed bi-weekly reports for active tracking of recruitment and study processes, and met bi-weekly to discuss progress.
      ii. Recruitment started on March 5th, 2014 and FPI was on March 7th, 2014.

3. <u>Prepare Standardized Patient Rating Protocol</u>
   a. *Develop and Pre Test Standardized Patient (SP) Rating Guide*
      i. During the second year of this project, the team developed the SP Rating Guide. Rating scales were developed, and underwent careful review for inter-rater reliability and finalization of all rating items, to assess adherence and competence for each training module.
   b. *External Review of the SP Rating Guide and Methods*
      i. Our team developed the rating guide and methods were reviewed by the metrics committee and Dr. Zafra Cooper (Oxford) assisted with final development and review.
   c. *Training of Independent Study Raters to Concordance*
      i. The team hired and trained four study raters.

4. <u>Develop Data Collection, Intervention and Standardized Patient Interviews</u>
   a. *Web screening of potential clinician applicants occurred.*
   b. *SP baseline interviews with eligible clinicians occurred.*

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    c. *Automated random assignment of participants with Completed SP Interview by Web Program to Web-Course, Web-Course + Web- Based Supervision, or Control*

  5. Analysis and Evaluation
    a. *Monitor Data Collection Rates and Data Quality*
      i. The NERI team collaborated with the VHA NCPTSD to monitor the collection rates and data quality on a weekly basis.
    b. *Create Interim and Final Analytical Data Sets*
      i. During the second year of this project, the initiation of the data sets was scheduled to begin.

Year 3:

  1. Develop Data Management System
    a. *Ongoing monitoring of study process*
      i. Between years 2 and 3 of this project, the NERI team actively monitored data collection, data management, and the study process. Bi-weekly reports were developed for active tracking of recruitment and study processes, and met bi-weekly to discuss progress. Study enrollment was completed in April 2015 with a total of 420 participants (VA = 209, Community = 211).

  2. Prepare Standardized Patient Rating Protocol
    a. *Develop and Pre Test Standardized Patient (SP) Rating Guide*
      i. The team developed the SP Rating Guide in year 2. During year 3, rating scales were developed and finalized.
    b. *External review of SP rating guide and methods*
      i. During year 3, raters utilized the finalized rating forms to rate the SPs from BTA and CA. These ratings underwent continued analyses for inter-rater reliability.
    c. *Training of Independent Study Raters to Concordance*
      i. The team hired and trained study raters for BTA and CA. Blinded independent ratings and reliability assessments began in Q2 of Year 2.

  3. Data Collection, Intervention and Standardized Patient Interviews
    a. *Schedule and Carry Out Post Training, Follow Up SP Interviews*
      i. This was an ongoing occurrence into year 3.

  4. Analysis and Evaluation
    a. *Monitor Data Collection Rates and Data Quality*
      i. The NERI team collaborated with the VHA NCPTSD to monitor the collection rates and data quality on a weekly basis.
    b. *Create Interim and Final Analytical Data Sets*
      i. During the second year of this project, the initiation of the data sets began. This task continued into year 4. A statistical analysis plan was in the process of being developed.

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Year 4:

1. Prepare Standardized Patient Rating Protocol
    a. *Training of Independent Study Raters to Concordance*
        i. All ratings were completed in year 4.
2. Data Collection, Intervention and Standardized Patient Interviews
    a. Data collection was completed on January 7th, 2016.
    b. A complete dataset was downloaded and saved to a secure server.
    c. SP ratings rubric was finalized.
3. Analysis and Evaluation
    a. *Monitor Data Collection Rates and Data Quality*
        i. The NERI team collaborated with the VHA NCPTSD to monitor the collection rates and data quality on a weekly basis.
        ii. Data recoding was performed.
    b. *Create Interim and Final Analytical Data Sets*
        i. During the second year of this project, the initiation of the data sets began. This task continued into year 4. A statistical analysis plan was developed.
    c. *Perform all analyses according to specification, share output and findings with all investigators*
        i. An analysis/proposal plan for the main results and web usage paper were created and reviewed by the investigators.
    d. *Convene advisory meeting*
        i. All advisory personnel have been kept informed of study progress throughout the study duration.
        ii. The study team met to review lessons learned.
    e. *Author and co-author evaluation findings*
        i. The effects of study interventions on primary and secondary outcomes of the study, in addition to web usage patterns are summarized in Appendix 2. These results will be presented also in two manuscripts, one of which has been submitted for publication and a second in final stages of preparation. Results are summarized in Appendix 2.

4. Other Items
    a. Conversion and long term hosting of the study website
        i. NERI completed conversion of the web-based training program from a Content Management System (CMS) to HTML, and provided final HTML files to the VA for long-term hosting. NERI remains available to discuss questions regarding hosting the HTML site on the VA/EES server. NERI and VA are in discussions regarding most appropriate long term solutions for hosting by the VA.
    b. CE/CME accreditation
        i. All CE/CME certificates have been issued for completion of the training. Four types of accreditation were offered: Social Work, Nursing, CME, and Psychology. Participants received 5 credit hours for completion of this training. All participants who completed the follow-up assessment were eligible to receive certification. In order to receive a certificate,

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participants were required to complete a CE evaluation (administered at post-test, and re-sent to participants who did not complete it during the study), and pass the knowledge assessment (at either post-test or follow-up) with a score of 70% or higher in order to earn the certificate. If a participant did not pass the knowledge assessment during the study, they were sent a re-test of the knowledge questions following completion of their participation. Participants were allowed to take as many re-tests as necessary in order to pass the knowledge assessment. A number of participants opted out of receiving a CE certificate, or did not respond to our requests to complete a re-test. In total, 139 continuing education certificates were issued.

KEY RESEARCH ACCOMPLISHMENTS

- Created two PTSD training modules (BTA and Chain Analysis)
    - CA training module approved under Section 508 of the Rehabilitation Act
- Developed standardized patient rating guides for the two modules
- Training approved for CE accreditation for four of the national professional organizations (psychology, social work, psychiatry, and social work)
- Exceeded our recruitment goals (209 VA, 211 community) to total 420 participants
- 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
- 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 study assessment methods and materials
- All post-test and follow-up questionnaires were completed in October 2015.
- 139 continuing education certificates were issued.
- All three intervention groups (written materials, web training only, and web training plus consultation) showed significant improvements in skills performance measured with standardized patient behavioral observation tasks, with few differences overall between the intervention groups.
- The web + consultation group showed better Chain Analysis skills adherence at follow-up, compared to the other two training interventions.
- For the other training module (Behavioral Task Assignment), all three training conditions showed significant improvements over time, but with no differences between training interventions.
- Similar findings were observed with the global ratings of competence: The web + consultation condition had better maintenance of global competence in Chain Analysis at follow-up assessment, and significant improvements over time were seen for Behavioral Task Assignment, but without significant differences between intervention arms.

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- Community-based clinicians showed better maintenance of improvement in skills performance compared to VA clinicians, particularly on the Chain Analysis skill.
- Clinicians' self-reported skills implementation of Chain Analysis showed significant improvements over time across all intervention conditions, with no differences between groups.
- For Behavioral Task Assignment, the web training + consultation group showed a significantly greater increase in self-reported implementation at follow-up assessment.
- Knowledge scores for both training modules increased significantly over time across all three training conditions, with no differences between training conditions or clinical settings.
- The majority of respondents rated the timeliness and relevance of the training program favorably or very favorably.
- Almost 95% reported that they planned to make changes in their clinical practice based on the specific skills acquired during the training, and 89% rated the course as relevant to improving their practice skills.
- For the Chain Analysis course, web training plus consultation was associated with significantly more time spent viewing web material than the other training modules, and for both Chain Analysis and Behavioral Task Assignment courses, participants assigned to the web training plus consultation arm viewed significantly more videos than those assigned to web alone.
- Among those assigned to the web training plus consultation condition, the number of consultation sessions completed was a significant predictor of pages viewed, time on course, and videos viewed.
- Each additional hour that participants spent on the training course significantly improved both adherence and competence for Chain Analysis, and competence for Behavioral Task Assignment.

REPORTABLE OUTCOMES/PRODUCTS

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

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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
Evaluating Clinicians' Use of a Web-based Training in Cognitive Behavioral Therapy for PTSD: Impact on Outcomes and Correlation with Self-Reported Use	J. Coleman	August 6, 2016
Assessment of Evidence-Based Training for Trauma Providers: Project OUTFIT Measures & Outcomes	R. Rosen	August 15, 2016
Measuring Clinicians' Use of a Web-Based Training in Cognitive Behavioral Therapy for PTSD: How Usage Impacts Knowledge, Competence, and Efficacy	J. Coleman	August 28, 2017
Evaluating Web-Based Consultation Combine with Online CBT Skills Training for PTSD Providers: Project OUTFIT	R. Rosen	August 28, 2017

Papers in draft:

Title	Authors	Status
Clinician usage of an online training for post-traumatic stress disorder treatment providers: measuring website usage patterns and their impact on outcomes	Coleman J, Marceau L, Graham BC, Kato B, Harty B, Magnavita A, Rosen RC, Ruzek JI	Submitted to Journal of Traumatic Stress

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Transdiagnostic Skills in Cognitive-Behavioral Case Conceptualization and Behavioral Task Assignment: A Randomized Trial of Scalable Training Methods in VA and Community Clinicians	Final author list TBD	In final stages of revision. To be submitted to the Journal of Traumatic Stress

Website:

http://cbttrainingforptsd.com/

http://core-exchange.org

Other products:

Various materials included in the training courses can function as stand-alone resources, including course handouts (e.g., self-monitoring forms) and especially, the set of brief video vignettes developed to facilitate the clinical supervision process.

CONCLUSION

What was the impact on the development of the principal discipline(s)?

Training in core PTSD treatment skills have been delivered to mental health treatment providers of several disciplines, including psychologists, social workers, and nurses. These practitioners have included both VA professionals and community-based professionals.

What was the impact on technology transfer?

The online training programs used in the study have been or are in progress of being made available to practitioners across VA and the American community via inclusion in the VA Employee Education Service training system, with continuing education units available. The courses will now be available to all interested clinicians for CEU credit. Magnets and notepads inclusive of the VA logo and the URL for the training course were created as training tools to help reinforce the online training courses to VA and community clinicians. In addition, to maximize the reach and impact of these courses, we have deployed an outward facing training website focused on providing all of the courses in a modular manner. This will allow clinicians to interact with the courses in whatever way is most helpful to them, including being able to revisit sections and get access to relevant documents, as desired. This website includes features such as "sticky notes" that clinicians can add wherever they would like with their own personal learning notes. Providing clinicians with both traditional, linear training courses and a stand-alone website for flexibly accessing all of the learning modules in one place will allow for deeper, ongoing engagement with the learning content while also providing requisite continuing education credits through VA.

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<u>What was the impact on society?</u>

This innovative study will add new knowledge to our understanding of skills dissemination in PTSD provider care. We have tested 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 VHA and other health systems.

SPECIAL REPORTING REQUIREMENTS

Quad chart can be found in Appendix 1.

APPENDICES

Appendix 1 – Quad Chart
Appendix 2 – Data Analysis Results

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PT110249
W81XWH-12-1-0531

PI: Josef Ruzek, PhD   **Org:** Palo Alto Veterans Institute for Research   **Award Amount:** $1,971,789

Study/Product Aim(s)

The purpose of this study is to design, implement and evaluate a web based training program providing skills-oriented continuing education for mental health professionals.
- To compare improvements in knowledge and attitudes following internet-based training with or without web-centered supervision and the control.
- To compare improvements in skills acquisition, knowledge, and attitudes following training in clinicians recruited from VHA mental health treatment settings compared to those providing services in civilian community-based clinics.
- To determine whether clinician implementation of skills assessed by means of a novel, patient-based measure of clinician skills implementation is predictive of changes in an objective (i.e., standardized patient) measure of skills
- 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

The study will test a large-scale, Web-based method of training with 414 VA (*n* = 207) and community-based clinicians (*n* = 207). Subjects will be recruited to participate in the evidence-based skills training and will be randomly assigned to 1 of 3 groups: Interactive Web-based training only; interactive Web-based training plus post training Web-based consultation; or training as usual control. Effectiveness will be evaluated using an intent-to-train design. Post-training and 3-month follow up assessment will be conducted.

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***.

Accomplishments: Two poster presentations were presented at the MHSRS meeting in August 2017. A manuscript on web usage has been submitted to Journal of Traumatic Stress (JTS). The main results manuscript is in the process of being finalized for submission to JTS.

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

Updated: 12/13/2017

Budget Expenditure to Date:
Projected Expenditure: $1,971,789
Actual Expenditure: $1,601,409

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

CY15-17 Goal
- ☑ Transfer of web-based modules to VHA
- ☐ 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

- All analyses are finalized and results are being written up for each of the main papers. The baseline results were combined into the main results paper and a manuscript is in the process of being finalized for submission. We also focused on completing a web usage paper to maximize dissemination of all relevant findings. We have transferred all content to VHA EES and we are just awaiting the final deployment by EES of the courses on TMS and TRAIN.

Appendix 2 – STUDY RESULTS AND FINDINGS

I.   Study Enrollment and Retention

   a. The Project OUTFIT study design and measures are illustrated in Figure 1
       below.

Figure 1. Design of Project OUTFIT

   b. Study enrollment and retention over the course of the study is shown in
       Figure 2 below. As shown, almost one thousand clinicians (N=998)
       completed the initial screening, of whom 420 clinicians were randomized to
       one of 3 training interventions. Almost 60% of participants (N=237/420)
       completed the post-training assessment, and a similar number (N=243/420)
       completed the follow up assessment 12 weeks later.

Figure 2. Consort Diagram
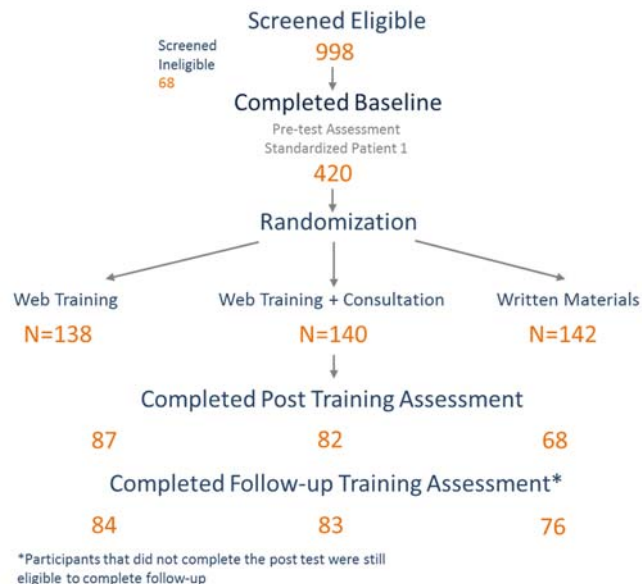
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c. Demographic information for the two clinician groups (VA; Community) is shown in Table 1 below. As shown, community clinicians were approximately 7 years older on average (mean age = 53.7 vs 46.7; p<.0001); although the ratio of female to male clinicians and race\ethnic composition was similar across the two groups. By design, we randomized a similar number (N~210) in both clinician groups.

Table 1. Demographic Characteristics of Study Participants

	VA		Community		P-value
	N	Mean (SD)	N	Mean (SD)	P-value
Age	203	46.7 (11.3)	209	53.7 (11.4)	<0.0001
Years in Practice	209	12.8 (9.3)	210	16.7 (10.5)	<0.0001
	N	%	N	%	
Gender					0.65
Female	150	71.8	141	66.8	
Male	58	27.8	68	32.2	
Other/Unknown	1	0.4	2	0.9	
Race/Ethnicity					0.36
White	175	83.7	171	81.0	
African American	14	6.7	20	9.5	
Other	20	9.6	20	9.5	
Hispanic or Latino	9	4.3	15	7.1	0.16

II. Training Effects over Time: ITT Analysis and Intervention Effects

a. Statistical analyses were conducted based on our pre-specified Statistical Analysis Plan (SAP). According to this plan, the intention-to-train (ITT) population was defined as all subjects who completed the pre-test evaluation and at least one or more of the post-test assessments. This population included 291/420 evaluable participants who completed the baseline and one or more SP assessments after study enrollment. For continuous outcome variables we used a linear mixed model (PROC MIXED in SAS) and included training condition (web + consultation; web-training only; written materials), clinical setting (VHA or community) and assessment period (baseline, post-training, follow-up) as main effects. Covariates included professional discipline, amount of training and self-reported expertise in evidence-based mental health care and CBT, age, gender and race-ethnicity. Our statistical model included two-way and three-way interactions between the main effects.

b. Primary outcomes for the study were pre-defined as standardized patient (SPE) evaluations of core skills in the two training modules of Chain Analysis (CA) and Behavioral Task Assignment (BTA). The study pre-defined two independently rated measures of therapy skills in each module: A) Total skills adherence and B) Global competence, as assessed by independent, trained raters (Ruzek et al., 2014). A third standardized patient measure (minimum competency) was found to be unreliable and was omitted from these analyses. Secondary outcome

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measured included CME course evaluations, in addition to self-ratings of skills implementation and a simple knowledge test of core concepts in the two skills domains (BTA, CA) (Ruzek, 2014).

c. Group differences across the intervention conditions (web + consultation, web only; reading materials only) at the 3 study timepoints (baseline, post-training; follow up) within the primary and secondary outcomes are shown in Tables 2 – 3 below. The results for the primary and secondary study outcomes, as defined above, are shown separately for the two training modules (CA, BTA) in each of the data tables below. On the two primary SP outcomes of skills acquisition (total adherence, global competence), all three groups showed significant improvements over time with few differences overall between the intervention groups. Specific results for the two primary outcomes are as follows:

Table 2. Primary and Secondary Study Outcomes – BTA

Global Competence - BTA									
Arm		**Pre**			**Post**			**Follow-Up**	
	N	Mean	Std Dev	N	Mean	Std Dev	N	Mean	Std Dev
Written	94	1.51	0.79	87	2.06	0.84	79	1.73	0.83
Web	102	1.39	0.90	94	1.86	0.86	84	1.80	0.99
Web+C	95	1.51	0.78	89	1.88	0.82	81	1.85	0.84
Total	291	1.47	0.83	270	1.93	0.84	244	1.80	0.89
Total Adherence - BTA									
Arm		**Pre**			**Post**			**Follow-Up**	
	N	Mean	Std Dev	N	Mean	Std Dev	N	Mean	Std Dev
Written	94	4.49	2.23	87	6.24	2.74	79	5.66	2.31
Web	102	4.58	2.30	94	6.18	2.61	84	5.94	3.01
Web+C	95	4.56	2.08	89	5.85	2.41	81	5.80	2.63
Total	291	4.54	2.20	270	6.09	2.58	244	5.80	2.67
Total Knowledge - BTA									
Arm		**Pre**			**Post**			**Follow-Up**	
	N	Mean	Std Dev	N	Mean	Std Dev	N	Mean	Std Dev
Written	93	5.80	1.98	67	6.64	2.02	70	6.13	1.78
Web	102	5.35	1.99	83	6.04	1.80	78	5.97	1.96
Web+C	95	5.71	1.86	80	6.80	1.70	78	6.38	1.56
Total	290	5.61	1.95	230	6.48	1.86	226	6.16	1.78
Self-reported Implementation - BTA									
Arm		**Pre**			**Post**			**Follow-Up**	
	N	Mean	Std Dev	N	Mean	Std Dev	N	Mean	Std Dev
Written	91	15.41	5.42	64	15.03	5.14	63	16.02	5.09
Web	98	15.65	4.95	76	16.36	5.10	70	16.46	5.27
Web+C	92	15.83	4.84	77	17.18	4.65	73	18.00	4.75
Total	281	15.63	5.06	217	16.26	5.01	206	16.87	5.09

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<div align="center">**Table 3. Primary and Secondary Study Outcomes – CA**</div>

Global Competence - CA								
Arm		**Pre**			**Post**			**Follow-Up**	
	N	Mean	Std Dev	N	Mean	Std Dev	N	Mean	Std Dev
Written	93	1.40	0.87	87	2.24	0.91	78	1.76	1.00
Web	102	1.31	0.93	94	1.93	1.10	84	1.75	1.05
Web+C	95	1.47	0.85	89	2.28	0.97	81	2.22	0.91
Total*	290	1.39	0.89	270	2.14	1.01	243	1.91	1.01
Total Adherence - CA								
Arm		**Pre**			**Post**			**Follow-Up**	
	N	Mean	Std Dev	N	Mean	Std Dev	N	Mean	Std Dev
Written	94	7.32	2.78	87	10.05	3.29	78	8.67	3.11
Web	102	7.25	2.98	94	9.07	3.45	84	8.50	3.18
Web+C	95	7.51	2.64	89	9.97	2.99	82	9.88	2.86
Total	291	7.35	2.80	270	9.68	3.27	244	9.02	3.10
Total Knowledge - CA								
Arm		**Pre**			**Post**			**Follow-Up**	
	N	Mean	Std Dev	N	Mean	Std Dev	N	Mean	Std Dev
Written	94	8.70	2.57	68	9.91	2.52	73	8.01	2.47
Web	102	8.91	2.63	84	9.73	2.45	80	8.91	1.90
Web+C	95	8.86	2.29	81	10.21	2.09	79	8.44	1.87
Total	291	8.83	2.50	233	9.95	2.35	232	8.47	2.11
Self-reported Implementation - CA								
Arm		**Pre**			**Post**			**Follow-Up**	
	N	Mean	Std Dev	N	Mean	Std Dev	N	Mean	Std Dev
Written	92	21.36	6.18	64	20.94	5.58	63	21.32	4.96
Web	100	21.15	5.11	78	20.44	5.71	71	21.00	5.31
Web+C	92	21.66	4.98	79	20.85	5.36	73	23.05	5.28
Total	284	21.38	5.43	221	20.73	5.53	207	21.82	5.25

III. Primary Outcome #1 Total Skills Adherence (Observer Rated)

   a. Total skills adherence scores for the CA module reveal that all 3 training
      conditions had improved skills adherence over time (F=59.01; p<.001). A
      marginally significant difference between training conditions was also seen in
      favor of the two web conditions (F=2.66; p<.07), in addition to a significant
      interaction between training conditions and study period (F-2.53; p<.05).
      Although all three training conditions had improved skills adherence from
      baseline to post-training assessment, the web + consultation group showed
      better skills adherence at follow-up, compared to the other two groups (See
      Figure 3A below). For the other training module (BTA), all three training
      conditions showed significant improvements over time (F=43.52; p>.0001),
      but with no differences between training interventions (F=0.56; p=0.57) or

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interaction effects over time. (For purposes of this report, figures showing non-significant interactions have been omitted).

Figure 3A: Intervention Effects on SPE Performance (Total Skills Adherence) over Time.
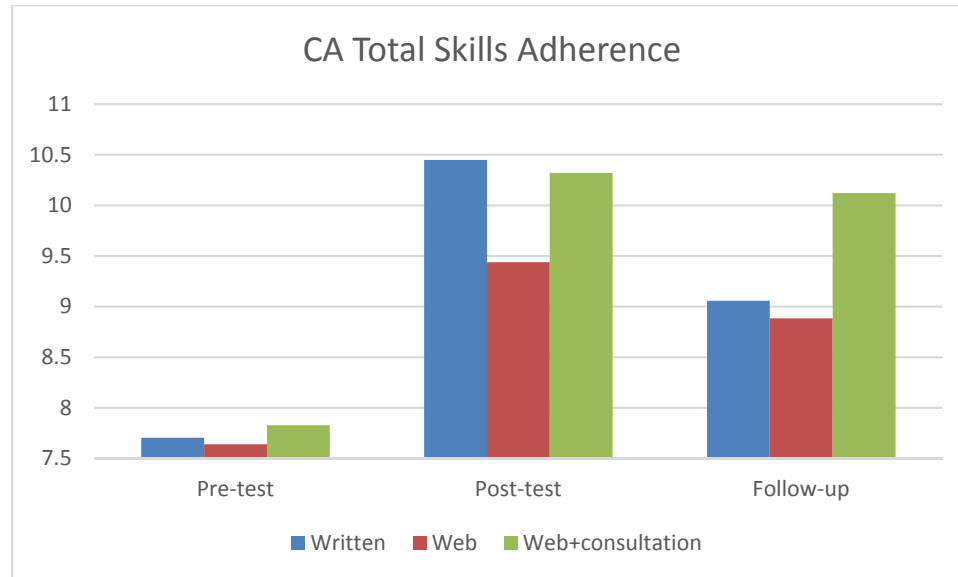
IV.   Primary Outcome #2: Global Competence (Observer Rated)

a. For our second primary outcome variable, changes in ratings of global competence in both clinical skills (CA, BTA) are shown in the tables above. On the CA training module, a significant effect of study period was seen ($F=59.01$; $p<.001$), as all three groups improved significanty over time. A significant interaction effect was also observed, as the web + consultations condition had better maintenance of global competence, as rated by independent, trained observers. Significant improvements over time were also seen in the BTA module for all three training conditions ($F=31.38$; $p<.0001$), but without significant differences between intervention arms ($F=0.41$; $p=.66$), or interactions beteen the training condition and changes over time.

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Figure 3B: Intervention Effects on SPE Performance (Global Competence Ratings) over Time

CA Global Competence Ratings

Legend: Written, Web, Web+consultation
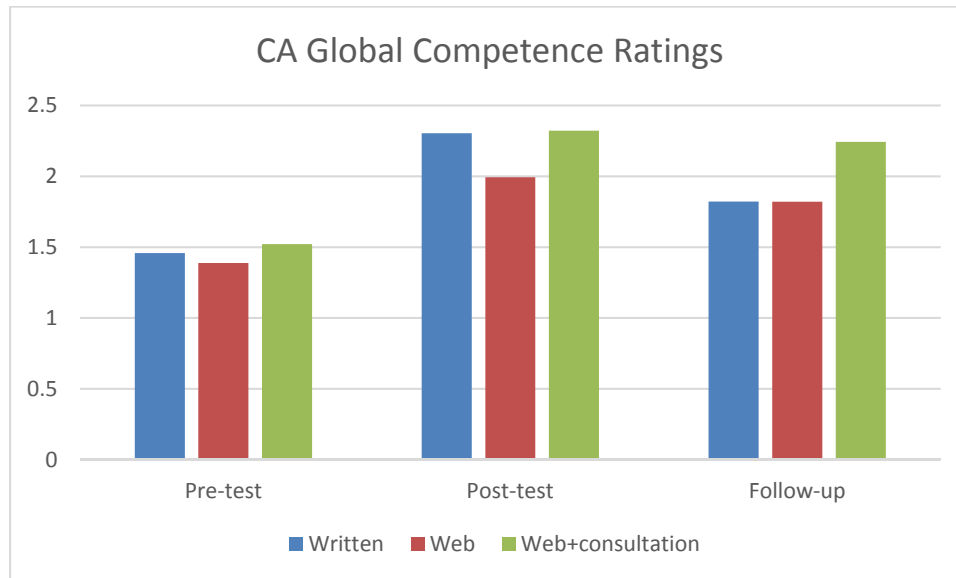
b. Additionally, a significant effect of the clinical setting in favor of community clinicians was also seen (F=8.41; p<.005). As shown in the Figure 4A and 4B below, both clinician groups improved significantly over time, although community clinicians showed better maintenance of improvement compared to VA clinicians, particularly on the CA module (Figure 4B).

Figure 4A: Training Effects on CA Global Competence in VHA Clinicians

VHA Clinicians: CA Global Competence Ratings (0-4)

Legend: Written, Web, Web+consultation

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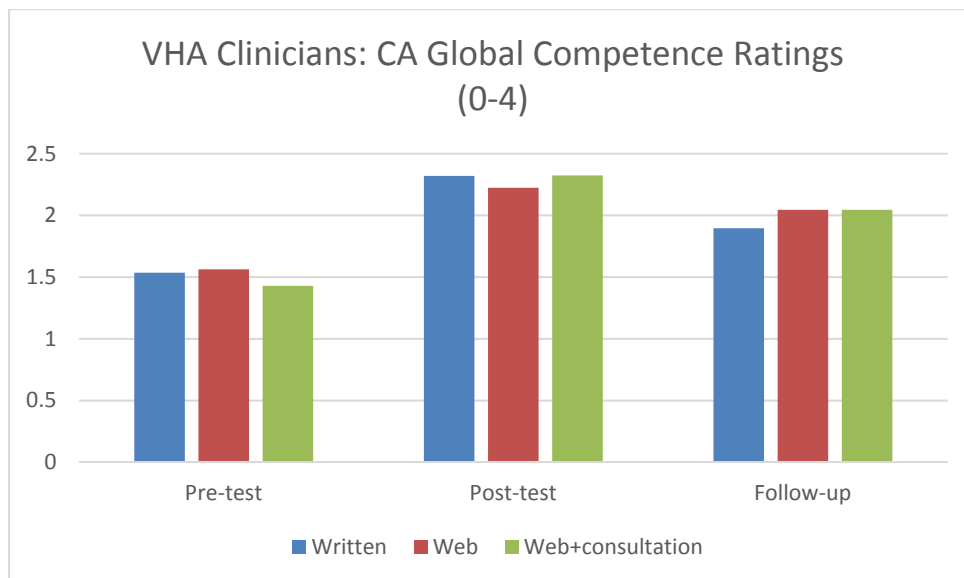
Figure 4B: Training Effects on CA Global Competence in Community Clinicians

Community Clinicians: CA Global Competence Ratings (0-4)

Written ■ Web ■ Web+consultation
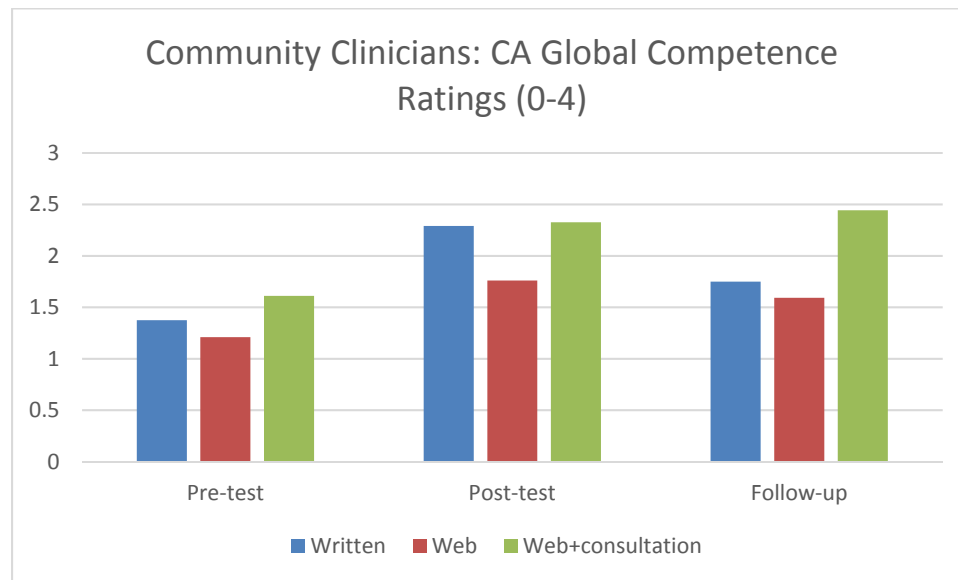
- c. Comment: Significant training effects were observed on both objective measures of skills performance (i.e. total adherence, global competence) in both training modules (CA, BTA), with a trend in favor of the web + consultation condition during follow up. This modality (web training + consultation) showed improved retention of skills at the follow up assessment compared to the other training conditions. Significant improvement in skills across all three training conditions may have resulted in an overall ceiling effect, which may have obscured between group differences over time.

V.   Secondary Outcome: Self-Rated Implementation of Skills and Knowledge Assessment

- a. Clinicians' self reported skills implementation on the CA module showed significant improvements over time across all intervention conditions (F=4.41; p<.01), similar to the intervention effects observed on our SPE outcomes above. The differences between training conditions were non-significant (F=0.34; p>.1) and interactions between training conditions over time were also non-significant (F=1.38; p=.24). (No figure needed for a non-significant interaction). A different, significant pattern of results was observed for this outcome for the BTA module, however, where significant differences were seen between the intervention conditions (F=3.56; p<.05) and between training periods (F=5.24; p<.01). As shown in Figure 5A below, the web training + consultation group showed a significant increase in self-reported implementation of BTA skills during the follow-up period (F=7.41; p<.001). As

shown in Figure 5B, community clinicians reported significantly more improvement in this outcome measure than their VA counterparts.

Figure 5A: Intervention Effects on Self-Rated Implementation of Skills: Interaction Effect on BTA Module

Self-Rated Implementation of Skills: BTA Module
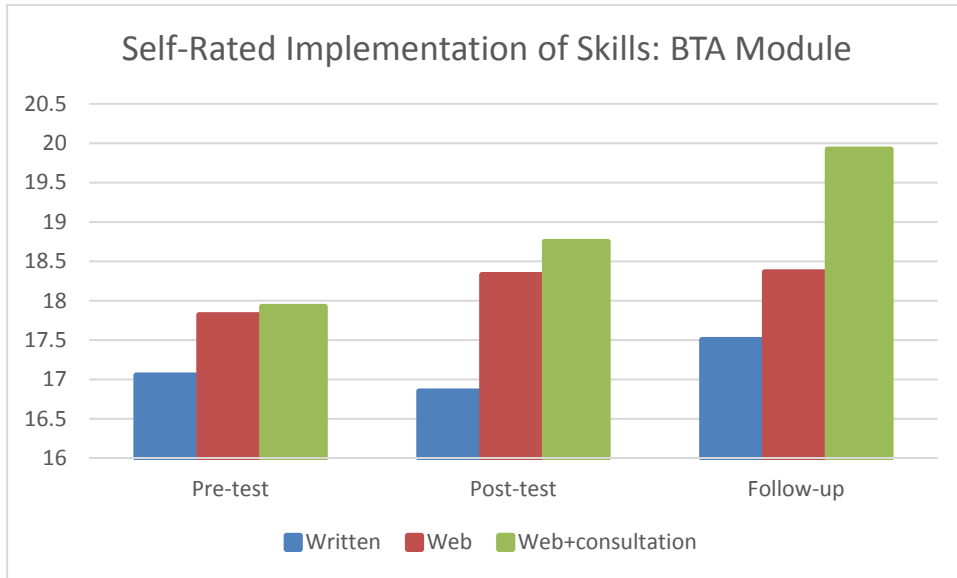
Figure 5B: Self-Reported Implementation of BTA Skills

BTA Implementation of skills: Community Clinicians report higher levels than VA
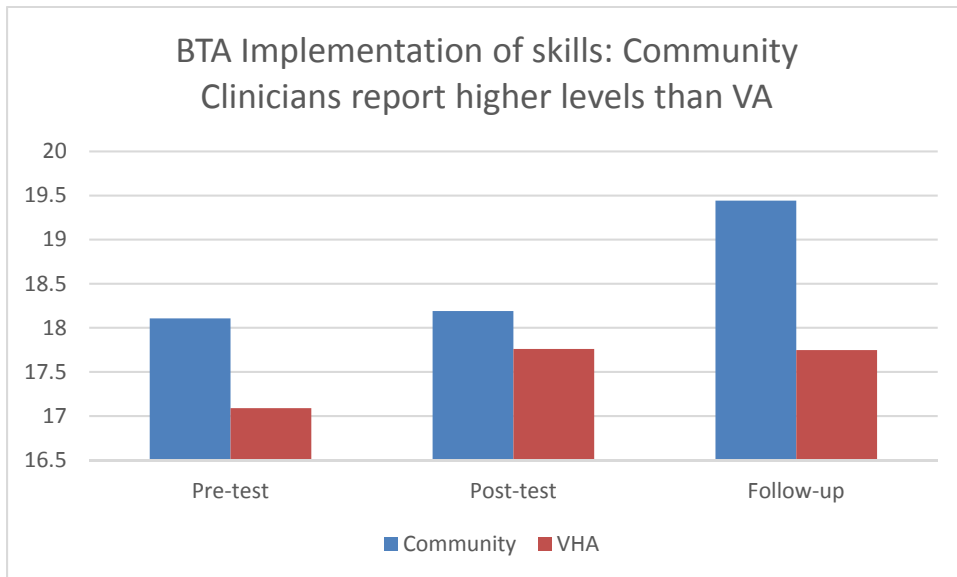
VI. Secondary Outcome Measure #2: Knowledge Assessment

a. Concept knowledge scores for both training modules increased significantly over time across all three training conditions (CA: F=38.53; p<.0001; BTA:

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F=27.18; p<.0001). However, no differences or interactions were observed with training conditions or clinical settings.

b. <u>Comment</u>: Despite the overall similarity in results between our objective skills (SPE) measures and the clinician-based, subjective measure of skills implementation, we noted a difference in the effects of the 3 training conditions on self-rated skills implementation for the BTA compared to the CA module. As shown above, a significant benefit in favor of the web + consultation condition was seen between the post-training and follow-up assessments. Also, as shown in Figure 5B above, the community clinicians showed significantly greater improvements in self-rated implementation compared to their VA counterparts. Knowledge scores improved significantly and to a similar degree across the three training conditions, with no differences between conditions at any time point. Since we were unable during the limited time span of the project to adequately pre-test reliability and sensitiviely of the knowledge items, lack of study differences may have been due to measurement insensitivity, rather than lack of effect.

VII. <u>Course Evaluation Ratings</u>

a. Course evaluation ratings were obtained in the context of CME evaluation following the training intervention completion. A brief course evaluation measure was administered along with other post-training measures. Specific questions included ratings of the course content on 1-5 scales of timeliness and clinical relevance, as well as a third rating of whether the participant planned to "make any changes in your practice or patient care based on what you learned in this activity?" The course evaluation did not differentiate ratings of the BTA and CA modules, but were framed for overall course evaluation.

b. Based on results of these ratings, the majority of respondents rated the timeliness and relevance of the program favorably or very favorably. Specifically, 83% (197/238) of participants who completed the post-training assessment rated the course content as "timely" or "very timely". Almost 95% (226/238) reported that they planned to make changes in their clinical practice based on the specific skills acquired during the training, and 89% rated the course as relevant to improving their practice skills.

c. A significant difference was observed in course content ratings among the 3 training conditions in favor of the web + consultation arm (F=10.88; p<.001). A significant interaction with clinical setting was noted also (F=3.14; p<.05), as community clinicians reported higher levels of satisfaction with the course content (See Figure 6A below). When asked whether they planned to make

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changes in their clinical practice, a larger percentage responded positively in the web + consultation arm compared to the other two conditions (F=4.42; p<.01), and community clinicians rated the course content more highly than VA counterparts (F=5.19; p<.02), although ratings of both groups was generally positive.

    d. <u>Comment</u>: CME course evaluation ratings were highly positive overall. A high level of course satisfaction was noted among both groups, but with slight preferences overall for the web + consultation condition. Community clinicians showed particular preference for the web + consultation condition, and rated the other training interventions less favorably than their VHA counterparts.

VIII.   <u>Web Analytics and Web-Usage Results</u>

    a. A unique aspect of Project OUTFIT was the availability of in-depth, highly granular information concerning web usage and web usage patterns, and the association between web usage and the main study outcomes above. These results are presented in the following sections.

    b. The range and distribution of web usage variables in the two web-based intervention groups (web alone, web + consultation) are shown in Table 4a and 4b below. These tables provide summary data on web usage patterns and the frequency of use by number of pages viewed, videos viewed, and time spent on course training by condition and demographic characteristics.

Table 4a. Web Usage Descriptive Statistics in Module 1 (Chain Analysis)

	Pages visited			Time on course (in hours)			Videos viewed		
	Mean	Std Dev	p-value	Mean	Std Dev	p-value	Mean	Std Dev	p-value
Randomization Group									
Web (n=139)	86.71	72.05		2.74	3.14		0.09	0.65	
Web + Consultation (n=140)	95.19	71.50	0.3596	3.77	3.65	**0.0143**	2.19	3.18	**<.0001**
# of Consultation Sessions									
0-3 sessions (n=82)	72.77	75.48	**<0.0001**	2.62	3.75	**<0.0001**	1.76	3.59	**<0.0001**
4-6 sessions (n=58)	126.88	51.26		5.39	2.81		2.81	2.39	
Service Sector									
VA (n=139)	88.77	73.32	0.6607	3.31	3.56	0.8569	1.17	2.52	0.9145
Community (n=140)	93.14	70.41		3.20	3.32		1.11	2.54	
Gender									
Male (n=80)	94.66	73.47	0.5883	3.50	4.03	0.9099	1.33	3.10	0.9190
Female (n=198)	89.92	71.12		3.17	3.17		1.08	2.26	
Age									
21-50 (n=127)	82.07	67.59	**0.0427**	2.60	2.63	**0.0272**	1.00	2.27	0.9621
51-80 (n=145)	98.86	74.39		3.86	3.95		1.30	2.78	

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	Mean	Std Dev	p-value	Mean	Std Dev	p-value	Mean	Std Dev	p-value
Hispanic/Latino									
No (n=262)	91.03	71.78	0.9943	3.22	3.44	0.6032	1.14	2.56	0.7346
Yes (n=15)	92.07	73.66		3.60	3.27		1.13	2.00	
Race									
White (n=231)	93.93	70.36		3.37	3.47		1.19	2.61	
Black (n=24)	68.38	76.02	0.2008	2.01	2.57	0.0911	0.38	1.35	0.0696
Other/Unknown (n=24)	85.00	79.50		3.43	3.71		1.50	2.55	
Education									
Master's Degree (n=200)	90.63	70.73		3.33	3.54		1.12	2.46	
Ph.D. or Psy.D. (n=70)	95.93	74.01	0.1274	3.14	3.10	0.4748	1.34	2.83	0.2858
Other (n=8)	47.75	73.44		2.51	4.25		0.13	0.35	

Table 4b. Descriptive Statistics for Module 2: Behavioral Task Assignment

	Pages visited			Time on course (in hours)			Videos viewed		
	Mean	Std Dev	p-value	Mean	Std Dev	p-value	Mean	Std Dev	p-value
Randomization Group									
Web (n=139)	23.00	13.65		1.64	1.48		5.84	5.32	
Web + Consultation (n=140)	24.17	12.82	0.3809	1.80	1.58	0.2814	7.43	5.94	**0.0044**
# of Consultation Sessions									
0-3 sessions (n=82)	20.57	14.25	**0.0001**	1.43	1.52	**<.0001**	5.95	5.88	**0.0003**
4-6 sessions (n=58)	29.26	8.20		2.34	1.53		9.52	5.40	
Service Sector									
VA (n=139)	23.47	13.32	0.6272	1.65	1.52	0.2934	6.63	5.64	0.9496
Community (n=140)	23.70	13.19		1.79	1.54		6.65	5.75	
Gender									
Male (n=80)	23.84	12.99	0.5306	1.94	1.78	0.3213	7.19	5.81	0.2413
Female (n=198)	23.49	13.39		1.64	1.41		6.40	5.65	
Age									
21-50 (n=127)	24.52	12.86	0.6043	1.47	1.12	0.0524	6.41	5.48	0.5340
51-80 (n=145)	22.64	13.58		1.97	1.80		6.88	5.94	
Hispanic/Latino									
No (n=262)	23.51	13.24	0.3221	1.73	1.54	0.7413	6.62	5.69	0.7819
Yes (n=15)	25.67	12.85		1.73	1.29		6.87	5.67	
Race									
White (n=231)	24.72	12.56		1.79	1.47		6.92	5.71	
Black (n=24)	16.71	15.35	**0.0093**	1.27	2.07	**0.0170**	4.46	5.36	0.0596
Other/Unknown (n=24)	19.58	14.95		1.53	1.45		6.13	5.42	
Education									
Master's Degree (n=200)	24.14	12.95		1.82	1.59		6.99	5.76	
Ph.D. or Psy.D. (n=70)	22.59	13.80	0.4993	1.52	1.34	0.2289	5.96	5.46	0.2544
Other (n=8)	18.50	15.94		1.20	1.43		4.00	5.42	

ii. For the Chain Analysis course, web plus consultation was associated with significantly more time spent viewing web material in the web + consultation training condition (p=.0143), and for both CA and BTA, participants assigned to the web plus consultation arm viewed

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significantly more videos than those assigned to web alone (CA p<.0001; BTA p=.0044).

iii. Among those assigned to the web plus consultation arm, the number of consultation sessions completed was a significant predictor of all three indicators for both training courses – pages viewed (CA p<.0001, BTA p=.0001), time on course (CA p<.0001, BTA p<.0001), and videos viewed (CA p<.0001, BTA p=.0003).

iv. For Chain Analysis, older age was a significant predictor of more pages visited (p=.0427) as well as more time spent (p=.0272). For Behavioral Task Assignment, participants who identified as white were more likely to view more pages (p=.0093) and spend more time on the training (p=.0170).

v. There were no significant differences in web usage for a range of other characteristics (service sector, gender, ethnicity, and educational attainment) for either training.

c. The association between web usage and two SPE outcomes (BTA, CA) is shown in Table 5.

Table 5. Change in Primary Outcomes by Three Exposure Metrics

	Pages visited (+ 10 pages)				Time on course (+1 hour)				Videos viewed (+ 1 video)			
	Est	tVal	CI	Probt	Est	tVal	CI	Probt	Est	tVal	CI	Probt
CA Adherence	0.144	3.43	0.061–0.227	0.0007	0.230	3.17	0.087–0.374	0.0018	0.030	0.28	-0.178–0.238	0.7775
CA Competence	0.050	3.46	0.022–0.079	0.0007	0.079	3.15	0.029–0.128	0.0019	0.014	0.38	-0.058–0.085	0.7045
BTA Adherence	0.351	1.69	-0.059–0.760	0.0926	0.181	1.36	-0.083–0.444	0.1771	**0.084**	**2.19**	**0.008–0.160**	**0.0296**
BTA Competence	0.125	1.69	-0.021–0.272	0.0936	**0.119**	**2.52**	**0.026–0.212**	**0.0126**	0.026	1.85	-0.002–0.053	0.0663

i. Viewing an additional 10 pages of course content significantly improved both adherence (CA p=.0007) and competence (CA p=.0005) for Chain Analysis, but did not have a significant impact on either measure for Behavioral Task Assignment.

ii. Each additional hour that participants spent on the training significantly improved both adherence (p=.0018) and competence (p=.0019) for CA, as well as competence (p=.0126) for BTA.

iii. When examining how viewing the supplemental skill modeling videos impacted outcomes, accessing an additional modeling video was only a significant predictor of improved outcomes for adherence in the BTA course (p=.0296), and did not have a significant impact on outcomes for the CA course.

iv. When examining the effect of each of these exposures on our secondary outcomes of knowledge and self-reported implementation of skills, but saw no significant changes for these outcomes using any of the three any exposure metrics.

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d. The correlations between actual time and subjective or self-reported time are shown in Table 6. This table shows Spearman Rank Order correlations between objective usage data and self-reported time separately for each training course.

Table 6. Association between Self-reported and Actual Time Spent (in minutes)

Variable	N*	Mean (SD)	P-value	Median	Min	Max	Spearman Correlation
CA Actual Time Spent (in minutes)	144	273.5 (216.5)		256.2	0.0	1492.5	0.348
CA Self-reported Time Spent (in minutes)	144	332.6 (320.4)	0.045	240.0	0.0	2160.0	(p< 0.0001)
BTA Actual Time Spent (in minutes)	144	129.5 (100.5)		116.2	0.0	588.2	0.19
BTA Self-reported Time Spent (in minutes)	144	281.0 (326.1)	< 0.0001	180.0	0.0	2160.0	(p=0.022)

* We excluded from analysis participants (n=3) whose self-reported time that was more than 3 standard deviations from the mean

    i. For Chain Analysis, self-reported time spent viewing the training was significantly correlated with actual time spent (r_s=.348, p<.0001), with participants self-reporting significantly more time than was actually spent (p=.045).

    ii. For Behavioral Task Assignment, the two measures showed a modest significant correlation (r_s=.19, p=.022), with participants self-reporting more time on the course than they actually spent by a factor of almost double (p<.0001), according to objective usage data.

e. Figure 7 presents a bar graph of the completion of each training course by unique number of pages viewed.

Figure 7. Completion of Training by Course
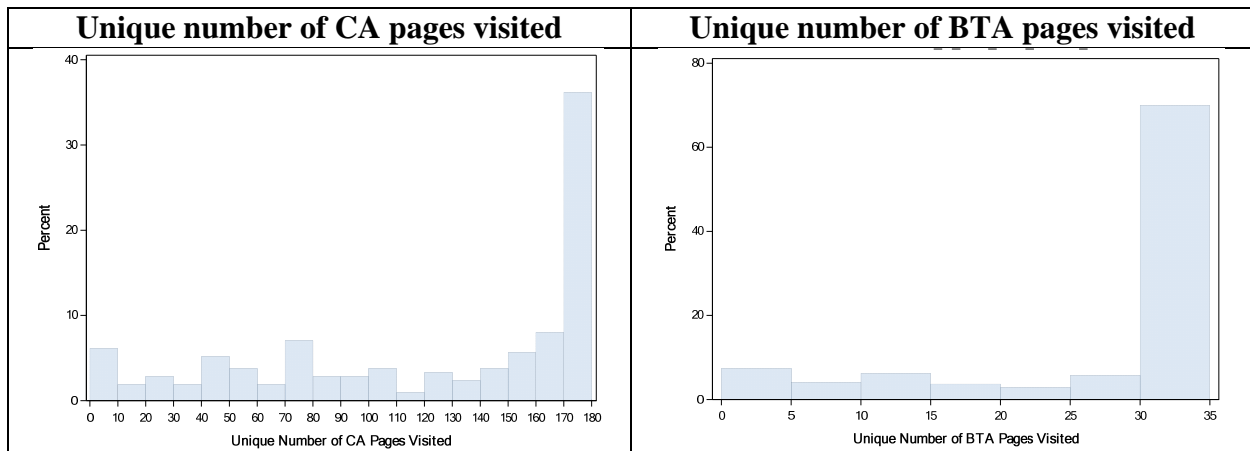
    i. Out of the 279 participants randomized to access the site (participants randomized to the web and web plus consultation arms), 243 unique visitors logged into the training website (87%).

    ii. Of those who viewed the site, all 243 participants viewed at least some of the BTA training, while only 213 participants viewed at least some of the CA training.

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