

Evaluating a Train-the-Trainer Approach for Increasing EBP Training Capacity in Community Mental Health

Noah S. Triplett, AB

Georganna Sedlar, PhD

Lucy Berliner, MSW

Nathaniel Jungbluth, PhD

Meredith Boyd, MA

Shannon Dorsey, PhD

Abstract

Research suggests the train-the-trainer (TtT) model may be an effective approach to training community mental health providers in evidence-based practice (EBP). This study compared pre- and post-training consultation outcomes as well as standardized measures of trainer attributes and behaviors between university-based master trainers and experienced community-based supervisors, trained under the TtT approach. Findings suggest local and master trainers are equivalent in terms of clinical teaching effectiveness and trainee-perceived charisma. Master trainers may have higher trainee-perceived credibility, but training and consultation outcomes are equivalent across the types of trainers, with the exception of behavioral problems where clinicians trained by local trainers and master trainers saw significantly greater growth than those who received training and consultation by master trainers.

Evidence-based practice (EBP) is now considered a standard in the provision of behavioral health care.¹ The challenges for achieving this standard have been extensively discussed.² In

Address correspondence to Noah S. Triplett, AB, Department of Psychology, University of Washington, 119A Guthrie Hall, Box 351525, Seattle, WA 98195, USA.

Georganna Sedlar, PhD, Department of Psychiatry and Behavioral Sciences, University of Washington School of Medicine, Seattle, WA, USA.

Lucy Berliner, MSW, Harborview Center for Sexual Assault and Traumatic Stress, Seattle, WA, USA.

Nathaniel Jungbluth, PhD, Seattle Children's Hospital, Department of Psychiatry and Behavioral Medicine, PO Box 5371, Seattle, WA, USA.

Meredith Boyd, MA, Department of Psychology, University of California, Los Angeles, CA, USA.

Shannon Dorsey, PhD, Department of Psychology, University of Washington, Seattle, WA, USA.

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behavioral health, they range from the need to have effective treatments for the range of psychiatric disorders, training the existing workforce to be willing and competent to deliver treatments that were initially developed and tested in mostly academic contexts, and identifying and creating the necessary conditions for implementation and sustainment within routine care settings. Despite the focus on EBPs and the availability of many effective treatments,³ the penetration rate of EBP continues to be low.⁴ It is well established that many children with psychiatric need do not receive behavioral health care, and even fewer receive adequate care.⁵⁻⁷

Increasing workforce competence in EBP is an essential ingredient in the overall effort to increase access to EBPs. Reviews of training approaches for delivery of EBPs conclude that didactic approaches alone are not sufficient for skill acquisition and competent delivery of EBPs; active, experiential training followed by expert consultation while applying the EBP models with clients may be needed for optimal outcomes.⁸⁻¹⁰ Experiential training and consultation is often led by program developers or developer-approved experts (“master trainers”); however, relying on a small cadre of master trainers to provide training and consultation in EBPs limits training capacity for scale up and sustainment efforts and may be more costly than alternative training models.¹¹

Train-the-trainer (TtT) models, which are designed to increase the number of potential trainers for an intervention, have shown preliminary effectiveness in disseminating evidence-based principles and increasing knowledge across a variety of fields, ranging from public health decision-making to opioid prescription education.¹²⁻¹⁵ In TtT approaches, master trainers provide training to locally embedded staff on program content and how to facilitate trainings. These community-based, “local trainers” can then provide training and consultation to frontline providers or other community members, dependent on the nature of the intervention.^{12, 15} Growing evidence suggests TtT models can be effective in increasing knowledge, improving clinical behavior, and producing better patient outcomes.¹³ TtT models have several advantages beyond expanding training capacity and program reach. Local trainers may also have more direct access to the communities they are training within and have a better understanding of contextual issues.¹⁴ However, little research has investigated how trainees might perceive local trainers and evaluate their attributes or teaching behaviors.

In Washington State, the Division of Behavioral Health and Recovery (DBHR) has provided funding for an evidence-based practice initiative, called the CBT Plus (CBT+) Initiative, since 2007. CBT+ trainings address the most common mental health conditions for children seeking mental health care across Washington State: anxiety, behavior problems, depression, and posttraumatic stress.¹⁶ CBT+ trainings employ a modified learning collaborative model that includes a 3-day in-person session and 6 months of twice-monthly telephone consultation focused on applying the CBT model to clients on trainees’ caseloads. A specific case presentation format is used for consultation calls. Calls involve reviewing assessment data to determine clinical focus, applying CBT+ components to cases, and problem-solving challenges with child and caregiver engagement. CBT+ trainees are expected to present at least 1 case over the consultation period and attend 9 of 12 calls in order to receive a CBT+ certificate of completion.

In-person training for CBT+ had been led by university-affiliated master trainers; however, in 2015 the Initiative piloted a TtT program to build a cadre of local trainers from within the community mental health organizations participating in the initiative. The Initiative’s goal was twofold: to increase the number of clinicians who could be trained each year by holding more trainings and to decrease reliance only on university-affiliated trainers while continuing to build local ownership of the CBT+ Initiative.

The primary goals of this manuscript are to describe the CBT+ Initiative’s TtT approach and to compare training and consultation effectiveness of local trainers with master trainers. This study extends the existing literature on TtT models by examining trainee perceptions of trainer attributes and behaviors for both local and master trainers. Research on TtT models has focused almost exclusively on evaluating training outcomes with little attention paid to trainee perceptions of training effectiveness, trainer attributes, or trainer behavior.¹³ Perception of trainer characteristics

may play an important role in overall training effectiveness given that, broadly, people automatically form impressions of others that impact both attitudes and behaviors,¹⁷ which might in turn impact training outcomes. More specifically, trainer and supervisor (who may operate in a similar capacity as the trainer) characteristics have been identified across disciplines that relate to various positive training outcomes including trainee motivation, goal commitment,¹⁸ and improved work performance.¹⁹ Our study is among the first to use standardized measures of trainer attributes and training behaviors, filling a gap in our knowledge about how trainees perceive local trainers and their training effectiveness. Our study is also among the first to examine local trainers' performance as post-training consultants, which may be needed for optimal outcomes of EBP training.⁸

Method

CBT+ Initiative train-the-trainer process

The Initiative invited longstanding CBT+ supervisors (some of whom would later become local trainers) to participate on a TtT steering committee with master trainers. The committee was convened to collaboratively decide what the local trainer role might look like, what supports would be needed, and what background and ongoing requirements would be appropriate. Potential local trainers were then identified by CBT+ master trainers: potential local trainers were experienced supervisors in community mental health organizations, who had participated in past CBT+ learning collaboratives, were active participants on CBT+ monthly statewide supervisor conference calls, and had served as co-consultants, alongside a master-trainer, on a series of 12 post-training consultation calls.

Our approach to training involved developing a "trainers' guide" for the CBT+ training, which included a standard set of training materials (PowerPoint didactic presentation, training handouts, role play guides) and specific goals and activities for trainers to cover during each segment of the training. Local trainers were asked to review the training guide and then to attend a 2-day training, during which master trainers provided instruction on facilitating and managing common challenges that arise in CBT+ trainings and consultation calls. In addition, local trainers were assigned one section of the CBT+ training to lead at the TtT training for the master trainers and other local trainer candidates. The mock training exercise included segments of didactic teaching as well as clinical role play facilitation and debriefing. Each local trainer received immediate individualized feedback (e.g., on their preparedness, presentation style, use of active learning strategies) from both the master trainers and peers after their session, as well as formal written feedback summaries. Following this TtT training, local trainers were asked to practice their training skills by hosting a half- or 1-day training at their organization. All trainers were deemed adequately prepared to move forward with co-leading a CBT+ training. Local trainers' participation was voluntary, although they did receive monetary compensation (provided directly to them or to their organization) for time spent preparing, training, and conducting consultation calls.

Local trainers were paired with one master trainer to conduct an in-person CBT+ training, ranging in size from 16 to 64 clinicians, during the 2015–2016 fiscal year. The local and master trainers alternated delivering sections of the training content, except for the Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) training, which had to be delivered by one of the two nationally approved TF-CBT trainers in the master trainer group. Prior to the TtT training, one-to-two trainings were held across the state of Washington each year and were staffed exclusively by university-affiliated master trainers. After implementing the mixed TtT-master trainer model, training capacity was increased such that 6 trainings were held across the state in 1 year with the same, or slightly lower time commitment from master trainers. Following the in-person training, local trainers also served as lead consultants for 6 months of consultation calls, which did not include a master trainer. Consultation calls were observed by a master trainer, who gave feedback to local trainers throughout their call series.

Procedure

Data for the current study comes from the yearly evaluation of CBT+ trainees who participated in the CBT+ Initiative during the 2015–2016 fiscal year and an online survey completed by master trainers and local trainers. CBT+ trainees completed questionnaires as part of a program evaluation prior to training (pre-training), immediately following training (post-training), and after the 6-month consultation period (post-consultation). No incentives were provided, but participating in the evaluation at all time points was one of the requirements for trainees to receive a CBT+ Initiative certificate of completion. All evaluation activities were reviewed by the Washington State IRB and were exempted from review.

Participants

CBT+ training participants were 228 clinicians and supervisors employed at community mental health organizations across Washington State. Local trainers were 7 experienced supervisors from community mental health organizations who participated in the TtT process described above. Master trainers were 5 university-affiliated trainers who had previously delivered CBT+ trainings.

Measures

Demographics

Trainee and trainer participants completed a questionnaire that included demographic items (e.g., sex, ethnicity) and background characteristics (e.g., role in the organization, years of experience).

Self-report of skill

Trainee participants rated their skill level for individual treatment elements for three of the four treatment approaches covered in the CBT+ training (CBT for anxiety, CBT for depression, behavioral parent training) prior to training (pre-training), immediately following training (post-training), and after the 6-month consultation period (post-consultation). The fourth treatment approach, TF-CBT, could not be trained by local trainers because of trainer accreditation requirements from that treatment's developers, and so self-report of skill on TF-CBT was not included in this evaluation. Assessment skill items were common across all problem areas and aggregated to create a separate assessment self-report score. Other items were unique by problem area (e.g., for depression: "Pleasurable activity scheduling (help the child identify, plan for, and engage in fun activities)"). Skill was reported on a 6-point Likert-type scale ranging from 0 (I do not use this skill) to 5 (Advanced skill).

Trainer attributes

Master and local trainer attributes were assessed using an initial version of the Measure of Effective Attributes of Trainers (MEAT).²⁰ The MEAT measures the trainer characteristics that literature has suggested facilitate effective trainings—as perceived by the trainee. The initial version of the MEAT contained 19 characteristics, which included two factors: charisma and credibility. The first factor, "Charisma," contains items related to characteristics that facilitate a positive personal relationship with the trainee (e.g., caring, approachable), and the second factor, "Credibility," contains items related to characteristics that emphasize the qualification of the trainer (e.g., expert, intelligent). Trainees are asked to rate the extent to which characteristics described the trainer on a 5-point Likert-type scale ranging from 1 (very slightly/not at all) to 5 (extremely). An examination of the final version of the MEAT's psychometric properties demonstrate evidence of

measure validity and reliability.²⁰ In the present study, internal consistency of the charisma subscale was $\alpha = 0.93$, and of the credibility subscale was $\alpha = 0.90$.

Trainer behaviors

Master and local trainer behaviors were assessed using a modified version of the clinical teaching effectiveness instrument (CTEI).²¹ The study team condensed the measure to be more relevant to CBT+ trainings and community mental health. The CTEI measures trainee perceptions of teaching effectiveness in a wide variety of clinical teaching settings. The modified CTEI contained 5 items (e.g., “Clearly specifies what I am expected to know and do during this training period”; “Gives clear explanations/reasons for opinions, advice, actions, etc.”). Trainees were asked to rate the extent to which trainers completed these behaviors on a 5-point Likert-type scale ranging from 1 (never/poor) to 5 (always/superb). The CTEI has been shown to have good reliability, content validity, and criterion-related validity.²¹ In the present study, internal consistency of the CTEI was $\alpha = 0.87$.

EBP certificate

Certificates of completion were provided to participants who fulfilled Initiative requirements of: completing electronic pre-training and post-consultation surveys, attending the training, presenting at least one case during a consultation call, entering data online for cases in which they applied the CBT+ training (for consultant review), and participating in 9 of 12 consultation calls.

Ratings of consult call helpfulness

Trainee participants completed a questionnaire that included an item to assess their consultants’ performance leading the post-training consultation calls. After 6 months of consultation concluded, trainees were asked to rate the extent to which consult calls were helpful on a 4-point Likert-type scale ranging from 1 (not at all) to 4 (a lot).

Analysis plan

Analyses were conducted using R Statistical Software version 3.3.3 (Foundation for Statistical Computing, Vienna, Austria).²² All significance tests were two-sided with $p < 0.05$ indicating significance. Paired t tests were performed to compare changes in self-report of skill before and after training for CBT+ trainees trained under the mixed TtT-master trainer model. A mixed ANOVA was performed for each training area to compare changes in CBT+ trainee self-report of skill before training and after consultation between the mixed-TtT and master-trainer only models. The master-trainer only scores came from previously published data from the CBT+ Initiative, which exclusively utilized master trainers.²³ Students’ two sample t tests were performed to compare MEAT, CTEI, and participant-rated consult call helpfulness scores between master and local trainers. A chi-square test was performed to compare EBP certificate completion rates between master and local trainers.

Results

Descriptive

Table 1 presents demographic and descriptive data stratified by local trainers ($N = 7$), master trainers ($N = 5$), and CBT+ trainees ($N = 228$). Local trainers were mostly female (85.71%),

Table 1
Sample demographics

Variable	Local trainers		Master trainers		CBT+ trainees	
	<i>N</i> = 7		<i>N</i> = 5		<i>N</i> = 228	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Female	6	85.71	4	80.0	176	78.57
Ethnicity or race						
Caucasian	7	100	5	100.0	186	82.67
African American	—	—	—	—	7	3.11
Hispanic or Latino	—	—	—	—	16	7.11
American Indian or Alaskan Native	—	—	—	—	2	0.89
Asian	—	—	—	—	10	4.44
Other	—	—	—	—	4	1.78
Education						
High school/AA	—	—	—	—	2	0.88
4-year college	—	—	—	—	6	2.63
MSW	6	85.71	2	40.0	57	25.00
Other masters	1	14.29	—	—	158	69.30
Doctoral	—	—	3	60.0	5	2.19
Age						
Under 25	—	—	—	—	6	2.63
25–29	—	—	—	—	75	32.89
30–39	6	85.71	1	20.0	88	38.60
40–49	—	—	2	40.0	29	12.72
Over 50	1	14.29	2	40.0	30	13.16

Caucasian (100.0%), and master’s-level educated (100.0%). Expert trainers were mostly female (80.0%), Caucasian (100.0%), and PhD-level educated (60.0%). Participating clinicians were largely female (78.6), Caucasian (82.7%), and master’s-level educated (94.3%).

CBT+ trainee change in self-report of skill

Table 2 depicts paired *t* tests indicating that CBT+ trainee participants—trained during the Initiative year that first utilized local trainers in conjunction with master trainers—reported significant improvements from pre-training to post-consultation on self-reported skills in four areas: anxiety ($t = -11.51, p < .001, d = 0.89$), depression ($t = -11.59, p < .001, d = 0.89$), behavior problems ($t = -8.09, p < .001, d = 0.63$), and assessment ($t = -15.08, p < .001, d = 1.16$) from pre-training to post-consultation. Cohen’s *d* effect sizes were moderate (> 0.5) to large (> 0.8) for most tests, with anxiety, depression, and assessment showing the largest effect sizes. Mixed ANOVAs were conducted to compare skills growth across the two training models (previously published data from master trainers only vs. mixed TtT-master trainer). Independent variables were time (pre-training vs. post-consultation) and cohort (master trainer vs. mixed TtT-master trainer model), and we ran the model for four different dependent variables (self-reported skill for anxiety, depression, behavior problems, and assessment). There were significant main

Table 2
Participant change in self-report of skill

	Pre-training		Post-consultation		<i>t</i>	df	<i>p</i>	<i>d</i> ¹
	Mean	SD	Mean	SD				
Skill–anxiety	3.21	0.8	3.91	0.64	– 11.51	168	< 0.001	0.89
Skill–depression	3.34	0.7	3.92	0.53	– 11.59	168	< 0.001	0.89
Skill–behavior problems	3.13	0.94	3.69	0.91	– 8.09	166	< 0.001	0.63
Skill–assessment	2.63	1.12	3.86	0.71	– 15.08	168	< 0.001	1.16

¹Cohen's *d*

effects of cohort across three skills: anxiety ($F(1, 359) = 12.4, p < .001$), depression ($F(1, 360) = 5.24, p < .05$), and behavior problems ($F(1, 355) = 3.96, p < 0.05$). This suggests that self-report of skill were significantly different across cohorts (irrespective of time) such that the average skill level of clinicians in the mixed TtT-master trainer model was significantly higher than that of clinicians in the master-trainer only model for anxiety and depression and significantly lower for behavior problems. There was a significant interaction between cohort and time for self-reported skill for behavior problems ($F(1, 355) = 5.255, p < 0.05$), meaning clinicians in the mixed TtT-master trainer cohort saw significantly greater changes in self-report of skill for treating behavior problems than clinicians in the master-trainer only cohort. Figure 1 illustrates pre-post changes in self-report of skill across areas and cohorts.

Figure 1
Participant change in self-report of skill by cohort

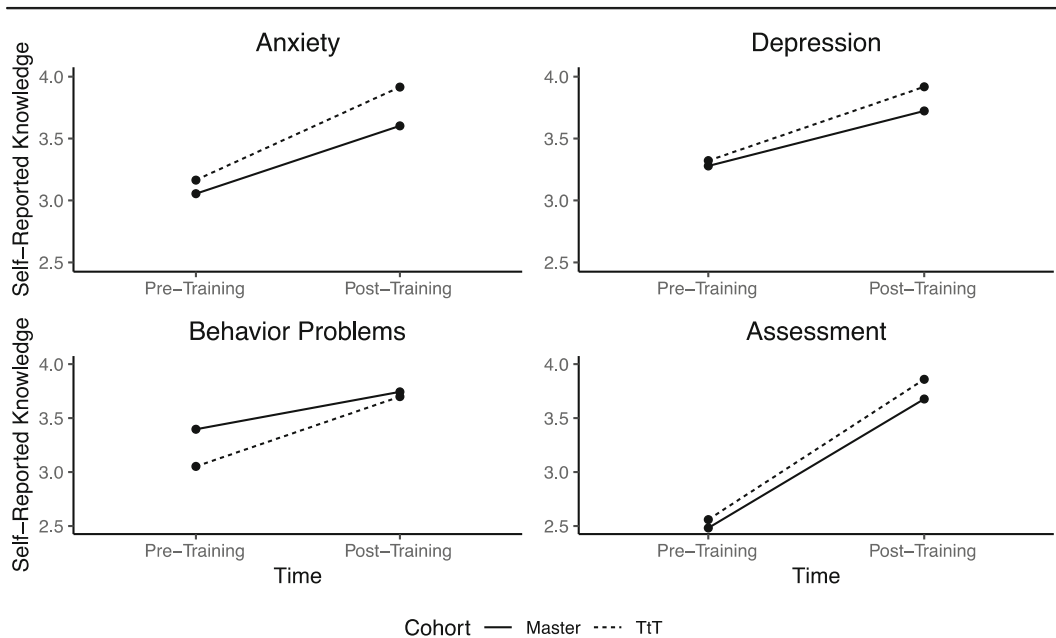


Table 3

Trainer attributes and behaviors

	Local trainers		Master trainers		<i>t</i>	df	<i>p</i>
	Mean	SD	Mean	SD			
MEAT	4.23	0.63	4.25	0.60	-0.42	556	0.82
Charisma factor	4.23	0.64	4.17	0.67	1.13	551	0.26
Credibility factor	4.28	0.70	4.54	0.56	-4.90	552	>0.001
CTEI	4.06	0.92	4.11	0.8	-0.61	506	0.54
Consultation call helpfulness	3.16	0.8	3.11	0.78	0.43	171	0.67

TtT performance as trainers rated by CBT+ trainees

Table 3 illustrates paired *t* tests between ratings of training effectiveness. Analyses indicated no significant differences in the overall MEAT ratings of master trainers and local trainers. There was also no significant difference in the charisma factor ratings of master trainers and local trainers. The charisma factor consists of characteristics that facilitate a positive personal relationship with the trainee (e.g., friendly, warm). There was a significant difference in the credibility subscale scores for master trainers ($M=4.54$, $SD=0.564$) and local trainers ($M=4.28$, $SD=0.700$), $t(552)=-4.90$, $p<0.001$). The MEAT credibility factor items asked CBT+ trainee participants to rate trainers on characteristics that emphasize the qualification of the trainer (e.g., expert, intelligent). Analyses also revealed no significant differences in the CTEI ratings of master trainers and local trainers.

TtT performance as consultants rated by CBT+ trainees

Analyses revealed no significant differences in post-consultation EBP certificate completion rates between master and local trainers, $\chi^2(1, N=218)=0$, $p=1.0$. CBT+ trainee participant-rated consult call helpfulness scores were also compared between master trainers ($M=3.11$, $SD=0.780$) and local trainers ($M=3.16$, $SD=0.800$), with no significant differences $t(171)=0.425$, $p=0.671$.

Discussion

These findings provide initial support for pursuing a mixed TtT-master trainer model as an effective method of training community mental health providers in EBPs. The mixed TtT-master trainer model enabled a greater number of participants to be trained in EBPs with comparable outcomes. On nearly all metrics evaluating trainers' performance—at the in-person training, in terms of participant learning and consult call experience, as well as successful initiative completion—local trainers' performance and outcomes did not significantly differ from master trainers. These findings suggest a mixed TtT-master trainer approach may be a promising approach across a variety of outcomes, including trainee perception of and acceptability of local trainers.

In concordance with existing literature on TtT approaches, CBT+ participants who were trained by both local and master trainers reported similar gains in self-reported competence in skills following consultation as those who were trained and received consultation exclusively by master trainers in prior cohorts, with the exception of behavioral problems. For these skills, clinicians trained by local trainers and master trainers saw significantly greater growth than those trained exclusively by master trainers. These findings extend the existing literature by examining local

trainer performance beyond self-reported knowledge and assessing effectiveness in the role of post-training consultants. The post-consultation EBP certificate completion rates were comparable across trainers, suggesting local trainers were able to support community mental health CBT+ trainees through the multi-step Washington State CBT+ certificate completion process, which includes telephone-based case consultation as well as using an internet platform for participants to document each case and receive trainer feedback. Further, there were no significant differences in CBT+ trainee-rated consult call helpfulness between local trainers and master trainers. This is impactful, as consultation calls are critical to extend learning and apply EBPs to clinicians' cases but often further limit EBP training capacity. To be effective, consultation calls cannot be overloaded or clinician participants do not get adequate time to present and receive case support. Further, these calls were led by local trainers without a master trainer co-facilitating.

This study is also among the first to evaluate a TtT model using standardized measures of trainer attributes and behaviors. Comparing scores on these measures, the only identified statistically significant difference between local trainers and master trainers was on CBT+ trainee-rated "credibility." Although the difference was significant, both groups had high credibility ratings (4.54 for master trainers and 4.28 for local trainers out of a possible 5). A rating of 4 corresponds to the attribute describing the trainer "quite a bit," suggesting local trainers were still, on average, considered "quite a bit" credible/expert by CBT+ trainees. A difference between the two groups on this factor is not surprising, given that all master trainers had more experience leading CBT+ and other EBP trainings and were known to be affiliated with a university. When comparing scores on items under the credibility factor, the largest discrepancy between the groups was on an item that asked the degree to which trainees considered trainers to be experts. The mean value for local trainers on this item was 4.23 (SD = 0.791), and the mean value for master trainers being 4.64 (SD = 0.607), $t(553) = -6.83$, $p < 0.001$. Though not assessed in this evaluation, local trainers likely have higher scores for other types of credibility, such as local knowledge or experience working within public mental health.

Previous studies have suggested that a large benefit of TtT models is that local trainers may have a better understanding of contextual issues¹⁴ and can utilize existing social capital in the community to maximize training benefits.²⁴ Reflecting on the trainings, master trainers suggested participants appeared interested and comfortable approaching local trainers with questions about day-to-day implementation of EBP in community mental health. Master trainers also noted the value of co-training with a local trainer, who works in community mental health and can share real-world application of EBP and solutions for implementation challenges (e.g., engaging parental participation in school-based clinics, delivering EBP with limited prep time, treating trauma with imaginal exposure in schools) in the same setting as the trainees. This is reflected in our data; when comparing the degree to which CBT+ trainees considered trainers to be approachable, the mean value for local trainers was 4.45 (SD = 2.57), and the mean value for master trainers was 4.14 (SD = 0.931), $t(551) = 1.85$, $p = 0.065$.

These findings should be considered within the context of important limitations. First, although an attempt was made to utilize standardized measures with the MEAT and CTEI, both measures were shortened versions of the final, validated versions. Thus, although each measure had high internal consistency, we cannot claim the full validity of either measure. The decision to use abbreviated measures was motivated by a desire to employ relevant and pragmatic measures. Research has called for greater use of pragmatic measures, which assess issues of importance to stakeholders in addition to researchers while being cognizant of participant burden, applicability, and actionability.²⁵ Second, the cohort of clinicians trained under local and master trainers reported significantly different levels of self-reported skills for anxiety, depression, and behavior problems. As such, we cannot be certain that changes in self-reported skill are due to inclusions of TtTs or other factors, such as revisions to training

materials and content or increased familiarity with EBPs. Further, metrics of local trainers' performance come mostly from clinician self-report and are thus subject to biases and limitations of self-report measures. To more rigorously assess the effectiveness of the TtT model, comparisons of observational measures of trainer skills, clinician fidelity, or client outcome data could be examined using randomized trainees. Other work has utilized coded tapes of clinical supervision to assess the quality of supervision in community mental health.²⁶ Future research on the TtT model would benefit from more objective sources of data. Relatedly, this evaluation was limited in its ability to assess the cost-effectiveness of the TtT model. Future research should assess the cost effectiveness of models that employ local trainers as opposed to those which rely on university-affiliated trainers.

Findings from this evaluation add to growing support for TtT approaches as effective methods of increasing EBP training capacity and program reach. It extends the literature by including trainee's perceptions of trainer attributes and teaching effectiveness. Our results show no significant differences in training outcomes across training models while also documenting only minor differences in trainee perceptions of local trainers and master trainers. The TtT training model offers a collaborative approach to increase training capacity and decrease reliance only on university-affiliated trainers while building local ownership of EBP training.

Implications for Behavioral Health

Growing evidence suggests TtT models can be effective in increasing knowledge, improving clinical behavior, and producing better patient outcomes in behavioral health.^{11, 12} This study adds to this support and extends the literature by reporting on trainee perceptions of local expert trainers' attributes and behaviors. Although predominantly based on self-report evaluation data, the study suggests TtT models do not have significant differences in training outcomes or trainee perceptions of trainer attributes and clinical teaching effectiveness. Trainees did not perceive local and master trainers to be equivalent in terms of "credibility," but both groups had high levels of perceived credibility. As more states roll-out EBP initiatives, TtT models may offer the potential to train a greater number of mental health providers in EBPs with fewer resources than traditional training and consultation models.

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Compliance with ethical standards

All evaluation activities were reviewed by the Washington State IRB and were exempted from review.

Conflict of interest Dr. Sedlar, Ms. Berliner, Dr. Jungbluth, and Dr. Dorsey were paid by WA DBHR to serve as the master trainers for the initiative outlined in this study. The remaining authors declare that they have no conflict of interest.

Human participants All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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