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Understanding Evidence-Based Treatment for Trauma-Exposed Children

Definition, Development, and Misconceptions

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Few topics in the mental health field have generated more controversy in recent years than the progressively greater role of research in the development and implementation of treatment approaches. Numerous governmental agencies, insurance companies, and other third-party payers and policymakers are encouraging, and in some instances requiring, the use of research-supported interventions; however, critics have voiced numerous objections against the move toward a more empirically based approach to treatment. Complicating the issue are numerous misconceptions and confusion about the development of these interventions and how they are implemented in practice.

Perhaps the greatest confusion derives from the multitude of names and definitions that describe the movement toward the greater use of research in practice. Terms such as *evidence-based practice* and *evidence-based treatment* are often used interchangeably with little recognition that each term actually denotes a different idea of clinical practice. The research community itself is unable to agree on a single term and definition (Self-Brown, Whitaker, Berliner, & Kolko, 2012). This lack of terminological and definitional consensus has resulted in disagreements about which treatment techniques or packaged

protocols possess adequate empirical support and are, therefore, appropriate for widespread implementation. Correspondingly, clinicians are often unsure about the interventions for which they should seek training (Allen, Gharagozloo, & Johnson, 2012) and may be confused and resistant when funders or agencies require that they change their practice to use specific evidence-based interventions.

DEFINING EVIDENCE-BASED TREATMENT

The most widely used term, *evidence-based practice* (EBP), typically represents "the integration of the best available research with clinical expertise in the context of patient characteristics, culture, and preferences" (American Psychological Association, 2006, p. 273). This definition recognizes the unique contributions of research-derived knowledge and clinical experience and emphasizes that treatment must be tailored for unique client considerations. By this definition, EBP is not a set of techniques or a manualized intervention, but rather encompasses a larger context that incorporates both clinician and client factors. EBP provides considerable clinician freedom to determine how these separate but related factors (research, clinical expertise, client characteristics) can be integrated to achieve the desired clinical outcome.

However, this general definition of EBP has not gone unchallenged. For instance, Baker, McFall, and Shoham (2008) noted that the American Psychological Association definition "equates the personal experiences of the clinician and client preferences with scientific evidence—a striking embrace of a prescientific perspective" (p. 84). The American Psychological Association definition may be exceedingly broad in defining EBP, placing each of the three components on equal footing. Technically, a clinician may use his or her expertise and judgment to decide what constitutes "best available research," continue practicing according to his or her own clinical preferences, and be in compliance with an EBP perspective. Given the broad nature of the American Psychological Association definition, it becomes very difficult, if not impossible, to specify what does and does not constitute EBP.

In contrast, an *evidence-based treatment* (EBT; also known as an *empirically supported treatment* or *empirically validated treatment*) is a specific intervention or sequence of techniques with documented ability to create therapeutic change in controlled clinical trials (Kazdin, 2008). The specification of a treatment manual provides the clinician with a structured treatment approach specifically designed for the presenting concerns of the client. The validation of the treatment model in controlled trials provides assurance that the intervention being employed is effective for treating the identified symptoms or problems.

Multiple agencies and organizations have completed intensive reviews of the scientific evidence to identify EBTs for specific emotional and behavioral problems. These reviews may employ different criteria, but generally agree that designation as an EBT requires (1) the treatment possesses a sound theoretical basis, (2) the treatment is clearly specified in a manual or book that describes how to implement each component, and (3) at least two randomized clinical trials demonstrate either the superiority of the treatment over an appropriate control group or results equal to those obtained by another EBT (California Evidence-Based Clearinghouse for Child Welfare, n.d.; Saunders, Berliner, & Hanson, 2004; Silverman & Hinshaw, 2008). The ultimate goal of identifying EBTs is to improve the dissemination and implementation of effective interventions, thereby improving the quality of service delivery (Addis & Cardemil, 2006; Gibbs & Gambrill, 2002). The process of evaluating and validating an intervention is explained in greater detail later in this chapter.

FACTORS AFFECTING TREATMENT OUTCOME

To understand the importance of EBTs, it is necessary to consider the many factors that affect successful treatment outcome. Asay and Lambert (1999) provide a useful framework by classifying these factors into four distinct categories: (1) client variables and extratherapeutic events, (2) expectancy and placebo effects, (3) therapeutic relationship, and (4) treatment techniques. Each of these factors is discussed next with respect to treatment outcomes for trauma-exposed children.

Client Variables and Extratherapeutic Events

It is generally believed that a significant portion of treatment outcome is *not* related to the events that occur during treatment sessions. Rather, unique strengths and experiences of the client, as well as events that occur outside of treatment, exert a profound influence on one's mental health. *Client variables* include individual, familial, cultural, or systemic factors specific to a given individual that influence the development, prevention, or amelioration of mental illness. For instance, a common finding is that children with supportive caregivers involved in treatment exhibit greater benefit from mental health interventions than children whose caregivers are not involved (Deblinger, Lippmann, & Steer, 1996; Dowell & Ogles, 2010). Another example is the repeated observation that children displaying more adaptive and effective coping skills following sexual abuse are less likely to develop significant emotional and behavioral problems (Shapiro, Kaplow, Amaya-Jackson,

& Dodge, 2012; Simon, Feiring, & Kobielski McElroy, 2010). Client variables also include the characteristics of one's trauma experience. In considering sexual abuse, more severe and chronic abuse tends to result in more significant psychopathology, as does a closer relationship between the victim and perpetrator (Yancey & Hansen, 2010). These few examples are illustrative; however, countless other client variables also are influential in determining treatment outcome.

Extratherapeutic events, defined as events that occur outside of treatment sessions, can exert a significant impact on mental health. Extratherapeutic factors include the passage of time, changes in school setting, changes in family structure (e.g., parental marriage or divorce), and other such events that affect the child's mental health. For instance, abused children are at significantly increased risk for experiencing future episodes of maltreatment, bullying in school, and other stressful or traumatic situations (Mohaptra et al., 2010; Villodas et al., 2012). These events may limit the rate of progress in treatment or exacerbate the concerns with which a child presents. Reducing or eliminating various extratherapeutic stressors (e.g., parental unemployment, medical illness) may improve a child's mental health irrespective of the treatment services provided.

These few examples are meant to demonstrate that a child's mental health, including response to trauma, depends on various factors; psychotherapeutic intervention is only one of a multitude of influences. Asay and Lambert (1999) suggest that many clinicians, particularly novice clinicians, may fail to recognize the significant impact that client variables and extratherapeutic events have on treatment progress, instead crediting their clinical skill or techniques for treatment success. Alternatively, clinicians may attribute treatment failure to these variables (e.g., client resistance, complexity of the case), preventing them from considering that their clinical skills or techniques were ineffective. Clinicians are encouraged to recognize the significant impact of client characteristics and extratherapeutic events at all stages of the treatment process, including treatment planning and posttreatment evaluation.

Expectancy and Placebo Effects

Many clinicians are familiar with the concept of the placebo effect, which occurs when an inert substance or procedure is delivered to the client who, by the very fact that he or she believes that the inert treatment will work, begins to show improvement. The placebo effect demonstrates the impact that one's perceptions or beliefs can have on emotional and physical well-being. The placebo is commonly used in clinical trials of psychotropic medications. In these trials, a group of patients receives the active drug (e.g., an

antidepressant), and a second group of patients unknowingly receives an inactive substance (e.g., a sugar pill). This simple design allows researchers to determine whether the active drug creates improvement in the targeted outcome or whether the improved outcome is only associated with the belief that improvement should occur.

In psychotherapy, expectancy effects manifest in similar ways. Caregivers may bring a child to a mental health clinician because they believe that a trained professional is needed to assist with the child's difficulties. This creates an expectation, from the initiation of services, that treatment progress is possible and that the clinician treating the child is competent and able to help. Treatment progress with children is often evaluated by the feedback of caregivers, and expectancy effects may implicitly influence caregivers' report of symptoms. In addition, positive expectations of treatment appear to predict better treatment outcomes, more consistent participation and attendance at sessions, and greater compliance with homework assignments (Lewin, Peris, Bergman, McCracken, & Piacentini, 2011; Nock & Kazdin, 2001).

The use of a true placebo condition in psychotherapy outcome studies is rare. To approximate the process and conditions encountered by those receiving the target intervention under examination, the control group is more likely to receive a psychotherapeutic treatment believed to create minimal change (i.e., nondirective supportive counseling) or standard clinical services. These control conditions typically include providing a therapeutic rapport with a supportive clinician, resulting in the control group receiving the effects associated with the expectation of positive outcomes (i.e., the placebo or expectancy effect) as well as any additional benefit provided by the therapeutic relationship.

The Therapeutic Relationship

An effective therapeutic rapport has been long considered a foundational principle of psychotherapy. Clinicians learn early in training to establish a therapeutic relationship by responding to the client in an empathic and genuine manner while demonstrating unconditional positive regard, factors that Carl Rogers (1957) deemed necessary and sufficient for therapeutic change to occur. The therapeutic rapport, if effectively established, provides the client with a sense of trust and respect that allows him or her to feel valued and accepted.

Some approaches to child psychotherapy maintain that the therapeutic rapport is the primary facilitator of change in treatment. Proponents of these types of treatment, therefore, suggest that establishing and maintaining rapport should be the primary treatment technique utilized by the clinician. For instance, in child-centered play therapy (Axline, 1969) the clinician is

instructed to provide a safe and supportive environment, allow the child to direct the activities of sessions, and provide empathic comments in response to the child's play. The theory is that providing a warm and supportive atmosphere will create a sense of safety for the child and thereby allow him or her to express and process troubling thoughts and emotions, either verbally or nonverbally through play. This processing of emotional material is thought to ameliorate the presenting concerns. Indeed, treatment outcome research suggests improvement of child emotional and behavioral concerns following the delivery of rapport-focused interventions (Bratton, Ray, Rhine, & Jones, 2005).

Remembering the impact exerted by client variables, extratherapeutic events, and expectancy and placebo effects on treatment outcome, the impact of therapeutic rapport must be examined in context. McLeod (2011) conducted the most comprehensive meta-analysis to date examining the link between the quality of therapeutic rapport and treatment improvement in child psychotherapy outcome studies. His results showed only a small association between the two variables (r = .14), suggesting that the quality of the therapeutic rapport had little impact on the degree of treatment progress. The implication of this research is that the impact of therapeutic rapport on treatment outcome with children may be much smaller than many clinicians believe.

However, therapeutic rapport is still an important factor to consider in the delivery of mental health treatment, including EBTs. If one is to effectively deliver treatment, the client must be agreeable to attending sessions on a consistent basis with the clinician; the client must be willing to implement changes or attempt exercises directed by the clinician; and, with many treatments, the client must be amenable to discussing memories that may prompt feelings of anxiety, shame, or guilt. All of these aspects of treatment can be aided by a supportive therapeutic relationship. In fact, some research suggests that a poor therapeutic rapport is a primary cause for early treatment termination (Garcia & Weisz, 2002).

Despite concerns from some clinicians that the use of treatment manuals and EBTs may impair therapeutic rapport (Nelson, Steele, & Mize, 2006), a recent study found that clinicians using trauma-focused cognitive-behavioral therapy (TF-CBT), an EBT, received comparable child-reported ratings of rapport quality as those clinicians providing usual care (Armstrong & Allen, 2013). Interestingly, caregivers with TF-CBT clinicians reported greater therapeutic rapport than caregivers receiving treatment from usual care clinicians. Further illustrating the point is a recently published clinical trial wherein adolescents with posttraumatic stress were randomly assigned to receive TF-CBT or standard community treatment (Ormhaug, Jensen, Wentzel-Larsen, & Shirk, 2014). Results indicated that the quality of

therapeutic rapport was comparable across treatment conditions, but TF-CBT yielded better treatment outcomes than standard community treatment. In addition, TF-CBT outcomes were enhanced by a better quality of therapeutic rapport, and clients were discharged in fewer sessions. These results suggest that a trauma-focused EBT, such as TF-CBT, does not impair the development of therapeutic rapport, and a quality therapeutic rapport may improve the effectiveness and efficiency of an EBT.

Within the context of EBTs, therapeutic rapport is valued; however, it is not considered sufficient for change. Rather, quality therapeutic rapport is considered an important treatment consideration that increases the likelihood of successful implementation of the prescribed treatment techniques. Indeed, treatment manuals for EBTs often provide discussions about the importance of therapeutic rapport near the beginning of the manual (e.g., Cohen, Mannarino, & Deblinger, 2006; Kendall & Hedtke, 2006). However, EBTs do not typically consider establishing and cultivating a therapeutic rapport as the primary or only treatment technique. Instead, the specific treatment techniques specified within the treatment manual are considered the primary psychotherapeutic agents of change.

Treatment Techniques

There are many theoretical orientations within the mental health field (e.g., behavioral, psychodynamic, humanistic), and each one defines a theory of psychopathology, or conceptualization of why a particular emotional or behavioral problem develops. These theories of etiology lead directly to ideas about the types of experiences the client needs to improve and the techniques that a clinician should employ to provide the needed experiences (Prochaska & Norcross, 2009).

One of the requirements for an intervention to be designated as an EBT is that the treatment be derived from a sound theoretical basis. Although there are numerous theories that explain the development of a particular problem, not all theoretical explanations are supported by the empirical literature. As an example, consider the popular belief that bullies and other aggressive people tend to have low self-esteem and that their hostile behavior allows them to feel better about themselves. A considerable amount of empirical research suggests that people with low self-esteem do *not* tend to display aggression, and bullies typically report having *above average* self-esteem (e.g., Allen, 2011; Baumeister, Bushman, & Campbell, 2000; Thomaes, Bushman, Stegge, & Olthof, 2008). As such, interventions attempting to treat aggressive children by boosting self-esteem do not appear to rest on a sound theoretical basis, and it is unlikely that the techniques employed are effective.

Even with an empirically justifiable theoretical basis, the specified

techniques themselves may or may not lead to therapeutic change. The specification of these techniques often is an iterative process wherein the results of previous research prompt revision of the techniques, which are then tested in future studies. Developing and testing complete treatment protocols and specific individual techniques utilize various methodologies; the process of developing an EBT is considered next.

TESTING AND VALIDATING PSYCHOLOGICAL TREATMENTS

Defining and testing an intervention to the point that sufficient evidence is available to designate it as "evidence based" takes considerable time, funding, and effort. In addition, the very suggestion that mental health treatments should undergo such rigorous evaluation and be graded based on the quality and quantity of scientific evidence is a relatively new development. Nonetheless, it is likely that any legitimate EBT has undergone a lengthy development process and that numerous methods of empirically examining the effect of the intervention were employed. Each method of empirical evaluation possesses specific strengths and weaknesses.

Case Studies

A *case study* is an in-depth examination of the delivery of treatment with a specific client. Detailed descriptions of the implementation of techniques and the client's responses are often provided as a way of demonstrating how other clinicians might use the techniques in their own practice. Clinicians of all theoretical persuasions report valuing case studies and view them as critical during the process of treatment planning (Allen & Armstrong, 2014). Many times a case study is the starting point as a clinician begins to develop ideas about what techniques appear most effective, and how to utilize those techniques, through the process of treating clients. Sometimes case studies serve as an invaluable tool for treatment dissemination as they can demonstrate how a seemingly routinized and predefined treatment package can be used with clients of different cultures and characteristics, how barriers to treatment implementation can be overcome, and how to apply the techniques to different presenting concerns.

Case studies require relatively little cost and time and can provide rich clinical information; however, case studies cannot demonstrate that the techniques themselves were influential in treatment progress. The mental health field has a long history of clinicians attempting to demonstrate the effectiveness of a particular treatment approach by providing a series of case studies. Often these clinicians use their own judgment to evaluate treatment outcome and postulate that the techniques were responsible for the

seeming improvement. Rarely do case studies include features that would improve the quality of inferences, such as using valid and reliable assessment instruments and assessing multiple domains of functioning (Kazdin, 1981). Even if these more rigorous standards are employed, the very nature of the method prevents one from determining how much of the noted treatment progress, if any, was due to the treatment techniques and how much progress was due to other influences (i.e., client factors, extratherapeutic events, placebo/expectancy effects, therapeutic rapport). In addition, single cases cannot demonstrate the generalizability of the techniques beyond the specific client(s) discussed.

Open, Non-Controlled Trials

After specification of the intervention protocol, the next step is evaluating the effectiveness of the treatment on a larger scale. Clinical trials typically involve implementing the intervention with a group of individuals who present with a common problem or set of problems. An *open, non-controlled trial* does not involve a control group; all participants receive the target intervention, and efforts are taken to ensure that the protocol is delivered to each participant with fidelity. Although the number of participants in the trial may vary, it is not uncommon for open, non-controlled trials to enroll a total sample of 15–30 participants. The goal of these pilot trials is to examine the feasibility of the protocol and collect preliminary data on the effectiveness of the intervention (Rounsaville, Carroll, & Onken, 2001). These designs are well suited to identifying any challenges or barriers that might arise across participants, which might indicate a problem with the protocol and in soliciting feedback from participants about their experiences in the study. In addition, these trials can provide initial impressions regarding the generalizability of the protocol to more diverse populations.

An open, non-controlled trial is more cost and time intensive than case studies, but does not tend to be prohibitively expensive or demanding. However, like case studies, an open, non-controlled trial does not allow the unique contribution of the treatment techniques to be parceled out from the other factors that affect treatment outcome. Although positive results of an open, non-controlled trial do not validate the treatment techniques, these designs are often an important part of the treatment development process because the information obtained can assist in the design and implementation of a randomized controlled trial.

Randomized Controlled Trials

A *randomized controlled trial* (RCT) includes two primary factors: (1) there are at least two groups of participants, one receiving the intervention under

examination and another not receiving that intervention (i.e., a control group), and (2) participants are randomly assigned to the groups. The purpose of random assignment is to attempt to distribute the impact of client variables and extratherapeutic events equally across the two groups. Because it is often difficult to predict how these factors will affect treatment outcome, randomly distributing them across the two groups serves to negate their influence by assuming that they affect both groups equally. For instance, random assignment typically results in roughly equal gender and ethnic distributions across groups. Theoretically, other client-specific factors (e.g., coping skills, intelligence, trauma history) are equally distributed as well. The result of random assignment is that treatment differences observed between the groups are not attributable to client variables and extratherapeutic events, removing this factor as a possible explanation for why the group receiving the intervention under examination performed better or worse than the control group.

Wait-List Control Group

Historically, wait lists were widely used as a form of control group for RCTs. In this approach, a number of participants receive the intervention of interest and a second group of participants receive no treatment. This second group is considered to be on a "wait list" and will receive the intervention after the first group completes treatment. The RCT typically concludes when the first group completes treatment, and the researchers determine whether the treated group achieved gains not observed in the wait-list group. Because both groups include client variables and extratherapeutic events as possible sources of change, finding superiority of the treatment group over the control group suggests that providing the treatment was the cause of the observed greater improvement. However, because the treatment group received three different potential sources of improvement not experienced by the control group (placebo/expectancy effects, therapeutic rapport, and treatment techniques), it is not possible to conclude from a wait-list RCT that the treatment techniques were effective and responsible for the greater improvement.

Wait-list control groups offer a relatively inexpensive way of testing an intervention in an RCT. Because not all participants receive treatment, fewer clinicians are required to complete the trial. In addition, wait-lists may already exist in general community settings because of understaffing, creating a natural opportunity to compare an active intervention to a wait-list control group. However, ethical concerns are raised about the use of a wait list as a designated and predefined control group to test an intervention (Cohen, 2007). In short, the researchers are knowingly withholding assistance to people who need treatment. An alternative option using a different sort of control group (e.g., community controls, active controls) would address this

ethical problem and increase the methodological rigor of the study. Given these considerations, wait-list control groups are being used less frequently in treatment outcome studies.

Community Control Group

Another type of control group for RCTs is a community control group, in which control group participants typically are referred to community providers for treatment. In this design, some participants receive the intervention under examination, and the other participants receive referral information or are assigned to various treatment providers available in the community. The use of a community control group is meant to imitate standard clinical practice. In the case of referrals, some children and caregivers will contact a provider and receive treatment, while others will not. During trials in which children and caregivers are directly assigned to community providers, the treatment will vary from clinician to clinician. Using a community control group removes ethical concerns about withholding treatment from participants and evaluates the intervention of interest against the standard care provided in the community.

Using community controls is fairly inexpensive, as researchers are only required to provide treatment for half of the total study sample; however, significant problems are associated with a community control group design. First, with the referral approach, a number of children in the control group typically will not receive treatment. This creates a control group in which some participants receive treatment and others do not. The result is that the group as a whole may perform worse than if all children received treatment. Second, when children are treated by a community clinician, the types of interventions received may vary widely. Many children may receive treatment that creates relatively little change, while other children may receive more effective treatment. In addition, some children might receive treatment similar to the intervention being tested, which can make it difficult to ascertain the true impact of the target intervention. When using community controls, researchers face considerable challenges in ascertaining the degree to which the tested techniques were responsible for any observed differences between the treatment group and the control group.

Active Control Group

Considered the "gold standard" of clinical research, an RCT with an active control group provides the strongest level of support for an intervention. In this design, the control group receives an intervention selected, or at least monitored, by the researchers. A widely used method is to provide the control

group with nondirective supportive treatment. Younger children in this type of control group often receive child-centered, nondirective play therapy. A clinician allows the child to select the activities of sessions, provides a safe and supportive environment, and only makes comments that are designed to demonstrate empathy, support, and positive regard. When treating adolescents, the control intervention often resembles nondirective supportive counseling in which the clinician allows the adolescent to determine the topics of conversation and the clinician responds with reflective and empathic listening. Consequently, the control group receives all sources of potential change (i.e., client variables, extratherapeutic events, placebo/expectancy effects, and therapeutic relationship) with the exception of more specific treatment techniques. As a result, superior performance by the group receiving the intervention being tested suggests that the greater observed change must be attributable to the delivery of the defined techniques. Findings of comparable results between the two groups suggest that the techniques were not particularly helpful.

Another form of active control design involves providing the control group with an intervention already possessing sufficient support to be designated as an EBT. In this case, both groups receive an intervention designed to treat the identified problem. Comparable results between the two groups indicate that the experimental intervention achieves treatment gains similar to an intervention already demonstrated as effective, and provides significant support for the intervention being tested. However, poorer results for the target intervention do not necessarily mean that it is ineffective. Rather, it could mean that the intervention is simply not as effective as the previously established treatment, but may still be superior to rapport-focused treatment if tested against such an intervention in another trial.

Although an RCT with an active control group is the most methodologically rigorous clinical research design available, it too has drawbacks. First, these trials tend to be expensive and time consuming. The researchers must fund treatment for all participants, as well as consider the costs associated with training, supervising, and monitoring the clinicians in the use of multiple interventions. It is rare that such a trial can be successfully completed without designated funding (e.g., a grant from an external agency). Second, regardless of whether one uses a pure nondirective supportive therapy or a previously established EBT, neither reflects true clinical practice in the community. Relatively few community-based clinicians are trained to fidelity in the use of a given EBT, and clinicians who primarily utilize a nondirective supportive approach may integrate more empirically based techniques. This makes it difficult to establish in an RCT that the tested intervention will perform better than the treatment provided by any given clinician using a different approach. Even with these limitations, an RCT with an active control

group provides the only effective avenue to demonstrate that the identified techniques are responsible for observed clinical progress.

The Importance of Replication

Even with a successful RCT utilizing an active control group, the possibility remains that the observed findings were obtained in error. Factors unique to the sample or specific to the clinicians utilized in the study (e.g., allegiance to a preferred theoretical approach, interpersonal skills) may have created the observed differences, and not the actual techniques. For these reasons, replicating the clinical trial with a different sample of participants is often required for designation of the treatment as an EBT. Some guidelines require that at least two different researchers demonstrate positive results of the intervention in order to minimize the impact of clinician-specific variables or self-interests influencing the results.

The standard of validating an intervention is necessarily high and includes a sound theoretical rationale, a manual specifying the techniques or protocol, and at least two RCTs demonstrating that the techniques themselves are responsible for clinical improvement. Completion of this process with positive results creates confidence among clinicians, policymakers, and the general public that the techniques being employed are effective in ameliorating the targeted presenting problems. However, concerns and objections to the wider utilization of EBTs remain, many of which reflect misunderstandings about EBTs or express concerns that are not validated by empirical research.

MISCONCEPTIONS OF EBTs

• ***EBTs are developed in academic settings and are not effective in the "real world."*** A common criticism of EBTs is derived from a belief that research performed in a controlled academic environment does not generalize to community settings. The logic typically emphasizes that studies focus on treating clients with one or two presenting problems, exclude complex and difficult-to-treat clients, and fail to simulate the daily pressures and complications of clinical work. These criticisms, however, often fail to distinguish between *efficacy trials* and *effectiveness trials*.

An *efficacy trial* is a treatment outcome study conducted within tightly controlled conditions, typically with multiple criteria for including and excluding potential participants. Efficacy trials often focus on treating only a specific presenting problem (e.g., posttraumatic stress, depression). Clients who demonstrate other significant presenting concerns may be excluded

from the study. In addition, the clinicians in the study typically receive intensive training in the model, have sessions observed by study coordinators to ensure fidelity to the protocol, and receive corrective feedback if deviations from the protocol are noted. Under such tightly controlled conditions, the criticisms regarding the ability of treatment protocols to generalize to "real-world" settings are legitimate. However, such rigorous experimental conditions are required to test the intervention, particularly in the beginning phases of protocol development. If a clinical trial did not have such rigid conditions and the treatment was found ineffective, numerous explanations could account for the findings. It could be argued that the treatment was not delivered in a standardized way to each participant; the treatment is successful for some participants, but not for clients displaying significant comorbidity; or clinicians were not sufficiently trained and experienced. In other words, with less rigorous conditions, the ability to judge the impact of the intervention is significantly reduced.

An *effectiveness trial* is a treatment outcome study that typically occurs in a community setting, not an academic one, utilizes community clinicians, and includes much less stringent criteria for selecting participants. The primary goal of an effectiveness trial is to examine whether an intervention with positive results in efficacy trials can achieve positive results in general community settings. In contemporary research, effectiveness trials are considered critically important, and significant financial resources from grant-making agencies (e.g., National Institute of Mental Health) are earmarked for the purpose of completing effectiveness trials. With positive results in effectiveness trials, the criticism regarding "real-world" applicability is addressed.

As one might expect, effectiveness trials commonly yield smaller treatment effects for EBTs than do efficacy trials (Weisz, Ugueto, Cheron, & Herren, 2013); however, EBTs still tend to outperform treatment-as-usual services (Weisz, Jensen-Doss, & Hawley, 2006). Multiple examples of effectiveness trials are available in the child trauma literature, including community-based trials of parent–child interaction therapy (PCIT) with child welfare–referred families (Chaffin, Funderburk, Bard, Valle, & Gurwitch, 2011), child–parent psychotherapy (CPP) and TF-CBT with children in foster care (Weiner, Schneider, & Lyons, 2009), and Alternatives for Families: A Cognitive-Behavioral Therapy in a child protection center (Kolko, Iselin, & Gully, 2011). Further demonstrating the point, Ollendick and colleagues (Ollendick, Jarrett, Grills-Taquechel, Hovey, & Wolff, 2008) conducted a literature review of treatment outcome studies and found that client comorbidity was common in treatment research samples, and that comorbidity did not typically affect treatment outcome.

It is appropriate to require EBTs to demonstrate their applicability to the "real world," and criticisms about the applicability of research-based

interventions in community settings are more valid when a specific protocol has not been evaluated in effectiveness trials. However, most EBTs, particularly those related to trauma-exposed children, have demonstrated the ability to produce positive results in community settings with complex cases. As such, the criticism that EBTs are too academic and are not relevant to "real-world" practice appears unwarranted.

• ***All treatments achieve the same results, so identifying EBTs is unnecessary.*** Smith and Glass (1977) conducted a seminal meta-analysis of the results of treatment outcome studies. They concluded that behavioral and nonbehavioral treatments resulted in comparable outcomes, leading many in the field to conclude that all treatment approaches are effective at achieving positive outcomes. These conclusions were controversial at the time; however, as clinical and research methods were refined, it became apparent that not all treatments yield similar outcomes.

From a contemporary perspective, the most significant flaw of the Smith and Glass meta-analysis and similar studies published in the years immediately afterward, is the emphasis placed on theoretical orientation. In these meta-analyses, studies were collapsed into categories based on the theoretical orientation of the treatment being tested and rarely considered the problem(s) being treated in the studies. This method obscures an important clinical question: what treatment is most effective for a client with a given problem or diagnosis? In the past 25 years, most meta-analyses and reviews have examined the treatment of a specific problem or set of problems, not broad theoretical orientations.

This altered emphasis has led to important advances and the identification of treatment protocols that perform significantly better than others in ameliorating a given problem. Presently, the belief that all treatments work equally well for a given problem or diagnosis is rarely advanced in academic settings and among policymakers. Clinicians are encouraged to seek training in EBTs that target the most common presenting concerns that one is to treat as opposed to searching for treatments from a specific theoretical orientation.

• ***EBTs are not culturally sensitive***. A legitimate concern of any clinician is being culturally sensitive. Cultural awareness and sensitivity represent foundational tenets of clinical practice. Two primary approaches to implementing EBTs with various cultural groups are evident in the literature. The first approach is to apply the standard protocol with different cultural groups and examine the effectiveness and acceptability of the intervention. For instance, the standard version of SafeCare (Lutzker & Bigelow, 2002), an EBT applicable in cases of child neglect, received high ratings of cultural sensitivity and acceptability by a sample of American Indian parents, and

outcomes were similar to those obtained by other cultural groups in the study (Chaffin, Bard, Bigfoot, & Maher, 2012). A recent meta-analysis examining outcome studies of trauma-focused cognitive-behavioral interventions, including 883 child participants, found that 61% of participants in the trials were ethnic minorities and that ethnicity did not moderate treatment outcome (Allen, Henderson, Johnson, Gharagozloo, & Oseni, 2012). These results demonstrate a common finding in research on the applicability of EBTs across cultures; similar results are typically obtained across cultural groups (Huey & Polo, 2008).

Nonetheless, it appears that ethnic minorities seek out mental health services at a lower rate than their white counterparts (Roberts, Gilman, Breslau, Breslau, & Koenen, 2011), and ethnic minorities are more likely to prematurely terminate treatment (Wierzbicki & Pekarik, 1993). Given these considerations, a second approach to implementing EBTs with diverse cultural groups is to modify certain components of the protocols or integrate cultural beliefs and practices as a means of increasing the acceptability of the interventions to various cultural groups. For instance, recommendations on modifying TF-CBT for use with individuals of Latino/Hispanic (de Arellano, Danielson, & Felton, 2012) and American Indian/Alaskan Native cultures (Bigfoot & Schmidt, 2012) are available. Clinical trials of culturally adapted EBTs tend to obtain results similar to those obtained using the standard protocol (Huey & Polo, 2008).

It is important to recognize that cultural sensitivity may be best achieved by having a culturally competent clinician providing treatment, regardless of the treatment approach employed. Indeed, most published policies and treatment guidelines related to cultural competence focus on the awareness, skills, and attitudes of the treating clinician (Whaley & Davis, 2007). It is impossible to provide cultural adaptations of EBTs for all cultural groups one may encounter in clinical practice; however, a culturally competent clinician can effectively implement an EBT with diverse clients. In other words, the clinician may be the most critical factor in determining whether an EBT is delivered in a culturally sensitive manner. Whaley and Davis (2007) and Hays (2009) provide excellent reviews and recommendations on integrating cultural competence and the use of EBTs.

- ***EBTs do not value clinical experience and creativity.*** Traditionally, the mental health field emphasized the role of clinical judgment and experience in deciding which interventions to implement and in evaluating the effectiveness of treatment. With the advent and expansion of EBTs, these tasks are primarily determined by the results of standardized assessment measures and scientific research, which many clinicians view as curtailing

their clinical freedom. Not surprisingly, some clinicians view this development as misguided and believe that their clinical experience and creativity is being undervalued or disregarded.

In actuality, EBTs do value clinical experience and creativity, albeit in a different manner than that to which many clinicians are accustomed. Although specific techniques are prescribed by the EBT, the clinician must determine how to deliver those techniques in a manner that will be most effective for a given client. For instance, if a treatment protocol directs teaching a client affect regulation skills, the clinician must determine what specific activities will be most effective given the client's unique characteristics. There are countless ways of teaching affect regulation skills, and many clinicians are quite creative in finding effective ways to achieve that goal. Despite concerns from some clinicians that EBTs neglect clinical skill and experience, an EBT must be implemented by a skilled and knowledgeable clinician to be effective.

• ***EBTs assume that everyone is the "mean" and do not recognize individual differences***. Some clinicians object to using EBTs on the premise that research-derived interventions do not recognize individual differences. Often this criticism is directed at using statistical procedures to examine mean differences between groups, leading to the assumption that these research methods examine the "average person" and fail to understand or recognize individual differences. The reasoning then follows that many clients do not resemble the mean of a particular treatment group and, therefore, EBTs are not applicable to these clients.

Two primary misunderstandings are evident in this reasoning. First, the criticized statistical procedures use not only mean scores, but also scores of variability within the groups (e.g., standard deviation, variance). The amount of variability within a group directly affects the likelihood that a statistical test will yield a significant finding. In essence, these statistical procedures evaluate a group of individuals against another group of individuals, not a group mean against another group mean. As a result, when positive results are found in clinical trials, it is more accurate to state that a group of individuals who receive a treatment demonstrate greater improvement than another group of individuals who do not. It is important to remember that descriptive statistics such as means and standard deviations are meant to describe the group as a whole, not to describe an "average person."

The second misunderstanding of this criticism is the assumption that the treatment protocol should be administered in an identical manner with each person. Clinical trials require that the protocol be delivered in a standardized way; "real-world" clinical practice does not. For instance, although a clinical

trial of TF-CBT may only allow for one session of teaching relaxation skills, it is often the case in clinical practice that two or three sessions are devoted to teaching a client relaxation skills. These variations in the delivery of the treatment will depend on various client characteristics.

Even though flexibility is permitted in the delivery of an EBT, it remains important to use the treatment as it was developed. Significant deviations from the treatment protocol, such as clinicians inserting favored techniques that are not prescribed by the protocol or declining to implement techniques with which they are unfamiliar or uncomfortable, may delay treatment progress and/or weaken the treatment's effectiveness. For example, it appears that some clinicians decline to directly discuss and process a client's trauma history (Allen & Johnson, 2012), even though this direct processing and desensitization to one's traumatic memories are considered critically important pieces of trauma-focused treatment (Deblinger, Mannarino, Cohen, Runyon, & Steer, 2011). Clinicians are encouraged to practice what Kendall and colleagues (Kendall, Gosch, Fur, & Sood, 2008) refer to as "flexibility within fidelity," in which the clinician practices in a manner consistent with the defined treatment protocol, but tailors the interventions to the needs of a particular client.

A CAUTIONARY NOTE

Terms such as *evidence-based practice* and *evidence-based treatment* are not copyrighted or otherwise protected by any legal or professional standard. Clinicians, authors, presenters, and others are free to use these terms at their own discretion and evaluate for themselves what constitutes sufficient empirical evidence. It is not uncommon for individuals to describe the intervention(s) they are promoting as evidence based, even if the quality and/or quantity of the research supporting the approach is weak. In the current mental health marketplace, amid the increasing emphasis by policymakers that EBTs be disseminated and implemented, it is almost a necessity that a treatment promoter convince clinicians that an intervention possesses sufficient empirical support to be considered "evidence based." One must remember that results from various research methods constitute "evidence," but not all evidence can demonstrate that the techniques are effective. Ultimately, clinicians are responsible for the interventions they implement with clients, and they are encouraged to verify claims that a particular intervention is "evidence based" before investing the time and money required to complete training in the treatment. The following online resources are available to help clinicians evaluate the strength of empirical support for interventions:

- California Evidence-Based Clearinghouse for Child Welfare
  www.cebc4cw.org
- Effective Child Therapy, sponsored by the Society of Clinical Child and Adolescent Psychology (Division 53 of the American Psychological Association)
  www.effectivechildtherapy.com
- Office of Juvenile Justice and Delinquency Programs (OJJDP), Model Programs Guide
  www.ojjdp.gov/mpg
- Substance Abuse and Mental Health Services Administration (SAMHSA), National Registry of Evidence-Based Programs and Practices (NREPP)
  www.nrepp.samhsa.gov

CONCLUSIONS

Developing, disseminating, and implementating EBTs significantly improves the quality of mental health care. The process involved in the development of an EBT is lengthy; however, demonstrating that therapeutic techniques are capable of creating change beyond the impact of client variables, extra-therapeutic events, expectancy/placebo effects, and therapeutic rapport is important in order to maximize the benefits of mental health treatment. The implementation of an EBT by a skilled clinician constitutes the best clinical care currently available for those we serve and should be the standard to which we aspire as a profession.

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