

Are Results of Randomized Controlled Trials Useful to Psychotherapists?

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ABSTRACT

Two clinicians provided opposite answers to the title question: Persons argued that information from randomized controlled trials (RCTs) is vital to clinicians, and Silberschatz argued that information from RCTs is irrelevant to clinicians. Persons argued that clinicians cannot provide top quality care to their patients without attending to findings of RCTs and that clinicians have an ethical responsibility to inform patients about, recommend, and provide treatments supported by RCTs before informing patients about, recommending, and providing treatments shown to be inferior in RCTs or not evaluated in RCTs. Silberschatz argued that RCTs do not and cannot answer questions that concern practicing clinicians. He advocates alternative research approaches (effectiveness studies, quasi-experimental methods, case-specific research) for studying psychotherapy.

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The question of whether the results of randomized controlled trials (RCTs) are useful to practicing clinicians is a controversial one in the field of the psychological therapies. We present the two sides of the argument, with Persons arguing that information from RCTs is vital to clinicians and Silberschatz arguing that information from RCTs is irrelevant. After presenting each of our points of view, each author rebuts the other's position. We conclude with a brief review of our key points of agreement and

disagreement.

Two Points of View

Results of RCTs Are Vital to Clinicians (Jacqueline B. Persons)

Clinicians must attend to the results of RCTs for clinical, ethical, and legal reasons. I present examples of clinically useful information provided by RCTs. I also describe factors that make it difficult to export RCT-supported protocols from research to clinical settings, and I propose strategies for alleviating some of those difficulties.

Importance of RCTs to Clinicians

Practitioners need information from RCTs for clinical, ethical, and legal reasons. I discuss each in turn.

Clinicians are routinely called upon to make decisions about alternative treatments. The RCT is designed specifically to assist in these decisions, because the RCT addresses questions of the form, Are Treatment A and Treatment B equally effective in the treatment of disorder X? Other types of studies, including naturalistic studies, can also address this question. However, a naturalistic comparison of Treatments A and B is a weaker design than the RCT because clinicians cannot be certain that the patients receiving Treatment A do not differ in some systematic way from the patients receiving Treatment B. RCTs (through random assignment, hence the name *RCT*) overcome this weakness (see [Chambless & Hollon, 1998](#)). Because clinicians need information about comparative treatment efficacy and because the RCT is one of the strongest designs to answer this question, I believe that unless psychotherapists attend to RCTs, they cannot offer their patients the best quality care.

Evidence from clinical trials is currently widely accepted by the scientific community as the gold standard of evidence about treatment efficacy. It is also generally accepted by the lay public; articles reporting results of clinical trials appear daily in the popular press. Because the RCT is the standard method of evaluating treatment efficacy, I believe that clinicians have an ethical responsibility to use RCTs to guide their work; this argument has also been made by others, including the Agency for Health Care Policy and Research, U.S. Public Health Service ([[AHCPR, 1993](#) ; [Klerman, 1990](#) ; [McFall, 1991](#)). Practicing without regard to the results of the RCTs can also have legal consequences ([Klerman, 1990](#)). Furthermore, because RCTs are the gold standard method for comparing treatments, I believe that in this debate the burden of proof falls on clinicians who assert that RCTs are not relevant to their work.

What Useful Information Do RCTs Provide to Therapists?

The RCT can answer the question, All else the same, what treatment is best for disorder X? RCTs can tell us which therapies are superior to other active therapies, which new therapies appear equal to older therapies of known efficacy, and which therapies are superior to placebo or to no treatment. I discuss

each of these points here.

Numerous RCTs comparing active treatments for a particular clinical problem show superior outcomes for one or another treatment modality. For example, exposure to somatic cues plus cognitive therapy has been shown to be more effective than relaxation in treating panic ([Barlow, Craske, Cerny, & Klosko, 1989](#)); cognitive—behavior therapy has been shown to be more effective than nondirective therapy, short-term psychodynamic therapy, and pharmacotherapy in treating bulimia nervosa ([Leitenberg, 1993](#)); behavioral interventions have been shown to be superior to insight-oriented psychotherapy in treating nocturnal enuresis in children ([Kaplan & Busner, 1993](#)); stress inoculation training has been shown to be more effective than supportive counseling in treating symptoms of posttraumatic stress disorder ([Foa, Rothbaum, Riggs, & Murdock, 1991](#)); cognitive—behavior therapy and applied relaxation have both been shown to be more effective than nondirective psychotherapy in treating generalized anxiety ([Borkovec & Costello, 1993](#)); dialectical behavior therapy has been shown to be more effective than treatment as usual in reducing parasuicidal behavior and hospital days in women with borderline personality disorder ([Linehan, Armstrong, Suarez, Allmon, & Heard, 1991](#)); behavior therapy has been shown to be superior to pharmacotherapy in treating obsessive—compulsive disorder ([Stanley & Turner, 1995](#)); and two different treatments (social skills training plus chemotherapy and family psychoeducation plus chemotherapy) have each been shown to be superior to chemotherapy alone in the aftercare treatment of schizophrenic patients living in high-expressed-emotion households ([Hogarty et al., 1986](#)). These are only a few examples of randomized trials showing superior outcomes for a particular treatment for a particular problem; many others are provided in the articles in this special issue.

RCTs also provide useful information when they show that a new treatment is equal in efficacy to a treatment that has repeatedly been shown to be superior to placebo or wait-list conditions. This type of evidence adds to our confidence in the efficacy of a new therapy. For example, RCTs have shown that interpersonal therapy and cognitive therapy do not differ in efficacy from pharmacotherapy for treatment of major depression ([AHCPR, 1993](#) ; [Clarkin, Pilkonis, & Magruder, 1996](#)). This example demonstrates that therapists must be familiar with results of RCTs of pharmacotherapy as well as psychological therapies—in fact, they must be familiar with clinical trials of any therapy for the disorders they treat.

Clinicians can also make use of RCTs showing that a therapy is superior to no treatment or to a placebo, even if the therapy has not been compared with other active therapies. In fact, much of what we know about effective therapies stems not from demonstrations that these therapies are superior to other active therapies, but from demonstrations that they are superior to placebo or to no treatment. Therapies demonstrated effective in this way include interventions to treat social phobia ([Hope, Holt, & Heimberg, 1993](#)), major depression ([Persons, 1993](#)), and anxiety disorders in children ([Kendall, 1994](#)), among others.

I also believe that clinicians have an ethical and professional responsibility to recommend therapies that have been shown in RCTs to be superior to a no-treatment condition before they recommend therapies that have not been evaluated in an RCT. This view entails a distinction between therapies that have not

been shown in controlled studies to be effective and ineffective therapies. The fact that a therapy has not been demonstrated effective in a controlled study does not mean that it is ineffective—in fact, it may be quite helpful. However, unless it has been studied in a controlled study, we have no compelling evidence that it is effective and we cannot be certain it is not harmful.

What Information Do RCTs Not Provide Clinicians? When Do RCT-Supported Treatment Protocols Fall Short?

Although RCTs are invaluable, they frequently fail to meet clinicians' needs, for several reasons. First, RCTs provide information about the average case, whereas clinicians make treatment decisions about specific, unique cases ([Howard, Krause, & Vessey, 1994](#)). Second, RCT-supported protocols are difficult to use in clinical practice because most currently available protocols guide treatment of single disorders and problems, whereas most patients have multiple disorders and problems. Third, even when patients seek treatment for single disorders for which empirically supported protocols exist, the protocols often provide clinicians with little assistance in overcoming common obstacles—such as noncompliance and patient—therapist relationship difficulties—to following the protocols.

Difficulties using the results of RCTs are counterbalanced by the clinician's obligation to do evidence-based practice, that is, practice that relies on empirical evidence and methods, including evidence from RCTs. A model of evidence-based practice that attends to RCTs while accommodating some of the difficulties clinicians encounter when using the RCTs is presented in the next section.

Essential Components of Evidence-Based Practice

Evidence-based practice has (at least) three components: formally informing patients about treatment options and making treatment recommendations, providing RCT-supported treatments, and conducting the treatment as a scientific experiment.

Formally informing the patient about treatment options and making treatment recommendations.

In an evidence-based approach to treatment, the therapist makes treatment decisions collaboratively with the patient and his or her family. In contrast, in a non-evidence-based approach to treatment, the clinician makes treatment decisions unilaterally and may even begin treatment without discussing options! The process of informing the patient about treatment options and offering treatment recommendations is elegantly described in the practice guideline for treatment of depression in primary care written by [AHCPR \(1993\)](#).

I believe that clinicians have an ethical responsibility to inform patients about the findings from RCTs that are relevant to the patient's condition. Clinicians, in my view, also have an ethical responsibility to recommend treatments supported by evidence from RCTs before recommending treatments that are not supported by evidence from RCTs or that are not evaluated in RCTs. I also argue that because RCTs are widely accepted as the gold standard of evidence about treatment efficacy, even clinicians who do not

view RCTs as useful to clinical practice have an ethical responsibility to rely on RCTs when providing information about treatment options and making treatment recommendations to their patients.

Providing RCT-supported treatments.

I believe that clinicians have an ethical and professional responsibility to provide, as first-line treatment, interventions that have been shown superior or efficacious in RCTs before providing interventions that have been shown to be inferior or ineffective in RCTs, or that have not been studied in RCTs. However, as described above, it may be difficult to adapt an RCT-supported protocol designed for the average patient to the needs of the particular patient in the clinician's office. To do this, the evidence-based practitioner can rely on an idiographic (individualized) case formulation. Viewing the protocol as a nomothetic application of a nomothetic theory, the therapist can adapt the protocol to a particular case by using the nomothetic theory underpinning the RCT-supported protocol to develop an idiographic theory of the case at hand; this is an idiographic case formulation. The idiographic formulation can guide all of the tasks of the therapy: developing a treatment plan, determining the type and order of interventions to be selected from the nomothetic protocol, managing treatment failure, handling noncompliance, and responding to patient—therapist interpersonal difficulties (see [Persons, 1989](#)). This method borrows from many, including [Eifert, Evans, and McKendrick \(1990\)](#), who used the term *principle-driven* therapy to describe this idea; it also relies on notions of idiographic conceptualization and treatment planning described in psychodynamic, behavioral, and other treatment modalities.

Treatment-as-experiment.

The clinician using this strategy conducts the treatment of each patient as a scientific experiment with a sample size of 1. This stance toward clinical work is well described by many ([Barlow, Hayes, & Nelson, 1984](#) ; [Hersen & Barlow, 1976](#) ; [Kazdin, 1993](#) ; [Stricker & Trierweiler, 1995](#)). As much as possible, all of the steps described here are carried out collaboratively with the patient. The therapist begins by conducting a comprehensive assessment, developing a problem list, specifying the goals of treatment, and choosing strategies for measuring progress toward the goals. Next, the therapist constructs an idiographic hypothesis about the mechanisms causing, controlling, or maintaining the patient's problems, or both; this is the case formulation. The formulation is used to develop a treatment plan. As treatment proceeds, patient and therapist monitor its outcome; if results are poor, the therapist reformulates the case in an attempt to generate an alternative treatment plan. This hypothesis-testing approach to therapy is orientation-neutral; in fact, it is illustrated in [Silberschatz, Fretter, and Curtis \(1986\)](#) ; see also [Fretter, 1984](#) , who use a cognitive—psychoanalytic approach to treatment).

Results of RCTs Are Useless to Clinicians (George Silberschatz)

For the past several years, whenever I have lectured on psychotherapy research or made clinical presentations to practicing psychotherapists, I have made it a point to ask my audience whether they were familiar with the findings of the National Institute of Mental Health Treatment of Depression Collaborative Research Program (NIMH Depression Study; [Elkin et al., 1989](#)). Typically, a number of

people have heard of the study or have read about it; however, I have never heard anyone say that the way she or he practiced psychotherapy was influenced by the NIMH research or by any other RCT. The problem is not that clinicians are ignorant about or indifferent toward research; most clinicians are well informed and keep abreast of the clinical and research literature (see, e.g., recent surveys by [Beutler, Williams, & Wakefield, 1993](#) ; [Beutler, Williams, Wakefield, & Entwistle, 1995](#)). I believe that RCTs have minimal impact on the practice of psychotherapy because the method and findings do not address the issues and concerns of the practicing clinician ([Goldfried & Wolfe, 1996](#) ; [Howard, Moras, Brill, Martinovich, & Lutz, 1996](#)).

When a patient seeks therapy, the therapist must try to answer several basic questions: What is bothering the patient? What does the patient hope to accomplish in treatment? What has impeded the patient from achieving his or her goals? How can the therapist best help this patient? I believe that certain kinds of research studies are capable of providing useful data to answer these fundamental clinical questions (e.g., [Crits-Christoph, Cooper, & Luborsky, 1988](#) ; [Howard et al., 1996](#) ; [Rice & Greenberg, 1984](#) ; [Silberschatz, 1986](#) ; [Silberschatz & Curtis, 1993](#)). However, RCTs do not provide any meaningful help in addressing these questions and, consequently, they have had very little impact on clinicians and on the practice of psychotherapy. [Goldfried and Wolfe \(1996\)](#) have similarly suggested that RCTs have had minimal impact on the practice of therapy because they simply do not address issues that are most pertinent to the practicing therapist: how to treat patients who suffer from multiple disorders, how to treat underlying personality problems, how to resolve clinical impasses, and how or why do treatments work—that is, what are the actual mechanisms and processes of therapeutic change?

Research on the effective ingredients in psychotherapy is in its infancy. Empirical studies of psychotherapy change processes are rare, and consequently relatively little is known about basic mechanisms of change in psychotherapy. In RCTs, therapeutic approaches, and the implicit or explicit theories of change embedded within them, are codified in treatment manuals. However, therapy manuals tend to be oriented toward specific therapy techniques, rather than effective therapy ingredients or other variables that may supersede techniques (e.g., empathy, the therapeutic relationship, and therapeutic alliance). [Goldfried and Wolfe \(1996\)](#) pointed to the dangers of treatment manuals functioning "as more of a straightjacket than a set of guidelines" (p. 1014). They reviewed research suggesting that therapists who adhere too closely to treatment manuals compromise their clinical effectiveness. Moreover, therapies that easily lend themselves to manualization, and hence to the RCT method, are not necessarily those that are widely practiced ([Parloff, 1979](#)).

From the clinician's point of view, RCTs lack external or ecological validity. In the effort to optimize internal validity in RCTs (i.e., to assure that differences between groups are attributable only to treatment conditions), external validity is severely compromised if not totally sacrificed ([Howard et al., 1996](#) ; [Seligman, 1995](#) , 1996). RCTs do not focus on the types of patients seen in practice, nor do they focus on the types of therapies that therapists actually do in their offices ([Parloff, 1979](#) ; [Persons, 1991](#)). This point was vividly driven home at an NIMH psychotherapy research conference when a participant reminded the audience (ostensibly in jest) not to overlook "the first law of research: Don't use real

patients" ([Goldfried & Wolfe, 1996](#), p. 1011). Similarly, in an article titled "Psychotherapy Research Is Not Psychotherapy Practice," [Fensterheim and Raw \(1996\)](#) argued that controlled research studies use subjects not patients; and even though they are drawn from a clinical population, research subjects differ markedly from psychotherapy patients. RCTs usually focus on patients with a single diagnosis; large numbers of patients are screened out of these studies in order to achieve a homogenous diagnostic sample. Clinicians frequently treat complex cases suffering from multiple problems and diagnoses. Indeed, the type of patient most likely to be screened out of the RCT is the patient seen by the typical practicing therapist. Fensterheim and Raw questioned the validity of applying results from this narrowly defined population of research subjects to therapy patients: "Considering the complexity of many of the patients [typically seen by therapists in practice], the comorbidities, and the myriad life problems, there is the question of whether it is possible or ethical to use these protocols with such patients" (p. 169).

In addition to marked differences in patients seen in research and practice settings, the kinds of treatments carried out in most therapists' offices differ markedly from the kinds of treatments studied in RCTs. In most RCTs, treatment is highly specified with regard to number of sessions, techniques to be used, and timing of interventions, and treatment must be administered as uniformly as possible to the entire patient sample. In good clinical practice, it is flexibility, rather than uniformity or strict adherence to treatment manuals, that is required ([Goldfried & Wolfe, 1996](#) ; [Howard et al., 1996](#)). Indeed, effective therapists tailor therapy to the problems and needs of the individual patient (for research bearing on this issue, see [Silberschatz & Curtis, 1993](#) ; [Silberschatz et al., 1986](#)). [Nezu \(1996\)](#) has argued that even among the most homogeneous groups of patients, therapists, and patient—therapist dyads, "a therapy cookbook does not and probably cannot exist. As [Hersen \(1981\)](#) noted over 15 years ago, complex problems require complex solutions." ([Nezu, 1996](#), p. 162).

[Seligman \(1995\)](#) has argued that the very properties that make the RCT scientifically rigorous, make it "the wrong method for empirically validating psychotherapy as it is actually done, because it omits too many crucial elements of what is done in the field" (p. 966). He delineated five properties that characterize psychotherapy as it is typically practiced and argued that each of these properties are absent from controlled clinical trial studies. (a) Psychotherapy as practiced in the field, is not of fixed duration; therapy continues until the patient improves or terminates treatment. (b) In clinical practice, psychotherapy is self-correcting; if a particular strategy or technique appears not to be working, the clinician adopts a different approach. (c) Psychotherapy patients in the field frequently enter treatment by actively seeking a therapist of their choosing (as opposed to a passive process of random assignment). (d) Patients seen in therapists' offices typically have multiple problems rather than a single diagnosis. (e) Psychotherapy in the field is aimed at improving patients' general level of functioning, not just symptomatic improvement.

RCTs can be a powerful tool for assessing circumscribed, highly specified procedures (e.g., agricultural methods, pharmacotherapy, and certain medical procedures). I do not believe that psychotherapy, as practiced in the field by experienced practitioners, lends itself to the RCT methodology. Indeed, [Howard et al. \(1996\)](#) succinctly and cogently pointed out that there are three different questions that can be asked about any treatment and that the answers to these questions require fundamentally different research

methods: Does a treatment work under controlled experimental conditions? Does it work in clinical practice? And does it work for this particular patient? RCTs are the standard method for addressing the first (efficacy) question; however, RCTs are the wrong method for studying psychotherapy as practiced in the field by experienced practitioners. To assess how therapy works in practice or whether it works for any given patient requires quasi-experimental procedures and a more case-specific research approach ([Howard et al., 1996](#)).

In arguing that RCTs are useless to clinicians, I am not saying that psychotherapy research is useless. In fact, I have been a strong advocate for scientific rigor in psychotherapy research ([Silberschatz, 1994](#)) as well as in training ([Silberschatz, 1990](#)); but scientific rigor is not synonymous with the RCT method. [Goldfried and Wolfe \(1996\)](#) argued that an alternative to the RCT is needed in psychotherapy outcome research: "What needs to be specified and replicated is not brand name therapies but identifiable processes of patient change and therapist behaviors that bring these about" (p. 1013; see also [Howard et al., 1996](#)). I will briefly review two psychotherapy research strategies that are likely to be more clinically useful and productive than the RCT.

The *events paradigm* ([Rice & Greenberg, 1984](#) ; [Stiles, Shapiro, & Elliott, 1986](#)) is a research approach that focuses on critical incidents between patient and therapist. The intensive analysis of such incidents is used to identify, describe, and empirically evaluate effective ingredients and therapeutic change processes in psychotherapy. Many researchers have productively used this paradigm; I shall give one brief illustration based on the work of the San Francisco Psychotherapy Research Group (formerly known as the Mount Zion Research Group; see [Silberschatz, Curtis, Sampson & Weiss, 1991](#) , for a review). [Weiss \(1993\)](#) developed a cognitive psychoanalytic theory of psychotherapy that includes explicit hypotheses about how therapy works. According to this theory, patients work in psychotherapy to disconfirm pathogenic beliefs either by testing them in the therapeutic relationship or by using the therapist's interpretations to disconfirm these beliefs. Thus, in Weiss's model, one critical change process in psychotherapy is the disconfirmation of pathogenic beliefs. Empirical studies have shown that when pathogenic beliefs are disconfirmed, patients show immediate progress within sessions ([Silberschatz & Curtis, 1993](#) ; [Silberschatz et al., 1986](#)) as well as improvement at outcome ([Norville, Sampson, & Weiss, 1996](#)).

A second research strategy that has more direct relevance to clinicians and to the practice of psychotherapy is the effectiveness study. Unlike an RCT, which attempts to show that one manualized treatment stringently implemented under tightly controlled conditions to a narrowly specified sample of patients is more effective than a contrasting treatment, the effectiveness study is designed to evaluate how well psychotherapy works in the field; that is, how effective is psychotherapy as practiced by clinicians with patients seeking treatment? One recent example of such a study is the *Consumer Reports* (*CR*) study ("Mental Health . . . ," 1995). With an sample of 2,900 participants, the *CR* study is the largest single psychotherapy study in the literature. The sample consisted of a clinical population with diverse and multiple problems; it is representative of the patients clinicians tend to see in their practices, rather than the selected patients (suffering from a single disorder) seen in RCTs. Also representative of clinical

practice was the fact that the type and duration of treatment was not specified or fixed in advance. "Because the *CR* study was naturalistic, it informs us of how treatment works as it is actually performed—without manuals and with self correction when a technique falters" ([Seligman, 1995](#) , p. 970). Although the *CR* study is not without methodological shortcomings (for a thorough review, see the October 1996, special issue of the *American Psychologist*; [G. R. Vandenbos, 1996](#)), its ecological validity makes its findings comprehensible and useful to the practicing clinician. [Seligman \(1996\)](#) outlined a number of methodological refinements that would enhance the scientific rigor of future effectiveness studies.

RCT and horse-race studies of psychotherapy are a waste of valuable resources, energy, and time. Although results from individual studies have suggested that one form of treatment is superior to another (some reviewers have suggested that these differences may be attributed to allegiance effects; [Luborsky, Singer, & Luborsky, 1975](#) ; [Robinson, Berman, & Neimeyer, 1990](#) ; [Smith, Glass, & Miller, 1980](#)), results from meta-analyses and literature reviews consistently show that no one school of therapy is superior to another ([Lambert & Bergin, 1994](#) ; [Lipsey & Wilson, 1993](#) ; [Smith et al., 1980](#) ; [Stiles et al., 1986](#)). My interpretation of this consistent finding is that there are certain effective ingredients that cut across different schools of therapy. Expert therapists, regardless of their particular theoretical orientation, have some intuitive understanding of what these ingredients are and use them effectively in their clinical work. The disconfirmation of irrational or pathogenic beliefs is an example of an effective ingredient in psychotherapy ([Weiss, 1993](#)). An RCT comparing cognitive, experiential, and interpersonal therapy would most likely find no significant differences between treatments, because therapists in each condition were disconfirming patients' pathogenic beliefs, albeit through the use of very different techniques. This effective ingredient hypothesis may explain the lack of differences between psychological treatments. For example, the so-called placebo—clinical management condition in the NIMH Depression Study was essentially supportive therapy ([Elkin et al., 1989](#)).

I believe that research and knowledge in our field would be further advanced by focusing more on basic change mechanisms and less on which technique or school of therapy should win the biggest prize. We need to identify what the effective ingredients of psychotherapy are, how they can be maximized to improve the overall effectiveness of therapy, and how therapists can be trained to use them most effectively.

Rebuttal: Jacqueline B. Persons

Silberschatz raises three objections to RCTs; I address each in turn.

First, RCTs do not address the fundamental clinical questions that are most pertinent to practitioners, such as questions about the mechanisms of change in effective therapy and the nature of the therapeutic alliance. Instead, RCTs focus on outcome and on technique.

This objection reflects a value difference between Silberschatz and me (cf. [Messer & Winokur, 1984](#)).

Silberschatz places a high value on process, whereas I place a high value on outcome (as do RCTs). Once this discrepancy is seen as a value difference, it is not meaningful to ask, Which is best? We can ask only which value is superior at guiding research or clinical work toward a certain goal (and even the choice of goals is likely to be based on values).

I argue that placing a high value on outcome (as RCTs do) enhances therapists' abilities to relieve patients' symptoms and improve their quality of life. Without controlled outcome studies to examine the efficacy of the treatments they provide, therapists may be providing treatments that do not alleviate suffering and may cause harm. Moreover, unless a therapy has been shown in controlled studies to be effective, I do not place a high value on studies of its mechanisms.

Therapists who emphasize the types of questions Silberschatz poses seem to me to be assuming that the therapy they do is effective. The effectiveness assumption is a risky one; the history of medicine is filled with reports of physicians who believed they were offering effective treatment but later learned (from RCTs) that their therapy was ineffective or even harmful ([Frazier & Mosteller, 1995](#)).

Silberschatz states that RCTs do not address topics that seem pertinent to practicing clinicians. This may be true. However, I speculate that RCTs do address topics of interest to patients. Second, RCTs lack ecological validity. They do not capture five properties of psychotherapy as it is usually practiced: (a) open-ended (vs. fixed duration in RCTs), (b) self-correcting (vs. specified in advance in RCTs), (c) treatment and therapist actively chosen by the patient (vs. randomly assigned in RCTs), (d) patients have multiple problems (vs. single problems in RCTs), and (e) therapy is intended to improve general functioning (vs. symptom relief in RCTs).

I agree with Silberschatz that RCTs frequently study phenomena that are distant from the phenomena of clinical practice. However, there is nothing inherent in the RCT that requires this ([Jacobson & Christensen, 1996](#)). All five phenomena listed as characteristic of clinical practice can readily be studied in an RCT. RCTs can study open-ended treatment (e.g., Jacobson, Dobson, Fruzzetti, Schmalung, & Salusky, 1989), self-correcting and nonmanualized treatment, multiple-problem patients (e.g., [Linehan et al., 1991](#)), and patients' general level of functioning (e.g., [Elkin et al., 1989](#) , and many others). To capture clinical practice as it actually happens, many RCTs randomly assign patients to receive treatment as usual in the community (cf. [Linehan et al., 1991](#)). It is even possible in an RCT to examine whether patients do better when they receive the therapy or therapist they prefer than when they are assigned to therapy or therapist. To address this question, an RCT could be conducted to compare outcomes for patients who are or are not assigned to their preferred therapy and therapist.

Although RCTs need not study homogeneous patient samples with manualized treatments, Silberschatz does correctly note that currently this is what usually happens. As a result, findings from RCTs are not easily generalized to clinical practice. However, I disagree with Silberschatz that, therefore, RCTs are irrelevant to clinical practice. Consider the following.

The patient in the clinician's office seeks treatment for depression. The patient meets criteria for major

depressive disorder, which has been studied in dozens of RCTs. However, the patient does not meet the usual selection criteria of those RCTs because in addition to major depression this patient has coronary artery disease, irritable bowel syndrome, and panic disorder. The therapist in this situation has two choices: She or he can offer the patient one of the treatments shown to be effective in the RCTs, adapting it to the patient's circumstances, or she or he can ignore the results of the RCTs and provide his or her usual or preferred mode of treatment. An evidence-based practitioner will choose the first option.

Similarly, imagine that you have been diagnosed with bladder cancer. Suppose that treatments for bladder cancer have been studied in RCTs, but your case does not meet the typical selection criteria used in the RCTs. Would you like your physician to treat your cancer by extrapolating from the findings in the RCTs to the specifics of your case, or would you rather she or he treat you with whatever methods she or he is familiar and has found helpful in his or her clinical experience, without regard to the results of the latest RCTs? I would like my physician to be guided by the results of the latest RCTs, and I speculate that many readers would agree.

Silberschatz argues that RCTs are not useful because they do not study the therapies that most clinicians do. This statement does not make sense to me. It is not sensible to argue that a RCT studying new therapies is irrelevant to clinicians because they are not currently using those therapies.

I agree with Silberschatz that the treatments conducted by most therapists bear little resemblance to the treatments that have been shown in RCTs to be effective. However, this does not mean that RCTs are useless to practitioners. Instead, I conclude that most therapists are conducting therapies of undemonstrated efficacy, and I recommend that they begin doing the therapies shown effective in RCTs.

I agree with Silberschatz that the discrepancy between treatment provided in RCTs and that provided in routine practice suggests that the money spent on RCTs is wasted; money spent on RCTs is wasted if their findings are not used by the professional community. However, unlike Silberschatz, I do not conclude that we ought to stop spending money on RCTs; instead, I conclude that we need to do a better job of disseminating the findings of RCTs to the professional community. I also recommend that we begin conducting RCTs that incorporate many of the features of psychotherapy as it is practiced, so that results would be more directly relevant to practicing clinicians.

Third, most RCTs have found no significant differences between treatments and those that have may be due to allegiance effects.

This argument seems to me to conflict with some of Silberschatz's earlier ones. It suggests that if RCTs did frequently show differences between treatments, RCTs would be relevant to clinicians, but that because they frequently do not, they are not relevant. Wouldn't the clinician who accepted this argument need to keep abreast of the results of RCTs?

Although many RCTs of psychological therapies fail to find significant differences between active treatments, many do find differences (for some examples, see studies listed in the earlier section, "What

useful information do RCTs provide to psychotherapists?"). Several writers have recently argued that "the dodo bird" verdict ("Everyone has won and all must have prizes") is no longer true, although perhaps it once was ([Chambless, 1996](#) ; [Giles, 1993](#)). I agree.

The common finding of tie results in RCTs pitting active treatments against one another does not support the conclusion that, therefore, all treatments are equal in efficacy and RCTs do not provide useful information. For example, exposure and response prevention (ERP) is widely considered the psychosocial treatment of choice for obsessive—compulsive disorder (OCD; [Steketee & Lam, 1993](#)). Thus, it is considered superior to psychodynamic psychotherapy, for example. However, the view of ERP as superior to psychodynamic psychotherapy is not based on the results of any RCT showing that ERP is superior to psychodynamic psychotherapy in the treatment of OCD. Instead, it is based on the fact that numerous RCTs examining hundreds of patients have uniformly shown ERP to be superior to wait-list, placebo, and alternative behavioral and cognitive—behavior treatments, and on the fact that psychodynamic psychotherapy for OCD has not been studied in a single RCT (see the review by [Steketee & Lam, 1993](#)).

Silberschatz argues that when RCTs do show differences between treatments, these differences may be due to allegiance effects. I agree with Silberschatz that allegiance effects may underlie some findings showing one therapy superior to another. However, I believe that the concern about allegiance effects demonstrates the importance of RCTs. We cannot assume that therapies work in the way we think they work—or even that they work at all—without careful measurement free of bias. It is for this reason that RCTs are essential. In fact, it is an RCT that would provide the most compelling test of the allegiance effects hypothesis. To test for allegiance effects, patients would be randomly assigned to therapists with high versus low allegiance to the therapy they were providing.

Rebuttal: George Silberschatz

Persons argues that clinicians typically must decide whether one form of treatment is more effective than another for a particular patient and that the RCT is the strongest available method for answering this question. It is not. RCTs address efficacy issues in terms of mean responses for average patients; they do not address questions of central importance to the practicing clinician: Will the treatment work for a particular patient? As I discussed earlier, this question can be answered in a scientifically rigorous manner but not with the RCT method.

Persons acknowledges the difficulties of applying RCT results to specific patients, and as one solution, she advocates using the nomothetic RCT data in an idiographic way. There are two problems with this position. First, psychotherapy RCTs have very poor external validity; generalizing from the experimental condition to clinical practice is very risky. As [Howard et al. \(1996\)](#) pointed out,

There is no logical connection between showing that a treatment can work and showing that a treatment does work. That is, a treatment that cannot be shown to produce

statistically significant mean group differences in a carefully conducted clinical trial may still be demonstrably beneficial as actually practiced. Similarly, a treatment that has been shown to be effective in a clinical trial may not be effective as practiced. (p. 1060)

The second problem with extrapolating from RCTs to clinical practice is the assumption of patient homogeneity. RCT advocates believe that by selecting a circumscribed group of patients (e.g., major depressive disorder) using highly specific inclusion—exclusion criteria, one can then generalize treatment results to a comparable homogeneous group in practice. [Kiesler \(1966\)](#) referred to this assumption as "the uniformity myth" in psychotherapy research. It is a myth that does not fit clinical reality. In my own work, for instance, I find substantial differences among my educated, intelligent, middle-aged dysthymic patients and would therefore find it difficult to evaluate a study that found that treatment X is superior for this group of supposedly homogeneous patients. It is not surprising that uniformity assumptions do not hold up for psychotherapy research participants any better than they do for patients. [Blatt \(1992\)](#) identified two different types of depression and found that responsiveness to psychoanalytic therapy differed as a function of the two types. In an analysis of data from the NIMH Depression Study, [Blatt, Quinlan, Pilkonis, and Shea \(1995\)](#) found that one type of depression (perfectionistic self-criticism) predicted a poor level of therapeutic response across all treatment conditions.

Persons seems to discount alternative research designs such as repeated-measures single-case studies because of difficulties with generalizability. Solutions for the problem of generalizability in small sample studies have been discussed in the literature (e.g., [Hersen & Barlow, 1976](#) ; [Kazdin, 1982](#) ; see also [Goldfried & Wolfe, 1996](#)), for instance, serial replication of findings across different patients, therapists, and treatments. In my view, RCT advocates have sacrificed clinical validity in the effort to maximize experimental control (internal validity); I don't see the value of generalizing clinically meaningless findings. Persons states that RCTs address the question " *All else the same* [emphasis added], what treatment is best for disorder X?" (p. 126). But in phenomena as complex and multidimensional as psychopathology and psychotherapy, all else is not the same, and no amount of experimental manipulation can force all other things to be equal. Patients are not equal, therapists are not equal, and the therapeutic interactions between them are not equal, regardless of how meticulously manualized the treatments may be (for further discussion, see [Davison & Lazarus, 1994](#) ; [Fensterheim & Raw, 1996](#) ; [Goldfried & Wolfe, 1996](#) ; [Nezu, 1996](#) ; [Stiles et al., 1986](#)). In designing studies that assume that all other things are equal (or can be equalized), RCT advocates end up studying a phenomenon that is unfamiliar to most practicing clinicians. There are other scientifically rigorous approaches to studying psychotherapy that do not require such simplistic and false assumptions.

RCTs, according to Persons, provide therapists with useful information for they tell us which treatments are scientifically proven to be superior. If the data were so unequivocal, I doubt there would be much of a basis for debate. In fact, most large-scale reviews and meta-analyses of psychotherapy outcome studies have consistently shown that psychotherapy is effective but that no one treatment is superior ([Lambert & Bergin, 1994](#) ; [Lipsey & Wilson, 1993](#) ; [Smith et al., 1980](#) ; [Stiles et al., 1986](#)). One can point to individual studies in which one treatment is found to be superior to another; however, such results must

be viewed cautiously because (a) randomization (the bedrock of RCTs) can rarely be achieved in a single experiment and thus requires replication, ¹and (b) individual studies are vulnerable to allegiance effects—that is, the treatment found to be superior is typically the one that is practiced or advocated by the investigator ([Luborsky et al., 1975](#) ; [Robinson et al., 1990](#) ; [Smith et al., 1980](#)).

The crux of my disagreement with staunch RCT advocates is that they zealously overvalue the RCT as the scientific gold standard. Persons, for instance, states that most therapists are conducting treatments of undemonstrated efficacy or value, suggesting that the only demonstration of value is the RCT. [Seligman \(1996\)](#) persuasively argued that efficacy studies (RCTs) do not "have a unique claim on the empirical validation of psychotherapy" (p. 1077). He made the case that effectiveness studies, which rely on observational methods with causal modeling, and efficacy studies, which rely on randomization and experimental controls, are both scientifically rigorous methods for assessing psychotherapy. They each have their flaws as well as their strengths:

They both narrow in on causation by eliminating alternative causes; the experimental method does this by random assignment of participants to control or experimental groups, and the observational method does this by measuring specified alternative causes and partialing them out. The experimental method has an edge in eliminating many unmeasured possible causes in one fell swoop, whereas the observational method has an edge in being able to generalize immediately to reality. (pp. 1075—1076)

[e14] I urge Persons and other psychotherapy research colleagues to guard against equating empirical validation with the RCT method. [Seligman \(1996\)](#) ; see also [Fox, 1996](#) , especially pp. 780—782) showed the perils of this false equation.

Persons and I disagree about many issues regarding psychotherapy practice and research, but there is one fundamental issue about which we agree wholeheartedly: the value of what she calls theory-driven idiographic treatment (see also [Persons, 1991](#)). I believe that most good clinicians rely (either implicitly or explicitly) on a model or theory to guide their understanding of human behavior and then apply their theory in a case-specific fashion. In fact, the therapist's ability to tailor interventions to the problems and needs of specific patients is, in my judgment, one of the key effective ingredients of psychotherapy. I believe that a theory-driven idiographic approach is essential to the scientific study of psychotherapy and that the results of such efforts are far more compelling than the results of RCTs.

Discussion

Two very different points of view are presented here. Silberschatz argues that the phenomena studied in RCTs diverge so sharply from clinical practice that no generalization from the research to the clinical setting is possible. Persons agrees that the phenomena studied in RCTs often differ from clinical practice but argues that the clinician can—and has an ethical responsibility to—generalize from RCTs.

Silberschatz and Persons agree that more studies of psychotherapy as it exists in the clinical setting are needed. However, they disagree about the details of the particular studies each would recommend.

Persons recommends that steps be taken to increase the ecological validity of RCTs, with the hope that this will make them more acceptable and useful to practicing clinicians. She recommends that researchers conduct RCTs that study heterogeneous populations and the characteristics of therapy as it occurs in nature, including idiographic treatment (cf. [Persons, 1991](#)). She suggests that reporting of results of RCTs focus more on individual cases and on clinical significance (cf. [Jacobson & Truax, 1991](#)) than is usually done. She also recommends that naturalistic outcome studies examine empirically the degree to which results of RCTs generalize to routine clinical practice (cf. [Persons, Burns, & Perloff, 1988](#)).

In contrast, Silberschatz views RCTs, even of naturally occurring clinical phenomena, as scientifically unproductive and clinically useless. Instead, he argues that process-outcome studies, effectiveness studies, and single case research provide more valuable information to clinicians and contribute to understanding how therapy works (cf. [Barlow et al., 1984](#); [Crits-Christoph et al., 1988](#); [Davison & Lazarus, 1994](#); [Norville et al., 1996](#); [Rice & Greenberg, 1984](#); [Seligman, 1995](#); [Silberschatz & Curtis, 1993](#); [Silberschatz et al., 1986](#)). Silberschatz agrees with [Seligman \(1996\)](#) that well-designed observational methods (with multiple regression analysis) can be used to test and rule out alternative explanations. Indeed, much of the work of the San Francisco Psychotherapy Research Group has used such methods to empirically evaluate competing hypotheses about how patients work in psychotherapy (for review, see [Silberschatz, Curtis, Fretter, & Kelly, 1988](#); [Silberschatz et al., 1991](#)). Persons agrees that these types of studies are useful but does not see them as supplanting the RCTs because they do not address the same questions the RCTs address.

We agree that it is useful to study therapy as it occurs in nature. Thus, we agree that studies such as the *CR* study are quite useful, and we recommend that more studies of this sort be undertaken. We also agree that the *CR* study could be improved in many ways (by collecting data prospectively rather than retrospectively and by using better measures that assess patients' functioning, rather than satisfaction with treatment, for example).

Because the difference between our two positions is so sharp, we believe it is noteworthy that we can agree on the importance of studies of therapy as it occurs in nature. We also agree on the value of single-case studies; this methodology has been underutilized and has much to contribute. We believe that our agreement about the value of naturalistic studies of psychological therapies and single-case studies deserves particular note. These are areas in which therapists who otherwise differ considerably can agree and those in which clinicians and researchers, often divided, can join.

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Investigators rely on random assignment in an effort to achieve comparable experimental and control groups. However, [Howard, Krause, and Lyons \(1993\)](#) have shown that randomization almost never perfectly equates groups in any single study (because of attrition, treatment confounds and high within-group variance on dependent variables).