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Manual-Based Treatment: Evolution and Evaluation

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The development of manual-based psychological treatments for a wide range of clinical disorders has had a significant impact not only on clinical research, but also on clinical practice. Theory-driven, manual-based treatments have become a defining feature of evidence-based treatments for specific clinical disorders that have been evaluated in numerous randomized controlled trials (RCTs). The advantages of manual-based treatment include well-documented efficacy, less reliance on intuitive clinical judgment, and greater ease in training and supervising therapists in specific clinical strategies and techniques (Wilson, 1998a). Another nontrivial benefit has been the development of various self-help interventions derived from manual-based protocols (Fairburn & Carter, 1997).

Nonetheless, the advent of manual-based treatment has generated considerable controversy (Addis, Wade, & Hatgis, 1999; Garfield, 1996; Wilson, 1998a). Different criticisms that have been leveled against manual-based treatment have focused not only on the use of standardized protocols (manuals; e.g., Strupp & Anderson, 1997), but also on the more general concept of empirically supported or evidence-based treatment (e.g., Garfield, 1996; Westen, Novotny, & Thompson-Brenner, 2004), and in some instances on the use of RCTs as a research methodology for

evaluating the efficacy of psychological treatments (Seligman, 1995; Westen et al., 2004).¹

The present chapter is limited to addressing three specific objections to manual-based treatment and the use of RCTs for documenting their efficacy and effectiveness. I focus on these particular criticisms because they ignore or misrepresent ongoing and evolving research that promises to enhance our clinical effectiveness and theoretical understanding of mechanisms of change.

It is a personal pleasure and privilege to participate in a festschrift honoring Dick McFall, a friend and distinguished colleague whose work I have long admired. An influential educator and researcher, Dick's unwavering commitment to the highest standards of clinical science in the study of clinical psychology serves as a model for all who seek to develop effective, evidence-based treatments.

MANUAL-BASED TREATMENT AND THERAPEUTIC INNOVATION

One of the most puzzling misconceptions about the development of manual-based psychological therapies has been the contention that it would hinder theoretical and clinical innovation. Gaston and Gagnon (1996), for example, predicted that it would result in a set of "stagnant, codified accepted treatments" (p. 17). This view is misguided. Indeed, the opposite has been the case. Manual-based treatment has significantly spurred therapeutic innovation, as illustrated in the context of the following three examples.

Exposure Treatment for Anxiety Disorders

A little history is informative. Consider what happened to systematic desensitization, which at one point in the early stages of behavior therapy was arguably the best-known, most widely used, and empirically supported treatment for phobic and other anxiety disorders (Lazarus, 1961;

¹The choice of the term *manual* to describe structured, evidence-based treatment was unfortunate. It conjures up images of a more-or-less mechanical approach to therapy. The connotative links are to "maintenance manuals" for lawn mowers and Toyota Camrys. The term invites clever—albeit misleading—references to "manual labor" (Parloff, 1998) in depicting therapists adopting this approach as mere technicians, compared with purportedly clinically sophisticated therapists who are in no need of such evidence-based protocols.

Wolpe, 1958). One of Wolpe's (1958) great contributions (he was primarily a practicing clinician) was that he spelled out in testable, operational detail the procedural elements of systematic desensitization. As part of his well-known doctoral dissertation, Paul (1966) developed what he called a *systematic desensitization treatment manual*. To my knowledge, this is the earliest formal use of the term *treatment manual* in the behavior therapy literature.

The availability of a detailed and therapist-friendly treatment protocol (manual) for Wolpe's clinically inspired treatment enabled theoretically sophisticated and methodologically expert clinical researchers to conduct controlled studies of the treatment in both the laboratory (Bandura, 1969; Lang, 1969) and the field (Paul, 1969). Innovative *dismantling studies*, as they came to be known, showed that the therapeutic efficacy of the treatment was not due to the therapist–patient relationship, therapeutic expectancies, or other so-called nonspecific influences. Similarly, some of the components that Wolpe (1958) believed to be vital to behavior change, such as progressive relaxation training or the invariable use of a hierarchical presentation of phobic stimuli, were shown to be nonessential. The collective outcome of these lines of research was the conclusion that exposure to relevant anxiety-eliciting cues was a necessary and sufficient condition for therapeutic success. Wolpe's (1958) theory of reciprocal inhibition was promptly discarded (Wilson & Davison, 1971; much to his displeasure), and more powerful and flexible forms of exposure treatment were increasingly adapted to the treatment of the full spectrum of anxiety disorders. Today there is little question that exposure-based therapy is the treatment of choice (Barlow, 2002). Only first- or second-generation behavior therapists would know much about systematic desensitization.

Cognitive Therapy for Depression

A more contemporary example is provided by Beck's cognitive therapy (CT), now well established as an effective treatment for depression. Recent evidence from well-controlled RCTs has shown that CT appears to be as effective as antidepressant medication even with severely depressed patients (DeRubeis, Gelfand, Tang, & Simons, 1999; DeRubeis et al., 2005; Hollon et al., 2005). As with Wolpe, one of Beck's many contributions was to spell out clearly in a manual how treatment was administered (Beck, Rush, Shaw, & Emery, 1979). Hollon (1999) succinctly deconstructed CT into the following list of overlapping and sequential

elements: rationale for treatment; systematic self-observation; behavioral activation (BA); monitoring thoughts; challenging the accuracy of thoughts; exploring core underlying beliefs; and relapse prevention. As with systematic desensitization, this detailed description of the therapy encouraged researchers to subject the treatment to rigorous experimental scrutiny.

Behavioral Activation. Jacobson and his colleagues (1996) carried out a component analysis (dismantling study) of CT for depression. They showed that the early phase of CT alone, which emphasizes behavioral activation (BA), was as effective as the complete treatment protocol both at the end of treatment and, most tellingly, at a 2-year follow-up (Gortner, Gollan, Dobson, & Jacobson, 1998). Most recently, Dimidjian et al. (2004) extended this finding in showing that BA was as effective as antidepressant medication and more effective than CT in the treatment of severe depression. Full analysis of the implications of these important—and, to many, surprising—findings is beyond the scope of this chapter. Suffice it to say that they challenge the necessity of some of the defining cognitive components of CT and possibly call into question the current cognitive theory behind CT. BA has been further refined into a distinctive therapy for depression—a functional analytic treatment that has been detailed in a treatment manual (Martell, Addis, & Jacobson, 2001). Hollon (2001) suggested that BA may be easier to learn than CT. Given our difficulties in disseminating evidence-based treatments (discussed later), the efficacy of BA is an encouraging development.

Mindfulness-Based Cognitive Therapy. Another manual-based innovation directly influenced by CT is mindfulness-based cognitive therapy (MBCT; Segal, Teasdale, & Williams, 2004). CT focuses explicitly on the content or validity of patients' dysfunctional beliefs. Teasdale et al. (2002) have argued that "this focus leads, implicitly, to changes in relationships to negative thoughts and feelings and to increased metacognitive awareness" (p. 275). The latter is defined as a cognitive set in which "negative thoughts and feelings are seen as passing events in the mind rather than as inherent aspects of self or as necessarily valid reflections of reality" (p. 285). Enhanced metacognitive awareness, rather than change in the content of beliefs, is posited to be responsible for the long-term efficacy of cognitive therapy. MBCT is designed to promote metacognitive awareness as a means of reducing the risk of relapse in

the face of future stress in patients who have recovered from a depressive episode. Preliminary findings suggest that MBCT is effective in reducing relapse in recovered recurrently depressed patients compared with treatment as usual (Ma & Teasdale, 2004; Teasdale et al., 2002). Moreover, the results are consistent with the hypothesis that increased metacognitive awareness mediated the therapeutic effect.

Early Response to Treatment. Ilardi and Craighead (1994) first pointed out that CT for depression produces much of its therapeutic benefit early in treatment. According to their analysis, approximately 60% to 80% of total reduction in depression assessed at posttreatment occurred within the first 4 weeks of therapy. Subsequent research has indicated that this is a robust finding that applies to other manual-based CBT treatments for different disorders (Wilson, 1999). The finding, directly attributable to the well-defined structure and sequencing of manual-based CT, has wide-ranging theoretical, methodological, and clinical implications.

In terms of theory, the finding raises serious questions about the mechanisms of action of CBT (Ilardi & Craighead, 1994). Existing theories did not predict this finding, and it has spurred constructive theoretical debate. The methodological implications are clear-cut—the study of the mechanisms of action of CBT (and perhaps of any psychological treatment?) requires targeted and repeated assessment of the hypothesized mechanisms from the onset of treatment (Kraemer, Wilson, Fairburn, & Agras, 2002).

From the practical, clinical perspective, the early response finding meshes with the evidence of the efficacy of BA (Jacobson et al., 1996). Simply put, the initial treatment procedures in CT for depression basically comprise behavioral activation. Is this sufficient for lasting therapeutic improvement? What then is the role of the more cognitive procedures that unfold later in the sequence of CT? Are they necessary? The early response phenomenon, combined with the findings on BA, challenges what is purported to be the distinctive added value of schema-focused therapy (SFT; Young, Beck, & Weinberger, 2001). This approach has proved popular with clinicians. SFT is aimed at underlying cognitive vulnerabilities, as opposed to a focus on symptom reduction. Presumably the focus of behavioral activation is on the latter, whereas SFT emphasizes a focus on core underlying beliefs or early maladaptive schemas. But if the heavily cognitive component of CT (the focus on core beliefs) apparently does not add to the efficacy of BA, why would a much-expanded

concern with hypothesized cognitive content of schemas be required? At present, there is no evidence of the specific efficacy of SFT, let alone data indicating that it might be superior to current CBT in the treatment of any clinical disorder.

Of particular practical significance is the finding that early response to treatment has emerged as a robust predictor of subsequent treatment outcome—not only in depression, but also in other disorders (Wilson, 1999; see the example of eating disorders discussed later in this chapter). Likely nonresponders to manual-based CBT can be identified more efficiently, and treatment can be modified or switched to enhance the chances of successful outcome.

In short, the brief history of Beck's manual-based CT for depression has seen the development of new and different treatments, and novel research on mechanisms of action of CT. This is hardly the stuff of which stagnation is made!

Cognitive Behavior Therapy for Eating Disorders

Theory-driven, manual-based CBT for eating disorders (Fairburn, Marcus, & Wilson, 1993) is now well documented as the current treatment of choice for bulimia nervosa (BN) and binge eating disorder (BED; National Institute for Clinical Excellence [NICE], 2004; Wilson & Shafran, 2005). As proponents of this approach were quick to note (Wilson, 1996a), this manual-based CBT still has limited efficacy and does not help a significant number of patients. Far from leading to stagnation or complacency, however, the treatment has been the target of theoretical and clinical analyses designed to develop an improved second-generation manual that is more effective and applicable to a wider range of eating disorders (including anorexia nervosa and eating disorders not otherwise specified [EDNOS]; Fairburn, Cooper, & Shafran, 2003; Wilson, 2005; also see later discussion).

Conclusion

Any development that enhances accountability and increases our ability to critically test the efficacy of specific treatments and their presumed mechanisms will lead to research and likely innovation. Manual-based treatment represents such a development and has clearly led to important innovations in psychological therapy. There is every indication that it will continue to do so.

THE DISSEMINATION AND CLINICAL UTILITY OF MANUAL-BASED TREATMENTS

The efficacy of CBT as a treatment for many clinical disorders is well established (Nathan & Gorman, 2002). Yet its lack of dissemination to routine clinical practice has been repeatedly documented (e.g., Barlow, Levitt, & Bufka, 1999; Mussell et al., 2000; Persons, 1997). One of the reasons for this unsatisfactory state of affairs, I would argue, is the misconception that the findings of RCTs evaluating manual-based treatments are of little if any relevance to routine clinical practice.

Exclusion and Inclusion Criteria in RCTs of Manual-Based Treatments

The misconception is based, in part, on the false assumption that RCTs typically exclude difficult patients—patients with multiple comorbidities—in a limited focus on a sample of patients with a single problem and a good prognosis. This charge has been analyzed in detail and found wanting (e.g., Barlow et al., 1999; Crits-Christoph, Wilson, & Hollon, 2005; Stirman, DeRubeis, Crits-Christoph, & Brody, 2003; Stirman, DeRubeis, Crits-Christoph, & Rothman, 2005; Weisz, Weersing, & Henggeler, 2005). Of course, some studies have broader exclusion criteria than others and have included patients with limited problems. Yet RCTs have increasingly included patients with severe psychopathology, high rates of psychiatric comorbidity, and frequent histories of previously failed therapy. As several commentators have noted, the most common reason for excluding individuals from RCTs is that their problems are not severe enough to meet the inclusion criteria (e.g., Crits-Christoph et al., 2005; Jacobson & Christensen, 1996). Not surprisingly, patient samples in some RCTs might have greater severity of the target disorder and more comorbidity than some unselected clinical samples in routine practice (e.g., Hirsch, Jolley, & Williams, 2000; Merrill, Tolbert, & Wade, 2003; Westbrook & Kirk, 2005). As always, it depends on the nature of the specific RCT and clinical samples in question.

In his commentary on evidence-based treatment and the individual patient, Summerskill (2005) had the following to say:

It can be tempting to consider the application of trial data in rigid terms: “Could my patient have been randomized in this trial? If so the results are applicable; if not, they may not be.” A more matter-of-fact approach to clinical complexity lies at the heart of Sackett, Richardson, Rosenberg, and Haynes’

(1997) message: "Is my patient so different from those in the trial that its results cannot help me make my treatment decision?" It is always easy to find reasons why a patient is different from trial participants. This is one reason that the more family practitioners feel they know their patients, the less likely they are to apply external evidence to guide management (Summerskill & Pope, 2002). But are paternalistic assumptions in patients' best interests? (p. 13)

Prognostic Effects of Comorbid Clinical Disorders

It is commonly assumed by critics that the comorbid disorders that are allegedly the basis for exclusion from RCTs (e.g., personality disorders) are known to result in a worse treatment outcome (Westen et al., 2004). In reality, whether psychiatric comorbidity influences the clinical effectiveness of manual-based treatments is a function of the specific clinical disorder, the nature of the comorbidity, and the particular treatment in question. There are well-documented instances in which neither Axis I nor Axis II comorbidity has a discernible impact on outcome (e.g., Barlow et al., 1999; Wilson, 1998b). Therefore, RCTs do not necessarily inflate treatment outcome.

Consider the following illustration of this general point. Westen and his colleagues (2004) contended that RCTs evaluating CBT for BN have excluded potential patients with Axis II psychopathology such as borderline personality disorder. Leaving aside the data showing that this is an inaccurate assertion (see e.g., Agras, Walsh, Fairburn, Wilson, & Kraemer, 2000), what do we know of the prognostic significance of comorbid borderline personality disorder in patients with BN? Scholarly analyses of the evidence have shown that it is premature to conclude that co-occurring borderline personality disorder predicts a worse outcome (Grilo, 2002; NICE, 2004). Moreover, the natural course of BN is not influenced by personality disorders (Grilo et al., 2003). More controlled research is needed to determine the specific relationship between personality disorders and treatment outcome in BN and other eating disorders.

Generalizability of Findings of RCTs of Manual-Based Treatment Studies

As with any experiment, the issue arises about the generalizability of the findings of RCTs to conditions other than those of the particular study—the question of external validity. Concerns about the external validity of

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findings are hardly specific to research on psychological treatment. The issues involved in the generalizability from RCTs in medical research in general were the focus of a recent series of reviews in *The Lancet* (Rothwell, 2005).

The generalizability of the findings of efficacy studies to diverse clinical samples across different clinical settings must be evaluated directly in clinical effectiveness research. In the ultimate analysis, the applicability of the findings of RCTs to clinical practice depends on the design of the individual study, the patient sample, and the clinical setting to which the results are to be generalized (Chambless & Hollon, 1998; Kazdin & Wilson, 1978). The critical dimensions along which generalizability must be assessed are the patient characteristics, clinical setting, therapist training and expertise, and specific treatment methods.

In marked contrast to such a systematic scientific approach, the clinical literature is replete with warnings that the findings of efficacy studies (RCTs) either do not—or, more cautiously, may not—apply to real patients treated in real-world settings (e.g., Goldfried & Wolfe, 1996; Havik & VandenBos, 1996). One does not need to be a cognitive therapist to identify the all-or-nothing thinking implicit in this common refrain. Miklowitz and Clarkin (1999) made this point some years ago: “We run the danger of dichotomous thinking in which RCTs are viewed as irrelevant to community health care whereas studies done in mental health clinics, however poorly designed, take greater precedence” (p. 2). Imagine two patients being treated for BN. One is a high-functioning young woman, attending a prestigious Ivy League university, who was referred to a therapist in independent practice in upper middle-class suburbia. The other is a young Hispanic woman, from a single-mother home in the inner city, who responded to a public announcement of free treatment as part of a National Institute of Mental Health (NIMH)-funded study of BN at a major urban medical school. She could not otherwise have afforded treatment. Who is the real patient here? Who has the better prognosis? What is the real world here? This example highlights the failings of drawing a simplistic dichotomy between a research study and routine clinical practice. The reality is that we must address the needs of a wide range of different patients drawn from a diverse spectrum of real worlds.

Innovative research that explicitly investigates the degree to which different treatments generalize to conditions other than those of controlled efficacy studies is a priority. As summarized later in this chapter, much

progress has already been made with encouraging results. Assuming, implicitly or otherwise, that the findings of RCTs that evaluate manual-based treatments do not generalize to routine clinical setting is premature, if not wrong.

History, again, is instructive. The 1970s were marked by controversy over the value of analogue research in behavior therapy. The methodology was designed to identify the necessary and sufficient conditions of behavior change and to test hypotheses about mechanisms of change under tightly controlled laboratory conditions. The participants were often research volunteers with a single problem behavior, rather than treatment-seeking patients with multiple problems. As noted earlier, exposure was shown to be the critical element in systematic desensitization (Lang, 1969). Subsequent research established the clinical applicability and efficacy of exposure-based treatments to a variety of anxiety disorders in real patients in RCTs in clinical settings. Exposure is now widely accepted as an effective treatment for anxiety disorders (Barlow, 2002). Similarly, in the early 1970s, McFall and his students pioneered laboratory-based evaluation of assertion training. An innovative feature of the research was an evaluation of how well the intervention's effects generalized to a real-life setting (McFall & Twentyman, 1973). Assertion training has since been widely incorporated into clinical practice (Alberti & Emmons, 2001).

Randomized Controlled Trials. As several commentators pointed out, RCTs need not be restricted to studies of treatment efficacy—they can also be used for evaluating the generalizability of treatment effects (Chambless & Hollon, 1998; Jacobson & Christensen, 1996). For example, Fairburn (2004) described an ongoing RCT of the treatment of eating disorders that has no exclusion criteria. All patients seeking treatment at two community psychiatric centers offering specialty treatment for eating disorders are randomly assigned either to current manual-based CBT (Fairburn, Marcus, & Wilson, 1993) or an enhanced version of the same basic approach (Fairburn et al., 2003). Any clinical eating disorder merits inclusion; the sample is not limited to any specific *DSM-IV*-defined diagnosis (e.g., BN). A major advantage of this innovative study of unselected patients is that it includes individuals with EDNOS who comprise the majority of patients in routine clinical settings, but who have previously been excluded from efficacy research (Wilson, 2005). The patients in this study exemplify a clinically representative and relevant sample. The therapists, however, are specifically trained and

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supervised in the administration of the treatments. On the therapist and treatment dimensions, therefore, the study does not meet criteria for clinical representativeness (Shadish et al., 1997).

Quasi-Experimental and Nonexperimental Strategies.

Comprehensive analysis of the generalizability of treatment effects requires a range of methodological strategies ranging from RCTs to nonexperimental and uncontrolled studies of outcome across diverse patients and clinical service settings. Different methodologies can be ordered along a continuum ranging from efficacy studies, on the one hand, to an uncontrolled, fully clinically representative approach, on the other hand. A complete review of the growing literature on this subject is beyond the scope of this chapter. Suffice it here to provide some illustrative examples.

In a quasi-experimental design, Juster, Heimberg, and Engelberg (1995) compared three groups of patients seeking treatment for social phobia. The first group comprised those who were included in the RCT, the second group were those excluded primarily for medical or diagnostic reasons, and the third group were those individuals who declined random assignment to treatment. The innovative feature of this study was that Groups 2 and 3 were treated with the same CBT used in the RCT, and their response was compared with that of the patients formally included in the study. The results show that all three groups of patients demonstrated comparable improvement. This study in essence manipulated patient characteristics while holding constant the clinical setting, therapists, and specific treatment.

Perhaps the most flexible yet informative research strategy for evaluating generalizability is benchmarking, a strategy first described by McFall (1996). In a benchmarking study, treatments of established efficacy in RCTs are administered in clinical service settings with unselected patients. The outcome in the service setting is then compared with that from RCTs completed in research clinics. The prototype of this research strategy is the Wade, Treat, and Stuart (1998) study conducted at the Center for Behavioral Health (CBH) in Bloomington, Indiana.² In this study, the Barlow and Craske (1989) treatment manual for panic disorder, which has been shown to be effective in RCTs (Barlow, 2002), was

²The investigators were past (Wade) and then current (Treat, Stuart) doctoral students from Indiana University; the inspiration behind the research was that of faculty member and clinical scientist Dick McFall.

implemented by therapists of varying levels of experience and training at the CBH in the treatment of unselected patients with panic disorder. The therapists were trained by Wendy Wade, who had learned the treatment during a visit to Barlow's research clinic. The results reveal that the CBH therapists achieved a success rate comparable to that of CBT evaluated in RCTs. Impressively, these results were maintained at a 1-year follow-up (Stuart, Treat, & Wade, 2000). The basic finding of the Wade et al. (1998) benchmarking study—that manual-based CBT produces outcomes in clinical service settings comparable to those of RCTs—has been replicated several times by different investigators treating a range of clinical disorders. Examples include obsessive-compulsive disorder (OCD; Franklin, Abramowitz, Kozak, Levitt, & Foa, 2000), social phobia (Lincoln et al., 2003), PTSD (Gillespie, Duggy, Hackmann, & Clark, 2002), and depression (Merrill et al., 2003).

Shadish et al. (1997) developed a set of criteria to define the clinical representativeness of treatment outcome research. The most clinically representative end of the generalizability spectrum includes a nonuniversity setting—patients with heterogeneous problems, rather than one focal disorder, and who are clinically referred, and therapists who are professionals with regular caseloads. Treatment conditions are uncontrolled—that is, no use of a formal therapy manual, no specific training or supervision of therapists for the purposes of the study, and no treatment integrity checks. Benchmarking studies such as Franklin et al. (2000) and Wade et al. (1998) would fall closer to the controlled research end of the continuum given these criteria. Other studies of CBT, however, have met the most stringent Shadish et al. (1997) criteria for clinical relevance (e.g., Hirsch et al., 2000; Persons, Bostrom, & Bertagnolli, 1999; Westbrook & Kirk, 2005).

In the largest study of its kind, Westbrook and Kirk (in press) analyzed the outcome of 1,276 patients (ages 18–65 years) treated by the specialized CBT service within the National Health Service in the United Kingdom. The authors reported effect sizes (ES) and clinical significance statistics on two standardized measures. The ES for the Beck Depression Inventory (BDI), for example, was 1.15, with the proportion of patients meeting criteria for reliable clinical change comparable to the findings of the Persons et al. (1999) clinical sample and the Elkin et al. (1989) RCT. Westbrook and Kirk (2005) concluded that their findings “suggest that CBT in this context is an effective treatment, albeit with probably not quite such good results as it achieves in research trials.”

Clinically representative analyses of this sort are inevitably flawed methodologically in several respects, such as lack of controls, missing data, and uncontrolled pharmacological treatment. I agree with Westbrook and Kirk (2005), who argue that the clinical relevance of research findings are ultimately determined by a range of methodologies varying in internal and external validity.

Conclusion

Evidence-based treatments for several disorders have been shown to be effective across clinical service settings, unselected patients with or without concurrent pharmacotherapy, and therapists with varying levels of training. Critics often ignore the evidence just summarized here or try to discount the methodological adequacy of studies of generalizability (see the Weisz et al., 2005, commentary on this issue). Ironically, calls for the evaluation of psychotherapy as it is practiced in clinical service settings typically ignore existing research showing that customary treatment in the child and adolescent treatment literature, which is not supported by controlled clinical research, appears to be ineffective, with ESs averaging about zero (Weisz et al., 2005).

Some preliminary findings from this early stage of research on generalizability that warrant further investigation are the following. Patients in uncontrolled studies have experienced comparable effects to patients in RCTs despite receiving fewer sessions of treatment in service settings (e.g., Merrill et al., 2003; Roy-Byrne et al., 2005). Contrary to the claims of advocates of longer term psychotherapy (Seligman, 1995; Westen et al., 2004), more is not always better either in RCTs or uncontrolled clinical practice.

As in RCTs, psychiatric comorbidity appears to be a negative predictor of outcome in some instances (e.g., Merrill et al., 2003), but not others (e.g., Roy-Byrne et al., 2005). Future studies need to identify what focal problems are influenced by what psychiatric comorbidity. Ideally, this research might pinpoint moderators rather than simple predictors of outcome, thereby allowing more rational treatment planning.

Necessary and sufficient levels of therapist training and expertise remain unclear. We know that within RCTs, therapists effects are usually nonsignificant (Crits-Christoph & Mintz, 1991; Loeb et al., 2005; Wilson, 1998a). This is attributable to the selection in efficacy studies of competent therapists who are then carefully trained and closely supervised.

As a result, the therapists acquire the technical expertise and have the interpersonal skills to administer manual-based treatments in a clinically sophisticated manner. The same is probably true for benchmarking studies, in which clinic therapists received specific instruction in the use of a specific treatment. Therapists in routine clinical service settings do not have this training or monitoring, and therapist effects are more likely under these uncontrolled conditions (Crits-Christoph & Mintz, 1991).

The level of therapists' training has varied considerably in studies that have evaluated the effects of evidence-based CBT in clinical service settings. Some benchmarking studies have provided intensive training and continuing supervision of doctoral- and master's-level therapists (e.g., Merrill et al., 2003). In the Roy-Byrne et al. (2005) study of the treatment of panic disorder in a primary care setting, CBT was administered by "a CBT naive, midlevel behavioral health specialist" (p. 290). Gillespie et al. (2002) trained five clinicians from a range of professional backgrounds (including nursing and social work) who were working in routine clinical positions. Training mainly comprised a 2-day workshop in CBT for PTSD, followed by monthly videoconferencing case supervision by experts in CBT thereafter. The therapists in Westbrook and Kirk's (2005) uncontrolled study were professionals as well as trainees. Consistent with other research (e.g., Bickman, 1999), effectiveness studies have shown that degree of therapist experience was unrelated to outcome (e.g., Hahlweg, Fiegenbaum, Frank, Schroeder, & von Witzleben, 2001; Lincoln et al., 2003). Nevertheless, specific expertise in using an evidence-based treatment such as CBT makes a difference. Howard (1999) found that, among doctoral-level therapists with the same level of experience, those with training in CBT for anxiety disorders were more effective in treating patients with those problems.

In summary, mental health providers with relatively little experience and less than a doctoral degree can be trained to deliver effective treatment for some problems in routine care settings. Nevertheless, therapist expertise in the principles and practice of CBT in general, aside from mastery of a specific treatment manual, is vital in complex and treatment-resistant cases. It is also important in the implementation of comprehensive and flexible protocols, which necessarily require more therapist judgment than more highly standardized or limited manuals (Wilson, 1998a).

The recent treatment of adolescents with major depression (TADS) study has been described as a bridge between efficacy and effectiveness

research (Curry & Wells, 2005). Conducted across 13 different sites, it included patients who were representative of adolescents treated by clinicians in routine clinical practice. The short-term results show that antidepressant medication was significantly superior to pill placebo. Medication plus CBT was most effective overall in reducing depression and suicidal risk. But the effects of CBT were poor—no better than placebo—and less successful than in previous studies of adolescents (TADS Team, 2004). Hollon, Garber, and Shelton (2005) have attributed the relative ineffectiveness of CBT in this study to the type of CBT used and how it was implemented. Many of the therapists were inexperienced, with minimal training in CBT. Many of the on-site trainers/supervisors had less than optimal experience in treating adolescent depression with CBT. Hollon et al. (2005) argue that the investigators opted for a manual that “seemed overly comprehensive and far too structured” (p. 150). As a result, experienced therapists may have been constrained “from implementing CBT in an individualized fashion, resulting in an intervention that did not fully represent the best or even typical clinical practice” (p. 151). Moreover, “CBT therapists had so many things to do that they did not have enough time to do anything as well as they would have liked” (p. 150). Whether the Hollon et al. (2005) interpretation of the poor showing of CBT is valid is debatable; additional analyses of the TADS data might provide answers to the questions they raised.

What is important in the current context is the acknowledgment that the efficacy of complex manual-based CBT treatments, both in controlled RCTs and in studies of their generalizability, is contingent on therapist expertise. This point has been made repeatedly in the CBT literature (e.g., Franks & Wilson, 1973; Jacobson & Hollon, 1996; Wolpe & Lazarus, 1966). Undoubtedly the same holds true for other psychological therapies.

INDIVIDUALIZING TREATMENT: THE EVOLUTION OF MANUAL-BASED THERAPY

Manual-based CBT requires that the therapist individualize treatment in several different ways. These include formulating a treatment plan for the individual patient within the overall treatment model; actively engaging patients in treatment within the collaborative framework of CBT; ongoing session-to-session assessment based on self-monitoring that helps determine the timing and nature of treatment; identification of specific

dysfunctional beliefs and specific triggers for problem behaviors; use of multiple techniques, some of which may be better suited to particular patients than others; and addressing comorbid disorders when necessary (Wilson, 1996b). Specific therapist skills, including the ability to develop a good therapeutic alliance and balance a focus on treatment structure with flexibility, are essential (Wilson, 1998a). In effective manual-based treatments, a highly positive therapeutic alliance is strongly correlated with adherence to the treatment protocol (Addis et al., 1999; Loeb et al., 2005).

Despite the many accounts of manual-based treatment—not to mention the content of actual manuals—over the past several years, some misconceptions persist. For example, Weisz et al. (2005) point out that the Westen et al. (2004) critique portrays manuals as “rigidly structured documents that minimize the patient’s active involvement in the treatment process, prevent therapists from using clinical judgment, reduce the therapist to a ‘research assistant’ whose job is to ‘run subjects’ ... and are incompatible with an emphasis on broad principles of change” (p. 422). Even a cursory review of the relevant literature would reveal that this is a gross misrepresentation of competently conducted manual-based treatment. More simply, however, we have only to ask how manual-based CBT could possibly be effective—as has been conclusively shown in efficacy and effectiveness studies—if this sort of criticism were valid?

Although manual-based treatment thus far has hardly ignored individualization, nor been ineffective in treating patients with multiple problems, much more can be done in developing manual-based therapies that address the specific needs of individual patients. One problem has been that the application of manual-based treatment thus far has been determined, in large part, by categorical *DSM-IV* diagnoses. Heterogeneity exists across individuals within *DSM-IV* diagnostic categories. The mechanisms that maintain the specific disorder vary across individuals, and therefore the same treatment is not equally effective for all members of a diagnostic category. Matching interventions to *DSM-IV* diagnoses as the sole basis for treatment selection is fundamentally at odds with the functional analysis of the individual patient that has been a core conceptual and clinical feature of behavior therapy from its earliest days. We need to move beyond the atheoretical, heterogeneous categories of *DSM-IV* to more refined matches of specific treatments with particular problems in individual patients guided by detailed functional analyses of the variables that maintain the problem behaviors in question. There is

nothing inherent in manual-based treatments that links them to DSM diagnoses, and there is no reason that they cannot be flexibly used in treatment driven by the functional analysis of behavior. Indeed, this has been the case in more flexible and comprehensive manuals, and in part accounts for the success of these interventions.

The challenge in emphasizing a greater individualization of treatment is to balance this clinically appealing flexibility with the well-documented strengths of the structured focus of manual-based treatment. The problems of intuitive clinical judgment have been amply documented (Dawes, 1994). Empirically supported, manual-based treatments are prescriptive in the same sense that the NICE treatment guidelines are. But they do not ignore clinical judgment: "Guidelines are not a substitute for professional knowledge and clinical judgement...there will always be some people and situations for which clinical guideline recommendations are not readily applicable. The NICE guidance does not, therefore, override the individual responsibility of health-care professionals to make appropriate decisions" (NICE, 2004, p.10). What is distinctive about this approach to treatment is the balance between research and clinical judgment. As Wilson and Shafran (2005) argued:

Clinical judgment is decisive when evidence is lacking on what treatment to use. It is essential when an evidence-based treatment needs to be adapted to the niceties of an individual or when an alternative approach is needed. On the other hand, where sufficient evidence exists to allow general recommendation...the best practice must be to implement the treatment that enjoys the most empirical support rather than invoke subjective judgment. (p. 81)

Enhancing Manual-Based Treatment: The Example of Eating Disorders

Fairburn et al. (2003) developed an innovative and enhanced manual-based treatment for the full range of eating disorders. Ultimately, valid matching of specific treatments to particular patients hinges on an improved understanding of (a) the mechanisms that maintain the clinical disorder in question, and (b) the mechanisms whereby specific treatments work. Accordingly, Fairburn et al. (2003) broadened the cognitive-behavioral model of the mechanisms that maintain BN, from which the first generation of manual-based therapy was derived (Fairburn et al., 1993), and extended it to all eating disorders. The expanded model

has solid theoretical and empirical foundations. A major goal of the enhanced treatment is to identify specific patient profiles so that treatment can be tailored to them using specific modules that target the expanded range of maintaining mechanisms.

In their emphasis on a psychological analysis of presenting problems, Fairburn et al. (2003) state that, “diagnosis is not of relevance to treatment” (p. 522). Instead, they propose a transdiagnostic theory and treatment of all eating disorders. Their fundamental rationale is that all the eating disorders share common maintaining mechanisms. Furthermore, Fairburn et al. (2003) underscore the necessarily idiographic nature of personalized treatment formulations in implementing this new framework. The latter emphasis, of course, harks back to the functional analysis that has been a seminal part of behavior therapy. This refined transdiagnostic treatment approach for manual-based treatment also addresses another common criticism of manual-based treatment. It is often argued that clinical practice in the real world is self-correcting—if one method is unsuccessful, another is adopted (Seligman, 1995). In contrast, it is alleged that manual-based treatment proceeds in an unchanging, lock-step fashion. There is, however, little evidence to indicate that routine clinical practice is self-correcting. The meager data that exist suggest that therapists tend to stick with the treatment they started, regardless of outcome (Wilson, 1998a).

Fairburn et al. (2003) build a self-correcting feature into their treatment. Stage 1 involves eight sessions of core CBT treatment with a primary focus on behavioral change. The next few sessions focus on formally evaluating progress. In the case of problems, the focus is on identifying barriers to change and assessing the role of additional maintaining mechanisms, with a view to formulating a revised, personalized treatment plan. This taking stock of initial progress fits with the evidence that manual-based CBT is marked by an early response to treatment that is the most robust predictor of outcome at posttreatment and longer term follow-up (Agras, Crow, Halmi, Mitchell, Wilson, & Kraemer, 2000; Fairburn, Walsh, Agras, Wilson, & Stice, 2004). Absent sufficient improvement at this early stage, treatment needs to be modified or switched to another modality (e.g., antidepressant medication). Fairburn (2004) reported encouraging initial results from this enhanced CBT treatment. A preliminary investigation by Ghaderi (in press) also suggested the superiority of a broader, more individualized CBT approach over a more focused, standardized CBT treatment for BN.

This transdiagnostic approach could be applied to other groups of related clinical disorders. A related development is Barlow, Allen, and Choate's (2004) proposal for the unified treatment of a negative affect syndrome featuring the anxiety disorders and depression. The core treatment consists of three fundamental components: antecedent cognitive reappraisal, overcoming emotional avoidance, and modifying emotional action tendencies. These core components could be modified or enhanced through additional strategies to accommodate different patient profiles across this spectrum of psychopathology.

PRINCIPLE-DRIVEN INDIVIDUALIZATION OF TREATMENT

Alternative proposals for individualizing treatment, while remaining responsive to clinical science, have emphasized principle-driven approaches (e.g., Beutler, 2000; Salkovskis, 2002). There is much to recommend this strategy, which overlaps heavily with manual-based treatment. Theory-driven, empirically based principles have been the life blood of CBT (Bandura, 1969). These principles are vital to therapeutic innovation and development (e.g., Clark, 2004), and they guide the flexible and scientifically informed implementation of manual-based treatment. As Stirman et al. (2005) observe, because "some of the treatments studied in RCTs are modifications of the same modality for different diagnoses, clinicians may find that they can apply the principles of those treatments to more than one diagnosis. With training in the treatments tested in RCTs, clinicians will be able to conceptualize the interactions between co-occurring diagnoses and use the concepts of these therapies to treat their patients" (p. 133).

In arguing against manual-based treatment in general clinical practice, Beutler (2000) cautioned that therapists would have to learn too many different manuals, some of which may undermine "clinicians' general therapeutic skill" (p. 6). The latter need not be the case, as noted earlier, but the former is a legitimate practical concern. As an alternative, Beutler recommended that clinicians flexibly apply a "refined list of empirically supported principles of treatment" that allow the use of their "favorite procedures" (p. 8)—thereby integrating science with clinical judgment.

One limitation of relying only on principles is that it may miss the rich clinical content and context of treatment manuals. Moreover, in a

related fashion, it might also miss specific maintaining mechanisms of different clinical disorders. This would be a problem especially for the mental health provider with less training in the treatment or lacking specialization in the target disorder. For example, Beutler (2000) advocates using the principle of “exposure and extinction”—and for good reason. This core principle of numerous CBT treatment strategies enjoys impressive empirical support (Barlow, 2002); it cuts across varied treatment manuals for different disorders. One of these disorders is BN. Consider, then, the treatment of BN based on the principle of exposure.

A critically important component of manual-based CBT for BN is the early intervention to reduce dysfunctional dietary restraint and restore more normal patterns of healthy eating (Fairburn et al., 1993). Helping a BN patient who skips meals and avoids entire classes of “forbidden foods” to resume eating three meals a day plus planned snacks, on the one hand, and to systematically incorporate previously forbidden foods into her meals, on the other hand, is classic exposure therapy (Wilson, Fairburn, & Agras, 1997). This procedure reduces to overcoming fear and avoidance of potentially gaining weight. But the principle of exposure alone, however, would not instruct therapists in how to overcome dysfunctional dietary restraint in an efficient or optimal manner. Missing from the manual derived in part from the principle, for instance, would be advice on the sequencing of specific interventions—about targeting dietary restraint early in therapy, and about focusing first on establishing a regular pattern of eating before attempting to address forbidden foods. We know that manual-based CBT effects change early in treatment, and that this change mediates subsequent outcome (Kraemer et al., 2002). Numerous other examples could be cited illustrating how evidence-based treatment manuals put flesh on the theoretical skeleton of fundamental principles of behavioral change and, in so doing, can offer invaluable practical guidance to clinicians.

Another limitation of purely principle-driven treatment is its reliance on the clinical judgment of the therapist. Empirically supported, manual-based treatment is, in part, prescriptive, as are the evidence-based NICE guidelines. Beutler (2000), among others, overlooks the evidence that therapists given free reign to select their preferred techniques will not necessarily choose the most effective methods. The best illustration of this problem, and one that makes the case for selective prescription, is Schulte, Kunzel, Pepping, and Schulte-Bahrenberg’s (1992) study of behavior therapists treating phobic disorders. To summarize, therapists who used

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standardized in vivo exposure achieved significantly superior results compared with those who were free to select whatever techniques they wished. The difference was attributable to therapists in the latter condition neglecting to use exposure treatment. As I noted previously, this finding that therapists rejected the empirically validated therapy in favor of their own personal predilections underscores the problems with personalistic case formulations. If behavior therapists can persuade themselves to ignore exposure treatment for specific phobia in favor of other methods based on their clinical judgment, there would seem to be no end to the possibilities with more heterogeneous disorders and other less empirically based theoretical approaches. It should come as little surprise, therefore, that in clinical practice empirically validated methods are routinely ignored in favor of intuition and personal experience (Wilson, 1996b).

Finally, the appeal to principle-driven treatment implicitly assumes that therapists will be doctoral-level clinical psychologists who combine clinical skill with knowledge of relevant scientific research. The reality is that psychological therapy increasingly is being provided by master's-level counselors from a wide range of disciplines with less than optimal backgrounds in the scientific foundations and principles of behavior change. These mental health providers, in particular, can benefit from the more specific guidance provided by evidence-based treatment manuals.

CONCLUDING COMMENTS

The fundamentally important questions in analyzing the outcome of psychological therapy are still what treatments work, for whom, and why. Research on manual-based treatments has begun to provide answers to these questions and will continue to play an important role in advancing future knowledge. Manual-based treatments specify therapeutic procedures and identify mechanisms that maintain the target disorder. By enhancing accountability, manuals have already spurred the development of new treatment methods and raised intriguing theoretical questions about mechanisms of action. Manual-based treatments provide a critical means of increasing dissemination of effective psychological therapies and facilitate broadening the range of mental health providers who can provide effective treatment.

Our best treatments currently are good but not good enough. The challenge is to make them more effective and for a broader range of clinical disorders. There is no more important goal than understanding the

mechanisms of change of effective treatments. Without the operational specification of treatment manuals, we will have trouble isolating the necessary and sufficient conditions of effective treatments—a precursor to unraveling mechanisms of action.

Of course manual-based therapies can be implemented badly. But any therapy—manualized or other—can be implemented poorly. Obviously, therapy can be effective without following a manual. Nonetheless, manuals are an important means within a science-based approach of improving efficacy and understanding how treatments work.

We need better and bolder visions of the future, rather than advocacy of the status quo in the training of clinical psychologists. Westen et al. (2004), for example, proposed a model of empirically informed treatments as an alternative to empirically supported, manual-based treatments tested in RCTs. As Crits-Christoph et al. (2005) pointed out, this proposal is more likely to prevent than promote the adoption of evidence-based practice:

While such a model might seem entirely reasonable, it begs the question. What evidence will inform whom, and how will it be evaluated? Actually, such a model already exists in the clinical psychology accreditation criteria of the American Psychological Association. To be accredited, doctoral programs in clinical psychology are required to expose students to the scientific underpinnings of psychology, but it is left to individual programs to adopt any philosophy of clinical training they wish provided they articulate it in a coherent manner. We can do better. Groups such as the Academy of Psychological Clinical Science have proposed a different view of a connection between science and practice from that of Westen et al. (2004) that emphasizes the importance of training in and dissemination of evidence-based treatment. (p. 415)

Dick McFall was the guiding force behind the establishment of the Academy of Psychological Clinical Science, as this volume makes clear.

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