The Case Formulation Approach to Psychotherapy Research Revisited

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ABSTRACT

This article revisits the case formulation approach to psychotherapy outcome research, first proposed by Persons (1991). Persons asserted that randomized clinical trials (RCTs) of psychotherapy do not test the theoretical underpinnings of psychotherapy models since these trials standardize rather than individualize patient problems, ignore the link between individualized assessment and treatment as described in these models, and employ standardized rather than individualized treatment. This article assesses the current status of these claims, concluding that they remain valid today. A reformulated case formulation approach is described and research strategies proposed. Investigating the reformulated case formulation approach will require increased resources for case formulation training, the addition of treatment arms in effectiveness trials that include case-formulation-based interventions, and expanded RCTs that include systematic case studies.

Key words: case formulation; randomized clinical trials (RCTs); psychotherapy research; treatment utility; clinical decision-making; case studies; clinical case studies

CASE FORMULATION IN RANDOMIZED CLINICAL TRIALS

More than 20 years ago, Persons (1991) identified a conceptual incompatibility between the design of psychotherapy outcome studies and the models of psychotherapy evaluated in those studies. She asserted that psychotherapy outcome studies do not actually study the models of psychotherapy as described in the literature. Instead, the design and methodological considerations typically employed distort the models to an extent that their theoretical underpinnings go largely unexamined. As an alternative, Persons proposed a "case formulation approach" to psychotherapy outcome research. The approach promised high fidelity with the theory underlying each model of psychotherapy being examined. Assessment and treatment planning components would be tightly linked, individualized, theory-driven, and all conducted by the therapist. The approach retained critical components of traditional outcome studies such as random assignment of patients to conditions and clear distinctions between levels of the independent variables, although changes were proposed in assessment and outcome methods and measures. Beyond closing the gap between the theoretical underpinnings of a psychotherapy model and the study of that model, Persons predicted that her approach could narrow the
scientist-practitioner gap and lead to a better examination of the differential efficacy of treatments. She further predicted that "all else being equal, outcome ought to be better for a patient treated with an accurate formulation than for a patient treated with an inaccurate formulation" (p. 103), a prediction she called the "case formulation hypothesis."

Persons's article drew critical attention (Garfield, 1991; Herbert & Mueser, 1991; Messer, 1991; Schacht, 1991; Silverman, 1991), but little has subsequently changed in how psychotherapy outcome research is conducted. Only a handful of studies have actually implemented the suggestions offered by Persons (e.g., Emmelkamp, Bouman, & Blaauw, 1994; Ghaderi, 2006; Persons, Bostrom, & Bertagnolli, 1995; Persons, Roberts, Zalecki, & Brechwald, 2006). The randomized clinical trial is still the predominant methodology in psychotherapy outcome research. The scientist-practitioner gap persists (Goldfried, 2010) and meta-analyses by and large fail to show differential efficacy of treatments intended to be therapeutic (Miller, Wampold, & Varhely, 2008; Wampold, 2001b, 2007).

The current article re-examines the case formulation approach from the vantage point of 20 years' hindsight. It considers whether the absence of a more vigorous consideration of Persons's recommendations represents a missed opportunity for psychotherapy researchers and, after responding in the affirmative, what can be done at this point. It asserts that her arguments are as relevant today as when they were originally made. At the same time, much has changed in the field of psychotherapy research in the last 20 years. Therefore, a revision of the case formulation approach and the related case formulation hypothesis is proposed, supporting evidence evaluated, and alternative research strategies are discussed.

**Persons's Critique**

Persons's (1991) criticism of randomized clinical trials is best described in her own words: "Despite the fact that nearly all models of psychotherapy describe treatment approaches in which the therapist's role is to devise and carry out an individual treatment based on the results of an individualized assessment, controlled outcome studies evaluate psychotherapies in which both assessment and treatment are standardized and in which assessment and treatment are rigidly separated. As a result, outcome studies do not study psychotherapy as it is described in the literature" (p. 99).

Persons (1991) gave multiple examples of models of therapy that include an explicit step in which the therapist's task is to conduct an individualized assessment and then develop and implement an individual treatment plan based on the theory of the therapy being proposed. These include brief psychodynamic treatments (Horowitz et al., 1984; Luborsky, 1984; Strupp & Binder, 1984; Weiss & Sampson, 1986), cognitive treatments (A. T. Beck, Rush, Shaw, & Emery, 1979) and behavioral approaches (Turkat, 1985; Wolpe & Turkat, 1985). For example, Luborsky's psychodynamic therapy involves formulating an individual's core relationship conflict and developing interventions to address it. Beck's cognitive theory presumes the presence of idiosyncratic maladaptive cognitive vulnerabilities that are associated with symptoms of depression, anxiety, and other psychological disorders. The therapy involves identifying these cognitive patterns and using a variety of interventions to ameliorate them. Additionally, Persons noted, behavior therapists have long advocated for individualized
assessment of the stimuli and reinforcers that elicit and shape problematic behavior.

The therapy model underlying the design of standard randomized clinical trials (RCTs), which Persons critiqued, is depicted in Figure 1. Step 1, "Gather Information," involves collecting standard, objective measures, usually administered by a person other than the therapist. This process does not ordinarily result in an idiographic case conceptualization that identifies the individual's specific problems, coping strategies, resources, and limitations. Nor does it offer a specific explanation of the set of problems based on the information obtained. Further, it does not yield an individualized treatment plan testing the explanatory hypothesis and addressing the specific constellation of problems selected for focus. Step 2, "Diagnose," emphasizes obtaining a reliable diagnosis to ensure that those accepted into the study meet specific inclusion criteria and do not meet other predefined diagnostic exclusion criteria. This is a critical step in that it contributes to a basis for generalization of results. Next, in Step 3, a standardized and manualized treatment is delivered, often with specific tasks and sequences prescribed for each session. Considerable effort is made to minimize the variability of treatment delivery within each experimental condition. The role of the therapist is to deliver the intended treatment in a reliable and efficient manner that adheres to the requirements of the manual. Although Persons acknowledged that standardized protocols allow for some individualization, she argued that the therapist's ability to individualize is hampered by the absence of an individualized assessment and a tailored treatment plan. Furthermore, she argued that standardized protocols do not address "the most demanding task of any therapist" (p. 101) which is to "choose a problem and an attack on that problem that will be helpful to that particular patient for that particular problem at that particular moment" (p. 101). In contrast, descriptions of psychotherapy models include a focus directly on this critical task. In Step 4, treatment is terminated, usually after a predetermined number of sessions and with no option to follow up with the treating therapist, although other follow-up options would ordinarily be offered.

**Persons's Remedy**

Persons (1991) proposed a solution to the incompatibility problem just summarized, calling her remedy "the case formulation approach to psychotherapy research" (p. 102). She proposed idiographic outcome studies using a case formulation model of assessment and treatment. As described earlier, these designs would be characterized by a tight linkage between assessment and treatment. The investigator would begin by randomly assigning patients to treatment conditions. In each condition, the therapist would conduct an individualized assessment and develop an individualized treatment plan using methods described in an "assessment-plus-treatment protocol" (p. 102) that would be developed for that treatment condition and based directly on the model of therapy being tested. Central to the design is that "the therapist uses the information obtained by the assessment procedures to develop a working hypothesis about the nature of the mechanisms underlying the patient's symptoms and problems; this working hypothesis is the case formulation" (p. 102). The proposed mechanisms are determined by the theory that underlies the psychotherapy model being tested. The formulation provides a basis for an individualized treatment plan that is then delivered.

Because outcome assessment is individualized, theory-specific, and idiographic, each patient would have a different set of problems assessed with a different set of measures, creating
a challenge in outcome assessment. To facilitate comparisons, Persons proposed three possible solutions. One is to convert all pre- to post-change scores to proportions and assess mean differences in proportion change for each problem. A second is to measure clinical significance by assessing the proportion of patients who achieve a non-deviant range on all problems, or mean improvement in measures of daily functioning. Third, nomothetic approaches could be used, similar to how they are used in standard RCTs. For example, one could select patients with similar problems, such as depression, substance abuse, or marital conflict, and use standard measures to assess these conditions. Note that psychiatric diagnosis is de-emphasized in favor of systematic problem identification and measurement. See below for the problems inherent in using diagnoses only.

An additional challenge that Persons described is the accuracy of the clinician's formulation, which she asserted must be evaluated before formulation-guided therapy may be judged as adequate. She took two approaches to overcoming this challenge. One is to subject formulations to measures of reliability and validity. The other is to judge the adequacy of the formulation through its contribution to outcome.

Response of Others

Commentaries on Persons's article fell into two general categories: Those who were sympathetic to her argument and found her approach promising, but who raised additional conceptual and methodological issues (Messer, 1991; Schacht, 1991); and those who were not persuaded (Garfield, 1991; Herbert & Mueser, 1991; Silverman, 1991).

Major points made by those in the former category are summarized below.

1) Some types of formulations do not translate well into empirically testable hypotheses or prescriptions for treatment since they are hermeneutic in nature and are validated through a process of logical and metaphoric coherence rather than empirical demonstration (Schacht, 1991). An example would be the formulation that a patient's dream about driving his car down a street that begins to flood symbolizes fear of being overwhelmed by affect.

2) Formulations can vary in scope from case-based to episode-based or even moment-based, and Persons did not address this issue (Schacht, 1991).

3) A confound may be introduced between the formulation itself and the effects of the therapist as a user and joint creator of the formulation in collaboration with the patient. Formulations, in part, are the product of the perception and thinking of a specific therapist in a unique dyadic relationship and may not easily be adopted by other therapists, regardless of their accuracy, thus limiting their contribution to outcome when adopted by other therapists (Schacht, 1991).

4) Formulations may evolve during the course of therapy and for this reason require outcome measures that had not been anticipated initially (Schacht, 1991).

Those in the second group criticized Person's critique of outcome research as "overdrawn" (Garfield, 1991), "exaggerated and flawed by overgeneralizations" (Silverman, 1991), inaccurate (Silverman, 1991), "nothing so new" (Silverman, 1991, p. 1351), and creating a false dichotomy of the differences between standardized and individualized treatments (Herbert & Mueser, 1991). The criticisms can be summarized as enumerated below.

1) Meaningful generalizations in terms of theory or approach are unobtainable when every treated case is unique or different (Garfield, 1991).

2) Diagnosis and standardized, objective broad- and narrow-based eligibility and outcome assessments represent improvements in outcome research since they aid in the understanding and generalization of findings, and they should not be abandoned (Garfield, 1991; Herbert & Mueser, 1991; Silverman, 1991).

3) A theory-driven assessment and treatment approach is impractical since there are several hundred different psychotherapy theories (Garfield, 1991).

4) Many assessment tools are not atheoretical but rather are derived from theory (Silverman, 1991).

5) Treatment in standard outcome research may be devised for specific diagnoses, but they are also based on theory about specific psychological mechanisms operating in individuals with those diagnoses (Silverman, 1991).

6) While assessment and treatment are conducted separately in standard outcome research, results from the assessment are shared with the therapist who "[in my outcome study] on the basis of the assessment . . . acquires a thorough understanding of the problem and uses this information both to help implement the treatments as efficaciously as possible and to help avoid patterns of resistance or noncompliance . . ." (Silverman, 1991, p. 1352).

7) The case formulation approach is similar to other approaches that are widely considered to be acceptable methods of scientific inquiry (e.g., Barlow & Hersen, 1984; Hayes, Nelson, & Jarrett, 1987; Turkat, 1985), and thus is "nothing so new" (Silverman, 1991, p. 1351).

8) Standard and individualized treatments are not as categorically distinct as Person suggests, and a review suggests that treatments are better classified on a continuum from standardized to individualized than as a dichotomy of the two (Herbert & Mueser, 1991).

As best I can determine, Persons did not publish a rebuttal to these points. However, she did recently revise her case formulation approach to cognitive-behavioral therapy in a way that is responsive to some of the critiques (Persons, 2008). For example, she included standardized, reliable, and normed symptom measures and tools for diagnostic and outcome assessment. She also included diagnosis as one explicit component of formulation and incorporated progress monitoring using brief quantitative tools. In addition, she recommended using the implicit
formulation embedded in an empirically supported treatment as the default formulation and recommended modifying it only as warranted by the problem list and the results of the diagnostic assessment. Finally, she recommended using an empirically supported treatment (EST) as a first intervention when it fits the formulation and moving to components of ESTs if a complete treatment is not indicated. If neither of these approaches fits the set of problems and range of diagnoses, she recommended developing an individualized explanatory hypothesis drawing from well-researched behavioral, cognitive, and emotional theories. Notwithstanding these developments, the approach remains highly individualized.

Looking at the above critiques and at Persons's most recent work with a goal of further developing a case formulation approach to psychotherapy research, several conclusions can be drawn. First, it is important to define the term "formulation" in an explicit and well-circumscribed way, focusing on its utility in an empirical hypothesis-testing context. This is not to say that other definitions of case formulation, as suggested by Schacht (1991), are not valid. They are, but they also create many complexities in outcome research that current RCT approaches do not address either. Second, constructing, applying, and revising a formulation should be viewed not as an outcome variable but as part of the therapy process to be investigated. Assessment of the formulation's contribution to outcome, apart from other process variables, could become a focus of research. Third, the reliability and validity of a formulation may be less important than its utility in contributing to outcome. Any of several formulations of a case could conceivably lead to similarly positive outcomes. Given the general finding that bona fide treatments are equally efficacious (Wampold, 2001b, 2007), such an outcome may not be surprising. Fourth, the case formulation approach should maximize the use of standard outcome measures in order to facilitate the generalization of results. Psychometrically sound assessment instruments might also strengthen a case formulation as it is being developed. Fifth, it should be recognized more widely that the basic ideas supporting the case formulation approach have a long tradition among cognitive-behaviorally oriented psychotherapy outcome researchers. One might expand to other theories of therapy what has been learned from the cognitive-behavioral tradition. Sixth, explicit incorporation of diagnosis into the case formulation approach may increase the value of a formulation and facilitate generalization of findings. Seventh, recognizing that evidence-based treatments lie on a continuum from highly standardized to individualized, and do not represent a dichotomy, could help increase appreciation of what both perspectives offer to research and treatment. As will be discussed later, empirical explorations have found that much individuation takes place in ostensibly manualized treatment. With this review of the case formulation approach concluded, we now move to a reformulation of the approach.

REFORMULATION OF THE CASE FORMULATION APPROACH

In this section I propose a reformulation of the case formulation approach and the case formulation hypothesis that flows from it. After reviewing why reconsideration is warranted, I will discuss the distinguishing characteristics of the reformulated approach.

Reconsideration of the case formulation approach is warranted by at least four developments in psychotherapy outcome research since the early 1990s. The first is increased accountability on the part of professional organizations, private and public third-party payers,
and the public for psychotherapy outcomes. As therapists are held more accountable, they face
greater scrutiny and more pressure to justify their treatment approaches and recommendations.
The case formulation approach to psychotherapy research is well suited to this task. A second
related development is the commissioning of task forces within the American Psychological
Association on empirically valid (now “supported”) treatments (Task Force on Promotion and
Dissemination of Psychological Procedures, 1995), evidence-based therapy relationships
(Norcross, 2002, 2011), and evidence-based practice (American Psychological Association,
2005). These efforts reflect a sense of urgency among psychologists to achieve and disseminate
effective, measurable, and efficient psychotherapy outcomes. These goals are highly compatible
with a case formulation approach to psychotherapy. They also reflect a response to “culture
wars” (Norcross & Lambert, 2011) that have erupted between those who believe that
psychotherapy outcomes are determined primarily by treatment techniques and those who
believe relationships are primarily responsible. A reformulated case formulation approach to
psychotherapy research could address this gap.

A third development is a renewed appreciation of the contribution of the patient (Bohart
& Tallman, 1999, 2010) and the therapist (Kim, Wampold, & Bolt, 2006; Wampold, 2001a;
Wampold & Brown, 2005) to outcome. The case formulation approach puts the patient, the
therapist, and the patient-therapist dyad at the center of the research. In contrast, RCTs focus
almost exclusively on techniques. A fourth development is a continued challenge from some
psychotherapy researchers who question the “gold standard” status of the RCT to the exclusion
of other methodologies (e.g., Beutler, 2009; Westen, Novotny, & Thompson-Brenner, 2004).
The identification of problems with the RCT design has led many to search for additional and
complementary research methods.

A final reason to reconsider the case formulation approach to psychotherapy research is a
development that has not occurred. Just as in the early 1990s and before, authors of diverse
psychotherapy models have continued to describe case formulation as an essential guiding
principle in the practice of their model. Many contemporary examples could be given, and the
following are a sample:

- From the cognitive therapy standpoint: “A cognitive conceptualization provides the
framework for the therapist's understanding of the patient . . . The therapist begins to
construct a cognitive conceptualization during his first contact with a patient and continues to
refine his conceptualization until their last session” (J. S. Beck, 1995, p. 13-14).

- From the cognitive-behavior therapy standpoint: "When we are in CBT sessions and are doing
our best work, we sense that the case conceptualization is directly guiding each question, each
nonverbal response, each intervention, and the myriad adjustments we make in therapy style to
enhance communication with the patient" (Wright, Basco, & Thase, 2006, p. 18-19).

- Also from the cognitive-therapy standpoint: "A crucible is a strong container for synthesizing
different substances so that they are changed into something new . . . The case conceptualization
process is like that insofar as it synthesizes a client's presenting issues and experiences with CBT
theory and research to form a new understanding that is original and unique to the client"
In regard to dialectical behavior therapy (DBT): "Case formulation is essential to efficient, effective DBT" (Koerner, 2007, p. 317).

Markowitz and Swartz (1997, p. 221) write that the interpersonal psychotherapy (IPT) case formulation "encapsulates both the guiding principles of IPT and the individual's particular issues (i.e., those that distinguish this patient from others with similar interpersonal issues or diagnosis). That the case formulation leads logically into the treatment plan is a sine qua non of IPT. Indeed, case formulation drives the treatment and becomes the focus of IPT."

From the brief dynamic psychotherapy perspective: "The ultimate goal of a diagnostic inquiry is the construction of a case formulation that can effectively guide therapeutic interventions. The essence of a dynamic-interpersonal formulation is an interpersonal story line or subplot that represents an important and distressing issue at this point in the evolving narrative of the patient's life" (Binder, 2004, p. 72).

As can be seen from these quotations, exponents of multiple psychotherapy models continue to emphasize the importance of case formulation; yet, RCTs ordinarily do not include a case formulation step. Having reviewed these reasons to reformulate the case formulation approach, we now move to a discussion of similarities between the reformulated approach and the 1991 version, and then a discussion of six distinguishing characteristics.

The reformulated approach retains key features that Persons (1991) initially proposed. These include individualization of treatment based on the development and assessment of a comprehensive problem list; a hypothesis that explains the factors causing, precipitating, and maintaining the problems that become the focus of therapy; and a treatment plan that flows from the preceding individualized steps. The revised approach thus retains the feature that assessment and treatment are tightly linked. In addition, it incorporates developments later described by Persons (2008), as discussed in the previous section.

I propose seven distinguishing characteristics of the reformulated case formulation approach to psychotherapy research. To be investigated, the approach requires that models of psychotherapy adhere to and be delivered within an explicit evidence-based, case-formulation-guided framework. One example of such a framework is shown in Figure 2, which is adapted from Persons (2008), Fishman (2002, 2005) and Peterson (1991), and represents a general model of evidence-based, case-formulation-guided psychotherapy. This framework accommodates multiple models of psychotherapy since the components are generic to all or most models. It also facilitates comparisons among formulations and the interventions that flow from them since information about each component and subcomponent is part of all formulations. In addition, the framework provides a guide to developing the formulation and ensures that specific categories of information considered essential to any formulation are addressed. Figure 2 is usefully contrasted with Figure 1. As can be seen, it adds a "formulate" component, which consists of four sequential subcomponents: create problem list, diagnose, develop explanatory hypothesis, and plan treatment. Each subcomponent will be described briefly below.
“Create Problem List” is the first subcomponent; multiple approaches have been proposed (e.g., Horowitz, 1997; Nezu, Nezu, & Lombardo, 2004; Persons, 2008). Each shares the goal of describing the full range of problems the patient has, including those the patient may not initially recognize as important. The entire problem list is ordinarily not addressed in therapy, but rather serves as the source for areas that selected for focus.

The “diagnose” subcomponent of the formulation is a second distinguishing characteristic of the reformulated case formulation approach. It is important for reasons beyond the practical requirements of billing and communication among providers. A reliable diagnosis contributes to later steps in the formulation. It can help the therapist develop evidence-based hypotheses to explain the problems that are selected for focus. Psychopathology researchers tend to organize their research by investigating specific diagnostic conditions. Similarly, RCT-based psychotherapy research is organized around specific diagnoses. Thus, empirically supported treatment interventions for specific diagnostic conditions can guide treatment planning in the case formulation approach. Despite the usefulness of diagnosis, it is important to remember, as Sturmey (2008) observed, that diagnosis alone is an insufficient guide to treatment since multiple treatments for the same diagnosis are efficacious and since the syncretic nature of the DSM-IV-TR diagnostic system allows for a wide variety of symptom combinations to meet criteria for a diagnosis. Different symptom configurations may warrant different treatment plans.

The third subcomponent of the formulation component in Figure 2, “develop explanatory hypothesis,” is the core of the formulation. It is the therapist’s best account of what is causing, maintaining and precipitating the problems selected for focus. This account may or may not be manipulated in psychotherapy research, depending on the questions investigated. As seen in Figure 2, the model shows two basic sources of information – theory and evidence – and four standard components of this step. Theory refers to any empirically supported theory that helps explain the problems. It can include basic research about behavioral, cognitive, and emotional processes results from RCTs, and findings from psychopathology research. Evidence refers to other sources of reliable information that can help account for the problems. These may include epidemiology studies, results from psychometric testing, and narrative or other autobiographical information provided by the patient. In a research context, one can explore specific explanatory hypotheses by observing responses to interventions based upon them. As shown in Figure 2, the general model requires that each explanatory hypothesis include an account of the precipitants, origins, resources (or strengths) and potential obstacles to treatment success. Including these standard elements in all formulations makes the researcher’s thoughts about them explicit.

The final subcomponent of the “formulate” step of Figure 2, “plan treatment” is an explicit statement of how the selected problems will be addressed by testing the hypothesized explanation. It may also include an explicit statement of both short-term and long-term goals, as well as process and ultimate goals, and the steps to be followed to achieve them. For research purposes, treatment plans and their components can be varied systematically, as is done in RCTs.

A third distinctive characteristic of the reformulated case formulation approach is that it includes a “monitor, test, and assess” component, as shown in the feedback loops of Figure 2. Monitoring can take the form of session-by-session progress reviews, accomplished with reliable and valid quantitative measures that can serve as dependent variables. Progress monitoring
provides frequent feedback and has been demonstrated to improve positive outcomes and reduce poor outcomes in routine clinical care (Lambert, 2007). It has the added therapeutic benefit of strengthening the patient-therapist alliance and helping address non-adherence to treatment (Persons, 2008). Testing and assessing refers to the therapist’s consideration of the impact planned interventions have on the patient’s problems. Opportunity exists to modify the formulation if an intervention does not have the hoped-for result. This monitoring, testing, and assessing feedback component represents an approach to process research, either at the case study level or by group. A researcher can assess the impact that specific interventions have over specific lengths of time.

A fourth distinctive feature of the reformulated case formulation approach, as already implied, is that it primarily employs standardized assessment tools, rather than idiographic measures, to determine patient status at the beginning of treatment, at termination, and at later follow-up. As critics of the original case formulation approach asserted, standard assessment tools offer many advantages over idiographic measures. Idiographic measures that focus on specific problems may be included as well.

A fifth distinguishing characteristic is an emphasis on competence in formulating cases. Since the formulation is viewed primarily as a process measure, issues related to reliability and validity of the formulation are less important than in the original description of the case formulation approach. Since the treatment is fundamentally guided and shaped by the formulation, however, and since elements of the formulation may serve as independent variables in an investigation, it is critical that formulation competence be assessed. Following earlier work (Eells, Lombart, Kendjelic, Turner, & Lucas, 2005), I propose seven criteria to evaluate the quality of a case formulation. A competently formulated case should (1) be adequately comprehensive by addressing multiple categories of information about a patient's functioning (e.g., global functioning, predisposing experiences, precipitants and consequences of symptomatic behavior, quality of interpersonal relationships, schemas of self and other, defensive and coping style, strengths, cultural influences); (2) these categories should be sufficiently elaborated; (3) the formulation should use language that is precise in describing a unique individual, not a stereotype; (4) the formulation should be appropriately complex in addressing multiple facets of a person's problems without being unnecessarily complex; (5) a formulation should be coherent by providing an internally consistent account of the individual's problems, why he or she has them, and what is to be done to address them; (6) the formulation should offer an explanatory hypothesis that is tightly linked to empirically supported theory or other sources of reliable evidence; and (7) the formulation should offer a treatment plan that credibly addresses the problems, provides a guide to action, and employs techniques with empirically demonstrated effectiveness. The treatment plan should flow logically from the explanatory hypothesis and should predict outcomes that are measurable. As can be seen, a competently developed, high quality formulation should go well beyond a summary of information about a patient (Eells, Kendjelic, & Lucas, 1998).

A sixth distinguishing characteristic of the reformulated case formulation approach is its greater focus on outcome in effectiveness and dissemination studies, although it is also applicable to process-related studies. Efficacy studies, in contrast to effectiveness and dissemination studies, emphasize minimizing threats to internal validity in order to establish a
causal link between the treatment and the outcome under highly controlled conditions. Once a causal link is established, the next task is to test the effectiveness of the treatment or treatment elements when they are generalized to other individuals, settings and outcomes. This task may include generalization from the experimental group to a single person, from those with a single diagnosis to those with co-morbid disorders, from patients with few problems to those with many, from the lab to a counseling center or a private practice, and from therapists receiving frequent feedback on adherence to those not held to strict adherence standards. Here, threats to external validity take precedence over those to internal validity (Nezu & Nezu, 2008). Once effectiveness in the “real world” is established, attention turns to disseminating or implementing the treatment, which involves a specified set of activities designed to put into practice an activity or program (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005; McHugh & Barlow, 2010).

While the RCT is well suited to the goals of an efficacy study, the case formulation approach is well suited to the tasks of effectiveness and dissemination research. This is because it fits closely with clinical training and practice of psychotherapy in which the therapist conducts the assessment, develops a treatment plan and then delivers a tailored treatment. Therapists have resisted and strongly criticized efforts to have them adopt manualized therapy (Carroll & Rounsaville, 2008). They complain that manuals are limited in their applicability to the broad range of populations and problems encountered in clinical practice, place excessive emphasis on technique and neglect the therapeutic alliance and other common factors, restrict clinical innovation and therapist expertise, are not feasible, and overemphasize adherence at the cost of competence (Carroll & Rounsaville, 2008). The case formulation approach may receive greater acceptance from clinicians since it is responsive to each of these complaints. At the same time, the case formulation approach is highly evidence-based as described earlier, and thus may serve as a vehicle to engage therapists in applying evidence-based practice more widely. For evidence-based clinical practice to be widely adopted, the readiness and willingness of clinicians to learn and implement it is critical (Fixsen et al., 2005). The case formulation approach to research may thus be a helpful tool in resolving the aforementioned “culture wars” between those who want clinicians to adopt manualized therapies that stress implementation of techniques and those who believe that client factors, the therapeutic alliance and therapist expertise explain much of outcome in psychotherapy (Norcross, 2011).

A final distinguishing characteristic of the reformulated case formulation approach to psychotherapy research pertains to the case formulation originally proposed by Persons. It emphasized comparing therapies based on reliable and valid case formulations and those without established reliability and validity. Based on the emphasis of the revised approach on effectiveness and dissemination research, and in light of the controversy between those advocating manualized versus individualized therapy, I propose the following hypothesis as one focus of research based on the reformulated case formulation approach to psychotherapy research: Evidence-based, case formulation-guided psychotherapy ought to equal or exceed outcomes generated by empirically supported, manualized therapies, all else being equal. The implication of the hypothesis is that, if supported and equivalence of outcome is demonstrated, policy makers would be justified on empirical grounds in disseminating either a manualized treatment or evidence-based case formulation guided therapy. Any case for choosing one approach over the other would rely on issues such as patient preferences, therapist acceptance, ease of treatment delivery, cost, and efficiency. Of note is that the American Psychological
Association’s (2005) definition of evidence based practice in psychology emphasizes taking into account client preferences when selecting treatment options and interventions. With this in mind, we now undertake a review of research exploring the case formulation approach and the hypothesis just proposed.

**Support for the Revised Case Formulation Hypothesis**

The purpose of this review is to summarize research that has been conducted from the standpoint of the case formulation approach, to illustrate designs that have been used, and to describe their strengths and weaknesses. It is not an exhaustive survey of all studies investigating the case formulation approach. First, one must note that there are relatively few studies comparing case-formulation guided psychotherapy to manual-based therapy. Most compare behavioral or cognitive-behavioral therapies and generally show either equivalence or give a slight preference to one or the other (Ghaderi, 2011; Wilson, 1996).

One way to test the case formulation hypothesis is to treat a group of patients using an evidence-based case-formulation-guided approach and compare outcomes with those of similar patients treated in randomized clinical trials. Equivalence of outcome would support the case formulation hypothesis. For example, Persons, Roberts, Zalecki, and Brechwald (2006) compared outcomes of 58 adult patients with depression and/or anxiety who received individual, formulation-guided cognitive therapy in a private-practice setting with those of comparable patients treated in several RCTs. The private practice patients met criteria for non-psychotic mood disorders and/or anxiety disorders, and most were co-morbid with at least one anxiety and one mood disorder. More than a third also had a personality disorder. The patients’ depression and anxiety symptoms were monitored weekly for at least four weeks using objective, normed symptom measures. The case-formulation-guided treatment was much like that described in Figure 2. Formulations included a problem list, a diagnosis, a hypothesis about causal mechanisms and maintaining factors of the problems and diagnoses, and a treatment plan. Interventions included self-monitoring, activity scheduling, cognitive restructuring, contingency management, social skills training, exposure, and homework. Patients received an average of 18 sessions with a range from four to 54. By multiple measures, treatment was highly effective and comparable with those found in RCTs. The mean pre-to-post effect size on the depression measure was 2.1 as compared to 2.2 for similarly symptomatic patients in the RCTs. The effect size on the anxiety measure was .98 in the Persons et al. (2006) study as compared with 1.5 across 14 RCTs in one summary of studies and 2.1 across 5 RCTs in another summary, without adjusting for initial severity of anxiety. Measures of improvement and recovery rates were also similar.

The above results show similar outcomes in a varied mix of depressed and/or anxious patients treated with the case formulation approach, as compared to patients treated in RCTs, thus supporting the case formulation hypothesis. Its major limitation is that it is a correlational study; therefore one cannot conclude that the use of a formulation caused the outcomes. To assess a causal hypothesis, we turn now to two studies using experimental designs in which patients were randomly assigned either to manualized treatment or to individualized treatment.
Schulte et al. (1992) is an example of a study that found manual-based therapy to be superior to individualized therapy at post-treatment, but no differences two years later. These researchers randomly assigned 120 phobic patients either to an experimental group with an individualized cognitive/behavioral treatment planned by the therapist, to a control group with manualized behavioral therapy, chiefly \textit{in vivo} exposure, or to a yoked control group in which patients were administered a treatment that was tailor-designed for a different patient. Seventy-eight percent of the patients had agoraphobia and almost all also had a simple phobia. Results showed that more patients treated with the manualized treatment were "totally cured" or "largely cured" at the end of treatment as compared to the "tailor-made" group. The authors ascribed this difference largely to one specific technique that was delivered more often in the manualized treatment, which is \textit{in vivo} exposure. Schulte et al. (1992) found that patients in the individualized treatment plan condition who received \textit{in vivo} exposure responded as well as those in the manualized treatment group. They also observed that many therapists in the manualized group made adaptations to the individual case. This study illustrates the difficulty of maintaining heterogeneity between conditions of the independent variable when investigating the case formulation hypothesis in an RCT.

In another study, Ghaderi (2006) assigned 50 adult patients with bulimia nervosa either to manual-based or formulation-guided cognitive-behavioral therapy. Both groups received an average of 19 weekly sessions. The manual-based group received a treatment developed by Fairburn and colleagues (2003) that is considered the "treatment of choice" for bulimia nervosa (Wilson & Fairburn, 2007). Treatment addressed dysfunctional thoughts related to eating, body shape and weight, and emphasized behavioral interventions aimed at restoring normal eating patterns. The formulation-guided condition involved conducting and revising a functional analysis of the perpetuating factors for the specific individual. Ghaderi noted that "this treatment condition showed to be very similar to the manual-based CBT in some cases" (p. 278). In other cases the formulation was different in that it included "a more intensive focus on rule governed behavior, acceptance strategies, interpersonal relations, and other issues that maintained the eating disorder (e.g., trauma, abusive relationships and social isolation)" (p. 278). Ghaderi noted further that "in order to keep this treatment structured and replicable, the same treatment protocol as in the standardized CBT was used as a base, and strategies were added and removed from that protocol dependent on what the functional analysis showed for that individual participant" (p. 278).

Results showed that both groups achieved sustained improvement. The formulation-guided group improved more with regard to bulimic episodes at post-treatment, but these differences vanished at six-month follow up. On some key measures, the formulation-guided group improved more than the manual-treated group. A greater percent of these individuals remitted, 92% versus 69%, as measured by having no bulimic episodes or compensatory behavior (e.g., excessive exercising) at post-treatment or no more than one bulimic episode or compensatory behavior during the last 4 weeks at post-treatment. As in the Schulte et al. study, adherence judges reviewing a sample of cases misjudged 20% of individualized treatment as being in the manualized condition, and similarly found "a relatively high level of individualization in the manual-based CBT condition as well, but within the frames of the manual" (p. 279). Whether one interprets these conclusions as indicating overall equivalence of outcome or as indicating slight superiority of the formulation-guided group, the revised case
formulation hypothesis as proposed earlier is supported.

This review of evidence supporting the revised case formulation hypothesis suggests several conclusions. First, the evidence reviewed suggests that future research may support the case formulation hypothesis by showing equivalence of outcome between manual-guided treatment and case-formulation guided treatment. Second, even within manualized treatment, much individuation occurs. Therapists appear always to be formulating and modifying the treatment in response to the conditions that arise in the therapy. Third, most of the work done to date comparing manual-based therapy to formulation-based therapy has occurred within the cognitive-behavioral or behavioral schools. Fourth, in many studies individualization appears to focus more on the selection of treatment interventions than on problem selection, diagnosis, or on generating an explanatory hypothesis. Fifth, as noted, there are few studies in this area. Finally, study design improvements are needed. It is to that task that we now turn.

**Alternative Strategies**

In this section I will review three examples of psychotherapy research strategies that could be followed from the perspective of the reformulated case formulation approach in order to investigate the case formulation hypothesis and other questions. The first is to expand upon the approach taken by Persons et al. (2006), described earlier, of comparing outcomes in clinical practice based on a case formulation approach to those published in RCTs. These efforts could be expanded to different disorders, populations, clinical settings and modes of therapy. They could be implemented through practice-research networks as described by Castonguay (2011), and could also be implemented in training clinics. Such an endeavor would require a significant effort to train clinicians in the evidence-based case-formulation approach, as shown in Figure 2, and to maintain an acceptable level of competence. This endeavor would be consistent with accreditation guidelines for both clinical/counseling psychology and psychiatry training programs. For those already credentialed, it could be conducted for continuing education credit as well as for certification of competence. It would be important to provide clinicians with ready access to the most current clinically relevant research for consideration in the empirically supported explanatory hypothesis and treatment planning components of the formulation. In this context, it should be noted that clinician training and maintenance of competence is a major challenge in all implementation efforts (McHugh & Barlow, 2010).

A second research strategy is to test for moderator and mediator effects of a case formulation (Baron & Kenny, 1986; Frazier, Tix, & Barron, 2004). One could ask whether a case formulation as a whole or its specific components moderate or mediate outcome, effectively testing the utility of a case formulation as compared to therapy delivered without a formulation. Further, it is possible that case formulation competence or a therapist’s ability to implement an individualized treatment plan moderates or mediates outcome. Using this strategy in a small study, for example, Easden and Fletcher (2010) showed that case formulation competence predicted outcome for patients treated with cognitive-behavior therapy. Additionally, it could be that a case formulation predicts outcome in more complex, co-morbid patients with a wide range of problems, but not in less impaired individuals. One could test the case formulation hypothesis by comparing three treatment conditions: (1) evidence-based, case formulation guided treatment, (2) manual-based treatment, and (3) treatment as usual. One could also assess
therapist acceptance of each of these approaches.

A third research strategy is in the area of process-to-outcome research. The case formulation approach has already been used in a single subject research context to explore psychotherapy processes. For example, Silberschatz (2005) investigated the contribution that formulation-consistent interventions make to micro-outcomes, such as an increase in a patient's openness to experience and sense of safety. Similarly, Luborsky (1996) demonstrated the relationship between symptom onset in brief dynamic therapy and the activation of a patient’s core conflictual relationship theme. These efforts could be expanded. One intriguing approach is offered by Dattilio, Edwards and Fishman (2010) who propose that scientific reporting of studies evaluating psychological treatments through RCTs be accompanied by parallel reports of representative systematic case studies of individuals participating in the RCT. These case studies would meet rigorous methodological standards for single case research, which intentionally are consistent with the case formulation approach proposed in this article. These case studies would add critical contextual information to the RCT report. For example, a series of single-case effectiveness studies could be conducted to evaluate whether the presumed mechanism of change in the RCT appears active in the case studies. The importance of this question was recently brought home to me as an investigator in a current RCT. The study research coordinator commented that a patient who had completed about one third of the study appeared remarkably improved. I immediately credited our treatment for the improvement. I then learned that the patient had been ambivalent about whether to end an unhappy marriage and was giddy with pleasure after his wife resolved his ambivalence by announcing her decision to file for divorce. It was no longer so straightforward to attribute his improvement to the treatment. Henriques (2011) describes similar experiences while participating in an RCT. As these illustrations suggest, systematic case studies add contextual understanding to the findings of RCTs. The process-outcome strategy proposed is an example of how the case formulation approach to research and the RCT framework can contribute uniquely to a deeper understanding of therapy processes and outcome.

CONCLUSIONS

In this paper, I have asserted that the case formulation approach to psychotherapy research, as originally articulated by Persons (1991), remains relevant today and with some revisions deserves reconsideration. While the randomized clinical trial is crucial in establishing cause-and-effect relationships to demonstrate that treatments work, the case formulation approach provides an important contextual tool for testing these treatments in clinical settings. The revised case formulation hypothesis provides a focus for research from the standpoint of the case formulation approach, both at the group-comparison and single-subject level. If supported, it would provide empirical grounds for giving clinicians more latitude in choosing evidence-based alternatives to treatment manuals.

It is well documented that clinicians have been less than enthusiastic about adopting empirically supported treatments into their practices (Baker, McFall, & Shoham, 2009; Carroll & Rounsaville, 2008). Translating the central components of these treatments into a case formulation format may be more readily accepted by clinicians. The case formulation approach provides a framework for conducting research in this area. Researchers might also consider
revising treatment manuals into more “therapist-friendly” formats that include a case formulation component. Several examples already exist (e.g., Kuyken et al., 2009; Persons, 2008; Ryle, 1990). This is particularly advisable in light of important findings that therapists using manual-based treatments tend to individualize treatment in any event. Carroll and Rounsaville (2008) offer several suggestions for how to make manuals more “therapist friendly.” These include anticipating “real-world” problems, including troubleshooting guidelines, paying attention to “the basics,” clarifying choice points, and building in flexibility and clarity as to what components are required and which are optional. The evidence-based, case formulation approach described herein may be well suited for implementing these recommendations.

REFERENCES

Dattilio, F. M., Edwards, D., & Fishman, D. B. (2010). Case studies within a mixed methods paradigm: Towards a resolution of the alienation between research and practitioner in


Figure 1
Therapy Model Underlying RCT Approach to Therapy

- Gather Information
- Diagnose
- Treat
- Terminate
Figure 2
General Model of Evidence-Based, Case-Formulation-Guided Therapy