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Abstract

We review studies of the effects on treatment outcome of the use of a case formulation to guide cognitive-behavior therapy (see earlier reviews by (Nelson-Gray, 2003; Haynes et al., 1997). We begin the chapter by describing cognitive behavior therapy (CBT) guided by a case formulation, and contrast it to CBT guided by a standardized protocol. Then we review evidence from randomized controlled trials, uncontrolled trials, and single case studies that test the hypothesis that treatment outcome is better when cognitive behavior therapy (CBT) is guided by a case formulation than when it is guided by a standardized protocol. Next we present some evidence that factors that are often included in a case formulation (e.g., the psychological mechanisms that cause and maintain the patient's symptoms, the patient's ethnic and/or cultural background, motivation for treatment) are predictors or moderators of outcome, or mediators of the change process. These types of evidence provide some support for the notion that using a case formulation to aid decision-making during treatment can improve treatment outcome. We conclude by discussing the implications of our findings for research, training, and clinical practice.

Cognitive Behavior Therapy Guided by a Case Formulation or by a Standardized Protocol

Cognitive Behavior Therapy Guided by a Case Formulation

CBT that is guided by a case formulation (case formulation-driven CBT) has three elements, as shown in Figure 1. First, the therapist collects assessment data and uses it to develop a formulation of the case. A comprehensive case formulation includes information about all of the following: (1) the patient's problems, symptoms, and disorders; (2) the psychological mechanisms (e.g., beliefs and attitudes, contingencies, skills deficits) that cause and maintain the patient's problems; (3) origins of the mechanisms; (4) precipitants that are activating the mechanisms to cause the symptoms and problems; and (5) features of the patient or the environment that are likely to affect treatment progress, including the patient's cultural and ethnic background, personality features, motivation for change, and social support.

<Insert Figure 1 here>

Second, the therapist uses the formulation to select interventions and to make other treatment decisions, such as to focus on increasing the patient's motivation to change before initiating exposure sessions, for example, in order to maximize the chances that the treatment will be successful in accomplishing the patient's idiographic goals. Third, as the therapist implements the treatment, she collects feedback. She collects progress monitoring data in every session to evaluate the patient's response to the therapy and to test the formulation, and, if necessary, uses the data to revise the formulation and the treatment in order to improve the patient's response.

A case formulation-driven approach to treatment is highly individualized, and based on a lot of assessment information that is collected at the beginning of the treatment and at every step during the treatment. Treatment is informed by feedback, so that decisions the therapist makes in later sessions are guided by the results of earlier decisions and interventions. The assessment and treatment process is quite collaborative, with the patient and therapist working together at every step.

Cognitive Behavior Therapy Guided by a Standardized Protocol

In a standardized protocol approach to treatment, the therapist conducts an assessment in order to make a diagnosis, and then follows the protocol to deliver the treatment. Assessment focuses on diagnosis, as most standardized protocols target a disorder, and a diagnosis is needed in order to determine which protocol is applicable. The interventions in the protocol are based on a nomothetic (general) formulation of the disorder the protocol is designed to treat. For example, Beck's cognitive therapy for depression specifies that schemas are activated by life events to cause symptoms that are made up of mutually causal emotions, automatic thoughts, and behaviors. Interventions target the mechanisms (automatic thoughts, behaviors, and schemas, in the case of Beck's cognitive model) described in the formulation. In addition to assessing diagnosis, assessment in standardized protocol therapy also focuses on getting information about the details of the patient's symptoms, and the idiographic details of the mechanisms the protocol targets in the treatment. For example, in the case of cognitive therapy for depression (Beck et al., 1979), the therapist identifies behaviors, automatic thoughts, and schemas that drive the particular patient's depressive symptoms, and the assessment information is used to guide intervention. However, the protocol typically does not describe detailed strategies to obtain this idiographic assessment information -- to obtain schema hypotheses, for example -- nor does it provide guidance on how to address problems that interfere with treatment (e.g., low motivation to change) and comorbid disorders. Treatment goals are standardised: the goal of treatment is to bring the disorder to remission. Standardised protocols tend to be fixed, not feedback-guided; typically the interventions and the order in which they are delivered are pre-determined.

Randomised Controlled Trials Comparing Formulation-guided and Protocol-guided CBT

Several randomised trials compare outcomes of standardised protocol treatment and some type of case formulation-driven treatment. We group these studies into categories based roughly on the type of information the investigators used to develop a case formulation or individualised treatment plan, and on whether a feedback element was included in the treatment. We describe studies in which the formulation was based on diagnosis or symptoms, those in which a formulation was based on a hypothesis about the mechanisms causing or maintaining the patient's problems and disorders, and those that included a feedback element. We describe the randomised controlled trials in each section in backwards chronological order, with more recent studies first.

Case Formulation Based on Diagnosis or Symptoms

Johansson and colleagues (2012) investigated the effectiveness of individually tailored internet-based CBT for depression in a randomised controlled trial in which participants were

assigned to one of three groups: individually tailored CBT, standardised CBT, or the control group. Individuals in the two active treatment groups completed a specified list of treatment modules over a 10-week period, and received email support from a therapist who answered questions about the material and provided feedback on the exercises. Individuals in the standardised treatment group received a set of eight self-help chapters, whereas each individual in the individualised treatment group received chapters that were chosen by the research team from a pool of 25 chapters, and chosen based on data about the patient's symptoms and disorders. For example, a patient with social anxiety would receive a chapter focused on that problem. Individuals assigned to the control group participated in a weekly moderated online discussion group focused on topics that related to depression or its treatment.

Both active treatment groups showed large treatment gains when compared with the control group. This treatment effect was moderated by pre-treatment depression severity. That is, individuals identified as severely depressed at pre-treatment (with Beck Depression Inventory-II scores of greater than 24) experienced greater gains in the individualised treatment group at post-treatment and six months later compared to the standardised one and compared to the control group. By contrast, there was no differential effect on outcome of group assignment for individuals who were less severely depressed at pre-treatment. These results provide some support for the benefit of individualising treatment on the basis of the patient's symptoms or disorders when patients are severely depressed.

Jacobson et al. (1989) compared the outcome of individualised and standardised social learning-based marital therapy. Thirty married couples were randomly assigned to a standardised treatment or a clinically-flexible treatment. The standardised treatment consisted of 20 sessions in which a series of modules was provided in order (behavior exchange, companionship enhancement, communication training, problem-solving training, sexual enrichment, and generalisation and maintenance) to all couples. In the clinically-flexible version of the treatment, the decision about which modules the couple received, the order of delivery of the modules, and the duration of the treatment, was determined on a case-by-case basis based on the team's judgment about each individual couple's needs. The authors do not describe how the team made these decisions, but presumably the decisions were based on the nature of the couple's presenting problems, so that if a couple did not have a sexual problem, the sexual enrichment module could be omitted from the treatment plan, for example. A social learning model was used to conceptualise all of the cases (that is, the same hypothesis about psychological mechanisms was used to conceptualise all of the cases). Although couples in both treatments showed significant gains on the two measures of global marital satisfaction, there were no differential treatment effects at post-treatment or at the six-month follow-up point. The treatments did not differ in average duration; couples in the standard treatment received 20 sessions, and those in the flexible condition received a mean of 22 sessions.

Case Formulation Based on Psychological Mechanisms

In another study examining the benefits of individualised internet-delivered CBT for depression, participants were randomly assigned to a standardised self-help treatment protocol, individualised email therapy, or a wait-list control condition (Vernmark et al., 2010). In the individualised treatment, a case formulation was developed based on each participant's assessment data, and therapists used the formulation to provide CBT strategies

via email. The authors do not describe in detail how they developed formulations for each patient, but refer to using a functional analysis and elements of the case formulation driven approach described by Persons (2008). The study found no difference between the two CB treatments on all depression outcome measures. Both treatments led to significantly better outcomes than the wait-list control condition.

Ghaderi (2006) compared treatment for bulimia nervosa that was guided by a formulation based on a functional analysis to a standardised protocol treatment. The individualised treatment was anchored in the standardised treatment developed by Fairburn and colleagues (1993), and elements were added to or deleted from that standard treatment based on the results of a functional analysis that was conducted to identify perpetuating factors for that particular patient. For example, if the functional analysis showed that social isolation was a maintaining factor for a particular patient's symptoms, interventions to target social isolation were included in that patient's treatment. Patients in both treatments showed statistically significant changes and maintained their gains at the six-month follow-up point. Patients in the individualised treatment showed superior gains on four of approximately 22 treatment outcome variables; the treatments did not differ on the remaining variables. Ghaderi (2006) pointed out that the failure to find more differences between the treatments may in part have been due to inadequate power.

Conrod and colleagues (2000) conducted a randomised controlled trial in which individuals with substance abuse problems were randomly assigned to receive interventions that matched the individual's personality profile, interventions that did not match the individual's personality profile, or a nonspecific intervention. In the matching treatment, individuals received interventions that addressed one of four personality profiles (anxiety sensitivity, introversion-hopelessness, impulsive sensation seeking, non-impulsive sensation seeking). This study was based on findings that these profiles increase an individual's susceptibility to using different drugs (Conrod et al., 2000). For example, individuals high in anxiety sensitivity were more likely to suffer from anxiolytic substance dependence, whereas individuals with an introversion-hopelessness profile were more likely to struggle with depressive symptoms and opioid dependence.

Individuals in the matched-treatment condition received detailed, individualised feedback about their personality type and the severity of their drug use relative to norms, and learned cognitive behavioral strategies targeting their motivations for substance use based on their personality profile. Individuals in the mismatched personality profile treatment condition learned about "potential" motivations to use substances (deliberately mismatched with their own profile) and strategies that "potentially" could be helpful to someone with substance use problems. Those in the nonspecific condition watched a motivational film on substance use, and discussed with a therapist their reactions to the film and how it related to their personal experiences with substance use. Each treatment was delivered in a single 90-minute session.

The authors do not report ANOVAs testing for a main effect of treatment condition on the post-treatment data, but in planned contrasts between the different treatment conditions, they found that six months after the intervention, individuals in the personality-matched treatment condition had a significantly greater reduction in substance dependence symptoms, higher rates of abstinence from drinking alcohol and using other substances, and fewer concerns about current consumption levels than those in the nonspecific treatment condition, but did not significantly differ from those in the mismatched treatment. The authors did not find

group differences in overall the amount of alcohol consumed or the frequency of prescription drug use.

Schulte and colleagues (1992) randomly assigned 120 patients with various types of phobias to one of three treatments: (1) standardised in vivo exposure treatment and retraining of self-verbalisations, (2) individualized treatment in which the therapist “is allowed to use all therapeutic methods commonly employed in behavior therapy and cognitive therapy” (p. 69), or (3) a yoked control group, in which each patient received a treatment that was assigned to one of the patients in the individualized group. The individualized treatment was designed on the basis of the therapist’s “behavioral analysis” (p. 68) or “problem analysis” of the case, which was “guided by a system of meta-rules about the important items of information to be gathered and about their interpretation” (p. 69). There were few differences among the treatments. A MANOVA showed that the three treatment conditions differed significantly at the $p < .05$ level for three of nine outcome measures at post-treatment, two of the nine measures at six-month follow up, and none at two-year follow up. No statistical tests reporting pairwise comparisons between the treatment conditions were reported.

Schneider and Byrne (1987) randomly assigned 35 children aged seven to 13 years old who were receiving treatment for anxiety, attention deficit disorder, or conduct disorder to receive standardized or individualized social skills training. All children in the standardized group received social skills training using the same 12 modules, and those in the individualized group received a selection of modules from the standardized treatment based on an initial assessment of both symptoms (e.g., aggression) and skills that were viewed as mechanisms underpinning the child’s behavioral symptoms (e.g., social perception skills). Increases in cooperative play were statistically significantly greater for children who received individualised than standardised treatment; the treatments did not differ in their effects on observed aggression.

Case Formulation-driven Treatment that Included a Feedback Element

We review two randomised trials comparing formulation-driven and standardised treatment that included a feedback element in the formulation-driven treatment: A study of modular treatment for youths (Weisz et al., 2012; Chorpita et al., 2013), and a study of behavioral treatment of alcohol abuse (Litt et al., 2009). We also briefly review research examining the effects on treatment outcome of feedback alone.

Weisz et al. (2012) and Chorpita et al. (2013) compared modular, standardised, and usual care for youths aged seven to 13 who sought treatment for mood, anxiety, and/or conduct problems. This study is particularly interesting, and therefore we examine it in some detail. The standardised treatment consisted of an empirically-supported CBT protocol for depression (Primary and Secondary Control Enhancement Training), anxiety (Coping Cat), or conduct problems (Defiant Children) that treated the child’s main presenting problem.

The modular treatment consisted of intervention modules that the therapist selected from the standardised protocols on the basis of assessment data and decision flowcharts. The flowcharts guided therapists to select modules on the basis of the child’s symptoms and problems (e.g., if anxiety was a problem, the flowchart suggested modules from the Coping Cat protocol), and to make adjustments as needed on the basis of feedback data that were obtained in every session. Thus, if another problem (e.g., conduct problems, or depression) interfered with the treatment the therapist was implementing, the therapist could select

modules from those protocols, and if the feedback data indicated, for example, that the patient was not practicing exposure, the flowchart prompted the therapist to consider adding a reward module to increase compliance. Independent assessors collected weekly feedback data on the patient's symptoms and problems, and on treatment compliance, and reviewed the data with the supervisor, who transmitted it to the clinician. In the usual care condition, "therapists agreed to use the treatment procedures that they used regularly and believed to be effective." (Weisz et al., 2012, p. 277).

The investigators compared the treatments on the child's mean number of diagnoses at post-treatment, controlling for number of pre-treatment diagnoses. Because treatment duration varied among the conditions, the investigators examined differences between treatments on the main symptom dependent variables (Brief Problem Checklist, Top Problems Assessment, Child Behavior Checklist (CBCL), and Youth Self Report (YSR) by conducting regression analyses that compared the slope of the change trajectory for the treatments, rather than comparing the post-treatment outcomes. The investigators compared the treatments on functional impairment and services utilisation at the 12 and 24-month follow-up points.

Results showed that youth who received modularised treatment had statistically significantly fewer diagnoses after treatment than those who received usual care, but did not differ from those who received standardised treatment (Weisz et al., 2012). Youths who received standardised treatment did not differ from usual care.

On both the Brief Symptom Checklist and Top Problems Assessment, youths who received modular treatment had statistically significantly steeper change trajectories between baseline and post-treatment than those who received standardised treatment and those who received usual care (Weisz et al., 2012). Youths who received standardised treatment did not differ from usual care. On the two other symptoms measures, Child Behavior Checklist (CBCL), and Youth Self Report (YSR), an examination of the trajectory of change over the entire study period, including the two-year follow-up, showed that modular care was superior to usual care but not to standardised treatment (Chorpita et al., 2013). Standardised treatment did not differ from usual care. The groups did not differ on functional impairment or service utilisation (Chorpita et al., 2013).

Thus, the study provides some support for the use of a case formulation-driven mode of treatment. The "formulation" that guided decision-making was based primarily on the patient's symptoms and disorders, and interventions were selected from a set of modules. The strongest support for the modular treatment was seen for diagnosis, and for the two measures of symptoms and problems (Brief Problem Checklist and Top Problems Assessment) for which feedback data were collected at every session.

In a treatment study of individuals with alcohol dependence, Litt and colleagues (2009) randomly assigned participants to receive a manualised or an individualised cognitive behavioral treatment (CBT) program. For both groups, treatment consisted of 12 weekly 60-minute outpatient sessions. During the two weeks before treatment and the two weeks after treatment ended, the study employed an experience sampling method in which participants answered a phone call multiple times every day, and responded to a series of questions about their current mood, thoughts, behaviors, and environment. For each participant in the individualised treatment condition, a research assistant used the experience sampling data to create a personalised functional analysis chart that was given to the participant's therapist

before the first session. Therapists used the data to identify the situations in which a patient was at high risk to drink or feel urges to drink, and tailored the treatment to target these vulnerabilities. Although the content of the treatment sessions was pre-determined (e. g., sessions 1-3 focused on analysing high-risk drinking situations), interventions in the individualised treatment were based on the difficulties identified in the functional analysis chart.

At post-treatment, individuals in the individualised treatment had outcomes that were superior to the standardised treatment on one of the three drinking outcome variables (proportion of days abstinent). The groups did not differ in the proportion of heavy drinking days or in the proportion of individuals who remained abstinent for at least 90 days. Using the post-treatment experience sampling data, the study found that patients in the individualised treatment reported significantly fewer urges to drink, were significantly less likely to drink in response to urges, and were more likely to use adaptive coping responses than those in the standardised treatment.

The study provides some support for the use of the case formulation approach, and includes all three elements of the approach we previously described. Although the study did not formally collect feedback data, the study therapists repeatedly referred to the case formulation and assessment data throughout treatment, and presumably gained informal feedback from the client as to the accuracy of the data when developing strategies to target their problems.

A substantial literature (see reviews by Goodman et al., 2013 and Carlier et al., 2012, and a meta-analysis by Knaup et al., 2009) examines the effects on treatment outcome of the feedback element of the model described in Figure 1. Large numbers of randomised controlled trials have shown that when clinicians collect feedback data to monitor the progress of their patients, those patients have better outcomes. The effect has been shown in many disorders and problems and populations, including students seeking treatment at a university counseling center (Lambert and Shimokawa, 2011; Reese et al., 2009), youth receiving home-based mental health treatment in community settings (Bickman, 2011), patients receiving treatment for schizophrenia or related disorders in community mental healthcare in Europe (Priebe et al., 2007), depressed patients treated in primary care settings (Yeung, 2012) and couples receiving treatment at a community clinic (Anker et al., 2009) or a training clinic (Reese et al, 2010). Two outcomes monitoring systems, Lambert's OQ-45 (Lambert et al., 1996) and the Partners for Change Outcomes Monitoring System (PCOMS; Miller et al., 2005) have sufficient empirical support to be included in the U. S. Substance Abuse and Mental Health Services Administration's (SAMHSA) National Registry of Evidence-based Programs and Practices (NREPP; SAMHSA, 2013).

In summary, randomised controlled trials provide some evidence in support of the notion that outcome of treatment that is guided by a case formulation is superior to standardised treatment. We did not find any studies that showed that standardised treatment was superior to case formulation-driven treatment. The strongest evidence supported the use of the feedback element of the model.

Uncontrolled Trials

Two uncontrolled trials conducted by this chapter's first author showed that treatment of depressed (Persons et al., 1999) and depressed anxious patients (Persons et al., 2006) that is guided by a CB case formulation and weekly progress monitoring has outcomes similar to outcomes of patients receiving CBT or CBT plus pharmacotherapy in randomised controlled trials. Patients in the Persons et al. (1999, 2006) studies were adult outpatients who had completed treatment in her private practice or her group practice in Oakland, California. Minimal selection criteria were used, in order to evaluate as heterogeneous a sample as possible. Patients in the Persons et al. (1999) study met the following criteria: Initial Beck Depression Inventory (BDI) score of 14 or greater, the clinical record had a written case formulation, and a minimum of three BDI scores were available. Patients in the Persons et al. (2006) study met the following criteria: At least four sessions of symptom data on the BDI or the Burns Anxiety Inventory were available, and the patient was aged 19 – 75 years. All patients were treated with individual CBT, and many also received adjunct therapies, such as pharmacotherapy or couples therapy. The major weakness of these studies is the lack of a control group to which the results can be compared. The major strength is that the studies examine treatment that included all three elements of the model of case formulation-driven CBT, a heterogeneous unselected sample of patients with multiple comorbid mood and anxiety disorders, and naturalistic treatment, including multiple adjunct therapies, that was provided in a real-world clinical setting.

Forand and colleagues (2011) reported results of an uncontrolled trial of CBT provided by trainees at a university-based outpatient training clinic. Treatment approximated the use of the model of case formulation-driven treatment described in Figure 1. Treatment was not manualised, so it was flexible and adjusted to meet the needs of the individual patient; however, there is no evidence that a formal, written case formulation was developed. The fact that “treatment plans are based on empirically supported treatment protocols...” (p. 615), suggests that therapists used interventions and, presumably, formulations they learned from those protocols, to guide their work. Treatment included a feedback element; therapists collected scores on measures of anxiety and/or depression at the beginning of every therapy session, and used the data “for assessing symptom change and treatment planning” (p. 615).

Minimal selection criteria were used to select the sample of 249 patients. Patients were selected for study if they had a primary diagnosis of a mood or anxiety disorder, a minimum Beck Depression Inventory score of 11 or Beck Anxiety Inventory score of 11 at intake, and at least three sessions of symptom data.

The authors found that the trainee therapists in their sample achieved rates of recovery and improvement that were comparable to those in the effectiveness and efficacy studies they used for comparison purposes, except that recovery rates for severely depressed patients were lower than in the comparison studies, and pre-post effect sizes were somewhat lower than in the comparison studies.

In summary, these three uncontrolled trials provide some support for the notion that a case formulation-driven approach to CBT produces outcomes similar to those achieved in the randomised trials for CBT for mood and anxiety disorders. These results were obtained even in the treatment of patient populations with high degrees of comorbidity and in the case of the Forand et al. (2011) study, when treatment was provided by carefully-supervised trainee therapists.

Single Case Studies

A large number of single case studies consistently provide compelling evidence to support the treatment utility of a functional analysis. For example, Iwata et al. (1994) reported the results of 152 single-subject analyses of the reinforcing functions of self-injurious behavior (SIB) in individuals with developmental disabilities. The investigators found that when interventions considered to be relevant to a particular function (e.g., extinction of attention for an individual whose SIB appeared to serve the function of obtaining attention) were delivered, SIB was reduced to below 10% of its baseline level in more than 80% of the cases. When interventions that did not address the function of the SIB were delivered, almost no change occurred. Many other single cases showing that when treatment is guided by the results of a functional analysis, outcome is superior to treatment that is not guided by the functional analysis; several are reviewed by Haynes et al. (1997).

The large majority of case studies investigating the treatment utility of a case formulation, examine the use of a functional analysis to plan treatment for children or adults with self injurious behavior or other severe behavioral problems. Less common are studies testing the treatment utility of functional analysis for patients with other problems. Examples include the case of the school-refusing child reported by Chorpita and colleagues (1996) and the two studies by Nelson-Gray and colleagues, described in the next paragraph, that report on results of multiple single case studies of depressed women.

Nelson-Gray and colleagues (1989) reported results of single case studies of nine depressed women who each were assessed to identify deficits in any of three response classes: Social skills deficits, pleasant events deficits, or irrational cognitions. Patients who had deficits in one or two but not all three of these response classes were selected for study. Three patients received eight weeks of treatment that was matched to their problematic response class, three patients received treatment mismatched to their response class, and three received a package treatment that addressed all the response classes. The matched and package treatments both produced significant gains on the Beck Depression Inventory, but the mismatched treatment did not. In a within-subjects study that addressed the same question ('do depressed patients benefit more from treatment that matches their deficits than from treatment that does not address their deficits?'), McKnight et al. (1984) collected data from nine depressed women, three who had social skills deficits, three who had irrational cognitions, and three who had both. All patients received alternating sessions of matched or mismatched treatment, and benefits of the previous session were assessed at the beginning of each session. All patients showed a greater reduction in depressive symptoms following matched than unmatched treatment.

All of the single case studies reported here (and many others not reported here; e.g., Haynes et al., 1997), provide convincing evidence of the treatment utility of an individualised case formulation. In all of these single case studies, the case formulation was based on a mechanism hypothesis (typically one obtained via a functional analysis). However, none of these treatments included a feedback element. Instead, treatment was pre-determined by the results of the functional analysis, although in some cases, the accuracy of the functional analysis was tested before treatment began, and the functional hypothesis (and thus the treatment plan) was revised based on the results of the testing (Hagopian et al., 2013).

Predictors, Moderators, and Mediators

Evidence that factors typically included in case formulations influence treatment outcome or the change process, provides support for the treatment utility of individualised case formulations. Therefore, we present some of that evidence here. We examine three types of influence on outcome and the change process: *Prediction*, *moderation*, and *mediation*. *Predictors* provide prognostic information about outcome (e.g., ethnicity predicts dropout). *Moderators* identify which subgroups of patients or specific factors lead to a differential response to treatment (e.g., when treatment motivation is low, high therapist adherence to the treatment leads to poor outcome, and when treatment motivation is high, high therapist adherence to the treatment leads to good outcome). *Mediators* explain why and how a treatment is effective (e.g., CBT for panic disorder is effective partly because it produces changes in anxiety sensitivity).

Ethnicity as Predictor and Moderator

One common finding is that individuals from ethnic minority groups are more likely to drop out of treatment than their Euro-American counterparts. For example, King and Canada (2004) showed that African Americans who began CBT for substance abuse dropped out of treatment at a rate five times higher than Caucasians. Austin and Wagner (2006) similarly found that Caucasian adolescent juvenile offenders in treatment for substance use problems ($n=420$), dropped out at a significantly lower rate than the ethnic minority participants, with the African American participants showing the highest rates of dropout. Using data from 11 randomised controlled trials of treatments for binge eating disorder, Thompson-Brenner et al. (2013) found that African-Americans were significantly more likely to drop out of treatment than their Caucasian counterparts. McFarland and Klein (2005) found that ethnic minority patients had significantly higher risk of dropping out from treatment for dysthymic disorder than their Caucasian patients. Reasons for the increased rate of treatment dropout among ethnic minority clients are unclear, but these studies provide compelling evidence of the importance of considering the role of ethnicity when treatment planning.

Ethnicity has also been shown to moderate the effectiveness of particular interventions. Clair et al. (2013) found that Hispanic incarcerated adolescents responded significantly better to motivational interviewing than to relaxation therapy to reduce their use of alcohol, whereas their Caucasian and African-American counterparts showed no difference in response to the two types of treatment. Patient ethnic background appears to also moderate how well the patient bonds with the therapist. In a longitudinal treatment study of 185 adolescents with a range of externalising behavioral problems, Hispanic adolescents who exhibited higher levels of problem behaviors early in treatment showed poorer treatment adherence and emotional bonding with their therapists than did Hispanics with lower levels of problem severity. By contrast, for those of African-American descent, higher levels of severity were associated with greater emotional bond and alliance with the therapist (Ryan et al., 2013).

Readiness to Change as a Moderator

Boswell and colleagues (2012) showed that readiness to change (Prochaska and DiClemente, 1986) moderates the relationship between initial symptom severity and outcome in the treatment of anxiety disorders. The study used data from an RCT examining the efficacy of a transdiagnostic CBT protocol for patients with a primary anxiety disorder diagnosis when

compared to a delayed treatment condition (Farchione et al., 2012). Higher levels of initial symptom severity on both measures of anxiety and depression were significantly associated with lower levels of symptom change, and levels of readiness to change moderated this relationship. Individuals who endorsed higher levels of symptom severity *and* higher levels of readiness to change showed more change during treatment. Thus, when individuals reported high levels of readiness to change, a high degree of symptom severity was a positive predictor of symptom improvement at post-treatment.

Another demonstration of the moderating role of patient motivation was provided by Huppert, et al. (2006), who showed that high therapist adherence to the protocol was associated with poor outcome of CBT for panic disorder when patients had low motivation to change.

Threat Overestimation as Predictor, Moderator, and Mediator

Cognitive factors that influence a person's disorders or symptoms are commonly included in the case formulation. We review the role of threat overestimation, with a specific focus on anxiety sensitivity (a type of threat overestimation) on outcome as an example of such cognitive factors.

Threat reappraisal as a mediator

Overestimation of threat, that is, the faulty belief that harm from a particular situation or cue is highly likely and/or costly, is a primary treatment target in CBT for anxiety. CBT treats overestimation by teaching patients to reappraise the threat. Smits and colleagues (2012) conducted a systematic review of studies looking at whether threat reappraisal mediates cognitive behavior therapy for anxiety disorders. The authors outlined the following criteria to determine support for a mediational role of threat reappraisal: (1) evidence of statistical mediation, (2) evidence that the change is specific to CBT and not other factors, (3) evidence that threat reappraisal causes anxiety reduction, and (4) evidence that changes in anxiety are specifically related to changes in threat reappraisal.

In their review the authors found that the majority of the identified studies did not test criteria 2-4 (listed above) and that none of the studies tested all four criteria. They also found that other factors (e.g., increased self-efficacy, perceived control) could independently explain the effects of CBT on anxiety, which suggests that the relationship between threat reappraisal and anxiety reduction is not specific. Despite this, the data strongly supported a relationship between threat reappraisal and anxiety reduction. Thirteen of the 25 studies reviewed examined whether threat reappraisal mediated the relationship between CBT and anxiety reduction, and all but one of them found that threat reappraisal played a statistically significant mediating role.

Anxiety sensitivity as a predictor

One type of threat overestimation that has featured prominently in CB treatments is anxiety sensitivity. Individuals with high anxiety sensitivity tend to interpret anxious bodily sensations (e.g., heart palpitations, dizziness, shortness of breath, depersonalisation) as being physically, psychologically, and/or socially dangerous or harmful (Reiss and McNally, 1985). Several studies have found anxiety sensitivity to be a predictor of treatment outcome. For

example, Teachman and colleagues (2010) found that reductions in anxiety sensitivity (assessed repeatedly) during the course of CBT for panic disorder predicted post-treatment reductions in symptom severity, panic frequency, and avoidance behaviors.

Anxiety sensitivity as a moderator

Wolitzky-Taylor and colleagues (2012) examined treatment response of a heterogeneous sample of anxiety disorder patients who were randomly assigned to CBT or acceptance and commitment therapy (ACT). They also investigated whether anxiety sensitivity moderated the response to the different treatments. They found that the treatments did not differ in efficacy (as measured by pre-post treatment changes on the Mood and Anxiety Symptom Questionnaire). As predicted, they also found that pre-treatment levels of anxiety sensitivity moderated patients' response to CBT, but not to ACT. Individuals with high (one standard deviation above the mean) or low (one standard deviation below the mean) pre-treatment anxiety sensitivity scores responded least favorably to CBT and those with scores near the mean showed favorable outcomes and demonstrated a significantly better response to CBT than individuals with similar scores in the ACT condition.

Anxiety sensitivity as a mediator

Smits and colleagues (2004) examined whether the efficacy of CBT in reducing panic disorder symptoms is mediated by changes in anxiety sensitivity. They collected data from panic disorder patients treated with CBT and those in a wait-list control condition. Using steps outlined by Baron and Kenny (1986), they found that anxiety sensitivity fully mediated the effects of CBT on global distress ratings, but only partially mediated the effects of CBT on panic attack frequency, agoraphobia, and self-reported anxiety. Despite the strength of their findings, the authors point out that the data were correlational and did not speak to the possibility that the change in anxiety sensitivity was a consequence of (not a cause of) panic disorder symptom reduction.

In this section we provided a sampling of evidence (many more studies could be cited) supporting the notion that factors that are common elements of a case formulation (ethnicity, patient motivation, threat overestimation) are predictors, moderators and mediators of change in CBT. These data provide some indirect evidence supporting the use of a case formulation that includes this information, to guide decision-making in treatment.

Implications for Research, Training, and Clinical Practice

We found, in the data from randomised controlled trials, uncontrolled trials, and single case studies, a moderate amount of evidence to support the notion that a case formulation-driven approach to treatment leads to improved outcome. Results of the studies of predictors, moderators, and mediators provided a considerable amount of evidence to support the notion that factors that are typically part of a case formulation predict or influence outcome, or mediate the change process, and these types of data indicate that using a case formulation to guide treatment has the potential to lead to improved outcome.

We discuss research, training, and clinical implications of our findings. We organise our discussion by the three parts of our model (Figure 1), taking up each part of the model in turn (the case formulation, using the formulation to guide treatment, and collecting feedback data), and concluding with a discussion of the complete three-part model.

Developing a Case Formulation

We found considerable evidence that features of a typical CB case formulation (e.g., patient features such as ethnicity and motivation to change, and psychological mechanisms such as overestimation of threat) are predictors and moderators of outcome, and to a lesser extent, mediators of the change process in CBT. We discussed only a sample of potential predictors, moderators, and mediators; many others deserve study. A key question for research is which aspects of the formulation have greatest treatment utility (Nelson-Gray, 2003). Is it most important to attend to ethnicity? Motivation to change? Psychological mechanisms that maintain the symptoms? Origins of the mechanisms?

Related, many case formulation formats and models, and many methods for developing a case formulation have been developed, (e.g., Haynes et al., 2011; Frank and Davidson, 2014; Kuyken et al., 2009; Nezu et al., 2004; Persons, 2008; Sturmey, 2008). These methods differ in the elements they assess and emphasise. For example Kuyken et al. (2009) emphasise assessment of strengths, whereas Frank and Davidson (2014) and Persons (2008) emphasise assessment of transdiagnostic mechanisms like contingencies, schemas, intolerance of uncertainty, and perfectionism. Research is needed to identify which models and which elements of the case formulation have the greatest treatment utility. Of the many strategies for developing a formulation, our review identifies the functional analysis as the one with the greatest empirical support, perhaps because it is the single strategy that has been most often studied. We conclude that functional analysis deserves more attention from researchers, trainers, and practitioners.

Using the Formulation to Guide Treatment

Treatment development

Evidence that features such as ethnicity, readiness to change, anxiety sensitivity, and others, are predictors, moderators, and mediators highlights the need for research to understand how these factors affect treatment and to inform clinicians about how to effectively address them in treatment. Research along these lines has the potential to help researchers strengthen available treatments and develop new ones.

Targeting factors like ethnicity is complicated by that fact that ethnicity is not a problem for which individuals seek treatment. In addition, the clinician is pressed to address the possibility of increased dropout or other culturally related responses without inflating stereotypes. One approach is to individually assess for factors that have been shown to be elevated within particular cultural groups and frequently associated with emotional difficulties (e.g., higher levels of emotion suppression among Asians; Butler et al., 2007). The clinician could then work collaboratively with the patient to examine whether changes in these factors help alleviate the individual's symptoms or are unrelated to the presenting problems (Hong, 2013).

Transdiagnostic mechanisms

A strength of the case formulation-driven approach to treatment is that it allows the clinician to develop a case formulation that identifies one or more transdiagnostic mechanisms (e.g., perfectionism, overestimation of threat, schemas, faulty contingencies) that cause and maintain multiple symptoms and problems, giving rise to the potential that treatments that target those common mechanisms might simultaneously treat multiple symptoms and problems. An important example is Acceptance and Commitment Therapy (ACT), which targets experiential avoidance, and has been shown to provide effective treatment for multiple disorders (Hayes et al., 2006; Ost, 2008). Other examples include treatments developed by Dugas and colleagues (Dugas et al., 1998; Dugas and Ladouceur, 2000) for intolerance of uncertainty, and by Shafran and colleagues (2002) for perfectionism. An alternate transdiagnostic treatment strategy is provided by Barlow's unified protocol for the emotional disorders (Barlow et al., 2011), which targets several mechanisms (including low motivation to change, distorted cognitions, and experiential avoidance) that maintain multiple anxiety and mood disorders. The focus on identifying and developing interventions to target transdiagnostic mechanisms is consistent with NIMH's current research agenda (Onken et al., 2014).

Modular treatment

Several of the studies that demonstrate the treatment utility of the formulation (e.g., Johansson et al., 2012; Schneider and Byrne, 1987; Weisz et al., 2013) use a modular design. That is, the clinician uses a case formulation of some sort, or decision flow chart, to select modules from a list. Modules are elements of protocols; Weisz and colleagues (2011) and Embry and Biglan (2008) use the term "kernels," to describe modules, and contrast them to "ears" (whole protocols).

Modular treatments of this sort have huge promise, for several reasons. One is that there is evidence that clinicians are more willing to adopt flexible modular treatments than single disorder protocols (Borntreger et al., 2009). Another is that the modular strategy can make training more efficient, and help solve the problem of the proliferation of protocols (Craske, 2012). A third is that modular treatments allow clinicians the flexibility they need without exposing them to the disadvantages of too much individualisation. Our review (see the study by Schulte et al., 1992, and the usual care condition of the Weisz et al., 2012, study) hints at the possibility that too much individualisation is not a good thing. Fourth, modular treatments facilitate the treatment of patients with multiple comorbidities, and of course these are the rule, not the exception.

Data supporting the effectiveness of modular treatments point to the need for more research examining the evidence base underpinning the modules (see Embry and Biglan, 2008).

Multiple comorbidities

Some of the strongest results in support of the treatment utility of a case formulation arose in studies of complex cases of patients with multiple comorbidities (Weisz et al., 2012; Johansson et al., 2012). The case formulation seems likely to be most useful in the treatment of complex cases with multiple comorbidities and difficulties such as low motivation for treatment, noncompliance, and poor response that raise problems for the clinician that she must address in some way (Persons, 2013).

Obtaining Feedback

In the feedback element of a case formulation-driven approach to treatment, the therapist collects data at every session to monitor the outcome and process of treatment. The therapist collects data to assess symptoms and functioning to evaluate the degree to which the patient is accomplishing his treatment goals (outcome). The therapist also collects data about therapy process (the alliance, adherence, change in mechanisms, what the patient is learning, satisfaction with treatment) in order to test the formulation and to identify any factors (e.g., low adherence, low motivation to change) that might interfere with treatment.

Large numbers of measures have been developed to assess symptoms; fewer are available to assess functioning, and even fewer to assess therapy process. To assess process, we have developed a paper and pencil scale, the Session Assignment and Feedback Scale (SAFF; Persons et al., in press) to track the patient's homework assignments and assess all of these aspects of process at every therapy session (available at no charge at www.cbtsience.com). Other process monitoring tools have been developed by Burns (1997) and Miller et al. (2005), among others.

The strength of the evidence supporting the benefits of collecting feedback data coupled with evidence that most practitioners do not monitor their patients' progress (Hatfield and Ogles, 2004) indicates that this topic deserves more attention from psychotherapy trainers and practitioners.

The Entire Three-Part Model

A striking finding of our review was that there were almost no studies (except Weisz et al., 2013; Litt et al., 2009; and Persons et al., 1999, 2006) that examined all three elements of case formulation-driven CBT (developing a formulation, using the formulation to guide treatment, and collecting feedback data). One question this finding raises is: Are all three elements truly necessary? Certainly the first two are essential to a case formulation-guided treatment: The therapist develops a case formulation and uses it to guide treatment. Is a feedback element necessary?

We argue that collecting feedback, or doing progress monitoring, is essential to treatment guided by a case formulation, and here is our reasoning. We do not view case formulation-guided CBT as a new treatment. Instead, we view it as a framework or systematic way to adapt nomothetic formulations and interventions, usually drawn from the empirically-supported treatments, to the individual case. The idiographic case formulation is a hypothesis that we use to guide intervention. Because the formulation is a hypothesis, we must collect data to test it. And because our goal is to provide evidence-based treatment, we must collect data to evaluate our patient's progress (Howard et al., 1996). Thus, we view the feedback element of the model as essential, and in fact we view it as an essential element of evidence-based treatment.

If the feedback element is essential to a case formulation-driven treatment, the fact that almost no studies of the method include the feedback element is quite striking, and indicates that there is an exceedingly wide gap between the research studies of case formulation and the model of case formulation-driven CBT that we describe.

Treatment development strategy

The gap between the model that clinicians use to do evidence-based practice and the psychotherapy research literature may result in part from the use of the stage model of treatment development that calls for clinical scientists to develop new treatments in the lab, carry out efficacy studies there, and then carry out effectiveness studies to examine the treatment's effectiveness in the clinic (Rounsaville et al., 2001). To bring clinical work and psychotherapy research closer together, Weisz (2014) has suggested an alternate treatment development model in which clinical scientists develop treatments with the populations of clinicians and patients who will be using them, not in the lab.

Studies of clinical decision-making

Most of the research studies we examined focus on the use of the formulation to select interventions (e.g., Jacobson et al., 1989; Johansson et al., 2012; Schneider and Bryne, 1987; Weisz et al., 2012). Intervention selection is an important decision. But clinicians make many other types of decisions, including: When ought I bring in the patient's significant other? Is it a good idea to shift the focus to work on increasing motivation for change? Would the patient benefit from less directiveness on my part? Is it time to make a change in the treatment plan? Research is needed to help clinicians improve their ability to answer these and the myriad other decisions they confront.

Michael Lambert has shown that a clinical support tool that he developed to help clinicians handle treatment failure leads to improved outcome of these problematic cases when compared to cases where the clinician does not have access to the support tool (Harmon et al., 2005). The clinical support tool prompts the clinician to focus on several elements (e.g., readiness for change) that we would view as part of a comprehensive case formulation.

A key role of the case formulation is to help the therapist make clinical decisions, and especially to identify and solve problems (e.g., low motivation, poor adherence, lack of progress). Therapists have particular difficulty making good decisions when their patients do not make progress (Hannan et al., 2005). As the model shown in Figure 1 illustrates, the case formulation-driven approach to treatment suggests that one possible action the therapist can take in this situation is to consider whether a different formulation of the case might suggest alternative and more helpful interventions (Persons and Eidelman, 2012). Case examples of the successful use of this strategy are provided by Persons and colleagues (2013; Persons and Mikami, 2002).

Types of treatment utility

Nearly all the studies of the treatment utility of the case formulation that we reviewed here, examined the dependent variable of treatment outcome. A few studied dropout. A wide range of other important dependent variables merit study when we examine the treatment utility of the use of a case formulation-driven approach to work, including: Patient adherence, patient acceptance of the treatment rationale (Addis and Jacobson, 2000), therapist willingness to adopt the treatment (Borntrager et al., 2009), and range of patient presentations that the treatment addresses (Chorpita et al., 2005).

Single case studies

Our review showed that single case studies provided valuable data. The single case design is well-suited to answer questions about the role of the case formulation in treatment. We encourage researchers and clinicians to rely more on this under-used research strategy to

carry out single case studies of the treatment utility of the case formulation, we encourage clinical science journals to publish those studies, and we encourage trainers to teach their students how to implement single case designs; outstanding texts are available for this purpose (Barlow et al., 2009; Kazdin, 2011).

Implications for clinical work

As this review shows, case formulation-driven CBT is supported by a moderate, but not an overwhelming amount, of data. What are the implications of this fact for the practitioner who is striving to do evidence-based work?

We offer the following suggestions for ways the clinician can strengthen the evidence base underpinning the use of a case formulation-driven approach to CBT (see also Persons, 2008). First, rely on evidence-based formulations and interventions (kernels) whenever possible. Second, rely on other evidence from the scientific literature (e.g., about attitudes toward mental illness that are common in individuals who share the patient's ethnicity or cultural heritage) to guide decision-making. Finally, and most important, use an empirical hypothesis-testing approach to each case, where the formulation is the hypothesis, and the therapist and patient collect data to test the hypothesis and to monitor the process and outcome of treatment at every session. The key empirical question the clinician confronts is, "Is this patient benefitting from the treatment I am providing?" and the way to answer this question is to collect feedback data to monitor the patient's progress.

This empirical approach to the case has its origins in the early history of behavior therapy (see Hayes et al., 1999) and also exemplifies the practice of evidence-based medicine described by Sackett and colleagues (1997).

Integrating science and practice

The model of case formulation-driven treatment described in this chapter allows for, indeed promotes, a gorgeous and elegant overlap of clinical work and scientific research that allows the clinician to both use and contribute to science. Using this model, the treatment of every case is an $n = 1$ experiment, a clinical scientific enterprise. We encourage clinicians to use the model we describe here to collect data that allow them to provide high quality evidence-based care, and to contribute to the research literature by publishing single case studies and other studies based on those data.

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