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Convergence and divergence in the delivery of cognitive therapy in two randomized clinical trials

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ABSTRACT

Objective: Research indicates that cognitive therapy (CT) can be differentiated from other treatment modalities based on in-session therapist behavior. However, to our knowledge, consistency in the implementation of individual CT across clinical trials has not been tested. We compared therapist adherence to CT, as well as the therapeutic alliance, in two randomized clinical trials (RCTs) of depression treatment.

Method: Data were drawn from two highly cited RCTs of CT for major depression, representing a total of three sites. Trained raters coded sessions for therapist adherence to CT and the therapeutic alliance.

Results: Significant differences were obtained between sites in overall level of adherence to CT, therapist emphasis on cognitive vs behavioral strategies, and therapist focus on homework. In contrast, no significant differences emerged in the collaborative structure of CT and in the therapeutic alliance.

Conclusions: Despite efforts to maximize the consistency of CT implementation (e.g., via the use of the same treatment manuals, delivered by carefully-selected and experienced therapists), differences in the implementation of CT can result. Although preliminary, these findings raise questions regarding the uniformity of CT delivery across published clinical trials, and underline the importance of assessing treatment integrity, both across clinical trials and in dissemination research.

In an effort to ensure that treatments are implemented as intended, psychotherapy researchers have emphasized the importance of monitoring *treatment integrity* (Perepletchikova & Kazdin, 2005), which has been defined as consisting of three components: therapist *adherence* (i.e., the extent to which therapists deliver the prescribed procedures of a given treatment modality, and avoid proscribed procedures), therapist *competence* (i.e., the skill with which these procedures are implemented); and *treatment differentiation* (i.e., when more than one treatment is being investigated, demonstrating that the conditions can be distinguished from one another along critical dimensions; Waltz, Addis, Koerner, & Jacobson, 1993).

Treatment differentiation in regard to theory-specified therapist behavior has been documented in comparative studies of psychotherapies. CT has been differentiated from other treatment modalities based on assessments of transcript material or audio or video recordings of sessions, including interpersonal therapy (e.g., DeRubeis, Hollon, Evans, & Bemis, 1982; Hill, O'Gray, & Elkin, 1992), psychodynamic psychotherapy (e.g., Watzke, Rueddel, Koch, Rudolph, & Schulz, 2008; for reviews, see Blagys & Hilsenroth, 2000, 2002), supportive-expressive psychotherapy (e.g., Luborsky, Woody, McLellan, O'Brien, & Rosenzweig, 1982) and drug counseling (e.g., Luborsky et al., 1982). However, we are aware of no published study that has examined the consistency of the implementation of individual CT across different clinical trials. Treatment outcome studies may assess and report therapist adherence/competence data in their individual outcome trials. However, conclusions about the consistency of treatment delivery across studies are limited until adherence/competence are assessed using the same set of raters (who undergo the same training), using the same measures and assessing adherence/competence at the same time points across studies. Moreover, in addition to comparing overall levels of therapist adherence/competence (i.e., overall mean

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on an adherence or competence scale) across studies, it is also important to examine adherence to the components of treatment (e.g., two studies may report similar mean scores on a measure of therapist adherence to CT, yet significantly differ in the emphasis therapists' placed on the differing components of CT, such as the use of cognitive vs behavioral techniques, homework assignment and review, etc.).

Although Malik, Beutler, Alimohamed, Gallagher-Thompson, and Thompson (2003) did not address the question of the consistency of individual CT across settings, they did compare levels of psychotherapy process variables in three different manual-based formats of CT (individual CT for major depression, group CT for major depression and couples CT for alcohol dependence and depression) as well as in six theoretically-diverse but noncognitive treatments. Using the observer-rated Systematic Treatment Selection Therapy Process Rating Scale (TPRS; Beutler, Clarkin, & Bongar, 2000), the authors compared the treatments on dimensions designed to assess: (1) therapist directiveness, (2) the extent to which the therapist made efforts to deepen the client's in-session emotional experience/arousal, (3) the degree of behavioral vs insight-focused interventions, and (4) the quality of the therapeutic alliance. Malik et al. (2003) found significant differences across the different variants of CT on all of the dimensions except therapist directiveness. As the authors note, the differences in levels of process variables across the CTs could have resulted, at least in part, from the fact that the treatments represented different formats of CT, and they targeted different populations. Moreover, they did not assess adherence to the CT protocol per se, but rather examined a range of broader process variables (e.g., therapist directiveness, the alliance) using a measure (TPRS) designed to differentiate a variety of different forms of therapy.

In the current exploratory study, we directly compared treatment processes in CT for depression at three sites, from two large randomized clinical trials (RCTs; DeRubeis et al., 2005; Dimidjian et al., 2006). Both studies were of individual CT, provided for a total of 16 weeks, for adults diagnosed with DSM-IV Major Depressive Disorder (MDD). Therapists in both studies followed the same CT treatment manuals (Beck, 1995; Beck, Rush, Shaw, & Emery, 1979). In the current study, by applying the Collaborative Study Psychotherapy Rating Scale-Cognitive-Behavioral subscale (CSPRS-CB; Hollon et al., 1988), a commonly-employed measure of therapist adherence to CT, to tape recordings of sessions from these studies, we were able to test for differences in the provision of CT across sites on central CT dimensions, including overall adherence to the CT protocol, delivery of cognitive and behavioral techniques, collaborative structure, and homework assignment. In addition, given the substantial attention the therapeutic alliance has received in the psychotherapy process literature (Horvath, Del Re, Fluckiger, & Symonds, 2011), sites were also compared for the quality of the alliance. To control and allow for tests of the influence of therapist effects on treatment adherence and alliance, therapists were included as a term in our statistical models testing for site differences (see below).

Method

Participants

Patients

All patients from the CT conditions of the Cognitive Pharmacotherapy-II (CPT-II; $N = 60$; DeRubeis et al., 2005) and University of Washington (UW; $N = 45$; Dimidjian et al., 2006) studies were included. The CPT-II study consisted of two sites: one at the University of Pennsylvania and the other at Vanderbilt University ($N = 30$ patients at each site). Both studies targeted adults with MDD, and CT was provided for a total of 16 weeks.

Therapists

In the CPT-II study, four male and two female clinicians (three therapists at each site) served as cognitive therapists. In the UW study, two male and one female clinician served as cognitive therapists (see [1] for additional information on study therapists).

Measures

Collaborative Study Psychotherapy Rating Scale (CSPRS; Hollon et al., 1988)

We utilized the CSPRS' Cognitive-Behavioral (CB) scale, which has been used to rate the extent to which therapists adhere to CBT procedures (e.g., Feeley, DeRubeis, & Gelfand, 1999). The CB scale consists of 28 items organized into 6 subscales, three of which (CB1-CB3) assess therapist use of cognitive methods: Cognitive Rationale (CB1; 3 items), Assessing Cognitive Processes (CB2; 5 items), Evaluating/Changing Beliefs (CB3; 7 items), Behavioral Focus (CB4; 4 items), Homework (CB5; 3 items), and Collaborative Structure (CB6; 6 items). Items are rated on a 7-point scale. The overall means on the CSPRS adherence scale reported in the current study are similar to those reported in previous studies (e.g., Shaw et al., 1999). Previous research suggests that the CB scale can be rated reliably (Hill et al., 1992).[2]

Working Alliance Inventory observer-rated version, short form (WAI-O-S; Tracey & Kokotovic, 1989)

The WAI-O-S is a 12-item observer-rated measure designed to assess the therapeutic alliance. It is a shortened and modified version of the original WAI scales. Based on Bordin's (1979) conceptualization of the alliance, the WAI-O-S consists of three subscales, each with four items: 1) the *bond* between therapist and patient, 2) agreement about the *goals* of therapy and 3) agreement about the *tasks*. Items are rated on a 7-point scale (0 = never to 6 = always). Previous research suggests that the WAI-O-S, referred to henceforth as the WAI, can be rated reliably (Intraclass Correlation Coefficient [ICC] = .77; Strunk, Brotman, & DeRubeis, 2010).

Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960)

The modified 17-item HRSD is a commonly-employed interview-based measure of depressive severity. This modified version includes atypical sleep, appetite, and weight symptoms. It was administered by clinical evaluators weekly for the first 4 weeks of treatment, and biweekly from week 6 to week 16 in the CPT-II

[1] In the CPT-II study, five of the therapists were licensed Ph.D. psychologists, and one was a psychiatric nurse practitioner (MSN). Four of the therapists had extensive CT experience (7–21 years) prior to the initiation of the study. Two of the therapists began the study with two years of CT experience and received additional training from the Beck Institute for Cognitive Therapy during the trial. In the UW study, two of the therapists were highly experienced cognitive therapists, had served as cognitive therapists in previous trials, and had received training at the Beck Institute. The third therapist had received training in CT for anxiety disorders. Each of the three therapists had acquired certification by the Academy of Cognitive Therapy during the course of the study. All three therapists were licenses, two with PhDs and one with an EdD degree. All therapists in both studies followed the procedures outlined in two standard texts of CT for depression (i.e., Beck, 1995; Beck et al., 1979). Local institutional review board (IRB) approval was obtained for all sites and all patients provided written informed consent (For more detailed information on each of the studies, see DeRubeis et al., 2005, CPT-II; Dimidjian et al., 2006, UW). Patients were neither assigned randomly to therapists in either of the studies, nor were they assigned systematically in any other way. The over-riding determinants were availability and the goal of balancing caseloads.

[2] On the original CSPRS, items are rated on a 1–7 scale. However, given that a rating of 1 on any item represents a session in which the given therapist behavior/technique is "not at all" displayed, to simplify the rating process for our coders, the scale was converted to a 0–6 scale prior to the initiation of the study. For consistency with previous research using the CSPRS, a constant of 1 was subsequently added to all ratings.