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Research paper

Patients' comprehension and skill usage as a putative mediator of change or an engaged target in cognitive therapy: Preliminary findings

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ABSTRACT

Background: The skills that patients learn in cognitive therapy (CT) and use thereafter may mediate improvement in depression during and after intervention.
Method: We used a sequential, three-stage design: acute phase (523 outpatients received 12–14 weeks of CT); 8-month experimental phase (responders at higher risk were randomized to continuation phases: C-CT, C-fluoxetine or C-pill placebo); and 24 months of longitudinal, post-treatment follow-up. Path analyses estimated mediation by skill measured by the Skills of Cognitive Therapy (SoCT: Patient and Observer [Therapist] versions).
Results: Better SoCT scores predicted lower depressive symptoms both in CT and C-CT. In CT depressive symptoms did not predict subsequent changes in skills. During CT and C-CT, when averaged across patients and therapists, skills predicted subsequent decreases in depressive symptoms.
Limitations: Generalization of findings may be limited by the trial's methodology.
Conclusion: Further rigorous investigation of the role of patient CT skills stands to increase understanding of mediators of change or engaged targets in psychosocial intervention.

1. Introduction

Cognitive therapy reduces depressive symptoms in adults with major depressive disorder as much as antidepressant medications (Wolf and Hopko, 2008; De Maat et al., 2006; Weitz et al., 2015). However, we do not know enough about how to identify causal processes of the effects in either treatment modality. Over more than three decades, results from randomized clinical trials (RCT) of psychotherapy for depressed adults have informed treatment guidelines and clinical practice (Hollon and Ponniah, 2010). Research sponsors in the United States and clinicians concerned about generalizability have questioned the extent to which not only the RCT methodology, but also taxonomies such as the Diagnostic and Statistical Manuals (e.g., American Psychiatric Association, 2013) can inform the next generation of findings to advance knowledge. For example, the National Institute of Mental Health (NIMH) has offered the Research Domain Criteria (NIMH, "Research Domain Criteria [RDoC]"; Insel and Gogtay, 2014) as a conceptual alternative to the DSM and has promoted experimental therapeutics, along with "target engagement" as a replacement and/or complement to randomized clinical trials to propel the field (Insel et al., 2013; NIMH, "Clinical Trials Funding Opportunity Announcement – Applicant FAQs"; Cuthbert and Insel, 2013). Therein, the target is the mechanism (e.g., molecules, circuits, neural systems, behavior, cognitive processes, provider and organizational responses) that the intervention (e.g., psychotherapy, pharmacotherapy) is hypothesized to change or to "engage" in the process of producing an effect (e.g., benefit or side effect).

Prior to these developments, investigators recognized this gap in the field of psychosocial intervention and called for the similar identification of: a) mediators of change, b) active ingredients, or c) mechanisms of change. The call for identification of processes that mirror what and how therapeutic change occurs is reminiscent of earlier efforts (e.g., Jarrett and Nelson, 1987). However, specific hypotheses paired with informative results on how and why psychotherapy works have been sparse (Forman et al., 2012; Kazdin, 2007). Perhaps progress has been slowed because a) our research methods typically have not been as advanced as our theories and/or b) the field needs first to demonstrate a greater level of therapeutic efficacy overall and/or for particular types

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of patients or conditions before mediators can be uncovered.

In this context, we examine one possible "target" or mediator of change for understanding how symptoms of (recurrent) major depressive disorder change when adults are exposed to cognitive therapy (CT). The overarching hypothesis is that the extent to which patients comprehend and use the skills taught during CT mediates changes in depressive symptoms, and perhaps in psychosocial functioning. We hypothesize that the skills patients learn in (cognitive) therapy develop according to the basic principles of human learning. This hypothesis grew out of the relapse prevention model underlying continuation-phase CT (C-CT) (Jarrett, 1989, 1992; Jarrett et al., 2008). This hypothesis is consistent with the idea and findings that therapy changes the underlying neural structures and/or brain function (Kandel, 2001; Kandel, 2008). As in our previous reports, we have used the term "CT skill" to denote both the patients' comprehension and their usage of skills taught and acquired (Jarrett et al., 2011).

Hundt and associates (Hundt et al., 2013) have described and critiqued the development of methods used to assess the extent to which patients comprehend and use the skills they learn in CT. They reviewed the literature related to the hypothesis that patient skills mediate CT outcomes, and found 13 studies on the frequency of CT skill use and 11 studies on the quality of CT use. They concluded that preliminary findings, although inconclusive, propel additional research evaluating CT skill as a mediator of CT outcomes.

To advance this hypothesis we developed a psychometrically sound, practical measure of patient comprehension and use of cognitive therapy skills, called the Skills of Cognitive Therapy (SoCT) (Jarrett et al., 2011). The SoCT has three valid and reliable versions: Patient (SoCT-P; Jarrett et al., 2011), Participant Observer (SoCT-O), typically the therapist (Jarrett et al., 2011), and Independent Observer (SoCT-IO; Brown et al., 2016). We found that all three SoCT versions predicted acute-phase CT response, SoCT-O predicted stable remission among C-CT patients, and SoCT-P predicted relapse/recurrence and recovery after acute-phase response (Jarrett et al., 2011; Brown et al., 2016; Vittengl et al., 2015). The prediction of relapse is consistent with that of Strunk et al. (2007) who suggested that use "competencies" predicted a lowered risk of relapse over 1 year (post-treatment) in 35 responders who presented with moderate-to-severe-depression. Further, in a sample of 44 depressed patients Adler et al. (2015) found that patients' skills may be related to symptom reduction over the course of CT.

Although researchers have identified some predictors of outcomes, evaluation of mediators of effects has been less frequent. To highlight a gap in the mediational literature, the purposes of this report include: a) to articulate more fully the preceding hypothesis in order to promote future tests of patients' skill comprehension and use in mediation, and target engagement in cognitive therapy, b) to illustrate clinical research methods for such research, and c) to develop the hypothesis further by offering some preliminary data that suggest that the hypothesis is viable, and d) to promote future meaningful tests of skills as a mediator of CT outcomes. Here we test the hypothesis that patients' skills, assessed with the SoCT-P, SoCT-O (Treating Therapist) and/or their combination, mediate improvement in depressive symptoms during and after the: a) acute phase of CT (A-CT) and b) continuation phase of CT (C-CT) in adult outpatients presenting with recurrent major depressive disorder.

2. Method

2.1. Design and participants

Data were drawn from the *Continuation-Phase Cognitive Therapy Relapse Prevention [C-CT-RP] Trial,* registered at ClinicalTrials.gov [NCT00118404, NCT00183664, and NCT00218764]) and described previously (Jarrett and Thase, 2010; Jarrett et al., 2013). Below we summarize methods from the parent trial that are relevant to the current mediational analyses.

Outpatients were recruited through the Internet, local media, printed announcements, and self- and practitioner referrals. Participants (a) met criteria for *DSM-IV* non-psychotic, recurrent MDD using the Structured Clinical Interview for Depression (SCID-I) (First et al., 1996); (b) scored ≥ 14 on the 17-item Hamilton Rating Scale for Depression (HRSD-17) (Hamilton, 1960) at the initial and second interview; (c) were 18–70 years old; and (d) provided informed consent. Excluded individuals (a) had concurrent medical disorders or treatments associated with depressive symptoms; (b) had psychotic or organic mental disorders, bipolar disorder, active substance dependence, predominant obsessive-compulsive or eating disorders; (c) could not speak or write English; (d) were pregnant or planned to become pregnant in the first 11 months after intake; (e) had previously failed to respond to either an 8-week trial of CT by a certified therapist or 6 weeks of 40 mg of fluoxetine; (f) required hospitalization for suicidal ideation; or (g) were unable or unwilling to comply with the treatment protocol.

Participants meeting inclusion criteria and consenting to acute-phase CT (A-CT) (N = 523) were M = 42.4 (SD = 12.1) years old and had completed M = 15.1 (SD = 2.9) years of education; 67.5% were women; 80.9% were white, 10.3% black, and 8.8% other races/ethnicities. Participants' age of MDD onset was 21.2 (SD = 10.8) years and their current major depressive episode had lasted M = 25.0 (median = 10; SD = 45.1) months.

Consenting responders to A-CT (response defined as no MDD and HRSD-17 ≤ 12) who were judged to be at higher risker risk for relapse (based on unstable remission [defined apriori as any of the last seven HRSD-17 scores during acute phase CT ≥ 7]) were randomized. The randomized sample (N = 241) consisted of three arms and included an 8-month continuation phase comparing continuation phase CT (C-CT) (n = 86) versus double-blinded, matched fluoxetine (n = 86) versus pill placebo (n = 69).[1]

After the continuation phase, patients entered a 24-month protocol-treatment-free follow-up. Because the current hypotheses concern CT skills, analyses focus on A-CT and C-CT.

2.2. Cognitive therapy

Patients were withdrawn from psychotropic medications prior to the acute phase. Pharmacotherapy was not provided to A-CT or C-CT patients. Patients were asked to refrain from non-protocol treatments prior to relapse or recurrence, when clinically feasible. As has been described previously, use of non-protocol treatment was monitored, minimal, and did not influence primary findings from the parent trial (Jarrett et al., 2013).

The A-CT protocol (Beck et al., 1979) included 16–20 individual sessions provided by 16 experienced therapists over 12 weeks, with 2 additional weeks allowed for rescheduling. The first 8 A-CT sessions were twice weekly. Thereafter, patients with < 40% reduction in HRSD-17 scores received 8 twice-weekly followed by 4 weekly sessions (20 total), whereas patients with greater early symptom reduction received 8 weekly sessions (16 total). Acute-phase CT aims to reduce depressive symptoms by teaching patients to identify, evaluate, and address negative thoughts via cognitive restructuring and behavioral experiments. Peer therapists and supervisors evaluated therapists' competence using the Cognitive Therapy Scale (Young and Beck, 1980); 93% of 368 sessions evaluated met full competence criteria.

The C-CT protocol (Jarrett, 1989, 1992) included 10 individual sessions provided by the patient's A-CT therapist over 8 months.

[1] The following important protocol violations occurred during the 10 years of data collection: Two patients entered CT with HRSD-17 = 13 at one of the two diagnostic visits. Four (1 early and 3 late) responders were misclassified as late and early responders. Three A-CT non-responders and one lower-risk responder were randomized to the continuation phase in error. As recommended by the Data Safety and Monitoring Board (DSMB), they are analyzed here as they were treated during data collection.