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Title: Modeling Multi-level Dyadic Behavior to Transform the Science and Practice of Psychotherapy Process and Outcome. (DAPPeR)
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2. METHODS

The study (Clinicaltrials.gov identifier NCT03594773) was conducted from July 2018 to March 2021 and enrolled patients at a large, urban, university-affiliated, mental health clinic. All study procedures were reviewed and approved by the Institutional Review Board of the University of Pittsburgh prior to the start of participant enrollment. Potential participants provided informed written consent after receiving a complete description of the study.

2.1 Study Design

This 10-week, randomized, parallel-group study enrolled adult participants with DSM-5-defined Major Depressive Disorder (MDD). We recruited study participants through University of Pittsburgh's online research registry and by advertisement. The study is divided into two phases because of disruptions caused by the COVID-19 pandemic. In Phase 1, psychotherapy was administered in-person. Recruitment and study procedures were halted in March 2020. The study resumed in July 2020 as a completely remote study (Phase 2). In Phase 2, consent forms were sent to participants electronically and then reviewed by telephone. Psychotherapy was conducted over a secure video platform. This study is part of a larger project, Dyadic Behavior Informatics for Psychotherapy Process and Outcome (DAPPeR), in which data from this randomized controlled trial is used to model the dynamics of individual and dyadic behaviors on a moment-by-moment basis within each therapy session and over the course of treatment. Results from the DAPPeR project have been reported elsewhere (Vail et al., 2021; Vail et al., 2022).

2.2 Eligibility

Participants were adults who met the following criteria: (1) age 18-65; (2) DSM 5-defined (American Psychiatric Association, 2013) MDD, current episode (3) Hamilton Rating Scale for Depression-17 items (HRSD-17) (Hamilton, 1960) score ≥ 14; (5) if currently on antidepressant medication, on a stable dose for at least one month at the time of study entry and agreeable to remaining on that dose for study duration; (6) ability to read and speak English fluently, (5) capacity to give informed consent. For Phase 2 (telehealth therapy), the following inclusion criteria were added: (6) access to a computer with a camera and microphone; (7) access to headphones or earbuds that connect to device; (8) access to a private area to complete psychotherapy sessions without interruption; (9) access to broadband internet connection that meets the bandwidth criteria of minimum of 10Mb/sec for upload and download. Participants were excluded from the study if they met any of the following criteria: (1) high risk for suicide, that, in the clinical opinion of the investigator, would warrant a higher level of care such as hospitalization or intensive outpatient programs; (2) current depressive episode has psychotic features; (3) current depressive episode has been present for > 104 weeks; (4) meets criteria for substance use disorders, as defined by DSM 5, in the past 3 months, except for caffeine or nicotine; (5) meets DSM 5 criteria for prior manic or hypomanic episode (bipolar I or II disorder) or a psychotic disorder including schizoaffective disorder or schizophrenia; (6) meets DSM 5 criteria for antisocial personality disorder; (7) significant, unstable, psychiatric co-morbidity that, in the opinion of the investigators, requires an alternative treatment approach (i.e., unstable eating disorder, unstable borderline personality disorder); (8) significant unstable medical illness that may explain depressive symptoms such as epilepsy, autoimmune disorder, chronic pain, or unstable endocrine disorder; (9) cognitive deficits that would preclude completion of study questionnaires or participation in psychotherapy; (10) unable or unwilling to comply with study requirements; (11) neurologic or medical condition that would interfere with nonverbal communication; at the discretion of the investigative team (e.g., severe visual impairment or facial paralysis).

Therapists were also research participants in this study and consented to participation. Inclusion criteria for therapist-participants were: (1) currently functioning as a therapist or supervisor for the Center for Advanced Psychotherapy (CAP) clinic; (2) capacity to give informed consent. There were no exclusion criteria for therapists.

2.3 Allocation

As shown in the CONSORT diagrams for Phase I and 2 (Figure 1), 638 potential participants during the Phase 1 study period and 149 during Phase 2 agreed to initial screening for inclusion in the protocol to yield 49 individuals eligible for randomization in Phase 1 and 28 in Phase 2. Participants were randomly allocated to either brief CBT (n=24 in phase 1; n=11 in phase 2) or brief IPT (n=25 in phase 1; n=17 in phase 2) by an independent data manager not otherwise involved in the clinical trial using a permuted block strategy (Matts and Lachin, 1988). The allocation sequence was concealed from all study personnel. Randomization was stratified by gender and depression screening scores, which accounts for imbalances in cell sizes.

2.4 Outcome Measures

Raters blind to treatment assignment conducted assessments in person (phase 1) or by telephone (phase 2) at baseline, midpoint (week 5), and post-treatment (week 10) except as indicated below. Self-report measures were collected online. Demographic data were recorded on standardized research forms. Psychiatric diagnoses were assigned using Mini-International Neuropsychiatric Interview (MINI version 7.0) (Sheehan et al., 1998). Information about antisocial personality disorder diagnosis was collected using the Structured Clinical Interview for DSM 5—Personality Disorders (SCID-5-PD) (First et al., 2016) Depressive symptoms were assessed using the clinician-rated HRSD-17 (primary outcome measure) and Montgomery Asberg Depression Rating Scale (MADRS) (Montgomery and Asberg, 1979), and the self-report Quick Inventory of Depressive Symptomatology-Self Report (QIDS-SR) (Rush et al., 2003). HRSD-17 scores range from 0 to 52, MADRS scores range from 0 to 60, and QIDS-SR scores range from 0-27, with higher scores indicating greater depression severity on all depression measures. QIDS scores were collected at each therapy visit. Anxiety was rated using the self-reported 7-item Generalized Anxiety Disorder Assessment (GAD-7) (Spitzer et al., 2006) with scores ranging from 0 to 21, with higher scores indicating greater anxiety severity. The self-reported World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0), a 36-item measure with higher scores indicating more impairment, was used to assess global functioning (Federici et al., 2017). Acceptability of the intervention was assessed post-treatment with the Client Satisfaction Questionnaire (CSQ) (Attkisson and Greenfield, 1994) which yields scores ranging from 8-32 with higher scores indicating greater levels of satisfaction.
Both patients and therapists completed brief versions of the Working Alliance Inventory (WAI) (Horvath and Greenberg, 1989) after each therapy session. The therapist (10 items) and patient (12 items) versions of the WAI are designed to yield three alliance scales, corresponding to Bordin's components: Goal, Task, and Bond (Bordin, 1979). Higher scores indicate a more positive rating of working alliance. Both patients and therapists completed the 21-item Strategies in Therapy Use Form (STUF) after each therapy session. The STUF measure, developed for this study, is derived from patient and therapist self-report measures of the Psychotherapy Quality Questionnaire (PQQ) developed by Miranda and colleagues (Hepner et al., 2010; Miranda et al., 2010) to assess psychotherapy use in usual care settings. STUF measures therapeutic strategies used in sessions and is scored to yield IPT, CBT, and non-specific (NS) subscales. Higher scores on the STUF subscales indicate greater use of strategies related to the therapy modality. The CBT, IPT and NS scales showed a high degree of internal reliability across all 8 sessions for both the patient and therapist ratings (Cronbach alphas: .72 - .97; McDonald's Omegas: .70 - .97).

2.5 Interventions

Each participant was assigned an individual therapist who administered up to 8 sessions of psychotherapy weekly over a 10-week period, allowing for missed/rescheduled sessions. Each session

lasted 50 minutes. In Phase 1, psychotherapy was administered in person; in Phase 2, psychotherapy was delivered over a HIPAA-compliant version of Zoom.
Brief IPT (IPT-B) addresses problematic interpersonal issues related to onset or maintenance of mood episodes (Weissman et al., 2018). IPT-B is designed to deliver a full course of IPT in 8 sessions, roughly half the length of "full dose" 16-session IPT (Swartz et al., 2004; Swartz et al., 2014). IPT-B offers the dual advantages of rapid relief from suffering and reduced practical barriers (time commitment) for overwhelmed populations (Swartz et al., 2014). In IPT-B, the therapist chooses one of three possible problem areas (grief, role disputes, or role transitions) to serve as the focus of treatment with the goal of selecting a relevant interpersonal issue that can be resolved in 8 sessions.
For *Brief CBT*, we adapted a CBT protocol designed to be administered over 4-8 sessions as an 8-session Brief CBT intervention (Cully and Teten, 2008). CBT focuses on modifying maladaptive thoughts and behaviors, using a combination of cognitive restructuring, behavioral activation, and problem solving and has a typical duration of 12-20 sessions (Beck et al., 1979). The first session consists of gathering additional information about current symptoms and goal setting. Each session began with setting an agenda and focusing on explicit goals, as well as eliciting feedback from the patient about the session. Patients were given homework assignments to practice skills between sessions. The relative focus on cognitive versus behavioral skills was adapted to the specific patient.

2.6 Statistical analysis

Analyses were conducted using SPSS28 and HLM8 (SSI, Inc.) statistical software. To compare groups by treatment and phase on baseline demographic and clinical characteristics, and treatment dropout rates and number of sessions completed, Cramer's V and Mann-Whitney Wilcoxon tests were used to compare nominal and ordinal variables, respectively. Independent samples t-tests were used to compare groups by treatment and phase on overall client satisfaction (CSQ). Analyses of outcome and process variables were conducted using hierarchical linear models (HLM, also known as linear mixed effects models) with weekly measures nested within persons (patients) and modeled with random slopes and intercepts, an unstructured variance/covariance matrix, and robust standard errors. HLM allows for inclusion of all subjects with at least baseline data and addresses missing data by using restricted maximum likelihood (REML) estimation. Time was centered at 10 weeks, and variables used for randomization stratification (gender and HRSD-17 screening scores) were included as covariates in all HLM models. Cohen's d-type effect sizes (absolute values) were calculated from model estimates for HLM models and from raw values for simple t-tests.