The Roles of the Therapeutic Alliance in Understanding the Effects of Attachment Orientations on Outcome in Psychotherapy

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Study design

The study is designed to reach an assignment ratio of 1:1 for supportive-expressive vs. supportive treatment. Assignment to treatment arm is conducted by an outside institution, not involved in the study, the Biostatistics Department of the Gertner Institute for Epidemiology and Health Policy Research. Assignment to treatment arm is based on the minimization algorithm). Factors for balancing are age (higher or equal vs. lower than 30), gender (male vs. female), family status (married/cohabiting vs. not married/cohabiting), baseline 17-item Hamilton Rating Scale, HRSD (higher or equal vs. lower than 20), baseline attachment avoidance (higher or equal vs. lower than 3.5 on the Experience in Close Relationships, ECR; see details in the Measures section), baseline attachment anxiety (higher or equal vs. lower than 3.5 on the ECR), and personality disorders (present vs. absent). Except for the therapist, the entire research team is blind to the patients' assignment to treatment.

Participants

One hundred patients with MDD are being recruited through advertisements in the central regions of Israel, offering free treatment at the psychotherapy research lab clinic.

Inclusion criteria

(a) MDD diagnostic criteria using the structured clinical interviews for DSM-V, with scores above 14 on the 17-item HRSD at two evaluations, one week apart, and current MDD based on the MINI (International Neuropsychiatric Interview;) (b) if on medication, patients' dosage must be stable for at least three months before the start of the study, and they must be willing to maintain stable dosage for the duration of treatment; (c) age between 18 and 60 years; (d) Hebrew language fluency; (e) provision of written informed consent.

Exclusion criteria

(a) current risk of suicide or self-harm (HRSD suicide item > 2); (b) current substance abuse disorder; (c) current or past schizophrenia or psychosis, bipolar disorder, or severe eating disorder, requiring medical monitoring; (d) history of organic mental disease; (e) currently in psychotherapy.

Treatments

Patients will receive 16 50-min sessions of SE treatment (SE), a time-limited psychodynamic therapy adapted for depression, either in an expressive-focused condition (including the use of expressive techniques, such as interpretation, confrontation, clarification), or in a supportive-focused condition (including the use of supportive techniques, such as affirmation and empathic validation). We use comprehensive treatment protocols. For SE treatment, we use the Luborsky manualized treatment. The supportive condition includes all supportive techniques detailed in the manual used by Luborsky, but forbids the use of any expressive techniques, as detailed in. After the end of treatment, once a month, a maintenance session will be provided to all patients with their treating therapists, for a total of 4 follow-up sessions.

Therapists

Therapists will act as their own controls to avoid nesting of therapists within treatment conditions, which may result in unwanted confounding. This approach has been found to be feasible in previous trials. To control for therapist allegiance, all therapists will be asked to report their preferences before the start of treatment, and we will control for these preferences in the analyses.

Therapists interested in participating in the RCT answered ads seeking psychologists with at least five years of expertise in psychodynamic treatment, willing to participate in an RCT on short-term psychodynamic treatment. After interviews, eight therapists were accepted into the study. All had formal training and experience in psychodynamic treatment. The therapists attended a 20-h training workshop in supportive and expressive techniques. The training included formal teaching and role playing, using the different techniques. Two of the therapists did not continue after the training phase for various reasons (one being offered a full-time position elsewhere, the other demonstrating low levels of adherence).

All therapists completed treatment of two pilot patients, one of each treatment type, and had to demonstrate sufficient adherence before moving into the trial phase. During the pilot phase, and after the start of the research, each therapist received weekly group supervision from two supervisors, as well as weekly individual supervision from one of the supervisors. Individual and group supervisions make extensive use of videotaped sessions for feedback. The supervisors are licensed clinical psychologists, with extensive supervision experience. The supervisors receive supervision concerning the supervision process from an international expert in SE, with more than 20 years of experience in psychodynamic treatment for depression, and more than 15 years of experience in SE treatments in RCTs.

Fidelity check

We use the Penn Adherence-Competence Scale (PACS) to examine the degree to which therapists adhere to the manual in the techniques they are using, whether they are competent in the use of the technique, and whether they avoid the use of techniques that are forbidden (based on the condition to which their patient was assigned). The PACS includes 3 subscales: general therapeutic behaviors, the supportive component, and the expressive component. The two conditions of the present study are expected to differ on the expressive component. The research team is supervised by an international expert on the use of the PACS, with vast experience in using the PACS in RCTs on SE treatment. In instances of low adherence or competence, relevant supervision tools will be deployed. As detailed above, therapists attend weekly individual and group supervisions for the entire duration of their participation in the study. In the supervision session, videotaped sessions are being analyzed, looking for instances of deviations from the manual to be worked through.

Procedure and randomization

Applicants are recruited by self-referral, based on advertisements. Recruitment information is disseminated by posters, local media, and online publications (social media, etc.). Application is by email or phone. In an initial phone screening, the interested individuals are informed about the study procedure and the relevant inclusion and exclusion criteria. If there are indications of depressive complaints, applicants who consent to the research intake procedure are asked to complete the BDI-II (Beck Depression Inventory). To ensure

high levels of severity of depressive symptoms, applicants must score at least 19 points on the BDI-II. Applicants who scored 19 points and above on the BDI-II are contacted to schedule an initial intake meeting during which researchers explain the study, and there is opportunity to discuss any questions. Applicants receive written and oral information about the content and extent of the planned study. This includes information about the treatment, including safety and possible risks, the information that all treatment sessions are videotaped, and about their right to withdraw from the research at any time. Applicants who agree to participate are required to sign the informed consent form. At the first face-to-face assessment, the HRSD interview is administered, and participants receive a baseline battery of questionnaires, including demographic information, concurrent medication, and measures of personality characteristics and comorbid conditions. At the second interview, the HRSD and the MINI are administered to measure the presence and severity of baseline symptom and comorbid conditions, and participants provide saliva samples.

The first and the second interviews of all participants, as well as all the assessments before and after each session, are administered by the same evaluator who has been extensively trained and was found to be reliable in the use of the HRSD and the MINI. The evaluators are trained in the administration of both measures. After successfully completing two months of extensive training and achieving high reliability, evaluators begin by observing another evaluator at work, after which they administer the measures with a trained evaluator for several weeks, before performing the evaluation by themselves. Throughout the trial period, the reliability of the evaluators is evaluated on a weekly basis.

After the second interview, a third face-to-face meeting is scheduled, at which the Structured Interview for DSM-IV Personality, SIDP [50] is administered by a different trained and reliable evaluator, to assess comorbid personality disorders. The evaluators are trained in the administration of the measure. After successfully completing extensive training and achieving high reliability, evaluators begin by observing another evaluator at work. Next, they administer the measures together with a trained evaluator for several weeks, before performing the evaluation by themselves. Throughout the trial period, the reliability of the evaluators is assessed every week. If eligible for the study, participants receive further written and oral information about the treatments and about the full research procedure and assessments, before being randomized to one of the treatment conditions. They also indicate whether they can be contacted again after the study for additional waves and for extending the follow-up period beyond the specified two years.

Applicants who are not eligible for the study (having not met the inclusion criteria or having met an exclusion criterion), yet request psychotherapy, are referred to appropriate care. Participants meeting inclusion criteria are randomized to one of the two treatment arms. Researchers, assessors, intakers, and the entire research team remain blind to treatment allocation. The only team members who are exposed to treatment assignment are, by necessity, the therapists and clinical supervisors. The following strategies are used to minimize bias that could arise from revealing treatment allocation: (a) all patients are blind to treatment allocation; (b) all process and outcome assessors are blind to treatment allocation; (c) therapists are regularly reminded that they are not allowed to disclose treatment allocation to any member of the team; (d) patients and outcome assessors are

asked to guess which treatment was given so that the effects of possible bias can be examined in the analysis; and (e) all outcome assessor interviews are audiotaped, and 30% randomly assigned tapes rerated by independent rates. If blindness is broken, all subsequent assessments will be carried out by an alternative assessor. If patients withdraw from treatment before the end of active treatment, dropout questionnaires are administered to both the patient and the therapist (Post Session Questionnaire, PSQ; [51]). In the course of the active phase of treatment, the HRSD is measured weekly, and self-report questionnaires are administered. Saliva samples and cognitive tasks are measured before the start of treatment and on weeks 4, 8, 12, and 16. The MINI and SIDP are measured at weeks 8 and 16.

After the completion of the active phase (16 weeks), the first four follow-up sessions include maintenance sessions with the therapist, HRSD administration, and completion of a battery of self-report questionnaires. The MINI is administered at the first and third follow-up meetings. The three subsequent follow-up sessions do not include sessions with the therapist, and are scheduled for two months after the last follow-up session (six months after the end of the active treatment phase of 16-weeks), one year after the end of the active phase, and two years after the end of the active phase. At these three additional follow-up sessions, the HRSD and the MINI clinical interviews are administered, and selfreport questionnaires are completed. In the first two additional follow-up sessions the SIDP clinical interviews is administered as well.

Measures

The primary outcome measure of the trial is the HRSD [41], a 17-item clinically administered measure assessing the severity of depression. The assigned score is calculated by summing up all 17 items. Using, among others, the measures listed below, we also assess secondary outcomes, such as self-reported symptoms (i.e., BDI; [49]; BAI, Beck Anxiety Inventory, OQ30), interpersonal functioning (i.e., IIP, Interpersonal Problems Inventory, ECR, Experience in Close Relationships), and quality of life (Q-LES-Q, Quality of Life Enjoyment and Satisfaction).
We also assess several process measures, such as the working alliance (WAI, Working Alliance Inventory) and therapeutic interventions (MULTI, Multi-theoretical List of Therapeutic Interventions).

Data analyses

All analyses will follow the intention-to-treat principle. Characteristics of the treatment groups will be described at baseline. To examine the potential moderating influence of attachment anxiety and attachment avoidance on the effect of treatment condition on outcome, we will use a multilevel hierarchical linear model with observations nested within patients. We will test two 3-way interactions of time, treatment condition, and attachment orientation (anxiety, avoidance) in predicting HRSD during active treatment (until Week 16).

Ethical considerations

The study design, procedure, and informed consent form were approved by the University of Haifa ethical committee (approval number: 118/15, Date: 10/10/2015). Participants receive detailed information about the study procedure in an oral explanation and in writing. Participants receive complete information regarding the implications of their participation, including potential risks, inconvenience, and benefits, their ability to stop their participation at any time without adverse consequences, issues of confidentiality, etc. An elaborate data management plan ensures careful handling of confidential data in all stages of the research process. In case of a serious adverse event (e.g., critical suicide risk), the RISK protocol will be activated, and a special committee trained to handle such situations, including three licensed clinical psychologists, will immediately take charge.