Shorter communication

Treatment preference, engagement, and clinical improvement in pharmacotherapy versus psychotherapy for depression

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ABSTRACT

Pharmacotherapy and psychotherapy are generally effective treatments for major depressive disorder (MDD); however, research suggests that patient preferences may influence outcomes. We examined the effects of treatment preference on attrition, therapeutic alliance, and change in depressive severity in a longitudinal randomized clinical trial comparing pharmacotherapy and psychotherapy. Prior to randomization, 106 individuals with MDD reported whether they preferred psychotherapy, antidepressant medication, or had no preference. A mismatch between preferred and actual treatment was associated with greater likelihood of attrition, fewer expected visits attended, and a less positive working alliance at session 2. There was a significant indirect effect of preference match on depression outcomes, primarily via effects of attendance. These findings highlight the importance of addressing patient preferences, particularly in regard to patient engagement, in the treatment of MDD.

Major depressive disorder (MDD) remains a significant public health problem worldwide. Clinical research suggests that the use of pharmacotherapy and psychotherapy, both singly and in combination, are efficacious treatments for depression (see Hollon, Thase, & Markowitz, 2002). However, it is widely recognized that the efficacy of treatments for depression in clinical practice is limited by multiple factors, including premature dropout and non-adherence (e.g., Keller, Hirschfeld, Demyttenaere, & Baldwin, 2002; Melfi et al., 1998). The preferences of patients for a given type of treatment for depression may influence their willingness to start treatment, complete treatment, and engage fully in the course of treatment (Corrigan & Salzer, 2003; Raue & Schulberg, 2007). Patient preference has been identified as a predictor of randomized trial recruitment (King et al., 2005) and attrition, with typically small effects on primary outcomes (Preference Collaborative Review Group, 2008), in randomized trials across clinical domains.

Studies examining patient preference as a predictor of outcome in randomized clinical trials (RCT) for the treatment of depression have provided equivocal evidence regarding the hypothesis that patient preferences directly affect clinical outcomes, with various studies reporting no relationship between preference and outcome (Dobscha, Corson, & Gerrity, 2007), small, inconsistent, non-significant relationships (Leykin et al., 2007), or significant effects (Kocsis et al., 2009). However, as suggested by TenHave, Coyne, Salzer, and Katz (2003), it is possible that preference matching may not have a robust effect on changes in severity of depression, but may have indirect benefits such as enhanced engagement with treatment protocols and better therapeutic relationships.

There appears to be some support for this indirect effect. Relationships between patient predilections for a specific depression treatment and early attrition and engagement in therapy have been demonstrated (Elkin et al., 1999). Laglietti et al. (2007) determined that lack of congruence between patients’ treatment preference and actual treatment was associated with decreasing therapeutic alliance over time, but only for those initially preferring psychotherapy over medication. Qualitative data show that those who dropout from psychotherapy cite a mismatch with the therapeutic approach as a reason for their decision (Wilson & Sperlinger, 2004).

Given the limited and at times equivocal findings, greater clarity of the relationship between preference and key clinical outcomes such as dropout, alliance, and clinical improvement is needed. Previous studies typically have not examined the relationship between preference and multiple direct (i.e., clinical improvement) and indirect (alliance, attendance, dropout) outcomes. A further limitation of previous studies is a lack of concrete assessment of preferences. For example, treatment attrition is often equated with non-preference, but explicit measurement of preference prior to the initiation of treatment often has not been carried out.
The current study builds on prior research by assessing preferences directly and examining multiple indirect and direct outcomes in the context of a large randomized clinical trial (RCT). This RCT compared two psychotherapies (behavioral activation and cognitive therapy) and pharmacotherapy (paroxetine plus clinical management) in a placebo controlled trial for adults with MDD. Specifically, we examined the role of patient preferences in predicting willingness to start treatment, treatment completion, development of a positive working alliance, and improvement in depressive severity over the course of acute treatment. We further examined whether there were significant indirect effects of preference match on changes in depression via attendance and early alliance. We hypothesized: 1) compared to those randomized to their non-preferred treatment, those randomized to their preferred treatment would be more likely to demonstrate acceptance of the intervention as defined by being more likely to a) start treatment, b) attend more sessions, and c) to complete treatment; 2) compared to those randomized to their non-preferred treatment, those randomized to their preferred treatment would have higher early ratings of alliance with their clinician; and 3) there would be a significant indirect effect of preference match on depression outcomes via attendance and early alliance.

Method

Participants

The University of Washington Institutional Review Board approved the protocol. All participants provided written informed consent prior to participation. Details regarding recruitment, eligibility criteria and screening are available elsewhere (Dimidjian et al., 2006). For the current study, the final sample consisted of the 106 individuals who completed a treatment preference questionnaire. See Table 1 for sample characteristics.

Procedures

Participants were randomly assigned to condition according to a computer generated randomization list: psychotherapy (behavioral activation (BA) or cognitive therapy (CT)), antidepressant medication (ADM; paroxetine), or pill placebo. The placebo group was only included in the analysis of who started treatment vs. withdrew following randomization, as we were primarily interested in the relationship between preference and active treatments. Participants completed a baseline questionnaire prior to randomization that included an assessment of treatment preferences. Participants completed standard outcome assessments at baseline, mid-, and post-treatment (approximately 8 and 16 weeks), and at non-standard time points as clinically indicated (e.g., early termination). Participants and clinicians also completed a measure of working alliance at Session 2 and at 4, 8, and 16 weeks after beginning therapy. For the purposes of this study, only the Session 2 ratings of the working alliance are included, as we were particularly interested in the effects of preference on alliance formation and later alliance ratings may be influenced by many factors, including symptomatic improvement (e.g., Feeley, DeRubeis, & Gelfand, 1999).

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Sample means/frequencies (N = 106)</th>
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</thead>
<tbody>
<tr>
<td>Age: M (SD)</td>
<td>38.4 (11.7)</td>
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<tr>
<td>Gender: N (%)</td>
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<tr>
<td>Female</td>
<td>68 (64.2)</td>
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<td>Race: N (%)</td>
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<td>White</td>
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<td>Relationship status: N (%)</td>
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<tr>
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<tr>
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<td>Income level: N (%)</td>
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<td>&lt; 10,000</td>
<td>13 (12.3)</td>
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<td>12 (11.3)</td>
</tr>
<tr>
<td>≥ 50,000</td>
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</table>

Measures and criteria

Depressive severity measures

Depressive severity was assessed at pre-, mid-, and post-treatment with the Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996) and a modified 17-item Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960). The BDI-II is a widely used self-report measure of depression and is psychometrically sound (Beck et al., 1996). The HRSD is a widely used interviewer-administered measure of depression and has been shown to be valid and reliable (Williams, 1988).

Treatment preferences

Preferences were assessed using the Expectations for Treatment Inventory (ETI; e.g., Leykin et al., 2007). At intake, participants reported whether they preferred “pharmacotherapy,” “talking therapy,” or had “no preference.” They also reported whether they expected pharmacotherapy or talking therapy to be more effective in treating their depression, or if they did not expect one to be any more effective than the other.

Therapeutic alliance

The therapeutic alliance between patient and therapist was assessed using a short form of the Working Alliance Inventory (WAI; Horvath & Greenberg, 1989). The short form of the WAI is a 12-item scale with three subscales, each with four items, for task, bond, and goal alliance. A total composite score represents overall alliance, with higher scores indicating greater perceived alliance (client: α = .93; therapist: α = .96).

Refusal of randomization

Those who terminated after being informed of their random assignment and prior to attending a single session were defined as “refusing randomization.” These participants are only included in the analysis of randomization refusal.
Study Attrition. Participants were categorized according to whether or not they completed the study. Study completion was defined as attendance at the final expected treatment session.

Session attendance
Session attendance was calculated as percent of allowable sessions attended. The maximal number of expected sessions varied by treatment condition. The protocol allowed 10 sessions for ADM and 24 for psychotherapy.

Treatments
CT was provided in a manner consistent with standard CT for depression, including an integration of behavioral and cognitive strategies (Beck, Rush, Shaw, & Emery, 1979; Beck, 1995). BA was provided as an expanded version of the behavioral interventions described by Beck et al. (1979) and consistent with Martell, Addis, and Jacobson (2001). Participants in BA or CT were seen up to 24 sessions over a 16 week period, with visits largely occurring twice a week for the first 8 weeks and once weekly after that point. The ADM condition followed the clinical management protocol developed for the TDCRP, modified for use with an SSRI (Fawcett, Epstein, Fiester, Elkin, & Autry, 1987). Participants in ADM were seen weekly for the first 4 weeks, and then biweekly through 16 weeks (with those in the placebo condition terminating at 8 weeks). All therapists were trained and supervised by experienced study personnel (see Dimidjian et al., 2006, for more details).

Analysis overview
The General Linear Model procedure was used for continuous outcomes and Binary Logistic Regression for dichotomous outcomes, using contrast codes for the preference variable. Individuals matched with their preferred treatment condition were coded +1. Those mismatched were coded −1, and those who had no preference were coded 0. Polynomial contrasts were specified in the GLM procedure. This allowed us to maximize power by utilizing all participants, including those who reported no preference. The linear contrasts compared means for the matched vs. the mismatched groups, ignoring the no-preference group, while quadratic contrasts compared means for the no-preference group to the preference groups. Where cell sizes permit, we examined interactions between experimental condition and preference to determine if the effect of preference on the dependent variables varied based on whether a patient received psychotherapy or ADM. Multilevel modeling was used to examine the direct effect of preference on changes in HRSD and BDI scores over time.

Indirect effects of preference match on changes in HRSD scores were estimated using a path analysis in AMOS 17.0, in which attendance and WAI-total scores were specified as mediators of the effect of preference match on depression. Two orthogonal contrast codes for preference match were specified as exogenous variables, one for the contrast of match vs. mismatch and one for the contrast of preference vs. no preference. Within-subject intercepts and slopes for changes in HRSD scores were calculated using individual regression models, and used as outcome variables. The model tested included direct paths from the preference codes to alliance and attendance, and from these mediators to HRSD slopes and intercepts. Following the recommendations of Preacher and Hayes (2008) for multiple mediator models, we performed a bootstrapping analysis, using 1000 samples and bias-corrected confidence intervals.

Results

Treatment preferences
On the ETI, 51 participants (48.1%) preferred psychotherapy, 19 (17.9%) preferred ADM, and 36 (34.0%) expressed no preference.

Intervention acceptance

Refusing randomization
Twelve of 106 participants (11.3%) refused randomization. Of those randomized to their non-preferred group, 7 out of 44 (15.9%) refused randomization. Five out of 36 individuals (13.9%) who expressed no preference refused randomization. No participants randomized to their preferred group refused randomization (vs. non-preferred, \( \chi^2 (N = 70, df = 1) = 4.60, p = .03 \); See Fig. 1). Among those who were mismatched, most (84.1%) did in fact start treatment; however, among those who refused randomization, none had been matched to their preferred treatment.

Of those randomized to psychotherapy (CT or BA), 2 out of 33 (6.1%) refused randomization. Of those randomized to pharmacotherapy (Placebo or ADM), 10 out of 73 (13.7%) refused randomization. Those randomized to pharmacotherapy had about 50% greater odds of refusing randomization than those randomized to psychotherapy, \( OR = 1.57, \) Wald \( \chi^2 (1) = 1.25, p = .26 \), although this effect was not statistically significant. The effect of preference mismatch on refusing randomization appeared about equal for those randomized to ADM but preferring psychotherapy (16.2% refused randomization) and those randomized to psychotherapy but preferring ADM (14.3% refused randomization). Logistic regression could not be used to test the interaction between condition and preference on refusing randomization because of the “empty” cell — i.e., there were no participants matched to their preferred treatment who refused randomization.

Study completion
Not including individuals randomized to placebo or refusing randomization, 73 participants started psychotherapy or ADM; of these, 18 (24.6%) did not complete the study. Of the 26 randomized to their non-preferred group, 12 (46.2%) did not complete the study as compared to 5 out of 27 (18.5%) of those expressing no preference, and 1 out of 20 (5.0%) of those randomized to their preferred group. Participants had significantly higher odds of dropping out of treatment if they had been randomized to their non-preferred treatment group as compared to those randomized to their preferred treatment group, \( OR = 7.19, \) Wald \( \chi^2 (n = 73, df = 1) = 6.45, p = .01 \) (Fig. 1).

![Fig. 1. Failure to start or complete treatment by preference match.](image-url)
Most of those who did not complete the study (77.8%) were in the ADM condition. The odds of completing the study were about 50 percent lower (OR = .54, Wald $\chi^2 = 3.75, p = .05$) for those in the ADM condition compared to the psychotherapy conditions. The effect of preference match on study completion did not depend on treatment group (Wald $\chi^2 = .22, p = .9$). However, the effect of preference mismatch on study completion appeared slightly lower for those randomized to ADM but preferring psychotherapy (50.0% completed) than those randomized to psychotherapy but preferring ADM (66.7% completed).

**Attendance**

Among all patients who started treatment, individuals matched to their preferred group attended 89.1% of expected visits, individuals without a preference attended 84.9% of expected visits, and mismatched individuals attended 70.4% of expected visits. Those randomized to their preferred treatment group attended a significantly greater proportion of expected sessions ($M = .89, SD = .12$) than those randomized to their non-preferred group ($M = .70, SD = .31$), partial $\eta^2 = .10$, $F(1,70) = 7.56, p = .007$. There were no differences in the proportion of sessions attended between those in ADM ($M = .80, SD = .26$) and those in BA/CT ($M = .82, SD = .20$), partial $\eta^2 = .00$, $F(1,71) = .08, p = ns$. The effect of preference (match vs. mismatch) on session attendance did not depend on treatment group, partial $\eta^2 = .01$, $F(1,67) = .65, p = .42$.

**Working alliance**

At session 2, patient-rated working alliance (total score) was significantly higher among those randomized to their preferred treatment condition ($M = 5.76, SD = .80$) than those randomized to their non-preferred treatment ($M = 4.96, SD = 1.12$), Partial $\eta^2 = .10$, $F(1,54) = 5.86, p = .02^{2}$ (Fig. 2). The effect of preference match on WAI-total scores did not depend on condition, $\beta = .14, SE = .17$, Partial $\eta^2 = .01$, $F(1,51) = .64, p = ns$. There were no significant differences in therapist-rated WAI-total scores for patients randomized to their preferred group ($M = 4.68, SD = .64$) compared to those randomized to their non-preferred group ($M = 4.38, SD = .87$), Partial $\eta^2 = .02$, $F(1,57) = 2.28, p = .26$. There were no effects of condition on the relationship between preference match and therapist-rated WAI scores, partial $\eta^2 = .00$, $F(1,54) = .14, p = ns$.

There were significant differences between conditions in both patient and therapist WAI ratings from session two. Patients in BA/CT rated the working alliance (total score) significantly higher than those in ADM ($M = 5.90, SD = .67$ and $M = 4.88, SD = 1.08$, respectively), partial $\eta^2 = .25$, $F(1,55) = 18.14, p < .001$. Similarly, BA/CT therapists rated the working alliance more positively than pharmacotherapists ($M = 4.79, SD = .70$ and $M = 4.30, SD = .79$, respectively), partial $\eta^2 = .10$, $F(1,58) = 6.45, p < .05$. Also, on average, patient-ratings were .86 ($SD = .96$) points higher than therapist-ratings, $t(52) = 6.56, p < .001$.

**Preference and outcome**

Fig. 3 shows changes in HRSD scores over time by preference match. The direct effect of preference match on change in HRSD over time was not significant, $\beta = -.08, SE = .09, F(1,98) = .77, p = .38$, although directionally this suggests slightly greater effects of preference match on changes in HRSD scores over time for those in ADM than those in psychotherapy. There was also no significant effect of match vs. mismatch on changes in BDI scores over time, $\beta = -.10, SE = 1.01, F(1,110) = 1.12, p = .29$ (effect size = .25, a small effect).

Indirect effects of preference match on HRSD scores were tested according to the model illustrated in Fig. 4. Initially, this model was not a good fit to the data, $\chi^2(N = 57, df = 4) = 10.14, p = .038$, CFI = .733, RMSEA = .17 (90% CI: .035, .296). Upon closer inspection of the covariance matrix, we noted a significant negative correlation between match vs. mismatch and HRSD intercepts. When allowing these variables to covary, the model fit was excellent, $\chi^2(N = 57, df = 3) = 1.72, p = .632$, CFI = 1.00, RMSEA = .00 (90% CI: .000, .18). In both models, there was a significant indirect effect of match vs. mismatch on HRSD slopes, est = -.12 (90% CI: -.21, -.05), $p = .003$, and 16% of the variance in HRSD slopes was explained (primarily by attendance). An identical analysis using BDI scores produced similar results.

**Discussion**

This study examined the effects of patient preferences on a range of outcomes in an RCT of the treatment of major depression. Results suggest several negative implications of being randomly assigned to a non-preferred mode of treatment. Mismatch had an effect on whether patients started treatment, such that none of those who refused randomization received a preferred treatment. Similarly, those randomized to a non-preferred treatment were more likely to dropout of the study and attend fewer expected visits. Patients assigned to a non-preferred treatment also reported a less positive early therapeutic alliance than those assigned to a preferred treatment. These findings converge with efforts in collaborative care highlighting the importance of patient preferences in staying in treatment for depression (Byrne, Regan, & Livingston, 2006). These results are thus consistent with the suggestion that preference matching influences indirect outcomes (Ten Have et al., 2003).

We did not find significant direct effects of preference mismatch on improvement in depression over the course of treatment. This is consistent with the findings of Leykin et al. (2007), who also found
small, non-significant effects of preference matching on depression outcomes, using a similar study design. MacKinnon, Lockwood, Hoffman, West, and Sheets (2002) have noted that a lack of such direct effects of distal factors on primary outcomes is not uncommon when effect sizes and sample sizes are small and that it is possible to observe significant indirect effects via more proximal mediators. Given the significant effects of preference match on both attendance and early alliance, we used a path analysis to examine whether these variables mediated the effect of preference match on improvement in depression. This hypothesis was supported by our data, with 16% of the variance in depressive severity improvement explained (a medium effect size), primarily by a direct effect of attendance.

Thus, preferences appear to have an indirect effect on depression outcomes via commitment to and engagement in therapy. When patients do not receive a preferred treatment, they may be less likely to start treatment, stay in treatment, and attend an adequate number of treatment sessions. Even for the most efficacious treatments, patients need to remain in treatment long enough to provide an opportunity to benefit from the treatment procedures. In fact, we may have underestimated the indirect effect of preference match on depression outcomes if symptom severity persisted or worsened for those who failed to start treatment (strongly predicted by preference match) or dropped out prior to 8 weeks (in which case their data were not available to be included in the analysis of change in depression). Furthermore, there are potentially other mediators of the preference-depression relationship not tested here (e.g., treatment adherence). It is also possible that some participants were generally unwilling to express a preference for fear of being excluded from the study.

These findings highlight the need to discuss a patient’s preferences at the outset of treatment or even prior to treatment assignment. A skilled therapist may help a patient who prefers one treatment see the value of alternative interventions, such as a more empirically-supported treatment. Persuasive strategies could be individually tailored to consider patients’ specific knowledge, beliefs and opinions about various treatment options (Hawkins, Kreuter, Resnicow, Fishbein, & Dijkstra, 2008). Preferences may be based on beliefs about the etiology of depression, beliefs about the purpose of emotion, and cultural or religious beliefs (Givens et al., 2006, 2007). Ignoring preferences could discount patients’ own valid perspectives on disease and alienate them in the process of seeking treatment. Inquiring about patient preferences may be especially important among specific patient populations who are highly vulnerable to non-engagement with recommended clinical interventions. For instance, a lack of attention to treatment preferences and beliefs is a barrier to the depression referral process for perinatal women, a group that experiences marked problems with depression treatment engagement (Flynn, O’Mahen, Massey, & Marcus, 2006).

A potential implication of these findings is that preferences may need to be addressed even before a patient has contact with a mental health professional. Although a mental health clinician may have the skills and time to address effectively a patient’s reluctance to try a treatment about which the patient is skeptical, providers in primary care settings who are most likely to have first contact with depressed patients may have fewer resources for addressing such preference-related barriers to care. Thus, as preferences seem to matter especially for starting treatment, effectively managing treatment preferences could be an important skill for those involved in referral processes.

These data also suggest that many people may prefer not to use medication as treatment for depression. It is possible that the greater preference for psychotherapy was reflective of selection factors, with individuals preferring psychotherapy being more likely to enroll in the trial given the greater availability of pharmacotherapy versus psychotherapy in routine clinical service delivery systems. However, it is also possible that greater preference for psychotherapy reflects the treatment preferences of many depressed adults, highlighting the importance of focusing on training, policy and service delivery to support empirically-supported psychotherapy for the treatment of depression and other mental disorders, allowing those who do prefer this option to have their preferences met.

It is important to emphasize potential limitations regarding generalizability of these findings. Preferences may impact outcomes differently (and may need to be addressed differently) outside the context of a randomized trial. Other research designs may be better suited to studying the effects of preferences on direct and indirect outcomes (e.g., patient preference trials). The results also do not speak to the question of for whom preferences are more important. Indeed, some studies suggest that not all patients want to participate in shared decision making. Schneider et al. (2006) found that those with high external health locus of control expressed lower preference for involvement in decision making. Thus, individuals with more internal health locus of control may be more content with any assigned or prescribed treatment, whereas those with more internal health locus of control may respond poorly to receiving a non-preferred mode of treatment.

Other methodological limitations are of note. The preference measure was administered to only a sub-sample of participants in this study. Although we found no significant differences in demographic or clinical characteristics between these groups, the limited...
administration did reduce statistical power. Also, although the use of the ETI was an improvement over other studies in that it explicitly assessed treatment preference, the ETI asks patients to make a forced choice response indicating discretely (rather than continuously) whether they preferred drug therapy, talking therapy, or had no preference. This measure does not allow for ambivalence or indication of to what degree a patient finds either mode of treatment acceptable. Also, it is not clear what “no preference” indicates for each individual. For example, it could mean that either treatment was acceptable, the patient had no opinion, or that the patient was unwilling to express an opinion.

In summary, patient preferences were important predictors of engagement in treatment, including starting treatment, staying in treatment, attending expected visits, and forming positive early therapeutic alliances, which ultimately predicted depression outcomes. Such findings underscore the importance of patient preferences in the design of RCTs, the provision of treatment recommendations, and the development of clinical services. It will be important for future research to address innovative ways of assessing, accommodating and modifying patient preferences, among general clinical populations and among specific groups vulnerable to non-engagement in treatment.

Acknowledgments

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References