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Patients' Depression Treatment Preferences and Initiation, Adherence, and Outcome: A Randomized Primary Care Study

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Abstract

Objective—We examined the association of treatment preferences with treatment initiation, adherence, and clinical outcome among depressed mid-life and elderly primary care patients.

Methods—60 primary care participants meeting DSM-IV criteria for major depression were randomized to receive treatment congruent or incongruent with their primary stated preference. Participants received either 20 weeks of escitalopram as monitored by a care manager, or 12 weekly sessions of interpersonal psychotherapy followed by 2 monthly booster sessions. Adherence to treatment and depression severity were reassessed at weeks 4, 8, 12, and 24.

Results—Participants expressed stronger preferences for psychotherapy than antidepressant medication. Preference strength was a more sensitive measure of outcomes than congruence versus incongruence of preference with the assigned treatment. Across age groups, preference strength was significantly associated with treatment initiation and 12-week adherence rate, but not with depression severity or remission.

Conclusions—A continuous measure of preference strength may be a more useful measure in clinical practice than preferences per se. Future research should focus on whether and how greater facilitation of the patient-clinician treatment decision-making process influences clinical outcome.

Treatments of depression in primary care settings are effective yet most depressed adults (1), particularly older ones (2), do not receive appropriate care. Even when guideline-based treatments are provided, patients often do not fully participate in them. Not surprisingly, therefore, randomized clinical trials have reported substantially poorer outcomes for "intent to treat" than "treatment completer" cohorts (3), indicating a need for strategies that maximize treatment participation.

A patient's decision not to initiate or complete treatment may stem from disappointment or dissatisfaction with the treatment offered by the clinician. While medications are the predominant intervention offered depressed primary care patients, 50%–86% of them prefer a psychosocial intervention (4–7). Thus, many patients conceivably refuse treatment offered in primary care because psychotherapy is not an available option.

In psychiatric outpatient settings, treatment preferences have been addressed through "negotiated treatment plans" whereby clinicians elicit patient requests and encourage their participation in treatment planning. Patient reports of greater participation in such negotiations

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have been associated with greater levels of satisfaction, sense of feeling helped, and adherence to treatment plans (8,9). Studies of mid-life patients in the primary care sector have endorsed the value of a negotiated treatment plan and the importance of patients playing active rather than passive roles in formulating it. Such participation enhances the patient's likelihood of initiating treatment and his/her satisfaction with it (10–12).

Despite these benefits, the few studies examining treatment negotiation and clinical outcome have failed to find a significant association between them. Thus, the Bedi et al. (13) and Chilvers et al. (14) reports of two and twelve-month outcomes, respectively, with the same sample of mid-life depressed primary care patients found generic counseling and antidepressant medication to produce similar improvement rates regardless of whether the patient had personally selected the treatment or been randomized to it. However, this study was an unbalanced comparison as only patients refusing the randomized assignment were then offered their personal preference (13,14). Consequently, the group receiving their preferred treatment was compared to a heterogeneous group of patients, some of whom preferred the treatment to which they were randomized while others did not prefer it but participated in the treatment despite their dislike of it (either their preferences were not very strong or they tended towards adherence regardless of preference). A related observational study found no differences in clinical outcomes of elderly primary care patients who were and were not provided access to their preferred treatment of medication or counseling (15). The impact of treatment preferences may have been underestimated in these studies, however, as the investigators conceptualized preferences as an 'either-or' condition, rather than as existing on a continuum.

Given the inconclusive findings regarding the relationship between treatment preference and clinical outcome, particularly among older adults, we sought to extend the knowledge base using a variant of the "partially randomized patient-preference design" (16). Thus, we randomly assigned primary care patients experiencing major depression to receive treatment either congruent or incongruent with their primary preference. A particular study aim was to determine whether *strength* of treatment preferences for antidepressant medication and psychotherapy, more so than sheer congruence of preferences with the assigned treatment, would be associated with treatment initiation, adherence, and short-term outcome. We hypothesized that stronger preferences for an offered treatment would be positively related to treatment initiation, 12-week adherence, and 12 and 24-week depression severity and remission. We also examined whether age (mid-life, i.e. age 21–59, versus elderly, i.e. age≥60), treatment type, and depression severity moderated the above relationships.

METHOD

This study was reviewed and approved by the Institutional Review Board of Weill Cornell Medical College.

Sample

The study was conducted at Cornell Internal Medical Associates (CIMA), a Manhattan-based academic ambulatory group practice. CIMA physicians referred patients age 21 or older that they judged depressed and not currently receiving either antidepressant medication or psychotherapy. After complete description of the study to the participants, written informed consent was obtained. Patients were informed that if they met study criteria, they would be randomly assigned to receive either antidepressant medication or psychotherapy free of charge for the study's duration. Patients were not informed, however, that randomization would be based on their stated *a priori* treatment preferences.

Inclusion criteria consisted of: age 21 and over; meeting SCID criteria for major depression; scoring ≥ 14 on the 24-item Hamilton Rating Scale for Depression (HRSD) (17); ability to

speak and understand English; and ability to give informed consent as evaluated by participant understanding of the study and its procedures. Exclusion criteria consisted of: Mini-Mental State Exam (MMSE) (18) score less than 24 out of 30; dementia diagnosis; history of mania, hypomania, or psychosis; current alcohol or substance abuse or dependence; suicide plan or intention; currently receiving treatment with antidepressant medication or psychotherapy; pregnancy; and inability to attend treatment sessions during CIMA office hours.

Participants meeting eligibility criteria were randomized to treatment that was either congruent or incongruent with their primary stated treatment preference (see "Measurement"). Power analyses determined that 60 participants were needed to detect hypothesized adherence and outcome differences. Of the 60 participants recruited between April, 2004-November, 2006, 29 were randomized to treatment congruent and 31 to treatment incongruent with their stated preference.

Intervention

Study participants were offered either an evidence-based antidepressant medication (escitalopram) or brief psychotherapy (interpersonal psychotherapy). The latter addresses one or more interpersonal problem areas (i.e., grief, role transition, interpersonal dispute, interpersonal deficit) (19) and effectively treats both mid-life and elderly depressed patients (20). Participants randomized to psychotherapy were offered, after approval by the primary care physician, 12 weekly in-person interpersonal psychotherapy sessions followed by two telephone sessions at weeks 16 and 20. For participants randomized to antidepressant medication, the study's care manager recommended that the primary care physician prescribe escitalopram 10mg daily for the 20-week study period. When the physician approved this pharmacotherapy, the care manager met with participants at weeks 1, 4, 8, 12, and 24 to ascertain whether they were taking the medication, monitor adverse side effects, encourage adherence, and assess clinical changes. When participants did not respond to escitalopram at week 4 or beyond, the primary care physician raised its dosage to 20mg daily based on the care manager's assessment and recommendation. Two care managers, each with more than five years of clinical experience, provided all treatment under the supervision of the PI (XXX) and study psychiatrist (XXX).

Given the study's aim of determining the impact of treatment preference strength on treatment adherence and outcome, participants received pharmacotherapy or psychotherapy without charge so as to avoid confounding associated with third-party reimbursement schedules.

Participants receiving study treatment were free to pursue any additional treatment throughout the study period. Participants refusing or prematurely terminating treatment were offered referrals for psychiatric services of their choice within or outside the study site.

Measurement of treatment preferences and expectations

Prior to study randomization, participants' baseline treatment preferences for antidepressant medication, individual or group psychotherapy, combined medication and psychotherapy, herbal remedies, religious spiritual activities, exercise, or "do nothing" were rank-ordered given their response to the following question: "Based on your experience and how you feel right now, which of the following treatments would be your first choice, second, and third choice?" While the actual study treatments were limited to either antidepressant medication or individual psychotherapy, we wished to document participants' preferences for other treatment approaches. The highest rank order which participants assigned to either of the two study interventions determined their treatment preference and, depending upon the group to which they were subsequently randomized, what treatment they were offered (i.e., congruent or incongruent). Congruence of treatment preference with the treatment to which participants

were randomly assigned served as the initial predictor variable. *Strength* of treatment preferences was also assessed before study randomization for *any* depression treatment ("I want to be treated for my depression at this time, e.g., with medication or psychotherapy"); for antidepressant medication ("I wish to receive medication for my depression"); and for psychotherapy ("I wish to receive counseling or psychotherapy for my depression") on 5-point Likert scales (1=strongly disagree, 5=strongly agree). Strength of treatment preference for the specific treatment to which participants were randomly assigned served as an additional main predictor variable. Treatment expectation, i.e. a participant's anticipated likelihood of improvement, was assessed through the following questions: "The probability that I will get better with antidepressant medication (or psychotherapy) is 0%, 20%, 40%, 60%, 80%, or 100%."

Randomization

Participants meeting eligibility criteria were randomized to treatment that was either congruent or incongruent with their primary stated treatment preference as described above.

Other baseline measures

Research assistants trained in administering the Structured Clinical Interview for Axis I DSM-IV Disorders (SCID) (21) assessed major depression and other psychiatric disorders. Diagnoses were assigned after review by the principal investigator (XXX). Severity of depression was assessed with the 24-item HRSD (17). Diagnostic status and presence of psychotic or manic symptoms, suicidal ideation, and alcohol or substance abuse were reported to the participant's primary care physician.

Baseline interviews determined demographic characteristics and history of previous psychiatric treatment. Cognitive impairment was assessed with the MMSE (18) and medical burden using the Chronic Disease Score (CDS) (22). Functioning was assessed using the World Health Organization Disability Assessment Schedule (WHODAS II, 12-item version), which measures 6 domains: understanding and communicating, getting around, self-care, getting along with others, household and work activities, and participation in society (23). Social service needs such as assistance with housing, finances, legal problems, adult protective services, medical coordination, and transportation were assessed with the 17-item Camberwell Assessment of Need for the Elderly (CANE) (24).

Follow-up measures of treatment initiation, adherence, and depression outcome

Research assistants collected information regarding psychotherapy attendance via care manager records, and daily medication use via participants' retrospective reports at weeks 4, 8, and 12. Treatment initiation was defined as taking at least one dose of medication, or attending at least one psychotherapy session. Adherence during the initial 12-week treatment period was defined as the proportion of antidepressant medication doses taken out of the 84 prescribed, or the proportion of therapy sessions attended out of the 12 scheduled ones. This operationally defined approach placed both treatments on relatively comparable adherence scales. At weeks 4, 8, 12, and 24, depression severity was assessed with the HRSD.

Statistical analyses

The nature and strength of participants' treatment preferences is described using percentages, means, and standard deviations. After testing equivalence of participants randomized to congruent versus incongruent treatment on sociodemographic and clinical variables, we performed separate analyses using two main predictor variables: 1. congruence versus incongruence of treatment preference with the treatment to which participants were randomly assigned, and 2. strength of treatment preferences for the assigned treatment. Thus, we used

Fisher's Exact Test to examine the impact of congruent treatment on treatment initiation, and logistic regression to examine the association of preference strength for the assigned treatment with its initiation. We used linear regression to examine the impact of congruent treatment, and then preference strength, on treatment adherence and on 12 and 24-week HRSD scores controlling for baseline HRSD score. We used Fisher's Exact Test and logistic regression to examine the association of congruent treatment and preference strength, respectively, with clinical remission (i.e., HRSD≤7). Sociodemographic and clinical characteristics were included as covariates if they were associated at the 0.05 significance level with any criterion variable. Finally, we examined the moderating effects of age (mid-life, i.e. age 21–59, versus elderly, i.e. age≥60), treatment type (medication versus psychotherapy), and HRSD severity in the above models. SPSS version 14.0 was used to carry out analyses (25).

RESULTS

Participant population

Figure 1 presents the study's Consort Chart. All 60 protocol eligible patients agreed to enroll; 38 (63%) were 21–59 years old, and 22 (37%) were 60 or older. The sample of 60 randomized participants was predominantly female and included diverse ethnicities (Table 1). Two-thirds of participants self-identified as minority group members. Participants typically experienced depression of moderate severity, extended duration and recurrent nature, with 35% reporting passive suicidal ideation at baseline and 64% having a prior history of antidepressant treatment and/or psychotherapy. Randomized groups did not differ on sociodemographic or clinical variables. Mean baseline HRSD scores for participants assigned to congruent versus incongruent treatment were 22.7 (sd=5.3) and 24.6 (sd=6.3), respectively.

Of participants with previous antidepressant experience (n=22), 14 (64%) agreed or strongly agreed that "the treatment was effective" and 15 (68%) agreed or strongly agreed that "the treatment resulted in troubling side effects, or made me more distressed." Of those with previous psychotherapy experience (n=31), 19 (61%) agreed or strongly agreed that "the treatment was effective" and 9 (29%) agreed or strongly agreed that "the treatment resulted in troubling side effects, or made me more distressed."

Follow-up data on treatment adherence were available for all participants. HRSD 12-week data were available for 26 (90%) congruent and 27 (87%) incongruent participants. HRSD 24-week data were available for 25 (86%) congruent and 24 (77%) incongruent participants. Participants who dropped out by week 12 had lower rates of treatment adherence throughout the study period (mean proportion of attended sessions or pills taken=0.09, sd=9.6 versus 0.67, sd=35.9 for participants who were followed; t=4.20, df=58, p<0.001). No other variable distinguished dropouts from completers.

Treatment preferences

Ranked treatment preferences are presented in Table 1. When patient preferences were restricted to either of the two study treatments, 42 (70%) participants selected individual psychotherapy while the remaining 18 (30%) selected antidepressant medication. An analysis of preference strength for the entire sample revealed stronger preferences for psychotherapy than antidepressants (paired t=5.6, df=58, p<0.001). The mean preference strength for psychotherapy was 4.1, signifying "agreement;" in contrast the mean preference strength of 2.9 for antidepressants, indicating "neutral or indifferent." Preference strength for the treatments was unrelated to age.

Participants anticipated greater improvement from psychotherapy (mean=0.72, sd=0.2) than from antidepressant medication (mean=0.49, sd=0.3; paired t=4.4, df=54, p<0.001). Expected improvement again did not differ by age group.

Preference strength and treatment initiation

All participants (n=29) randomized to a treatment congruent with their preference initiated treatment; only 23/31 (74%) of the incongruent group did so (Fisher's Exact Test=0.005). All 8 participants failing to initiate treatment had been assigned antidepressant medication. While these participants were offered extra-protocol psychotherapy referrals, none had pursued such treatment when assessed at periodic follow-ups.

Using logistic regression, treatment initiation was associated with stronger preferences (OR=5.3, 95% CI=4.3, 6.3, df=1, p=0.001; Figure 2), expectation of improvement from the assigned treatment (OR=2.5, 95% CI=1.9, 3.1, df=1, p=0.002), but no sociodemographic or clinical variable. In a combined model, preference strength was associated with treatment initiation over and above expected improvement (OR=4.4, 95% CI=3.3, 5.5, df=1, p=0.009). Interaction terms of preference strength by age group (mid-life versus elderly) and depression severity (HRSD score) were not significant.

Preference strength and treatment adherence

Preference strength for assigned treatment, but not simply congruence, was associated with higher 12-week treatment adherence rates (Beta=13.40, p=0.002; Figure 3). Differences in adherence rates between participants assigned to psychotherapy (mean=0.68, sd=31.9) and antidepressant medication (mean=0.52, sd=42.9) were not significant. No other variables were associated with adherence, although expected improvement from the assigned treatment approached significance (Beta=6.65, p=0.060). Interaction terms of preference strength by age group (mid-life versus elderly), treatment type (antidepressant medication versus psychotherapy), and depression severity (HRSD score) were not significant.

Preference strength and outcome

Across groups, mean HRSD ratings at 12 and 24 weeks were 16.4 (sd=8.3, range=3–38) and 16.3 (sd=9.9, range=2–42) respectively. Remission rates (HRSD≤7) at 12 and 24 weeks were 21% (11/53) and 29% (14/49), respectively.

Congruent treatment was not significantly related to 12 and 24-week HRSD scores in linear regression models controlling for baseline HRSD score. Contrary to prediction, preference strength was negatively associated with symptom severity at 12 weeks (Beta=1.9, p=0.028) and had no effect at 24 weeks. Neither treatment congruence nor preference strength was related to 12 and 24-week remission (using Fisher's Exact Test and logistic regression, respectively). .

Participants assigned psychotherapy achieved significantly lower 24-week HRSD scores (mean=14.0, sd=9.4) than those assigned medication (mean=18.9, sd=10.1; F=4.12, df=1, p=0.048). These treatment groups did not differ in 12-week HRSD scores, or in 12 or 24-week remission rates.

Interaction terms of preference strength by age group, treatment type, and depression severity were not significant. Results did not change when available 8-week HRSD scores for 2 participants were substituted for missing 12-week scores. Finally, application of mixed-effects regression models as sensitivity analyses that accommodated all observed data across all assessment time points yielded results consistent to that which are reported above.

Other predictors of outcome

Regressions controlling for baseline HRSD scores found degree of adherence (i.e., proportion of pills taken or therapy sessions attended) unrelated to 12 or 24-week depression severity or remission.

A simultaneous regression of significant bivariate demographic and clinical predictors indicated that lower baseline HRSD (Beta=0.48, p=0.010), being White (Beta=4.32, p=0.062), lower CANE scores (Beta=0.90, p=0.007), and higher MMSE scores (Beta=−1.61, p=0.013) predicted lower 12-week HRSD scores (R^2=0.57, p<0.001). In a separate regression, higher MMSE scores (Beta=−2.24, p=0.007) and higher functioning as measured by the WHODAS (Beta=0.44, p=0.012) predicted lower 24-week HRSD scores (R^2=0.49, p<0.001).

DISCUSSION

The study's primary finding is that strength of *a priori* treatment preferences for either antidepressant medication or psychotherapy was associated with treatment initiation and adherence. Congruence of preferences per se with assigned treatment was related to treatment initiation but not adherence, suggesting that a continuous measure of preference strength may be a more useful measure in clinical practice.

Neither congruence nor preference strength was positively associated with depression severity or remission at 12 or 24 weeks. This finding is consistent with previous research (13–15), and suggests that the intensity of a patient's primary *a priori* treatment preferences is unrelated to clinical outcomes.

The present findings also indicate that both mid-life and elderly participants had stronger preferences for, and expected a higher likelihood of improvement from psychotherapy as compared to antidepressant medication. Mean ratings of preference strength indicated that the average participant "agreed" to receive psychotherapy but had "neutral or indifferent" feelings about antidepressant medication. Indeed, only two participants randomized to psychotherapy had neutral or negative preferences regarding it, and both nevertheless initiated treatment. In contrast, all 8 participants failing to initiate treatment had been randomized to antidepressant medication. Thus, physicians should address negative patient attitudes towards antidepressants as needed (26).

Our findings concerning stronger patient preferences for psychotherapy and the better 24-week outcomes achieved by those randomized to this intervention compared to medication are especially noteworthy as primary care settings typically do not offer this treatment. Thus, it is timely for administrators and clinicians to integrate psychotherapy into the primary care setting.

Our finding that the positive association of preference strength with treatment initiation and adherence is not moderated by age group or depression severity suggests that preferences operate similarly across these spectrums. These findings should be interpreted cautiously, however, given the study's small sample size and possible referral bias by primary care physicians.

The low depression remission rates achieved by participants at weeks 12 and 24 warrant analysis. They may have resulted from the treatment resistant nature of the study cohort which was moderately depressed, had experienced recurrent depressive episodes, and had a history of previous treatment. Participants were also ethnically diverse, and many had several unmet social service needs. We suspect that participants receiving either antidepressant medication or interpersonal psychotherapy could have benefited from more aggressive treatment. For example, primary care physicians increased medication dosages for only some clinical non-

responders. This may partially explain the more severe depression experienced at 24 weeks by participants assigned to medication rather than psychotherapy. The total sample's low remission rates may have also restricted the variability in depression outcomes needed to test hypotheses regarding the association of treatment preference strength with clinical outcomes.

Study limitations to be noted are that while all participants agreed to be randomized to either medication or psychotherapy, 14 physician-referred patients (9%) refused to be screened for eligibility. Individuals with strong preferences regarding depression treatment may have refused the study, although their reasons for refusal are unknown. A further study limitation is our operational definition for treatment adherence, i.e. proportion of psychotherapy sessions attended or pills taken. While this places each treatment on a relatively comparable scale, there are alternative metrics for scaling adherence. Furthermore, our analytic approach focused on a single dimension of treatment adherence. Thus, in addition to session attendance, psychotherapy participation involves engaging in an interactive process both in and out of the session such as completing homework assignments. Pharmacotherapy similarly involves taking pills but also attending physician appointments where clinical status and side effects are monitored and managed.

CONCLUSIONS

Our randomization strategy whereby participants were assigned treatment that was either congruent or incongruent with their primary stated preference extends the small body of research investigating the value of meeting a patient's treatment preferences. Our results suggest that strength of such *a priori* preferences, more than preferences per se, is positively related to treatment initiation and adherence albeit not clinical outcomes. Thus, primary care physicians can enhance the likelihood of depressed patients initiating and completing treatment by inquiring about how strongly they prefer various treatments. Our findings suggest that when preferences lack intensity or are similarly intense, the most accessible treatment should be offered first. Alternatively, where patient treatment preferences are particularly strong, that option should be offered.

Conversely, assessment of treatment preferences might ideally be integrated into a process of education and treatment negotiation, which offers physicians an opportunity to educate patients about depression treatments. We suggest that future research focus on enhanced patient-clinician decision-making processes since they can potentially improve medical decisions (27) and are applicable to psychiatric disorders (28,29). These models involve a mutual process whereby the clinician elicits patient experiences and preferences, clarifies patient values about different aspects of treatment, provides balanced information on all treatment options, and collaborates with the patient in formulating a treatment decision. Shared decision-making may be particularly relevant for improving depressive outcomes as it seeks to enhance patient autonomy and empower him/her in a manner that directly addresses depression-induced helplessness and hopelessness. Future research should also examine such relevant contingencies as cost and access to determine the complex impact of preferences in real-life primary care practice settings.

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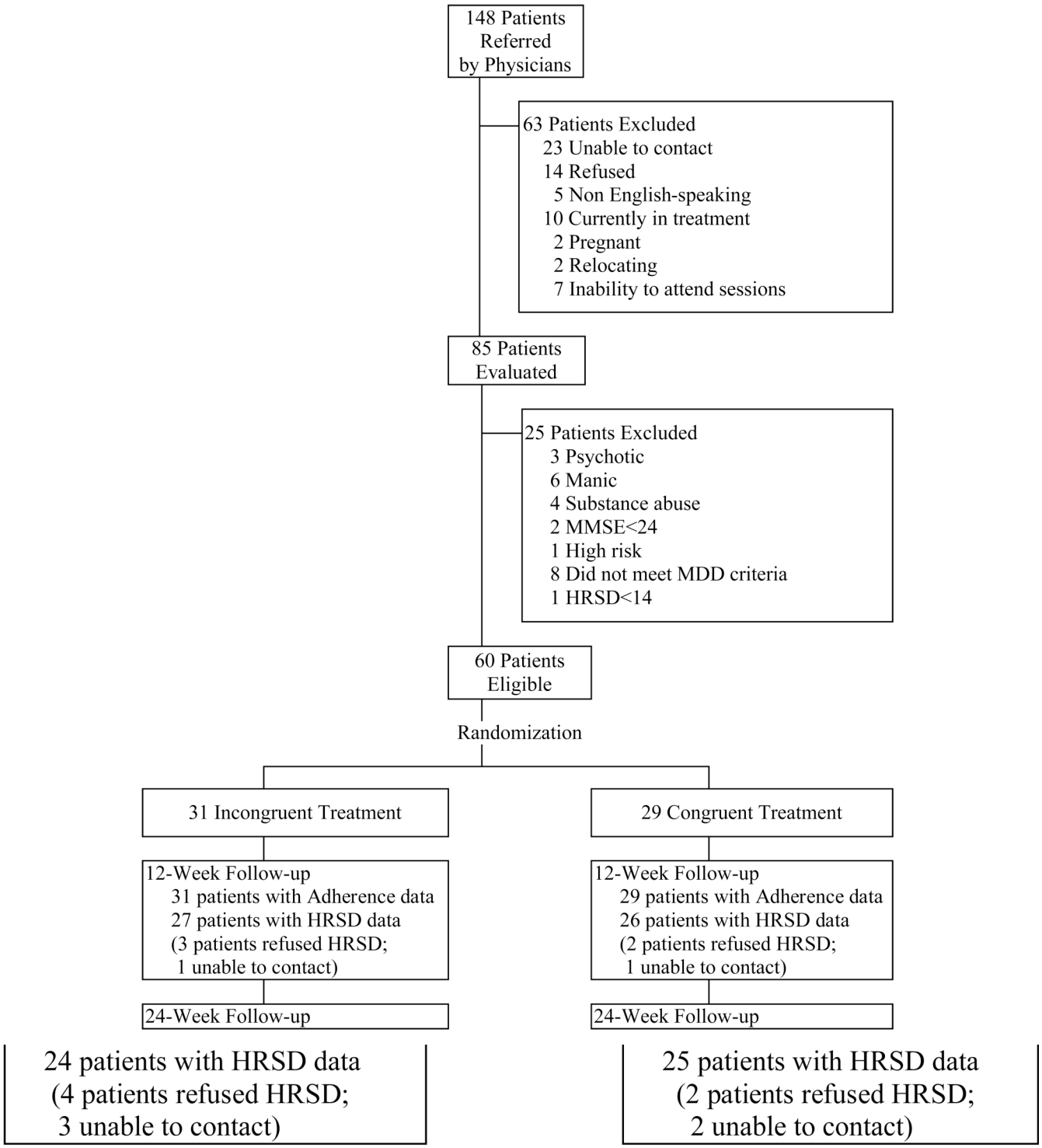

Figure 1.
Consort chart

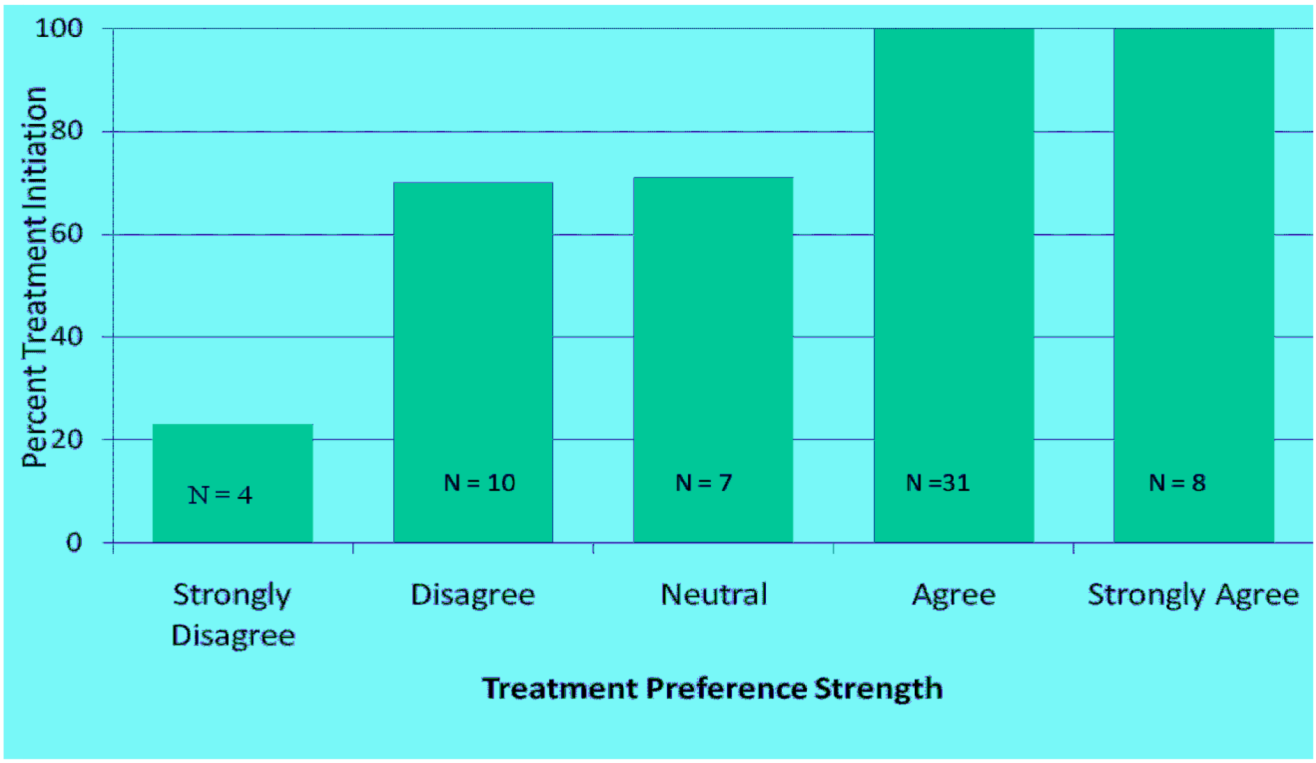

Figure 2.
Treatment initiation by preference strength

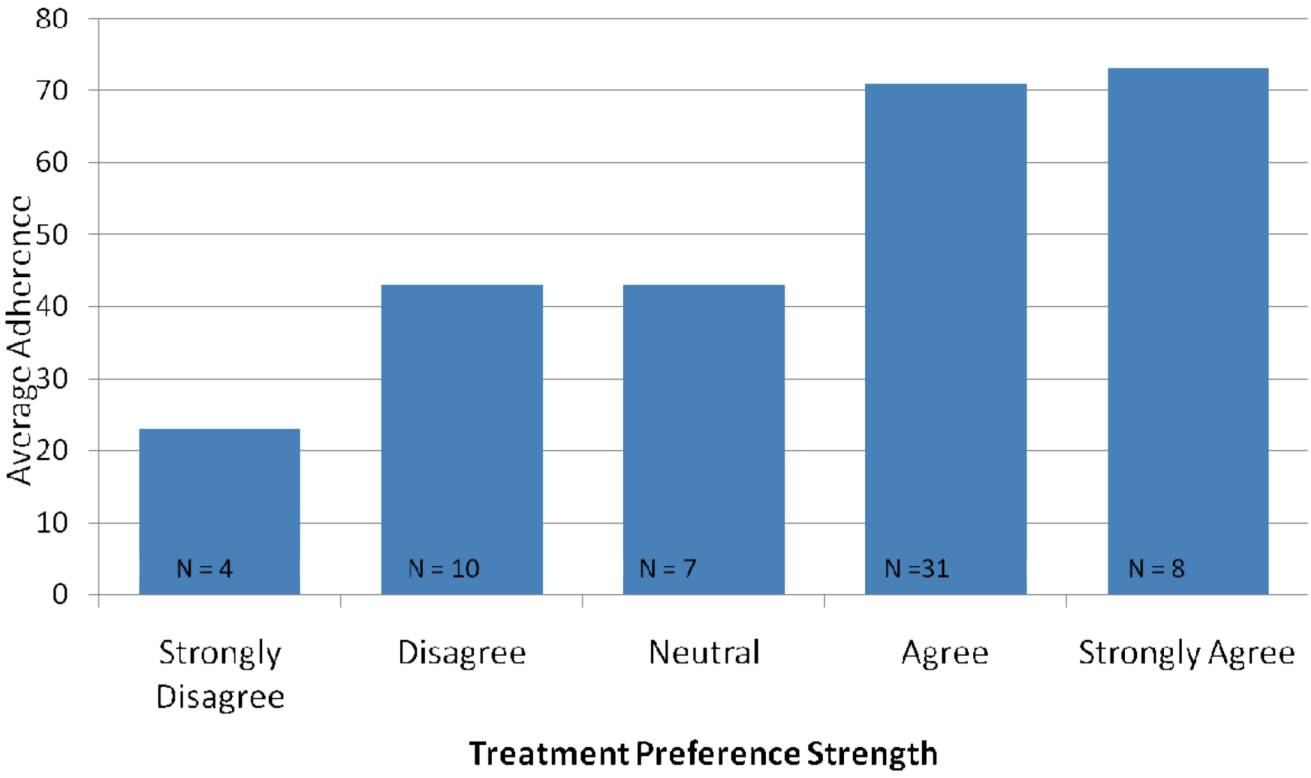

Figure 3.
Average level of adherence by preference strength

Table 1

Characteristics and treatment preferences of study participants (N=60)

Demographics	**N**	**Percentage**
Age (mean±sd; range)	51.2±17.4; 21–84	
Female	47	78%
Ethnicity		
White, non-Hispanic	20	33%
White, Hispanic	19	32%
Black, Hispanic	5	8%
African-American	12	20%
Asian	1	2%
Other	3	5%
Below high school	9	15%
Married	14	23%
CANE total (mean±sd; range)	3.0±3.5; 0–12	
Clinical characteristics		
HRSD score (mean±sd; range)	23.7±5.9; 14–40	
Duration of MDD (mean months±sd)	14.6±16.1	
Recurrent MDD	39	65%
Total # MD episodes (mean±sd; range)	2.6±1.7; 1–7	
Anxiety disorder	13	22%
Medical and functional Characteristics		
Chronic Disease Score (mean±sd)	2.7±3.5	
WHODAS (mean±sd)	28.9±7.6	
Cognitive functioning		
MMSE score (mean±sd)	28.0±1.8	
Previous treatment		
Antidepressant medication	8	13%
Psychotherapy	17	28%
Antidepressants and Psychotherapy	14	23%
Treatment preferences		
Antidepressant medication	10	17%
Individual psychotherapy	33	55%
Group psychotherapy	1	2%
Combined treatment	10	17%
Herbal remedies	3	5%
Religious/spiritual activities	1	2%
Exercise	2	3%
Do nothing	0	
Strength of treatment preferences[+]		

Demographics	**N**	**Percentage**
Any treatment (m±sd; range)	4.3±0.5; 4–5	
Antidepressant medication (m±sd; range)	2.9±1.2; 1–5	
Individual psychotherapy (m±sd; range)	4.1±0.8; 1–5	

* Data are presented as mean±sd for the continuous variables and as number and percentage for the categorical variables. CANE: Camberwell Assessment of Need for the Elderly; HRSD: Hamilton Rating Scale for Depression, 24 item; MDD: Major Depressive Disorder; WHODAS: World Health Organization Disability Assessment Schedule; MMSE: Mini Mental Status Examination.

+ Preference strength based on 5 point Likert scale (1=strongly disagree, 5=strongly agree).