

Religious vs. Conventional Cognitive Behavioral Therapy for Major Depression in Persons With Chronic Medical Illness

A Pilot Randomized Trial

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Abstract: We examine the efficacy of conventional cognitive behavioral therapy (CCBT) versus religiously integrated CBT (RCBT) in persons with major depression and chronic medical illness. Participants were randomized to either CCBT ($n = 67$) or RCBT ($n = 65$). The intervention in both groups consisted of ten 50-minute sessions delivered remotely during 12 weeks (94% by telephone). Adherence to treatment was similar, except in more religious participants in whom adherence to RCBT was slightly greater (85.7% vs. 65.9%, $p = 0.10$). The intention-to-treat analysis at 12 weeks indicated no significant difference in outcome between the two groups ($B = 0.33$; SE, 1.80; $p = 0.86$). Response rates and remission rates were also similar. Overall religiosity interacted with treatment group ($B = -0.10$; SE, 0.05; $p = 0.048$), suggesting that RCBT was slightly more efficacious in the more religious participants. These preliminary findings suggest that CCBT and RCBT are equivalent treatments of major depression in persons with chronic medical illness. Efficacy, as well as adherence, may be affected by client religiosity.

Key Words: Religious, spiritual, psychotherapy, CBT, major depression, chronic illness, randomized clinical trial

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Depression is common among those with chronic medical illness, in whom rates of major depression are up to three times more prevalent than in the general population (Koenig et al., 1997; Rosemann et al., 2007). Religious coping has also been shown to be widely prevalent among those with medical illness and has been associated with less

depression and faster recovery from depression (Koenig, 2007; Koenig et al., 1992, 1998). Psychotherapy that integrates the religious beliefs of medically ill clients into therapy may be particularly effective in relieving depression in this setting.

Cognitive behavioral therapy (CBT) is a standard treatment of depression (Butler et al., 2006). Not surprisingly, psychological approaches such as CBT have been particularly effective in treating depression in medical patients who need help addressing maladaptive beliefs about their illness that initiate and maintain depression (Bower et al., 2000; Kessler et al., 2009; Serfaty et al., 2009; Ward et al., 2000). Most studies in primary care patients have compared CBT with control conditions such as “usual care” by the physician, a “talking control” condition, or alternative forms of therapy such as nondirective counseling (Bower et al., 2000; Katon et al., 1996; Kessler et al., 2009; Serfaty et al., 2009; Ward et al., 2000). Head-to-head comparisons of varying forms of CBT are rare.

Historically, there has been little common ground between religious and psychological concepts of mental health (Freud, 1927/1962). This has generated negative attitudes toward religion among mental health professionals as well as negative attitudes among religious clients toward psychological treatments, which they may view as unsympathetic to their religious beliefs and values (Weaver, 1995). Religious patients may also avoid psychotherapy because they feel that depression is shameful and that seeking therapy means abandoning their faith. Some may feel guilty about being depressed and thus fail to address it with their clergy and avoid seeking support within the faith community. Religious psychotherapy may help to normalize depressed religious patients' need for psychotherapy and thus overcome a major barrier to treatment. Many depressed persons have expressed a desire to have their religious beliefs considered in psychotherapy, especially those with comorbid medical illness (Rose et al., 2001; Stanley et al., 2011).

The efficacy of religiously integrated psychotherapy—therapy that takes into account and uses the religious beliefs of clients—has not been previously evaluated for the treatment of depression in individuals with chronic medical illness. Religiously integrated CBT (RCBT) has been shown in small clinical trials to speed time to remission in depressed religious clients without medical illness compared with conventional CBT (CCBT; Propst, 1980; Propst et al., 1992). Likewise, a number of studies that addressed clients' religious beliefs in therapy have reported results superior to secular treatments or usual care in religious patients (Azhar and Varma, 1995; Razali et al., 1998; Rosmarin et al., 2010; Xiao et al., 1998). This may not be as true, however, in those who are less religious (Razali et al., 2002). Furthermore, a number of preliminary clinical trials have not found religious-integrated therapies to be more effective than secular treatments in religious patients (Hook et al., 2010; Rye and Pargament, 2002).

In this pilot randomized clinical trial, we compared CCBT and RCBT (delivered primarily by telephone) for the treatment of major

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depressive disorder in individuals with chronic medical illness. Although the goals of the study were to assess recruitment, acceptability of the treatment, and attrition rates in anticipation of conducting a fully powered trial, a further major aim was to compare the efficacy of the two treatments at 12 weeks in terms of depressive symptoms (primary end point). We hypothesized that RCBT would be more efficacious than CCBT in participants who were at least somewhat religious or spiritual, especially in those who were most religious. Secondary aims included comparing treatment effects at 24 weeks, effects on physical functioning, treatment response (50% reduction in depressive symptoms), likelihood of achieving remission (lower than the threshold of significant depression), and effects in those who completed at least five therapy sessions (per-protocol).

METHODS

Participants

Individuals were recruited from two sites, Durham, North Carolina, and Glendale, California, into a randomized clinical trial to compare the efficacy of CCBT versus RCBT. Inclusion criteria were a) ages 18 to 85 years; b) one or more chronic medical illnesses present for 6 months or more; c) religion or spirituality is at least somewhat important; d) major depressive disorder; and e) moderately severe depressive symptoms. Exclusion criteria were a) significant cognitive impairment; b) psychotherapy in the past 2 months; c) psychotic disorder, alcohol or substance abuse, or posttraumatic stress disorder within the past year or a history of bipolar disorder; d) active suicidal thoughts; e) medical illnesses affecting immune or endocrine functions (due to measurement of immune and endocrine outcomes not discussed here); f) non-English speaking; and g) no remote access (*i.e.*, lack of a telephone). The Duke University Medical Center institutional review board (protocol 26533) and Glendale Adventist Medical Center (March 17, 2011) approved the study.

Procedure

The study was conducted in two phases involving separate samples. During phase I ($n = 39$), the delivery method of the therapy was determined (telephone versus online versus Skype) because all therapy was to be delivered remotely; telephone was client preference from the beginning. Phase I follow-up assessments were conducted at 4, 8, and 12 weeks from baseline. During phase II ($n = 93$), all treatment sessions were conducted by telephone because of client preference, and an additional 24-week follow-up assessment was added. Otherwise, screening, recruitment, randomization, interventions, and all assessments were essentially the same for phase I and phase II samples. Finally, treatment phase did not significantly affect outcome, further justifying combining the samples for analysis.

Measures

Screening

Participants were first screened by telephone to determine whether preliminary inclusion/exclusion criteria applied. During the in-person screening evaluation, the MINI Neuropsychiatric Inventory (Sheehan et al., 1998), a structured psychiatric interview, was used to identify the presence of major depressive disorder and rule out mental disorders and suicidal thoughts that were exclusions. The Beck Depression Inventory (BDI) (Beck et al., 1961) assessed baseline severity of depressive symptoms necessary for study entry (10–40). The abbreviated Mini-Mental State Examination identified significant cognitive impairment, defined as 13 or lower on a 0- to 18-point scale (Koenig, 1996).

Baseline

After passing the screening evaluation, physical functioning was assessed using the Duke Activity Status Index (DASI; Hlatky et al.,

1989), severity of medical illness by the Cumulative Illness Rating Scale (Linn et al., 1968), and ICD-10 comorbid medical illnesses by the Charlson Comorbidity Index (Charlson et al., 1987). Social support was measured using an abbreviated version of the Duke Social Support Index (Landerman et al., 1989). Religious involvement was assessed with single items measuring importance of religion, religious attendance, and private religious activity as well as multi-item measures of spiritual experiences (Underwood and Teresi, 2002) and intrinsic religiosity (Hoge, 1972) (Cronbach's $\alpha = 0.94$ and 0.87 , respectively, in the present sample). An overall religiosity measure was created by summing importance of religion, religious attendance, private religious activity, spiritual experiences, and intrinsic religiosity (standardized Cronbach's $\alpha = 0.89$).

Randomization and Blinding

After enrollment, a clinical trials coordinating center randomized the participants to either RCBT or CCBT using a four-person block design to ensure approximately equal numbers in each group. The center then connected the participants with their respective therapists and monitored the treatment process and other aspects of the trial. Interviewers who conducted the screening, baseline, and follow-up evaluations were masked to treatment group, a blind that was carefully maintained throughout the study by repeated reminders to both participants and interviewers.

Therapists

Eight master's-level therapists administered the interventions. The four conventional therapists delivering CCBT were experienced in CBT but had no experience integrating religious beliefs into therapy. The four therapists who delivered RCBT were experienced with both CBT and integrating religious beliefs into therapy. The CCBT and RCBT therapists were trained for the trial and supervised by Duke faculty members who were skilled in CCBT or in both CCBT and RCBT. Regular supervision by telephone continued throughout the trial for both CCBT and RCBT therapists. To qualify as a study therapist, a score of 40 or higher on recordings of therapy delivered (rated by therapist supervisors) was required on the Cognitive Therapy Rating Scale (Vallis et al., 1986; Young and Beck, 1980).

Interventions

The intervention in both groups consisted of ten 50-minute sessions administered during 12 weeks. All sessions were delivered remotely by telephone (94%), Skype (5%), or online instant messaging (1%).

Conventional CBT

CCBT was delivered using a manual following CBT for depression described by Beck et al. (1979). When clients brought up religious issues during the therapy, CCBT therapists gently redirected them to more secular ways of approaching the issue and, if necessary, addressed religious issues in the broadest conventional way possible, relating those issues to other cognitions and behaviors usually addressed in CBT.

Religiously Integrated CBT

RCBT followed the same principles and style as CCBT. However, RCBT was unique in its explicit use of the client's religious beliefs to identify and replace unhelpful thoughts and behaviors to reduce depressive symptoms. When clients brought up religious issues, therapists listened and sought to understand the concerns, determined whether they were grounded on dysfunctional cognitions, and, if so, gently directed the client to more healthy ways of thinking based on religious teachings in their particular tradition. For example, therapists provided clients with a passage from their holy scriptures that was relevant to a particular session's topic, which they were asked to memorize so that they could more easily draw on the scripture to challenge and change

their negative thinking. Clients were also taught to regularly meditate on these passages to help them remember and apply them. RCBT also addressed behaviors. Religious beliefs and practices were used to help clients build positive behavioral patterns to combat depression. For example, RCBT emphasized praying for self and others and encouraged regular contact with members of their faith community, both seeking support from members of the congregation and offering it to those dealing with difficult life situations.

RCBT was a manual-based intervention specific to the religion of the client. Starting with the CCBT manual above, a Christian RCBT manual was developed (Pearce et al., 2014). Doctorate-level university faculty members from Jewish, Muslim, Hindu, and Buddhist religious traditions with extensive experience using CBT and integrating clients' religious beliefs into therapy then adapted the prototype Christian RCBT manual to their religious tradition, resulting in five religion-specific RCBT manuals (Duke University Center for Spirituality, Theology and Health, 2014). When participants of a particular faith tradition entered the study, the faculty members who had developed the RCBT manuals and workbooks helped to supervise the therapists as they delivered the intervention.

CCBT and RCBT

Both CCBT and RCBT integrated broadly spiritual content into therapy, with elements that focused on forgiveness, gratefulness, altruistic behaviors, and engagement in social activities. CCBT also included training in mindfulness meditation, departing from traditional CBT in this regard. CCBT and RCBT interventions were identical in all respects except that RCBT integrated the religious beliefs and practices of clients into the therapy and used them to motivate changes in cognition and behavior. Because both therapies focused on forgiveness, gratefulness, altruistic behaviors, and others, it was *the religious language* that really distinguished the two treatments. Religious language, however, is crucial because it specifies the nature of *the source* in therapy used to drive or motivate changes in cognitions or behaviors that lead to less depression. The RCBT therapists used the religious beliefs and behaviors of clients to generate forgiveness, meaning and purpose, altruism, social engagement, and others, whereas the CCBT therapists used more secular sources to generate positive cognitions and behaviors. This was the primary difference in the two therapies and what we wanted to test.

Treatment Credibility

Treatment adherence was assessed using an adapted version of the Adherence Rating Scale (ARS; Waltz et al., 1993). Sessions ($n = 85$) were tape recorded, transcribed, and rated by trained and supervised raters who were otherwise not directly involved in the study. The first one third of taped sessions were of consecutive sessions at the beginning of the study, and the remaining two thirds were randomly selected from the remaining sessions.

Primary and Secondary End Points

Continuous BDI score was the primary outcome, with the primary end point chosen at 12 weeks (although data at 4 and 8 weeks were used in the mixed model). Secondary end points included a) outcome analysis at 24 weeks, b) treatment response (>50% reduction in BDI scores), c) remission of depressive symptoms (BDI < 10), d) trajectories of change in physical functioning (DASI scores), e) a per-protocol analysis that included only those who completed 5 to 10 therapy sessions, and f) the interaction between treatment group and overall client religiosity.

Statistical Analyses

Our main aim was to test the viability of the trial design in terms of level of recruitment, adherence to therapy, and attrition from the trial.

However, our relatively large sample size also offered the opportunity to compare CCBT and RCBT in terms of treatment efficacy. The numbers in the trial were chosen on pragmatic grounds to demonstrate whether a larger trial of this type might be possible. An estimation before the trial began indicated that the chance (power) of detecting an advantage for either therapy of 3 points or more on the BDI (SD, 9.5), the smallest difference felt to be clinically significant, at an alpha of 5% (two-tailed test) with 66 in each treatment group, was 40%. Thus, our analyses should be regarded as exploratory.

Except for the per-protocol analysis, both primary and secondary end points were analyzed using the intention-to-treat (ITT) principle. Growth curve analyses using random intercept and slope were used to compare the trajectory of change in BDI scores between the two treatment arms. This allowed for participants with data for at least one time point to be included in the analysis and thus helped to address the problem of missing data. The model included the fixed effects of treatment group, time, time squared, and the interaction of treatment group with time. Study site and phase were also examined in these models and found not to have a significant effect and thus were dropped from the analysis. Logistic regression was used to compare response and remission between the two groups in both the ITT and per-protocol analyses, adjusting for baseline BDI score. Effect sizes (Cohen's d) were determined using t -statistic values and df .

To test the interaction between treatment group and overall client religiousness, we entered the summed measure of religiosity and the interaction with treatment group into the growth model. To examine the effect in those with high versus low religiosity, the summed religiosity variable was dichotomized into those scoring greater than or equal to one-half SD above the mean (high religiosity) versus others (low religiosity). All statistical analyses were done using SAS (version 9.3; SAS Institute Inc, Cary, North Carolina). The significance level was set at $p < 0.05$ for the primary end point at 12 weeks and other end points as well, considering the exploratory nature of these analyses.

RESULTS

Participant Enrollment

Between June 2011 and June 2013, a total of 385 potential participants were screened by telephone for eligibility. Among the 290 who were eligible, 187 underwent in-person screening and 132 were enrolled in the study, completed the baseline evaluation, and were randomized to either CCBT or RCBT. Three subjects who did not fulfill inclusion/exclusion criteria were erroneously randomized and included in the study (two scored >40 on the BDI and one had active substance abuse). Sensitivity analysis revealed that including them did not affect the major findings, and these subjects were therefore included in the final sample. Of the 132 enrolled subjects, 67 were randomized to CCBT and 65 were randomized to RCBT. Follow-up assessments are displayed in Figure 1.

Pretreatment Group Differences

A comparison of demographic, social, psychological, health, and clinical characteristics between treatment groups is presented in Table 1. The two groups were equivalent at baseline.

Treatment Credibility

Therapist Competence

The mean therapist competence based on supervisor Cognitive Rating Scale (CTS) ratings of three sessions per therapist was 57.7 (SD, 5.3; range, 43.0–66.0). There were no important differences between CCBT therapists and RCBT therapists (55.8 [SD, 5.6] vs. 59.7 [SD, 4.2], respectively).

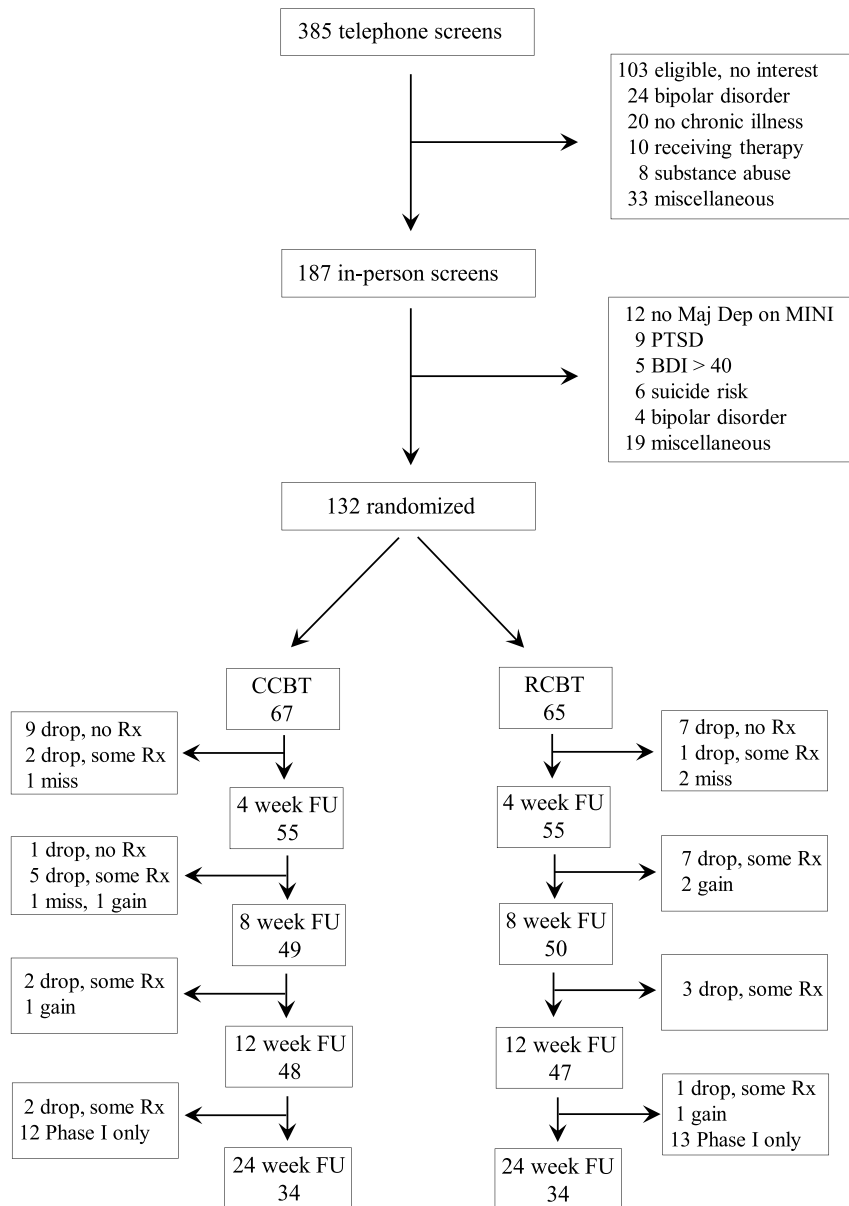


FIGURE 1. Trial profile. FU indicates follow-up; Maj Dep, major depression; MINI, MINI Neuropsychiatric Inventory; PTSD, posttraumatic stress disorder; Rx, treatment.

Therapy Adherence

A total of 85 transcripts (9.0% of 940 total sessions) were rated by outside CBT experts using an adapted version of the ARS on the dimensions of session structure (range, 0–15), therapeutic relationship (range, 0–6), adherence to manual (range, 0–8), therapist competence (range, 1–4), and flexibility (range, 1–4). The overall mean (SD) scores were 13.2 (2.0) for session structure, 5.4 (0.8) for therapeutic relationship, 6.8 (1.0) for adherence to manual, 3.2 (0.6) for competence, and 3.2 (0.6) for flexibility, with a total score of 31.8 (4.1). The CCBT and RCBT therapists were equivalent for each dimension and the total score (Table 1).

Treatment Attrition

Of those randomized, 18 (13.6%) dropped out without receiving a single treatment session (CCBT, 11; RCBT, 7), whereas 93 (70.5%) completed 5 to 10 sessions (CCBT, 46; RCBT, 47) (Fig. 2).

Primary Outcome (ITT)

BDI score decreased from baseline to 12 weeks in the overall sample (25.3 to 11.8). In the mixed model, the B for time was -8.39 (SE, 1.54; $p < 0.0001$), and the quadratic term for time was also significant ($B = 0.74$; SE, 0.30; $p = 0.015$), indicating that the reduction in BDI was greater in sessions 1 to 4 than in sessions 5 to 10. At 12 weeks, the mean between-group difference on the BDI was 1.2 points (95% confidence interval [CI], -2.6 to 5.1). Growth curve analyses indicated no significant difference between treatment groups from baseline through 12 weeks (main effect of group: $B = 0.33$; SE, 1.80; $df = 301$; $t = 0.18$; $p = 0.86$; Cohen's $d = 0.02$) (Table 2, Fig. 3).

Antidepressant use at any time during the trial (either at the beginning or during the trial itself) was not different between the treatment groups (40.3% CCBT vs. 33.9% RCBT, $\chi^2 = 0.59$, $p = 0.44$) and did not significantly affect overall treatment response or differences

TABLE 1. Baseline Characteristics of Participants in CCBT and RCBT Intervention Groups (N = 132)

	CCBT (n = 67)	RCBT (n = 65)
Demographics		
Sex (female), % (n)	65.7 (44)	72.3 (47)
Age, mean (SD), yrs	52.5 (13.7)	50.7 (13.3)
Race (white), % (n)	58.2 (39)	47.7 (31)
Education, mean (SD), yrs	15.2 (3.2)	15.0 (3.5)
Living situation (alone), % (n)	29.9 (20)	23.1 (15)
Social characteristics		
Marital status (married), % (n)	41.8 (28)	36.9 (24)
Social support (DSSI), mean (SD)	22.2 (4.1)	22.8 (4.2)
Religious characteristics		
Affiliation, % (n)		
Christian	92.5 (62)	83.1 (54)
Catholic	28.4 (19)	23.1 (15)
Protestant (conservative/fund)	22.4 (15)	24.6 (16)
Protestant (mainline/liberal)	20.9 (14)	9.2 (6)
Nontraditional	20.9 (14)	26.2 (17)
Jewish	1.5 (1)	6.2 (4)
Hindu	1.5 (1)	3.1 (2)
Muslim	0.0 (0)	1.5 (1)
Buddhist	4.5 (3)	6.2 (4)
Importance (very), % (n)	44.8 (30)	49.2 (32)
Attendance (1 or more per week), % (n)	41.8 (28)	43.1 (28)
Prayer (1 or more per day), % (n)	38.8 (26)	35.4 (23)
Intrinsic (IRS), mean (SD)	34.5 (8.3)	35.2 (8.4)
Experiences (DSE), mean (SD)	57.5 (16.1)	57.7 (15.9)
Physical illness severity		
Physical function (DASI), mean (SD)	29.1 (5.6)	28.7 (5.9)
Severity (CIRS), mean (SD)	6.5 (4.7)	7.1 (5.7)
Comorbidity (CCI), mean (SD)	2.7 (2.4)	2.1 (2.0)
Comorbid disorders, % (n)		
Peripheral vascular disease	14.9 (10)	13.9 (9)
Heart/circulatory (other)	17.9 (12)	9.2 (6)
Gastrointestinal (other)	29.9 (20)	18.5 (12)
Diabetes (no complications)	17.9 (12)	12.3 (8)
Musculoskeletal disorders	47.8 (32)	40.0 (26)
Urogenital diseases	14.9 (10)	12.3 (8)
Depression		
Symptoms (BDI), % (n)		
Mild (10–19)	28.4 (19)	26.2 (17)
Moderate (20–28)	31.3 (21)	43.1 (28)
Severe (29–42)	40.3 (27)	30.8 (20)
Symptoms (BDI), mean (SD)	25.8 (9.2)	24.8 (7.6)
Antidepressant treatment, % (n)	37.3 (25)	32.3 (21)
Onset (past 12 mos), % (n)	70.2 (47)	73.9 (48)
Recurrent depression (>2), % (n)	76.1 (51)	70.8 (46)
Study design		
Site (Durham), % (n)	47.8 (32)	46.2 (30)
Therapy route (telephone), % (n)	94.0 (437)	94.1 (447)
Phase (II), % (n)	70.1 (47)	70.8 (46)
RCBT type, % (n)		
Christian	—	87.7 (57)
Jewish	—	1.5 (1)

TABLE 1. (Continued)

	CCBT (n = 67)	RCBT (n = 65)
Hindu	—	1.5 (1)
Muslim	—	1.5 (1)
Buddhist	—	7.7 (5)
Therapy		
CBT Training (CTS), mean (SD)	55.8 (5.6)	59.7 (4.2)
Manual fidelity, mean (SD)		
Structure	13.0 (2.3)	13.3 (1.6)
Therapeutic relationship	5.4 (0.9)	5.4 (0.8)
Adherence	6.8 (1.1)	6.8 (1.0)
Competence	3.3 (0.6)	3.2 (0.6)
Flexibility	3.4 (0.6)	3.1 (0.7)
Total fidelity	31.9 (4.5)	31.8 (3.8)

BDI indicates beck depression inventory; CBT, cognitive behavioral therapy; CCBT, conventional CBT; CCI, Charlson comorbidity scale; CIRS, cumulative illness rating scale; CTS, cognitive rating scale; DASI, Duke activity status index; DSE, daily spiritual experiences scale; DSSI, duke social support index; IRS, intrinsic religiosity scale; SD, standard deviation; RCBT, religiously integrated CBT.

in treatment response between the treatment groups. Overall religiosity score was unrelated to use of antidepressants (103.1 [SD, 25.6] for those not using antidepressants vs. 102.7 [SD, 25.1] for those using antidepressants, $t = 0.09, p = 0.93$).

Secondary Outcomes (ITT)

BDI Change at 24 Weeks

At 24 weeks, the mean between-group difference was 0.6 points on the BDI (95% CI, -6.1 to 4.9). Growth curve analyses indicated no significant difference between treatment groups from baseline through 24 weeks ($B = 1.19; SE, 1.74; df = 369; t = 0.68; p = 0.50$; Cohen's $d = 0.07$).

Response (>50% Reduction in BDI)

Adjusting for baseline BDI, no significant difference in response rates was found between treatment groups at 12 weeks (58.3% CCBT vs. 53.2% RCBT; odds ratio [OR], 0.81; 95% CI, 0.36–1.82) or at 24 weeks (58.8% CCBT vs. 61.8% RCBT; OR, 1.10; 95% CI, 0.41–2.93).

Remission (BDI < 10)

No significant difference in remission rates was also found between treatment groups at 12 weeks (47.9% CCBT vs. 44.7% RCBT; OR, 0.90; 95% CI, 0.38–2.11) or at 24 weeks (47.1% CCBT vs. 59.2% RCBT; OR, 1.17; 95% CI, 0.43–3.18).

Physical Functioning Change

Finally, there was no significant difference in the trajectory of DASI score change between treatment groups from baseline through 24 weeks ($B = 0.66; SE, 1.14; df = 159; t = 0.58; p = 0.56$; Cohen's $d = 0.09$).

Per-Protocol Analysis

Again, no significant difference in trajectories of BDI response was found between treatment groups at either 12 weeks ($B = -0.24; SE, 2.05; df = 264; t = -0.12; p = 0.91$; Cohen's $d = 0.02$) or 24 weeks ($B = 0.87; SE, 1.99; df = 325; t = 0.44; p = 0.66$; Cohen's $d = 0.05$). Similarly, no significant difference in treatment response or

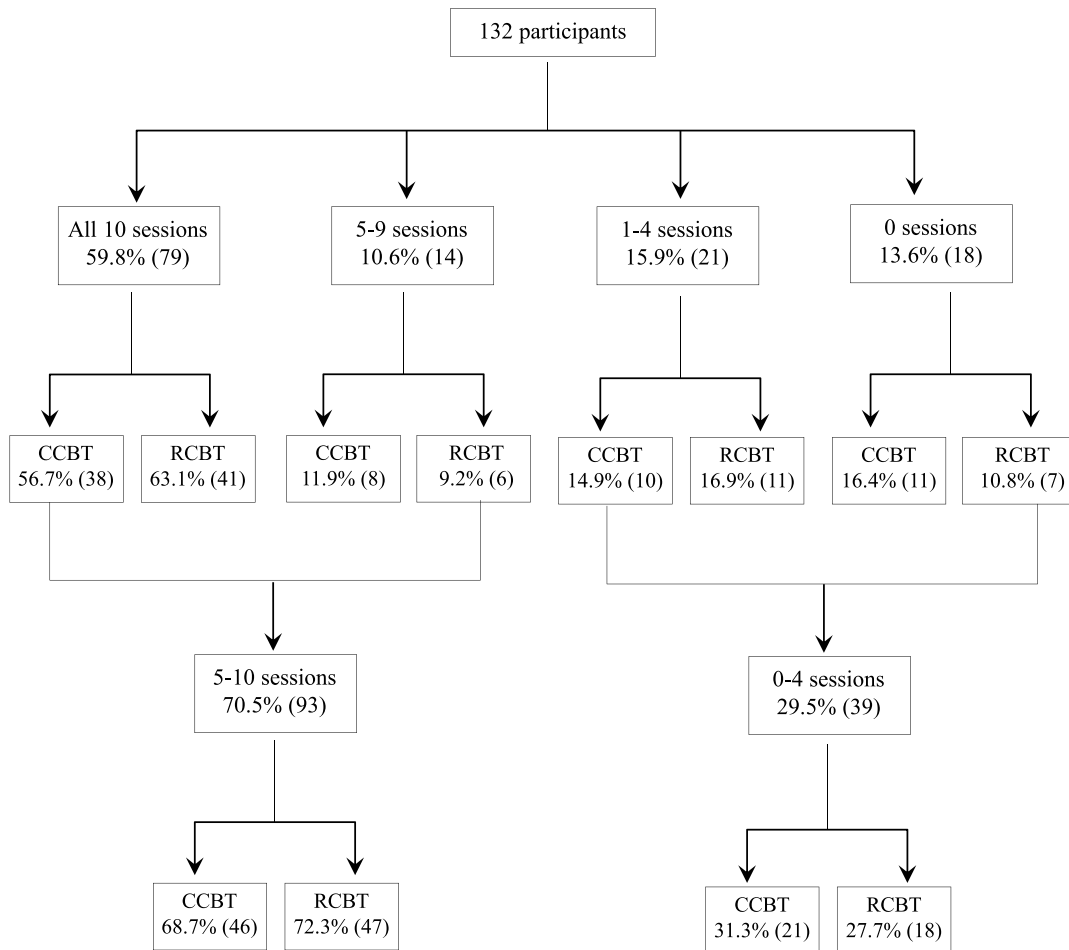


FIGURE 2. Treatment sessions.

remission rates was found between groups at the 12- or 24-week follow-ups (Table 2). No significant difference was also found between groups for changes in physical functioning through the 24-week follow-up ($B = 0.80$; SE, 1.36; $df = 145$; $t = 0.59$; $p = 0.56$; Cohen's $d = 0.10$).

Religiosity

Given the concern that including clients in the RCBT group who were spiritual but not religious may have affected the results, we reran the primary analysis after deleting those in the sample for whom religion was "not important" or only "somewhat important" (*i.e.*, 22/65 participants). Doing so, however, did not significantly alter the results. However, the ITT analysis did show that there was a significant interaction between treatment group and overall subject religiosity ($B = -0.10$; SE, 0.05; $df = 301$; $t = -1.99$; $p = 0.048$) at 12 weeks. Among the highly religious (those scoring one-half SD greater than the mean or higher, $n = 45$), the reduction in BDI scores slightly favored RCBT ($B = -2.26$; SE, 3.08; $df = 104$; $t = -0.73$; $p = 0.46$; $d = 0.14$), whereas in those with lower religiosity ($n = 87$), outcomes slightly favored CCBT ($B = 1.72$; SE, 2.22; $df = 194$; $t = 0.78$; $p = 0.44$; $d = 0.11$). In the per-protocol analysis, the interaction was in a similar direction but did not reach statistical significance ($B = -0.09$; SE, 0.06; $df = 264$; $t = -1.51$; $p = 0.13$).

Among the participants receiving RCBT, those with high religiosity were also slightly more likely to complete at least five therapy

sessions compared with those with low religiosity (85.7% vs. 65.9%, $\chi^2 = 2.8$, $p = 0.10$, $n = 65$); in those receiving CCBT, the difference in therapy adherence between the participants of high versus low religiosity was smaller (66.7 vs. 69.8%, $\chi^2 = 0.07$, $p = 0.79$, $n = 67$).

DISCUSSION

The Findings

To our knowledge, this is the first study to examine the effects of RCBT compared with CCBT in the treatment of major depressive disorder in persons with chronic medical illness. We have shown that such a trial is feasible and that adherence to the two forms of treatment seems to be similar, except possibly in highly religious clients. Although we recruited only people for whom religion or spirituality was at least somewhat important, we found that the religiosity of this group was actually somewhat less than that of Americans in general. A Pew Foundation survey of a random sample of 35,000 adults in the United States found that 56% of Americans said that religion is very important in their lives (Pew Forum, 2007), compared with 47% of the participants in the current study.

Our results suggest that baseline religiosity may have affected the efficacy of RCBT versus CCBT in this client sample. Given that the highly religious participants were also slightly more adherent to therapy in the RCBT arm, these findings suggest that RCBT may be

TABLE 2. Analyses of Primary and Secondary Outcomes

	CCBT	RCBT	B (SE)/OR (CI) ^a	p
ITT				
Primary				
BDI score baseline, mean (SD)	25.8 (9.2)	24.8 (7.6)		
BDI score at 4 wks	18.9 (9.3)	18.7 (8.6)		
BDI score at 8 wks	16.2 (10.3)	14.3 (8.5)		
BDI score at 12 wks ^b	12.5 (10.8)	11.2 (7.8)	0.33 (1.80)	0.86
Secondary				
BDI score at 24 wks ^b	11.4 (9.6)	12.1 (12.8)	1.19 (1.74)	0.50
Response ^c at 12 wks, % (n)	58.3 (28)	53.2 (25)	0.81 (0.36 to 1.82)	0.60
Response at 24 wks	58.8 (20)	61.8 (21)	1.10 (0.41 to 2.93)	0.85
Remission ^c at 12 wks, % (n)	47.9 (23)	44.7 (21)	0.90 (0.38 to 2.12)	0.80
Remission at 24 wks	47.1 (16)	52.9 (18)	1.17 (0.43 to 3.18)	0.76
DASI baseline, mean (SD)	29.1 (5.6)	28.7 (5.9)		
DASI at 12 wks	28.3 (6.0)	28.1 (5.9)		
DASI at 24 wks ^b	29.7 (5.2)	28.3 (6.4)	0.66 (1.14)	0.56
Per-protocol				
BDI score baseline, mean (SD)	26.1 (9.0)	25.5 (6.7)		
BDI score at 12 wks ^d	12.6 (11.1)	11.0 (7.3)	-0.24 (2.05)	0.91
BDI score at 24 wks ^d	11.2 (9.9)	11.7 (12.1)	0.89 (1.99)	0.66
Response ^c at 12 wks, % (n)	62.2 (28)	55.8 (24)	0.77 (0.33 to 1.80)	0.54
Response at 24 wks	61.3 (19)	63.3 (19)	1.02 (0.36 to 2.93)	0.95
Remission ^c at 12 wks, % (n)	46.7 (21)	46.5 (20)	1.01 (0.41 to 2.47)	0.98
Remission at 24 wks	48.4 (15)	53.3 (16)	1.05 (0.36 to 3.08)	0.94
DASI baseline, mean (SD)	28.9 (5.9)	28.4 (5.7)		
DASI at 12 wks	28.1 (6.1)	28.5 (6.0)		
DASI at 24 wks ^d	29.5 (5.4)	29.0 (6.3)	0.86 (1.36)	0.53

The DASI was used to assess physical functioning.

^aB = Unstandardized beta (standard error) for the mean difference between treatment groups (CCBT, 0; RCBT, 1) from mixed models; OR adjusted for baseline BDI (95% CIs) from logistic regression models.

^bn = 132.

^cn = 95 at 12 weeks, n = 68 at 24 weeks.

^dn = 93.

^en = 88 at 12 weeks, n = 61 at 24 weeks.

more acceptable and therefore more effective than CCBT for highly religious depressed people and that CCBT may be slightly more effective than RCBT in clients with lower religiosity.

Interpretation

One reason for our not finding a difference in efficacy between RCBT and CCBT is that the traditional components of CBT, particularly when combined with mindfulness meditation, may have been so effective for the treatment of major depression of moderate severity that the religious form had little extra benefit. Approximately 60% of the participants who received at least five treatment sessions responded to treatment (decreased their BDI > 50%) and nearly one half went into remission by the end of treatment (BDI < 10), benefits that persisted for at least 12 weeks after treatment ended. Perhaps future treatment studies that compare RCBT with CCBT should include patients with more severe depression or treatment-resistant depression to evaluate whether adding a religious component to CBT is more or less efficacious than CCBT (especially in those who are highly religious).

Our main question was whether integrating a religious component into CBT would increase its efficacy in religious patients with chronic medical illness, but two aspects of our design may have reduced the likelihood of detecting a difference. First, we conducted a head-to-head

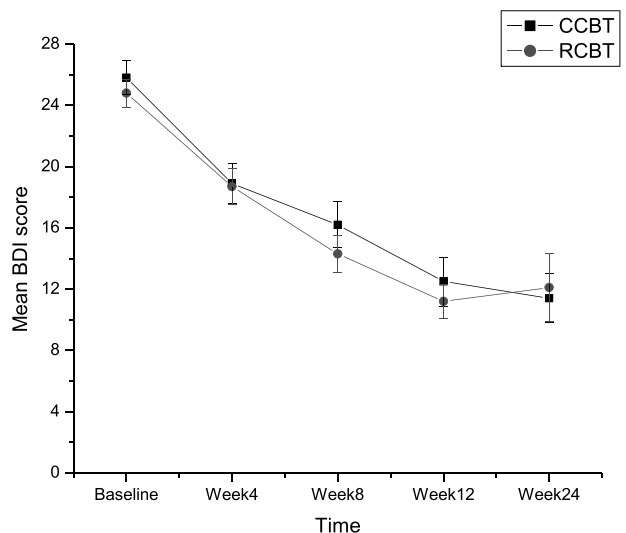


FIGURE 3. Mean (standard error) BDI total scores from baseline to week 24 of follow-up by treatment group.

comparison of two forms of CBT (not a comparison with “usual care”), and trials of this type often do not find a difference between similar psychotherapies (Wampold et al., 1997). Second, at least part of the content of CCBT and RCBT concerned the broadly spiritual issues of forgiveness, meaning and purpose, generosity, and engagement in altruistic activities, as well as meditation. This ensured that any treatment differences would be due only to the religious nature of the therapy.

These preliminary results suggest that RCBT is not inferior to CCBT in the treatment of major depression in persons with chronic medical illness who are at least somewhat religious or spiritual. As noted earlier, at least one study has found that many in the United States with challenging health problems prefer to have their religious beliefs integrated into treatment, and many other religious persons might also desire such beliefs to be honored and respected as a resource to them (Stanley et al., 2011). Failure of clinicians to do so has likely resulted in many depressed religious patients either not seeking or not continuing with psychotherapy despite their need for it (Mayers et al., 2007). The findings from the present study, especially if replicated in a future noninferiority trial, may help to dispel concerns of some clinicians that religious beliefs either are always neurosis inducing or act counter to treatment goals (Power, 2012; Watters, 1992).

Limitations and Strengths

Our pilot trial's main objective was to assess the viability of the design and was not powered to detect a minimal clinically significant difference between CCBT and RCBT or the effect of religiosity on treatment response. As noted above, the moderate severity of depression may also have affected the results reported here. Another limitation is that we did not measure the degree to which clients integrated into their lives what was taught during the RCBT sessions (*i.e.*, the degree to which clients prayed, memorized, and meditated on scriptures or sought support from or offered it to members of their faith community), which may have influenced the results. Finally, the RCBT intervention used here was heavily scripture based, and this approach may appeal more to some faith traditions than to others. Nevertheless, there are also a number of strengths, including the multicenter nature of the study (participants from both the East and West Coast), the relatively wide range of religiosity among participants, the use of a structured psychiatric interview to identify major depression, the use of multiple therapists of similar level of experience and training, and the close adherence of all therapists to the treatment manuals.

Next Steps

There are at least two potential next steps. First would be to conduct a noninferiority trial. The present study was not powered to determine whether CCBT and RCBT were equivalent treatments, and a larger sample size would be needed for this purpose. Second would be to repeat the study in a large sample of highly religious depressed clients. Although the clients in the present sample were at least somewhat religious or spiritual, as noted above, they were not as religious on average as the general US population. We found here that RCBT was more effective in those who were more religious (based on a significant interaction between religiosity and treatment group). Although the effect size in those who were highly religious was small ($d = 0.14$), the number in this subgroup was also small ($n = 45$). Thus, it would be useful to repeat the study with a larger, more adequately powered sample, while using the information gathered in this pilot study to modify the RCBT intervention. It should be noted that the current RCBT protocol had 30% more content to cover than the CCBT protocol, leaving RCBT therapists with little flexibility in terms of taking time to just listen to clients' concerns, be supportive, and build the therapeutic alliance. Thus, reducing the content and focusing on aspects of the RCBT protocol that seemed most helpful to clients might be even more effective.

CONCLUSIONS

The present study indicates that comparing CCBT and RCBT is feasible. Although not planned as a noninferiority trial, the findings suggest that RCBT and CCBT are equally efficacious in the treatment of major depression in clients with chronic medical illness who are at least somewhat religious. Furthermore, the religiosity of the client may make a difference in treatment outcome, depending on whether RCBT or CCBT is used. Thus, on the basis of these preliminary results from this underpowered study, integrating religious clients' beliefs into CBT does not seem to significantly reduce its effectiveness, especially in religious clients. The form of RCBT tested in the current study (Pearce et al., 2014), however, may increase the access of religious persons with depression and chronic medical illness to a psychotherapeutic treatment that they might otherwise not seek, and those who are highly religious may be more likely to adhere to this type of therapy and benefit from it.

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DISCLOSURES

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