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A Home-Based Intervention to Reduce Depressive Symptoms and Improve Quality of Life in Older African Americans:

A Randomized Trial

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Abstract

Background—Effective care models for treating older African Americans with depressive symptoms are needed.

Objective—To determine whether a home-based intervention alleviates depressive symptoms and improves quality of life in older African Americans.

Design—Parallel, randomized trial stratified by recruitment site. Interviewers assessing outcomes were blinded to treatment assignment. (ClinicalTrials.gov: NCT00511680)

Setting—A senior center and participants' homes from 2008 to 2010.

Patients—African Americans aged 55 years or older with depressive symptoms.

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Intervention—A multicomponent, home-based intervention delivered by social workers or a wait-list control group that received the intervention at 4 months.

Measurements—Self-reported depression severity at 4 months (primary outcome) and depression knowledge, quality of life, behavioral activation, anxiety, function, and remission at 4 and 8 months.

Results—Of 208 participants (106 and 102 in the intervention and wait-list groups, respectively), 182 (89 and 93, respectively) completed 4 months and 160 (79 and 81, respectively) completed 8 months. At 4 months, participants in the intervention group showed reduced depression severity (difference in mean change in Patient Health Questionnaire-9 score from baseline, -2.9 [95% CI, -4.6 to -1.2]; difference in mean change in Center for Epidemiologic Studies Depression Scale score from baseline, -3.7 [CI, -5.4 to -2.1]); improved depression knowledge, quality of life, behavioral activation, and anxiety ($P < 0.001$); and improved function ($P = 0.014$) compared with wait-list participants. More intervention than wait-list participants entered remission at 4 months (43.8% vs. 26.9%). After treatment, control participants showed benefits similar in magnitude to those of participants in the initial intervention group. Those in the initial intervention group maintained benefits at 8 months.

Limitation—The study had a small sample, short duration, and differential withdrawal rate.

Conclusion—A home-based intervention delivered by social workers could reduce depressive symptoms and enhance quality of life in most older African Americans.

Primary Funding Source—National Institute of Mental Health.

Depression is a common, major mental health problem with debilitating consequences for older adults. Although primary care is the principal setting for depression detection and treatment, symptoms are often underrecognized and undertreated in this setting, particularly for older African Americans (1–3). Compared with white persons, older African Americans are at greater risk for not receiving standard depression care (4–6) or participating in psychotherapy or other guideline treatments because of system-level (lack of access or minimal time spent on mental health) and patient-level (stigma or lack of symptom recognition) factors (7). Furthermore, prevalence rates of depressive symptoms among older African Americans, particularly those with chronic illnesses, may be as high as 30%, double the rates previously reported (8–11). Improving access to depression care for this group remains a public health concern.

Depression has profound harmful health and psychosocial consequences, including increased risk for dementia (12), prolonged inflammatory responses after infection (13), functional decline (3, 14), poor quality of life, and death (3, 15). Even mild to moderate symptoms, if not successfully treated, are associated with poor health outcomes, erode quality of life, and increase health care utilization and costs (13, 14).

Limitations of previous depression trials (psychosocial or medication) include an almost exclusive focus on primary care patients, lack of attention to approaches addressing barriers to accessing depression care, and lack of inclusion of older African Americans (16–27). Community- and home-based nonpharmacologic depression treatment approaches are

promising, but few are tailored to or specifically tested in older African Americans (18, 25, 28–30).

Building on previous trials (18, 27, 28), we designed the BTB (Beat the Blues) trial to address depressive symptoms in older African Americans. The trial represents a partnership between a university research center and senior center, with each contributing to intervention design, study plan, and execution. Senior centers are overlooked and underused settings providing disease prevention, health education, and social services to more than 1 million older adults daily, many of whom are vulnerable and underserved (20, 31). Yet, few senior centers offer depression care. Involving senior centers in depression care may reduce barriers to mental health services for older adults who may view clinical treatment as stigmatizing.

The BTB trial was tailored to older African Americans. Recruitment strategies were spearheaded by the senior center, the program name reflected the language of the targeted group, behavioral activation was included as a treatment approach because activity is a preferred coping strategy of the targeted group, and stress reduction was tailored to participants' personal preferences (32).

We hypothesized that BTB participants would have reduced depressive symptoms (primary end point) and, secondarily, improvements in depression knowledge and efficacy, quality of life, physical function, anxiety, and behavioral activation at 4 months compared with wait-list control participants. We also considered whether control group participants showed similar benefits after receiving BTB and whether the initial BTB group maintained benefits at 8 months. Finally, we examined proportions of participants in remission, with clinically meaningful score reductions and improvement in diagnostic category.

Methods

Design Overview

We conducted a single-blind, parallel, randomized, controlled trial comparing a home-based intervention (BTB) with a wait-list control group at 4 months. Participants were allocated in a 1:1 ratio to each study group. The control group received BTB after 4 months, whereas the initial BTB group did not receive further intervention contact. All participants were assessed at baseline and reassessed at 4 months (primary end point) and 8 months using self-report measures by trained interviewers blinded to group allocation. Trial participants and interventionists knew patient assignment status. Enrollment occurred between May 2008 and November 2010. All study procedures, consents, and brochures were approved by data safety monitoring and institutional review boards.

Setting and Participants

Recruitment involved outreach to the community at large (senior center members and nonmembers living in the Philadelphia, Pennsylvania, region) and temporarily homebound elderly persons in a short-term assistance program (In-Home Support Program [IHSP]) administered by the senior center (32). For the latter, 12 IHSP senior center care managers were trained to use the Patient Health Questionnaire-9 (PHQ-9) in routine assessments.

Individuals scoring 5 or higher were provided with information about mental health services and BTB. Participants from IHSP who were interested in BTB were contacted by the on-site research coordinator at the senior center who, by telephone, explained study procedures and readministered the PHQ-9 within 2 weeks to confirm depressive symptoms.

Recruitment from the community at large involved print media, presentations, and distribution of institutional review board–approved study brochures at health fairs, agencies, senior housing, and libraries. The senior center research coordinator explained study procedures and administered the PHQ-9 by telephone to individuals who expressed interest by telephone or postcard. Those who were eligible at this initial screening (PHQ-9 score ≥ 5) were readministered the PHQ-9 within 2 weeks by telephone.

Eligible individuals had PHQ-9 scores of 5 or higher, consistent with depressive symptoms, at 2 testing occasions 2 weeks apart and were African American, aged 55 years or older, English-speaking, and cognitively intact (Mini-Mental State Examination score ≥ 24). Participants met other criteria to minimize loss to follow-up, including telephone access and expectation of remaining in the region. Individuals were excluded if they had histories of serious mental illness, life-limiting illness, or involvement in another depression trial or were a long-term care resident.

Randomization

We stratified by recruitment source (IHSP or community), then randomly assigned within each stratum using random permuted blocks to control for possible changes in participant mix over time. The blocking number was developed by the project statistician and was unknown to others. Randomization lists and 2 sets of randomization forms were prepared using opaque envelopes. The on-site project director at the research center randomly assigned each participant within 48 hours from baseline.

Intervention

The BTB intervention involved up to ten 1-hour in-home sessions that occurred weekly for the first few weeks then biweekly for up to 4 months. The intervention involved 5 interrelated components: care management involving a systematic assessment of unmet care needs, referral and linkage involving resource identification and linking participants to social and medical services, depression education instructing participants in symptom recognition, stress reduction techniques (for example, signal breadth or music) for coping with stress-inducing events, and behavioral activation to identify personal activity goals and a plan of action to accomplish them. The intervention sought to help participants identify and complete behavioral goals despite negative mood states and to break the behavior–mood cycle by addressing environmental circumstances that provide low levels of positive reinforcement and minimal control (33). Participants received all 5 treatment components, with each component tailored to participants' prioritized care needs, preferred language in referring to depressive symptoms, depression knowledge level, preferred stress reduction technique, and personal activity goals. Activity goals included, but were not limited to, managing chronic conditions, socialization, exercise, addressing unmet care needs, preparing family meals, traveling, and attending classes. Each treatment component

supported participants becoming behaviorally activated: Providing education helped participants understand linkages between behavior and mood; care management, referral, and linkage helped minimize external factors contributing to depressed mood and preventing behavioral activation; and stress reduction helped participants manage situational stress associated with conditions contributing to depressive symptoms.

Participants in the wait-list control group did not receive any study-based intervention between baseline and 4 months. They received BTB in its entirety after completion of their 4-month reassessment. Six licensed social workers served as interventionists and received 35 hours of intervention training. Each participant remained with the same interventionist.

Outcomes and Follow-up

The primary outcome was severity of depressive symptoms assessed with the PHQ-9, a brief, psychometrically valid, 9-item self-report measure. The second screening was used as the participants' baseline values. A total severity score was calculated by summing responses across items rated as occurring not at all (0 points), on several days (1 point), on more than half the days (2 points), or nearly every day (3 points). Possible scores ranged from 0 to 27. Higher scores indicated greater severity (Cronbach α , 0.769 for sample).

Secondary outcomes included 7 measures, which are summarized in Appendix Table 1 (available at www.annals.org). We used the 10-item Center for Epidemiologic Studies Depression Scale (CES-D) to assess depressive symptoms (34, 35). Depression knowledge and efficacy were assessed using 10 items reflecting symptom awareness ("can identify depression symptoms") and efficacy ("know how to explain feelings") (36), and well-being was assessed using 14 items (for example, "energy" or "feel sad") (37). We assessed quality of life by using 12 items of the Quality of Life in Alzheimer's Disease scale with 1 item, "relationship with caregiver," eliminated (38). For activation, we used a modified Behavioral Activation Scale; we eliminated 10 of the 25 original items that were irrelevant to this sample (for example, "My work/schoolwork suffered ..."), reworded 2 items, and added 2 items ("I accomplished the goals I set out to do" and "I rewarded myself in some way for doing things good for me") (39). Finally, we used the 10-item State Anxiety Scale (40) and assessed functional difficulty for 18 self-care, mobility, and instrumental activities (41). No intermediate measures (between baseline and 4 months or between 4 and 8 months) were assessed.

To examine clinically meaningful change in depressive symptoms for participants with 4-month follow-up, we a priori applied recommended cutoff scores. Using PHQ-9, we examined percentages of participants with decreases of 5 or more points (42). On the basis of PHQ-9 scoring guidelines and criteria from the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*, we categorized symptoms as "in remission" or "minimal/no" (0 to 4 points), "mild" (5 to 9 points), "moderate" (10 to 14 points), "moderately severe" (15 to 19 points), or "severe" (20 to 27 points). The proportion of participants in remission at 4 months was then examined (43). Using these categories, we also examined percentages of participants changing diagnostic categories (improved, worsened, or stayed the same) by 4 months. Finally, using CES-D, we examined the proportion of participants with scores less than 8 (no depressive symptoms) by 4 months.

Adverse event documentation included event description, date of occurrence, resolution, and attribution to study participation (highly probable, somewhat probable, or not probable).

All interviews were triple-check coded before data entry to identify and resolve missing data and coding errors. Double data entry was used, and entered data were periodically reviewed to evaluate accuracy and identify missing data. Treatment fidelity of interviewers and interventionists was monitored by using checklists applied to randomly selected audiotaped sessions and interventionist case presentations at supervisory meetings. Completed intervention documentation was reviewed for protocol adherence. Interventionists did not have contact with interviewers.

Statistical Analysis

We based the sample size calculation on the main study hypothesis at 4 months. To have 90% power to detect a moderate effect size (Cohen d , 0.50) with a type I error rate of 0.05 using a 2-sample t test and an expected attrition of 10% by 4 months, we planned to randomly assign 192 participants. In the last recruitment wave, an additional 16 individuals had positive screening results and were included for a total sample size of 208. Statistical power for secondary analyses was the same as for the primary analysis.

We used descriptive statistics of baseline characteristics to examine potential differences between eligible individuals willing and unwilling to participate, between IHSP and community participants, and between participants who did and did not complete 4 months in the study.

For the primary outcome, the PHQ-9 severity score was the dependent variable with the stratification variable, recruitment source (IHSP or other), entered as a covariate with its interaction with time. The time-by-covariate interaction corresponds to a main effect of the covariate in a change score analysis. We used a mixed-effects model (PROC MIXED in SAS, version 9.2 [SAS Institute, Cary, North Carolina]) using data from all 3 times (0, 4, and 8 months), with the covariate and intervention as fixed effects. The 3 error terms for each participant were treated as correlated with an unstructured covariance matrix. The Kenward–Roger approximation was used for degrees of freedom. The primary treatment effect was the between-group difference in change from baseline to 4 months, estimated using the ESTIMATE statement in SAS. For the secondary comparison of 4 to 8 months, we computed the difference in response for each treatment group from 4 to 8 months, also using the ESTIMATE statement. Analyses that included living arrangement (alone or with others) and employment status (employed or unemployed) as covariates were also done. Similar analyses were performed for CES-D and secondary outcomes. These analyses used all 208 participants in the group as randomly assigned.

For each outcome, we conducted sensitivity analyses by adding a score for propensity to withdraw from the study by 4 months. To determine a propensity score, we used logistic regression to determine a function that discriminated between participants who did and did not withdraw by 4 months. Candidate variables were employment status, living arrangement, sex, and baseline values of all outcomes. To avoid overfitting, a step-down approach was used with an inclusion significance level of 0.25. Variables selected were sex,

employment status, living arrangement, and baseline well-being. We then divided participants into 4 groups based on quartiles of the propensity score. Withdrawal rates were 7.8%, 9.4%, 7.7%, and 25.0%, so we also condensed to 2 groups: highest propensity (25.0% withdrawal rate) versus remaining (8.3% withdrawal rate). We then repeated the mixed-model analysis and included terms for propensity score group and its interactions with intervention, time, and intervention by time. The last interaction allows for differential treatment effect by propensity group. We used SAS for all analyses. Statistical tests were 2-sided with a significance level of 0.05.

Role of the Funding Source

The National Institute of Mental Health funded the trial but did not have a role in the design or conduct of the study; collection, management, analysis, or interpretation of the data; or preparation, review, or approval of the manuscript.

Results

The Figure shows the flow of study participation. Of 703 persons initially screened, 390 (55.5%) scored positively for depressive symptoms (PHQ-9 score ≥ 5) (137 of 440 [31.1%] from IHSP and 253 of 263 [96.2%] from the community at large).

Of 390 persons with positive initial screening results, 279 (71.5%) were successfully contacted for the second screening, of whom 241 (86.4%) were eligible and 208 (86.3%) were willing to participate. No large or statistically significant background differences were found between enrollees and those who were eligible but declined to participate ($n = 33$ [13.7%]).

By 4 months, 182 (87.5%) participants remained in the study (89 in the BTB group and 93 in the control group), whereas 26 (12.5%) had discontinued participation (17 in the BTB group and 9 in the control group). There were no large or statistically significant differences in baseline variables between participants who continued and those who did not. By 8 months, 160 (76.9%) were available for follow-up (79 in the BTB group and 81 in the control group). Total attrition was 48 participants (23.1%) (27 and 21 in the BTB and control groups, respectively).

Sample

Table 1 shows characteristics of participants at baseline. Participants had a mean age of 69.6 years, and most were women (78.4%), were unemployed (90.9%), were not married (88.0%), lived alone (56.7%), had no more than a high school education (50.5%), and had some financial difficulty (67.8%). An average of 6.4 health conditions were reported, with high blood pressure (79.3%), high cholesterol level (58.7%), arthritis (76.4%), and diabetes (42.8%) most frequently reported. Forty participants (19.3%) reported antidepressant medication use, and 35 (17.0%) reported antianxiety medication use. In the 4 months before enrollment, 97 (46.6%) spoke to physicians or clergy, 40 (19.2%) spoke to mental health specialists, and 16 (7.8%) participated in support groups for depressive symptoms.

Participants enrolled from the IHSP were older than community participants (72.2 vs. 68.5 years), had more health conditions (7.1 vs. 6.2 conditions) and pain (4.5 vs. 3.9, as measured by the Short Form-36 pain item), had less education (less than high school, 37.3% vs. 14.8%; high school, 32.2% vs. 28.2%; beyond high school, 30.5% vs. 57.1%), and were less likely to be employed (0.48% vs. 8.65%). There were no differences in PHQ-9 scores between IHSP and community participants. Most (71.1%) were moderately to severely depressed: 60 (28.9%) scored mild, 73 (35.1%) scored moderate, 50 (24.0%) scored moderately severe, and 25 (12.0%) scored severe.

Treatment Implementation

Of 106 BTB participants, 7 declined treatment for unknown reasons. For 99 with treatment data, an average of 7.7 sessions and 66.1 minutes per session were completed. Per protocol, most sessions involved behavioral activation (mean, 6.8 sessions) followed by care management (mean, 6.4 sessions), depression education (mean, 3.9 sessions), referral or linkage (mean, 3.7 sessions), and stress reduction (mean, 4.6 sessions). Ninety-three (93.9%) completed at least 3 sessions, the minimum required for treatment benefit; 6 (6.1%) completed fewer than 3 sessions.

There was no crossover in assignment during the first 4 months of the trial. After the 4-month follow-up, 82 of 102 control group participants (with documentation data) participated in slightly fewer intervention sessions (mean, 6.4 sessions) than the initial BTB group, with a difference of -1.3 sessions (95% CI, -2.2 to -0.5 sessions; $P = 0.003$). However, the number of sessions for each treatment component was similar for both groups. In the control group, 72 (87.8%) participants completed at least 3 intervention sessions, whereas 10 (12.2%) completed 1 or 2 sessions.

4-Month Outcomes

At 4 months, reductions were found in depressive symptoms for BTB compared with control participants on PHQ-9 severity score (between-group difference in change from baseline to 4 months, -2.9 [CI, -4.6 to -1.2]; $P = 0.001$). We also saw improvements in BTB participants compared with control participants for all secondary outcomes: CES-D score (difference, -3.7 [CI, -5.4 to -2.1]; $P < 0.001$), depression knowledge and efficacy (difference, 0.3 [CI, 0.2 to 0.5]; $P < 0.001$), well-being (difference, 0.7 [CI, 0.5 to 0.9]; $P < 0.001$), quality of life (difference, 3.2 [CI, 1.9 to 4.6]; $P < 0.001$), behavior activation (difference, 0.8 [CI, 0.5 to 1.2]; $P < 0.001$), anxiety (difference, -0.4 [CI, -0.6 to -0.2]; $P < 0.001$), and functional difficulty (difference, -0.2 [CI, -0.3 to 0.0]; $P = 0.014$) (Table 2).

The results of the analyses that included living arrangement and employment status were similar (data not shown). Sensitivity analyses that incorporated a score for the propensity to discontinue the study before month 4 also produced consistent results (Appendix Table 2, available at www.annals.org).

Of participants with 4-month service use data ($n = 182$), 74 (40.9%) spoke to physicians or clergy, 32 (17.7%) spoke to mental health specialists, and 16 (8.8%) participated in a support group for persons with depressive symptoms during the trial. No large or

statistically significant differences in service use existed between the control and BTB groups.

Clinical Significance

Of participants with 4-month data ($n = 182$), a greater proportion of BTB participants (43.8% [$n = 39$]) than control participants (26.9% [$n = 25$]) were in remission (absolute difference, 16.9 percentage points [CI, 3.2 to 30.6 percentage points]; $P = 0.020$). Similarly, a greater proportion of BTB participants in each diagnostic category at baseline entered remission (Table 3). Also at 4 months, 57 (64.0%) BTB participants compared with 38 (40.9%) control participants showed clinically meaningful reductions in severity (decrease of 5 points) (42). Sixty-eight (76%) BTB participants versus 58 (62%) control participants improved (moved to a lower symptom category), 5 (6%) BTB participants versus 11 (12%) control participants worsened (moved to a higher symptom category), and 16 (18%) BTB participants versus 24 (26%) control participants did not change. For those with 4-month CES-D data ($n = 181$), approximately twice as many BTB participants (46 of 88 [52.3%]) as control participants (24 of 93 [25.8%]) scored less than 8 (the clinical cutoff for depressive symptoms).

8-Month Outcomes

Participants in the control group showed benefits from 4 to 8 months that were similar (Table 4) to the adjusted benefits for the initial BTB group (Table 2). Changes in the BTB group from 4 to 8 months were small relative to their initial adjusted benefits (Table 2), and none reached statistical significance (Table 4). Also, 68.6% (24 of 35) of initial BTB participants who were in remission at 4 months remained so at 8 months (CI, 50.7% to 83.1%). An additional 11 BTB participants entered remission, but 11 also moved from remission for a net gain of zero.

Discussion

The BTB trial demonstrates the feasibility of involving a senior center in depression care (detection and treatment) for older African Americans. Thirty-one percent of the African Americans in the senior center's temporarily homebound assistance program who were screened for trial enrollment had depressive symptoms. Routine ascertainment for depression in such a medically compromised group may be particularly important. Of potential enrollees who were recruited from the community at large, 96% met screening criteria for depressive symptoms, suggesting that older African Americans correctly self-identify depressive symptoms and seek help from a trusted source.

At 4 months, the BTB intervention improved mood and quality-of-life indicators, with gains sustained to 8 months. Effect sizes for all outcome measures were moderate to large and compared favorably with those seen in other depression trials (16 – 19, 28). Control participants showed similar benefits after receiving the BTB intervention. Reductions in depressive symptoms were clinically meaningful according to common cutoffs for PHQ-9 and CES-D measures. Nearly 70% of BTB participants in remission at 4 months remained

so at 8 months, although booster sessions may be necessary for those (less than one third) not faring as well.

The cause and treatment of depressive symptoms are unclear. The BTB intervention assumed a behavioral explanation that links mood to daily stressors. For minority and low-income patients, context is an underaddressed risk factor for depressive symptoms that BTB addressed (7). Trial results add to the evidentiary base supporting socio-ecological understandings of depressive symptoms. The intervention reflects an integrated approach and components that work in concert (for example, behavioral activation plans were linked to unmet care management needs). The active treatment components are unclear, although we did see gains in specific components as indicated by measures of depression knowledge and efficacy, anxiety, and behavioral activation. Future research should examine mediation models to understand potential underlying mechanisms.

Although at-home care may be labor-intensive and senior center involvement is not without its challenges, advantages may outweigh disadvantages (20). An English-language literature search to April 2013 revealed trials showing benefits similar to those of BTB (18, 30). A systematic review of 23 trials of community- and home-based interventions for late-life depression found better treatment acceptance and fewer nursing home admissions and inpatient days with such interventions compared with usual care (45).

We note several study limitations. The BTB intervention was tested in a single urban senior center. Volunteers may have been motivated by their relationship with or knowledge of this senior center. Another limitation may be reliance on self-reported outcomes only. Nevertheless, self-report is highly associated with clinical determinations, and the PHQ-9 is widely used in clinical and research contexts. We did not control for attention and cannot rule out its contribution to outcomes. Other limitations include the trial's small sample, small percentage of men, involvement of 1 minority group, and differential withdrawal rate between the BTB and control groups.

Most African Americans have limited mental health care options, possibly because of system-level (for example, lack of access to nonpharmacologic approaches) and patient-level (for example, stigma or mistrust) factors (1, 11, 46, 47). Findings from this trial suggest that involving a trusted community-based agency may improve access to symptom detection and treatment for this group. Because specialist care may be required for only a small proportion of persons with complicated depression or those who are nonresponsive to nonpharmacologic treatments (48), senior centers represent a promising resource for addressing mental health disparities. However, the sustainability of BTB is challenged by current reimbursement mechanisms. A related point is how BTB fits within existing health services. The participants in our trial had significant and unresolved medical issues; therefore, integrating BTB with primary care may boost treatment effects. New mental health policies are urgently needed to support community-level models that overcome persistent inequities and address contextual issues related to depressive symptoms (26, 49, 50). Our approach warrants replication and reimbursement consideration.

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Figure 1. Study flow diagram

BTB = Beat the Blues; IHSP = In-Home Support Program.

* Three participants had 8-mo follow-up but missed 4-mo follow-up.

† One participant had 8-mo follow-up but missed 4-mo follow-up.

Table 1

Baseline Characteristics, by Treatment Group*

Characteristic	BTB (n = 106)	Wait-List Control (n = 102)	Total (n = 208)
Recruitment source, n (%)			
IHSP	31 (29.3)	28 (27.5)	59 (28.4)
Community at large	75 (70.8)	74 (72.6)	149 (71.6)
Sex, n (%)			
Male	22 (20.8)	23 (22.6)	45 (21.6)
Female	84 (79.3)	79 (77.5)	163 (78.4)
Age, y			
Mean (SD)	68.9 (8.9)	70.3 (8.4)	69.6 (8.7)
Range	–	–	55.6–96.1
Financial difficulty, n (%)			
Not difficult at all	16 (15.1)	25 (24.5)	41 (19.7)
Not very difficult	15 (14.2)	11 (10.8)	26 (12.5)
Somewhat difficult	38 (35.9)	40 (39.2)	78 (37.5)
Very difficult	37 (34.9)	26 (25.5)	63 (30.3)
Employment status, n (%)			
Unemployed	92 (86.8)	97 (95.1)	189 (90.9)
Employed	14 (13.2)	5 (4.9)	19 (9.1)
Marital status, n (%)			
Not married	90 (84.9)	93 (91.2)	183 (88.0)
Married/living as married	16 (15.1)	9 (8.8)	25 (12.0)
Education, n (%)			
Less than high school	20 (18.9)	24 (23.5)	44 (21.2)
High school	28 (26.4)	33 (32.4)	61 (29.3)
Beyond high school	58 (54.7)	45 (44.1)	103 (49.5)
Living arrangement, n (%)			
Alone	50 (47.2)	68 (66.7)	118 (56.7)
With others	56 (52.8)	34 (33.3)	90 (43.3)
Health conditions, n			
Mean (SD)	6.4 (2.8)	6.5 (3.2)	6.4 (3.0)

Characteristic	BTB (n = 106)	Wait-List Control (n = 102)	Total (n = 208)
Range	–	–	0–19
Physical pain			
Median (IQR)	4 (4–5)	4 (3–5)	4 (4–5)
Range	–	–	1–6
Medications			
Median (IQR), n	1 (0–2)	1 (0–2)	1 (0–2)
Range, n	–	–	0–5
Depression medication, n (%) [†]	24 (22.6)	16 (15.8)	40 (19.3)
Anxiety medication, n (%) [†]	18 (17.1)	17 (16.8)	35 (17.0)
Depression level (PHQ-9), n (%)			
Minimal/none (0–4 points)	0 (0.0)	0 (0.0)	0 (0.0)
Mild (5–9 points)	30 (28.3)	30 (29.4)	60 (28.9)
Moderate (10–14 points)	36 (34.0)	37 (36.3)	73 (35.1)
Moderately severe (15–19 points)	24 (22.6)	26 (25.5)	50 (24.0)
Severe (≥ 20 points)	16 (15.1)	9 (8.8)	25 (12.0)
PHQ-9 severity score			
Stage 1			
Mean (SD)	14.0 (4.6)	13.1 (5.1)	13.6 (4.9)
Range	–	–	5–25
Stage 2			
Mean (SD)	13.3 (5.2)	12.7 (4.7)	13.0 (4.9)
Range	–	–	5–25
Service use for depressive symptoms, n (%)			
Discussed with medical professional or clergy	52 (49.1)	45 (44.1)	97 (46.6)
Discussed with mental health specialist	21 (19.8)	19 (18.6)	40 (19.2)
Attended support group	7 (6.6)	9 (8.8)	16 (7.7)

BTB = Beat the Blues; IHSP = In-Home Support Program; IQR = interquartile range; PHQ-9 = Patient Health Questionnaire-9.

* Percentages may not sum to 100 because of rounding.

[†] Among 207 participants.

Table 2

Comparison of BTB and Control Participants at 4 mo

Outcome	BTB (<i>n</i> = 106) [*]		Wait-List Control (<i>n</i> = 102) [*]		Mean Difference (95% CI)	<i>P</i> Value	
	Baseline Score	Score at 4 mo	Difference	Baseline Score			Score at 4 mo
PHQ-9	13.3 ± 0.5	6.4 ± 0.6	-6.9 ± 0.6	12.7 ± 0.5	8.9 ± 0.6	-3.8 ± 0.6	<0.001
CES-D	14.9 ± 0.6	8.4 ± 0.6	-6.5 ± 0.6	14.6 ± 0.6	11.6 ± 0.6	-3.0 ± 0.6	<0.001
Depression knowledge	3.1 ± 0.04	3.5 ± 0.05	0.4 ± 0.05	3.1 ± 0.04	3.2 ± 0.05	0.1 ± 0.05	<0.001
Well-being	2.6 ± 0.1	3.5 ± 0.1	0.9 ± 0.1	2.7 ± 0.1	2.9 ± 0.1	0.2 ± 0.1	<0.001
Quality of life	25.7 ± 0.5	29.7 ± 0.5	4.0 ± 0.5	26.3 ± 0.5	27.2 ± 0.5	0.9 ± 0.5	<0.001
Behavior activation	2.9 ± 0.1	3.9 ± 0.1	1.0 ± 0.1	2.9 ± 0.1	3.2 ± 0.1	0.3 ± 0.1	<0.001
Anxiety	2.6 ± 0.06	2.0 ± 0.07	0.5 ± 0.07	2.5 ± 0.06	2.3 ± 0.07	0.2 ± 0.07	<0.001
Functional difficulty	2.0 ± 0.06	1.8 ± 0.06	-0.2 ± 0.05	2.0 ± 0.06	1.9 ± 0.06	0.1 ± 0.05	0.016

BTB = Beat the Blues; CES-D = Center for Epidemiologic Studies Depression Scale; PHQ-9 = Patient Health Questionnaire-9.

* Data are least-squares means (±SEs) from the mixed-model analysis using all 208 randomly assigned participants. Differences (BTB minus control) use the ESTIMATE statement in SAS.

Table 3

Participants Transitioning to Remission at 4 mo*

PHQ-9 Depression Category at Baseline	Participants, <i>n</i>		BTB (<i>n</i> = 89)		Wait-List Control (<i>n</i> = 93)	
	BTB	Wait-List Control	In Remission at 4 mo, <i>n</i> (%)	95% CI	In Remission at 4 mo, <i>n</i> (%)	95% CI
Mild (5–9 points)	28	27	19 (67.9)	47.4–84.1	12 (44.4)	25.5–64.7
Moderate (10–15 points)	30	33	10 (33.3)	17.3–52.8	7 (21.2)	9.0–38.9
Moderate/severe (16–19 points)	18	25	4 (22.2)	6.4–47.6	3 (12.0)	2.6–31.2
Severe (20–27 points)	13	8	6 (46.2)	19.2–74.9	3 (37.5)	8.5–75.6
Total 4-mo sample	89	93	39 (43.8)	33.5–54.7	25 (26.9)	18.5–37.3

BTB = Beat the Blues; PHQ-9 = Patient Health Questionnaire-9.

* Data are for participants with 4-mo follow-up (*n* = 182). Those with a PHQ-9 score of 0 to 4 were considered to be in remission. The CIs were calculated using the

Table 4

Comparison of BTB and Control Participants at 8 mo^{*}

Outcome	Wait-List Control		Difference (±SE) [‡]	BTB			
	Mean Score at 8 mo (±SE) [†]	Change Between 4 and 8 mo Mean (95% CI) [‡] P Value		Mean Score at 8 mo (±SE) [†]	Change Between 4 and 8 mo Mean (95% CI) [‡] P Value		
PHQ-9	5.4 ± 0.5	-3.7 (-4.9 to -2.5)	<0.001	2.7 ± 0.9	6.2 ± 0.5	-0.4 (-1.7 to 0.7)	0.47
CES-D	7.9 ± 0.7	-3.9 (-5.3 to -2.5)	<0.001	1.7 ± 1.0	9.5 ± 0.7	0.9 (-0.5 to 2.3)	0.20
Depression knowledge	3.5 ± 0.05	0.3 (0.2 to 0.4)	<0.001	0.0 ± 0.08	3.5 ± 0.05	0.0 (-0.1 to 0.1)	0.94
Well-being	3.4 ± 0.1	0.5 (0.3 to 0.7)	<0.001	-0.3 ± 0.1	3.4 ± 0.1	-0.1 (-0.3 to 0.1)	0.34
Quality of life	29.1 ± 0.6	2.1 (1.1 to 3.2)	<0.001	-1.6 ± 0.7	30.0 ± 0.6	0.5 (-0.5 to 1.5)	0.31
Behavior activation	3.8 ± 0.1	0.7 (0.4 to 1.0)	<0.001	-0.2 ± 0.2	3.7 ± 0.1	0.2 (-0.4 to 0.1)	0.179
Anxiety	2.0 ± 0.1	-0.3 (-0.5 to -0.2)	<0.001	0.1 ± 0.1	2.0 ± 0.1	0.0 (-0.2 to 0.2)	0.94
Functional difficulty	1.7 ± 0.1	-0.2 (-0.4 to -0.1)	<0.001	0.1 ± 0.1	1.9 ± 0.1	0.1 (-0.0 to 0.2)	0.148

BTB = Beat the Blues; CES-D = Center for Epidemiologic Studies Depression Scale; PHQ-9 = Patient Health Questionnaire-9.

^{*} See Table 2 for 4-mo data.[†] Least-squares means from the mixed-model analysis using all 208 randomly assigned participants.[‡] Control group (4 to 8 mo) minus BTB group (0 to 4 mo).

Appendix Table 1

Secondary Outcome Measures

Measure	Items, <i>n</i>	Time Frame	Response Format	Possible Scores	Scoring and Interpretation	Cronbach α for Sample
CES-D	10	Past week	0 (rarely/never) to 3 (most or all of the time)	0–30	A total score was derived representing the sum of scores across items; higher scores indicate more symptoms	0.759
Depression knowledge and efficacy	10	Present	1 (not at all confident) to 4 (absolutely confident)	1.0–4.0	A mean score was derived by summing across items and dividing by number of items; higher scores represent improved knowledge/efficacy	0.734
Well-being	14	Past month	1 (much worse) to 5 (improved a lot)	1.0–5.0	A mean score was derived by summing across items and dividing by number of items; scores >3 indicate improvement	0.920
Quality of life	12	Present	1 (poor) to 4 (excellent)	12–48	A total score was derived representing the sum of scores across items; higher scores indicate better perceived quality of life	0.792
Behavioral activation	17	Past week	0 (not at all) to 6 (completely)	0.0–6.0	A mean score was derived by summing across scores and dividing by the number of items; higher scores indicate greater activation	0.829
Anxiety	10	Past week	1 (very much) to 4 (not at all)	1.0–4.0	A mean score was derived by summing across scores and dividing by the number of items; lower scores indicate less anxiety	0.848
Functional difficulty	18	Past month	1 (no difficulty) to 5 (unable to perform because of health problem)	1.0–5.0	A mean score was derived by summing across scores and dividing by the number of items; lower scores indicate less functional difficulty	0.903

CES-D = Center for Epidemiologic Studies Depression Scale.

Appendix Table 2

Comparison of Propensity to Withdraw Between BTB and Control Participants

Outcome	4-Category			2-Category			Continuous		
	Mean Difference (95% CI)*	P Value		Mean Difference (95% CI)*	P Value		Mean Difference (95% CI)*	P Value	
PHQ-9	-3.1 (-4.8 to -1.4)	<0.001		-3.1 (-4.7 to -1.4)	<0.001		-3.0 (-4.7 to -1.3)	<0.001	
CES-D	-3.6 (-5.3 to -2.0)	<0.001		-3.6 (-5.2 to -2.0)	<0.001		-3.4 (-5.0 to -1.7)	<0.001	
Depression knowledge	0.3 (0.2 to 0.4)	<0.001		0.3 (0.2 to 0.4)	<0.001		0.3 (0.1 to 0.4)	<0.001	
Well-being	0.7 (0.5 to 0.9)	<0.001		0.7 (0.5 to 0.9)	<0.001		0.6 (0.4 to 0.8)	<0.001	
Quality of life	3.2 (1.8 to 4.5)	<0.001		3.2 (1.8 to 4.5)	<0.001		3.1 (1.7 to 4.4)	<0.001	
Behavior activation	0.8 (0.4 to 1.1)	<0.001		0.8 (0.4 to 1.1)	<0.001		0.8 (0.4 to 1.1)	<0.001	
Anxiety	-0.4 (-0.6 to -0.2)	<0.001		-0.4 (-0.6 to -0.2)	<0.001		-0.4 (-0.6 to -0.2)	<0.001	
Functional difficulty	-0.2 (-0.3 to 0.0)	0.017		-0.2 (-0.3 to 0.0)	0.018		-0.2 (-0.3 to 0.0)	0.033	