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The effects of telephone-delivered cognitive-behavioral therapy and nondirective supportive therapy on sleep, health-related quality of life, and disability

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Abstract

Objectives—The purpose of this study is to compare the effects of cognitive-behavioral therapy delivered by telephone (CBT-T) and telephone-delivered nondirective supportive therapy (NST-T) on sleep, health-related quality of life, and physical disability in rural older adults with Generalized Anxiety Disorder.

Design—Secondary analyses of a randomized clinical trial

Setting—Participants' homes

Participants—141 rural-dwelling adults 60 years and older diagnosed with Generalized Anxiety Disorder

Intervention—CBT-T vs. NST-T

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Measurements—Sleep was assessed with the Insomnia Severity Index. Health-related quality of life was assessed with the SF-36. Physical disability was assessed with the Pepper Center Tool for Disability. Assessments occurred at baseline, 4 months, 9 months, and 15 months.

Results—Insomnia declined in both groups from baseline to 4 months, with a significantly greater improvement among participants who received CBT-T. Similarly, Mental and Physical Component Summaries of the SF-36 declined in both groups, with a differential effect favoring CBT-T. Participants in both interventions reported declines in physical disability although there were no significant differences between the 2 interventions. Improvements in insomnia were maintained at the 15-month assessment, while between-group differences shrank on the Mental and Physical Component Summaries of the SF-36 by the 15-month assessment.

Conclusions—Telephone-delivered cognitive-behavioral therapy was superior to nondirective supportive therapy in reducing insomnia and improving health-related quality of life. The effects of CBT-T on sleep were maintained up to 1 year after completing the treatment.

Keywords

cognitive-behavioral therapy; supportive therapy; psychotherapy; GAD; late-life anxiety; RCT

Introduction

Generalized Anxiety Disorder (GAD) is characterized by excessive and uncontrollable worry and is accompanied by restlessness, fatigue, poor concentration, irritability, muscle tension, and/or sleep disturbance (1). GAD is one of the more common anxiety disorders, affecting up to 7.3% of older adults (2). The impact of GAD extends beyond mental health; late-life GAD is associated with worse physical health and even mortality (3–5).

One of the associated symptoms of GAD is sleep disturbance. Thus, it is not surprising that older adults with GAD report a greater degree of insomnia than older adults without GAD (6). Further, older adults with GAD report greater sleep disturbance than younger adults with GAD (6). Yet, few studies have reported on sleep as an outcome of psychotherapy trials, and those that do report conflicting outcomes. Brenes and colleagues (7) found that cognitive-behavioral therapy (CBT) for GAD was superior to enhanced usual care in reducing insomnia among older adults. Similarly, Bush and colleagues (8) found that CBT for late-life GAD was associated with greater improvements in the ability to fall asleep compared with enhanced usual care. However, others have found that sleep difficulties often remain after the treatment of GAD (9).

Late-life GAD is also associated with poor health-related quality of life (HRQL) even after controlling for medical conditions and comorbid depression (10–11). The greatest differences between older adults with GAD and healthy older adults are in the HRQL constructs of social functioning, energy, and role limitations due to emotional health (11). Compared with other anxiety disorders, GAD is associated with the greatest impairment in HRQL (12).

Disability within the context of GAD has often focused on work productivity. However, physical disability and self-care are more relevant to older adults. Older adults with GAD

report more difficulty with activity limitations and impaired ability to participate in activities as frequently as they would like (10). GAD has also been associated with impairments in self-care activities and participating in non-work activities such as hobbies (13).

This study is based on data from a randomized clinical trial comparing telephone-delivered cognitive-behavioral therapy (CBT-T) with nondirective supportive therapy (NST-T) for the treatment of GAD in rural elders (14). We found that CBT-T was superior to NST-T in reducing worry, GAD symptoms, and depressive symptoms. The purpose of this report is to examine the effects of treatment on the non-mood-related secondary outcomes of sleep, HRQL, and disability in older adults with GAD. It was hypothesized that CBT-T would be superior to NST-T in improving sleep, HRQL, and disability.

Methods

Participants

Participants were part of a randomized clinical trial comparing CBT-T and NST-T for the treatment of rural-dwelling older adults with GAD. For more information about recruitment procedures, please see Brenes et al. (15). In brief, participants were adults aged 60 years and older with a principal or co-principal diagnosis of GAD who lived in rural counties within North Carolina. Participants were randomized to receive either CBT-T or NST-T. Data from this study are based on the baseline assessment conducted prior to randomization and the post-intervention (4, 9, and 15 months after baseline) assessments.

Measures

The Insomnia Severity Index (ISI; 16) is a 7-item self-report measure of type and severity of insomnia symptoms, including problems with sleep onset, sleep maintenance, or early morning awakening; satisfaction with current sleep pattern; interference with daily functioning; noticing impairment attributed to sleep problems; and level of concern or distress caused by the sleep problem. Responses are summed, with higher scores indicating greater sleep impairment. The ISI has demonstrated good reliability, validity, and sensitivity to change with treatment in older adults (16).

The SF-36 (17) is a self-report measure of HRQL consisting of 36 items that form 8 subscales: physical functioning, role limitations due to physical health problems, role limitations due to emotional health problems, social functioning, freedom from pain, energy, emotional well-being, and general health perceptions. These 8 subscales are also combined into two domains: the Physical Component Summary (PCS) and the Mental Component Summary (MCS). All of these scales range from 0 (maximum impairment) to 100 (no impairment).

The Pepper Center Tool for Disability (PCT-D; 18–19) is a 19-item self-report measure of perceived difficulties with mobility and performing basic and advanced activities of daily living during the last month. Participants rate how much difficulty they had performing each of the activities on a 5-point Likert scale ranging from 1 “no difficulty” to 5 “unable to do” the task, and items are averaged to yield the final score. This measure has been validated in

four large samples of older adults and has demonstrated response to change in physical activity interventions (18).

Interventions

CBT-T consisted of up to 11 weekly psychotherapy sessions that addressed recognition of anxiety symptoms, relaxation, cognitive restructuring and the use of coping statements, problem solving, worry control, behavioral activation, exposure therapy, and relapse prevention. Optional sessions focused on sleep and pain. Each session was accompanied by a workbook chapter. NST-T consisted of 10 weekly sessions of supportive therapy described as “high-quality therapeutic relationship that provides a warm, genuine, and accepting atmosphere through the use of supportive and reflective communications” (p. 9; 20–21). Booster sessions were provided for both interventions at 2, 4, 8, and 12 weeks after completion of the weekly sessions. Ten percent of therapy sessions were reviewed by 2 independent evaluators to assess therapist adherence and competence in delivery of the interventions. Mean ratings for all therapists were above the a priori minimum of 6.0 (good) on 9-point scales of adherence and competence.

Statistical Analyses

Demographic and health characteristics were summarized with means, standard deviations, counts, and percentages. Comparison of the outcomes between intervention groups was made using constrained mixed-model repeated measures analysis of covariance with an unstructured covariance matrix to account for the fact that the multiple measurements (at baseline, 4, 9, and 15 months post-randomization) from participants are not independent. The models contained terms for therapist (a factor to which participants were randomized), baseline presence/absence of a depressive disorder (used to stratify randomization), use of psychotropic medications at baseline (used to stratify randomization), and intervention effects that were specific to each follow-up time. Because this was a randomized trial, pre-randomization intervention-specific outcome means were constrained to be the same (22). For randomized trials, constrained mixed-models can provide more efficient estimates of post-randomization treatment differences when either baseline or post-randomization measures are missing (23). A contrast was used to test the effect of the intervention on all four outcomes at the 4-month visit, the pre-specified time point for which the primary outcomes were tested. Standardized intervention differences were calculated at 4-months using the t-statistic from the contrast to obtain an estimate of the standard difference. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

To control the false discovery rate at the 0.05 level, we used the multiple-comparison procedure of Benjamini and Hochberg (24) across all four hypothesis tests (for the four tests of hypotheses at the 4-month visit). Results for the 8 subscales of the SF-36 and results for other outcomes collected at the 9- and 15-month visits are presented as differences between intervention groups with 95% confidence intervals.

Results

Participants ranged in age from 60 to 87 years with a mean age of 66.8 (SD=6.2). The sample consisted of largely white (90.8% white, 5.7% black, 3.5% Native American), well-educated (37.6% had some college, 44.7% had a college degree) women (81.6%). Demographics, health-related characteristics, and baseline values of the secondary outcomes for the sample are presented in Table 1. Figure 1 presents participant flow from randomization through the 15-month follow-up.

ISI and SF-36 measures were missing for 15% of participants at the 4-month visit, 27% at the 9-month visit, and 21% at the 15-month visit. PCT-D was missing for 17% of participants at the 4-month visit, 30% at the 9-month visit, and 23% at the 15-month visit. Missingness was similar between groups at 4 and 9 months, however, it is significantly higher for the CBT-T group at the 15-month visit (13% vs 30% for ISI and SF-36, Chi-Square=6.32, df=1, p=0.01; 15% vs 31% for PCT-D, Chi-Square=4.99, df=1, p=0.03).

The modelling results are shown in Table 2 and Figure 2. Using the Benjamini and Hochberg multiple comparisons procedure to control the false discovery rate at the 0.05 level resulted in declaring 4-month intervention differences significant for the ISI and both SF-36 domains, but not the PCT-D. In summary, symptoms of insomnia (ISI) declined on average among participants in both interventions at the 4-month visit, but participants in the CBT-T intervention experienced significantly greater improvement ($F=10.21$; $df=1,136$; nominal $p=0.002$). Similarly, on average, all participants reported improvements in HRQL (SF-36) at 4 months on both the PCS and the MCS. Further, participants in the CBT-T intervention experienced significantly greater improvements on both subscales (PCS: $F=5.43$; $df=1,136$; nominal $p=0.021$; MCS: $F=5.58$; $df=1,136$; nominal $p=0.020$). Although participants in both interventions reported, on average, declines in physical disability symptoms (PCT-D) from baseline to 4 month follow-up, there was no differential effect by intervention ($F=2.60$; $df=1,134$; nominal $p=0.109$). Scores on the individual subscales of the SF-36 are presented in the supplement (Data, Supplemental Digital Content 1 and 2). In order to estimate the clinical significance of these findings, we computed the standardized effects (ES) of treatment on the outcomes. The differential effects of CBT-T and NST-T on sleep (ES = 0.27) and HRQL (PCS component ES = 0.20; MCS component ES = 0.20) were moderate in size. The between-group estimates and confidence intervals for the ISI scores at 9 and 15 months post-intervention are also shown in Table 2 and Figure 2. They are consistent with that observed at the immediate (4-month) post-intervention assessment. There is some shrinkage of the between-group differences at the 9- and 15-month follow-up assessments for both the PCS and the MCS. Nine and 15-month follow-up findings for the PCT-D were similar to the immediate post-intervention findings.

Discussion

We examined the effects of telephone-delivered CBT and NST on sleep, HRQL, and physical disability among rural elders with GAD. While we found that both treatments were associated with improvements in each of these domains at the 4-month follow-up, participants who received CBT-T demonstrated significantly greater declines in insomnia

and improvement in HRQL. Thus, this study provides further support that the impact of CBT-T for the treatment of late-life GAD extends beyond mood symptoms.

Sleep is a common complaint among anxious older adults (6), and reports of insomnia at baseline were high in the current sample. There was a differential effect favoring CBT-T for reducing symptoms of insomnia. This difference may be due to the inclusion of one CBT-T session specifically focused on sleep. We also found CBT-T had a significantly greater impact on worry and depressive symptoms (14) which may account for sleep improvements. One meta-analysis of GAD treatment studies found that CBT for GAD had a large effect on sleep (9); however, the included trials did not include studies of late-life GAD. In fact, few studies of older adults with GAD have reported on sleep as an outcome of psychotherapy treatment trials. Two studies that have included it found that CBT was superior to enhanced usual care for improving sleep (7–8). Insomnia in older adults has been associated with a number of negative health outcomes, including greater risk of falls (25), poorer physical functioning (26), and increased risk of developing depression (27). Thus, improvements in insomnia may have other health benefits.

HRQL was also significantly improved, with a greater improvement experienced by participants who received CBT-T. Examination of subscale scores showed improvement in both physical and emotional domains of HRQL. Other studies of late-life GAD have found improvements in HRQL, generally with respect to the MCS (28–29) or other mental component subscales (30–31). To our knowledge, this study is the first to report significant improvements in the PCS of HRQL with treatment of late-life GAD. The PCS includes general health perceptions, pain, physical functioning, and role limitations due to physical health problems. As part of the CBT-T intervention, some participants received an optional session on pain if they reported pain at baseline or during the course of the intervention. Further, CBT-T encouraged participants to increase pleasant activities and face feared situations, both of which could have resulted in improved scores on physical functioning and role limitations due to physical health problems. In spite of significant improvements in HRQL, post-intervention scores on the SF-36 subscales were closer to scores of older adults with GAD than scores of healthy older adults without GAD (10). This suggests that even with treatment, HRQL does not improve to the levels of those without GAD.

There is a dearth of information on the impact of late-life GAD on physical disability, as most studies focus on work and social disabilities. Hendriks and colleagues (13) found that GAD was associated with significant limitations in mobility, self-care, life activities and responsibilities, and participating in community events; however, their sample was limited to adults under the age of 65 years. Porensky and colleagues (10) found that older adults with GAD report increased physical disability compared with older adults without GAD. In the current study, while we found that participants in both interventions demonstrated improvement from baseline, there were no differential effects of the interventions on physical disability. This may be due to the high level of functioning of participants at baseline, leaving little room for improvement. Inclusion of age-appropriate measures of functioning, including physical disability, in studies of late-life GAD is needed.

In addition to the immediate effect of the interventions, we also examined the effects 6 months and 1 year after completion of the intervention. We found that the effects of CBT-T on insomnia were maintained through the 1-year follow-up. However, improvements in HRQL diminished from baseline to 1 year follow-up by 17% for the MCS component and almost 30% for the PCS component. Thus, CBT-T produced a sustained reduction in insomnia, and a partially sustained improvement in HRQL at 1 year post intervention.

The findings of this study must be interpreted in light of the following limitations. The sample consisted of predominantly well-educated, white women, limiting generalizability. Further, measures of insomnia are self-reported and do not include any objective measures. Nonetheless, these findings suggest that CBT-T is superior to NST-T for reducing insomnia and improving HRQL in rural-dwelling older adults with GAD. Further, the effects on insomnia are maintained up to 1 year after completing treatment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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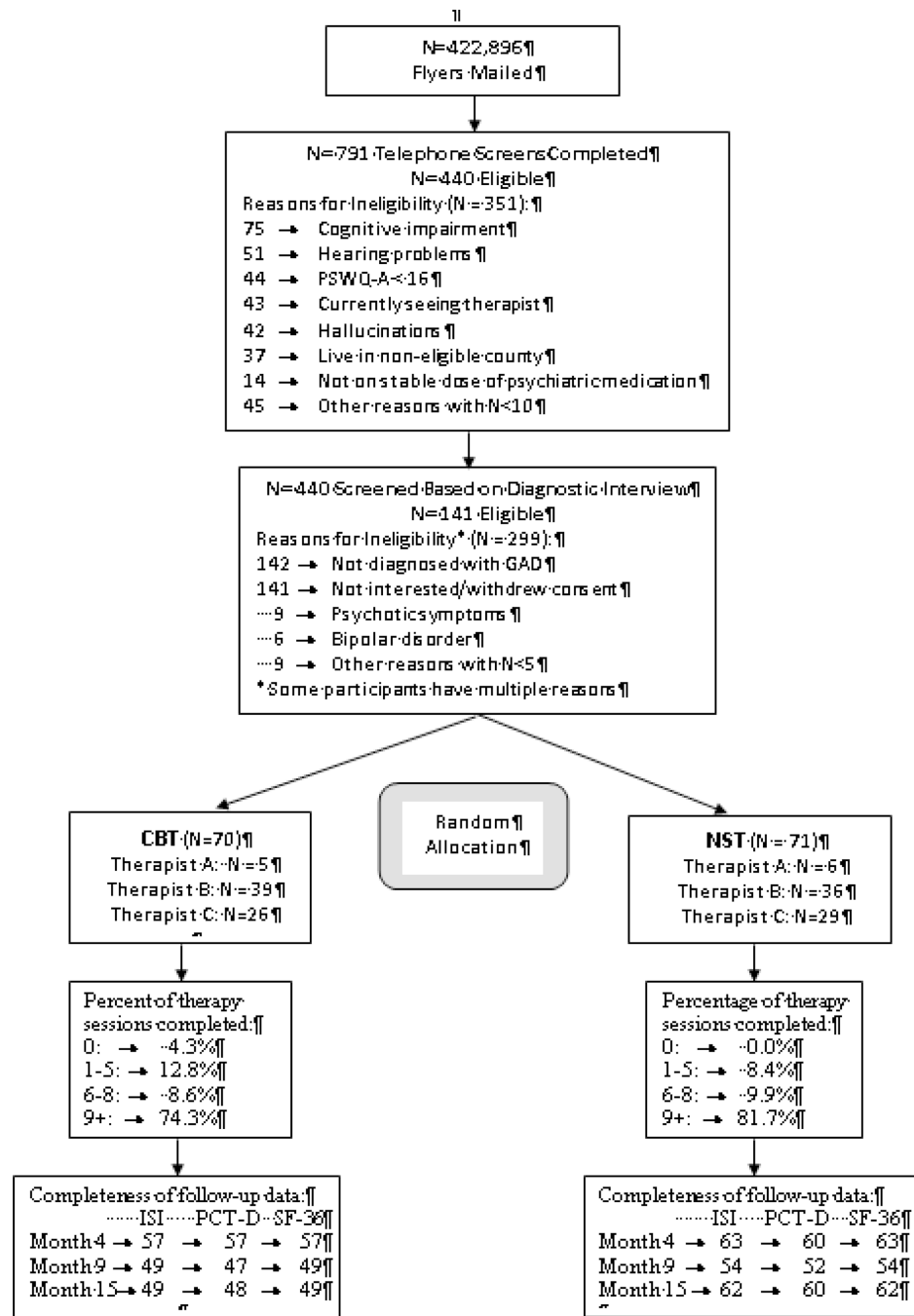


Figure 1.
CONSORT Diagram

Note: CBT = Cognitive-behavior therapy; GAD = Generalized Anxiety Disorder; ISI = Insomnia Severity Index; NST = Nondirective supportive therapy; PCT-D = Pepper Center Tool for Disability; PSWQ-A = Penn State Worry Questionnaire-Abbreviated.

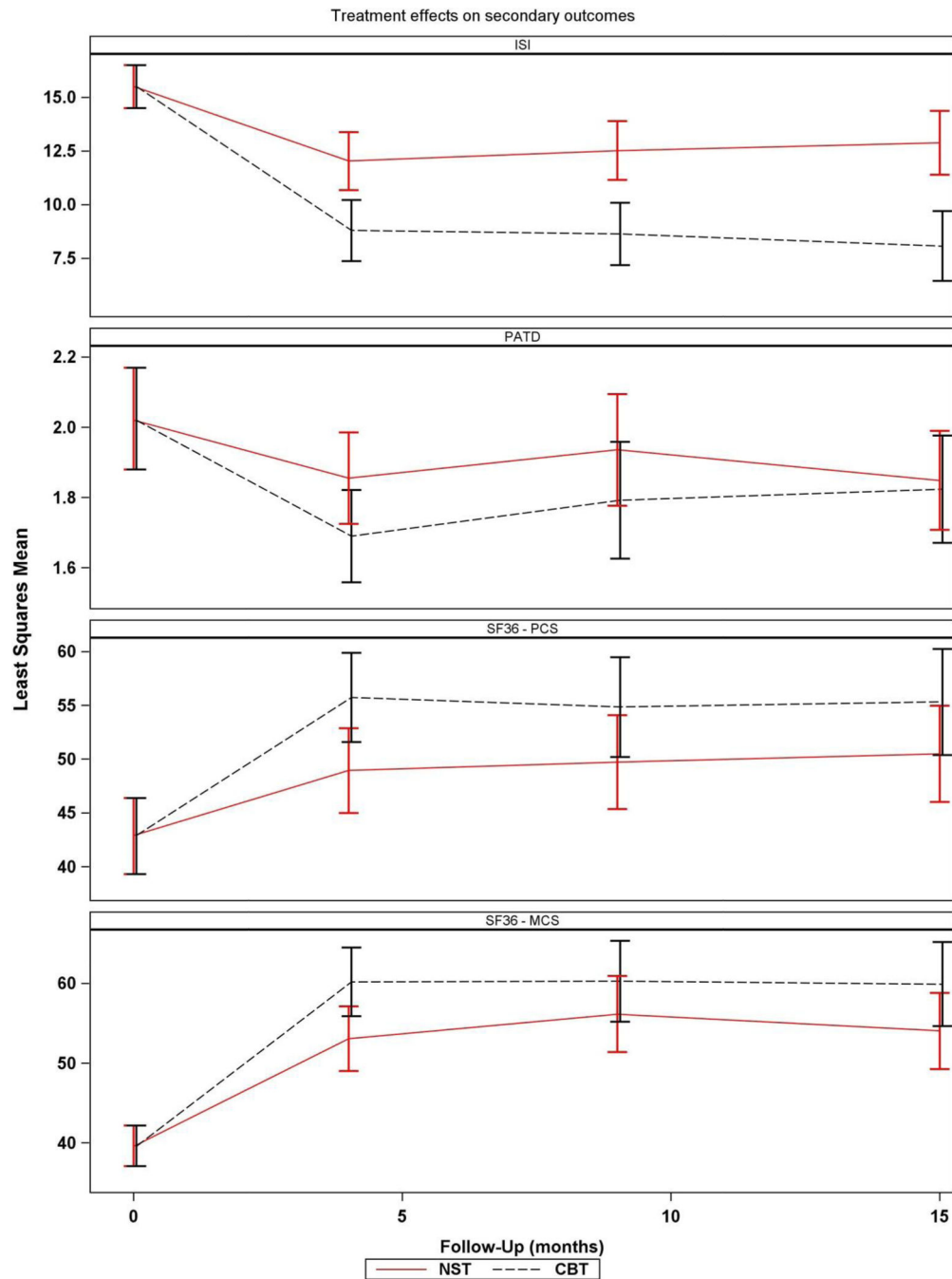


Figure 2. Least squares means and 95% confidence intervals obtained from constrained mixed models. Note: CBT = Cognitive-behavior therapy; ISI = Insomnia Severity Index; MCS = Mental Component Summary; NST-Nondirective supportive therapy; PCS = Physical Component Summary; PCT-D = Pepper Center Tool for Disability.

Table 1

Baseline Characteristics of Randomized Participants

Characteristic	Total (N=141)	CBT (N=70)	NST (N=71)
Gender, n (%)			
Male	26 (18.4)	12 (17.1)	14 (19.7)
Female	115 (81.6)	58 (82.9)	57 (80.3)
Race, n (%)			
Black or African American	8 (5.7)	4 (5.7)	4 (5.6)
Caucasian or White	128 (90.8)	64 (91.4)	64 (90.1)
Other	5 (3.5)	2 (2.9)	3 (4.2)
Age, n (%), years			
60–64	66 (46.8)	29 (41.4)	37 (52.1)
65–69	38 (27.0)	20 (28.6)	18 (25.4)
70–74	19 (13.5)	8 (11.4)	11 (15.5)
75+	18 (12.8)	13 (18.6)	5 (7.0)
Education, n (%)			
Less than high school (HS)	7 (5.0)	4 (5.7)	3 (4.2)
HS grad or GED	18 (12.8)	9 (12.9)	9 (12.7)
Some college	53 (37.6)	19 (27.1)	34 (47.9)
College degree	63 (44.7)	38 (54.3)	25 (35.2)
Income, n (%)			
Less than \$24,999	33 (23.4)	12 (17.1)	21 (29.6)
\$25,000 to \$49,999	41 (29.1)	21 (30.0)	20 (28.2)
\$50,000 to \$74,999	19 (13.5)	10 (14.3)	9 (12.7)
More than \$75,000	16 (11.4)	7 (10.0)	9 (12.7)
Missing	32 (22.7)	20 (28.6)	12 (16.9)
Marital status, n (%)			
Never been married	1 (0.7)	1 (1.4)	0 (0.0)
Married or living with someone	75 (53.2)	37 (52.9)	38 (53.5)
Divorced	27 (19.2)	13 (18.6)	14 (19.7)
Separated	9 (6.4)	4 (5.7)	5 (7.0)
Widowed	29 (20.6)	15 (21.4)	14 (19.7)
Currently employed, n (%)	38 (27.0)	17 (24.3)	21 (29.6)
Living status, n (%)			
With others	87 (61.7)	41 (58.6)	46 (64.8)
Alone	54 (38.3)	29 (41.4)	25 (35.2)
Smoking status, n (%)			
Never	68 (48.2)	37 (52.9)	31 (43.7)
Current	14 (9.9)	6 (8.6)	8 (11.3)
Former	59 (41.8)	27 (38.6)	32 (45.1)

Characteristic	Total (N=141)	CBT (N=70)	NST (N=71)
Current psychotropic medication usage, n (%)			
Anxiolytics	38 (27.0)	22 (31.4)	16 (22.5)
Hypnotics	12 (8.5)	5 (7.1)	7 (9.9)
Antidepressants	54 (38.3)	29 (41.4)	25 (35.2)
Antipsychotics/neuroleptics	3 (2.1)	1 (1.4)	2 (2.8)
Stimulants	1 (0.7)	0 (0.0)	1 (1.4)
History of self-reported health problems, n (%)			
Hypertension	92 (65.7)	43 (62.3)	49 (69.0)
Myocardial infarction	9 (6.4)	4 (5.8)	5 (7.0)
Congestive heart failure	8 (5.7)	4 (5.7)	4 (5.6)
Stroke	11 (7.9)	5 (7.2)	6 (8.5)
Diabetes	29 (20.6)	9 (12.9)	20 (28.2)
ISI score, mean (SD)	15.5 (5.59)	15.3 (5.17)	15.7 (5.98)
SF-36 MCS, mean (SD)	39.7 (13.89)	42.1 (12.36)	37.4 (14.88)
SF-36 PCS, mean (SD)	42.9 (19.70)	45.6 (19.13)	40.4 (20.0)
PCT-D score, mean (SD)	2.0 (0.76)	1.9 (0.65)	2.2 (0.84)
Presence of comorbid depression diagnosis, n (%)			
Total	102 (72.3)	51 (72.9)	51 (71.8)
Current	54 (38.3)	23 (32.9)	31 (43.7)
Past	48 (34.0)	28 (40.0)	20 (28.2)
Presence of comorbid anxiety diagnosis, n (%)	72 (51.1)	31 (44.3)	41 (57.8)

Note: CBT = Cognitive-behavioral therapy; ISI = Insomnia Severity Index; NST = Nondirective Supportive Therapy; PCT-D = Pepper Center Tool for Disability; SF-36-MCS = SF-36 Mental Component Score; SF-36-PCS = SF-36 Physical Component Score.

Table 2

Summary of Secondary Results through All Follow-Up

Outcome	Month	CBT		NST		Difference in Means Between Groups (95% CI)	P value for Intervention Effect*
		Mean (95% CI)	Mean Change from Baseline (95% CI)	Mean (95% CI)	Mean Change from Baseline (95% CI)		
ISI	4	8.70 (7.10, 10.3)	-6.69 (-8.16, -5.23)	11.9 (10.4, 13.4)	-3.48 (-4.87, -2.09)	3.21 (1.23, 5.20)	0.002
	9	8.60 (7.01, 10.2)	-6.79 (-8.27, -5.32)	12.4 (10.9, 14.0)	-2.94 (-4.34, -1.55)	3.85 (1.86, 5.84)	
	15	8.00 (6.30, 9.70)	-7.39 (-9.04, -5.73)	12.8 (11.2, 14.4)	-2.59 (-4.11, -1.07)	4.80 (2.62, 6.98)	
SF36 – MCS	4	60.5 (55.9, 65.1)	20.29 (15.99, 24.60)	53.5 (49.1, 57.9)	13.27 (9.19, 17.35)	-7.03 (-12.91, 1.15)	0.020
	9	60.6 (55.2, 65.9)	20.38 (15.24, 25.51)	56.4 (51.4, 61.5)	16.25 (11.40, 21.09)	-4.13 (-11.14, 2.88)	
	15	60.3 (54.7, 65.8)	20.08 (14.74, 25.41)	54.4 (49.3, 59.4)	14.17 (9.32, 19.01)	-5.91 (-13.06, 1.24)	
SF36 – PCS	4	55.0 (50.1, 60.0)	12.53 (8.38, 16.67)	48.3 (43.5, 53.1)	5.82 (1.89, 9.75)	-6.71 (-12.40, -1.02)	0.021
	9	54.2 (48.8, 59.6)	11.67 (7.04, 16.31)	49.0 (43.9, 54.1)	6.50 (2.13, 10.87)	-5.17 (-11.51, 1.17)	
	15	54.7 (49.2, 60.3)	12.22 (7.29, 17.16)	49.8 (44.6, 55.0)	7.29 (2.82, 11.75)	-4.94 (-11.56, 1.68)	
PCT-D	4	1.71 (1.55, 1.87)	-0.30 (-0.44, -0.17)	1.86 (1.70, 2.01)	-0.16 (-0.29, -0.03)	0.15 (-0.03, 0.33)	0.109
	9	1.82 (1.63, 2.02)	-0.19 (-0.36, -0.02)	1.96 (1.77, 2.15)	-0.05 (-0.21, 0.11)	0.14 (-0.10, 0.37)	
	15	1.83 (1.65, 2.01)	-0.18 (-0.33, -0.03)	1.87 (1.70, 2.04)	-0.14 (-0.28, 0.00)	0.04 (-0.17, 0.25)	

P-values are based on F tests from constrained mixed-model repeated measures analysis of covariance, adjusting for therapist, baseline presence of depressive disorder, and baseline use of psychotropic medications. DF=136 for ISI and SF-36 scales, and DF=134 for PCT-D.

Note: ISI = Insomnia Severity Index; PCT-D = Pepper Center Tool for Disability; SF-36-MCS = SF-36 Mental Component Score; SF-36-PCS = SF-36 Physical Component Score.