Cognitive Behavioral Therapy for Treatment of Chronic Primary Insomnia
A Randomized Controlled Trial

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Persistent primary insomnia (PPI), a sleep disorder that predicts clinical depression and enhanced health care use, affects up to 5% of the general population and about 20% of those insomnia patients seen clinically.1-15 Currently, sedative hypnotics or antidepressant drugs remain the most common treatments offered PPI patients.3,12,16 However, numerous adverse effects encumber traditional hypnotics (eg, benzodiazepines), and evidence supporting the long-term efficacy/safety of antidepressants among nondepressed insomnia patients is currently lacking.16-20 Moreover, these agents provide only symptomatic relief since they fail to address underlying mechanisms that sustain PPI. Consequently, patients commonly show a full return of their insomnia symptoms on termination of these treatments.12,13,16-20

Alternative, behavioral interventions, which target presumed perpetuating mechanisms of patients with PPI, have shown much more durable improvements following treatment. First-generation behavioral therapies, designed to correct sleep-disruptive habits (eg, stimulus control) or reduce bedtime arousal (eg, relaxation training [RT]), have proven very effective for treating sleep onset problems, but their results among the larger PPI subgroup reporting sleep maintenance complaints have been mixed.21-28 However, use of nonpharmacological behavioral therapy has been suggested for treatment of chronic primary insomnia, but well-blinded, placebo-controlled trials demonstrating effective behavioral therapy for sleep-maintenance insomnia are lacking.

Objective To test the efficacy of a hybrid cognitive behavioral therapy (CBT) compared with both a first-generation behavioral treatment and a placebo therapy for treating primary sleep-maintenance insomnia.

Design and Setting Randomized, double-blind, placebo-controlled clinical trial conducted at a single academic medical center, with recruitment from January 1995 to July 1997.

Patients Seventy-five adults (n=35 women; mean age, 55.3 years) with chronic primary sleep-maintenance insomnia (mean duration of symptoms, 13.6 years).

Interventions Patients were randomly assigned to receive CBT (sleep education, stimulus control, and time-in-bed restrictions; n=25), progressive muscle relaxation training (RT; n=25), or a quasi-desensitization (placebo) treatment (n=25). Outpatient treatment lasted 6 weeks, with follow-up conducted at 6 months.

Main Outcome Measures Objective (polysomnography) and subjective (sleep log) measures of total sleep time, middle and terminal wake time after sleep onset (WASO), and sleep efficiency; questionnaire measures of global insomnia symptoms, sleep-related self-efficacy, and mood.

Results Cognitive behavioral therapy produced larger improvements across the majority of outcome measures than did RT or placebo treatment. For example, sleep logs showed that CBT-treated patients achieved an average 54% reduction in their WASO whereas RT-treated and placebo-treated patients, respectively, achieved only 16% and 12% reductions in this measure. Recipients of CBT also showed a greater normalization of sleep and subjective symptoms than did the other groups with an average sleep time of more than 6 hours, middle WASO of 26.6 minutes, and sleep efficiency of 85.1%. In contrast, RT-treated patients continued to report a middle WASO of 43.3 minutes and sleep efficiency of 78.8%.

Conclusions Our results suggest that CBT represents a viable intervention for primary sleep-maintenance insomnia. This treatment leads to clinically significant sleep improvements within 6 weeks and these improvements appear to endure through 6 months of follow-up.
cognitive behavioral therapy (CBT), which combines cognitive therapy with strategies to improve sleep habits and limit time in bed, appears a promising, more universally effective treatment. Early results suggest CBT effectively addresses sleep-onset and maintenance problems, and it produces better long-term outcomes than pharmacotherapy (temazepam) and medication placebo. Absent from the literature are reports of controlled trials comparing CBT with behavioral placebo and with first-generation behavioral interventions for treating sleep-maintenance complaints. Herein we report our double-blind, randomized trial conducted to compare CBT with a behavioral placebo therapy (PT) and with RT, for treating primary sleep-maintenance difficulties. We predicted (1) CBT would produce greater short-term and long-term improvements in sleep and related subjective symptoms than would PT or RT; and (2) RT would not outperform PT.

**METHODS**

**Design**

A double-blind, placebo-controlled, randomized group design was used. Participants were randomly assigned to treatments (CBT, RT, or PT) and therapists (1 female, 1 male). Enrollees were blinded to hypotheses and the nature of the PT, but they were told they had a 1 in 3 chance of PT assignment. Therapists were blind to hypotheses and were uninformed that 1 of the treatments they administered was a placebo. The protocol was approved by the Duke University Medical Center institutional review board. The first author met individually with volunteers prior to enrollment to obtain written informed consent, to inform them about therapist blinding, and to instruct them not to inform their therapists about the placebo condition. No payment was offered for study participation nor were there charges for the study’s evaluations/treatments.

**Participants**

Recruitment occurred between January 1995 and July 1997 through newspaper advertisements and occasionally, via face-to-face solicitation (e.g., sleep clinic patients). Volunteers between the ages of 40 and 80 years were considered for inclusion if they (1) met criteria for PPI; (2) showed a 1-week average wake time after sleep onset (WASO) of 60 minutes or longer (sleep logs); (3) reported insomnia onset after age 10 years; and (4) had insomnia for 6 months or longer. Because poor sleep hygiene is commonly viewed as contributory to PPI, we also required enrollees to report 1 or more sleep-disruptive practices (e.g., napping, erratic sleep scheduling). Excluded were those who (1) were pregnant; (2) had terminal illnesses or sleep-disruptive medical conditions (e.g., angina pectoris); (3) met criteria for an Axis I psychiatric disorder; (4) were habitual substance abusers; (5) would not abstain from sleep aids (hypnotics, antidepressants); (6) required psychotropic medication for a psychiatric condition; (7) had periodic limb movements during sleep associated with more than 10 arousals/h (screening polysomnogram); (8) had symptoms of sleep apnea; (9) met clinical and polysomnogram criteria for sleep state misperception.

Volunteers underwent telephone (newspaper respondents) or brief face-to-face (clinic patients) screening, and those passing this stage completed structured interviews, sleep log monitoring (1 week), a medical examination, thyroid testing, and screening polysomnogram. The interviews were conducted by a clinical psychologist using the Structured Interview for Sleep Disorders and the Structured Interview for Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition Psychiatric Disorders, Patient version since these were the most current instruments of their nature available when the study commenced. Medical examinations were conducted by a physician who is board-certified in neurology and sleep medicine. Seventy-five volunteers qualified, underwent pretreatment assessment, and subsequently were randomly assigned to the study’s 6 treatment and therapist cells using computer-generated randomized blocks within sex and age strata (ie, <55 years vs ≥55 years). Prestudy power calculations deemed this sample size sufficient to accommodate a 15% drop-out rate yet detect the 49-minute posttreatment WASO (sleep logs) difference between CBT and RT found in our pilot work. Figure 1 shows the participant flow whereas Table 1 presents descriptive data for the whole sample and each treatment group. Statistical tests (analysis of variance, χ²) showed no significant demographic differences among these subgroups.

**Measures**

All participants completed the same screening and outcome measures prior to, during, and after treatment as described below.

**Polysomnography.** A screening polysomnogram and 2 subsequent polysomnograms for outcome assessment were requested of each enrollee. The first of the latter 2 polysomnograms was conducted 1 to 2 weeks before treatment whereas the second was conducted during the 2 weeks following the end of treatment. All polysomnogram studies were conducted in participants’ homes using 8-channel Oxford Medilog 9000 (Oxford Medical Inc, Clearwater, Fla) analogue cassette recorders. The screening polysomnogram montage included electroencephalographic, electromyographic, electrooculographic, nasal/oral air flow, and anterior tibialis monitoring. Airflow and tibialis were excluded during the subsequent polysomnograms before and after treatment. Sleep stages and leg movements were scored using standard criteria and our validated Medilog scoring approach. For polysomnograms before and after treatment, scorers were blind to polysomnogram dates and participants’ treatment assignments. Polysomnogram outcome measures included total sleep time, middle WASO (MWASO) defined as the cumulative time awake between sleep onset and the final morning awakening, ter-
minal WASO (TWASO) defined as the
time between final awakening and ris-
ing time, and sleep efficiency (sleep effi-
ciency percentage = [total sleep time/ total time in bed] × 100%). In these
calculations, sleep onset was conser-
vatively defined as the time between lights out and the first 10 minutes of
sleep containing no more than 2 min-
utes of wake time, stage 1, or move-
ment time.41

Sleep Logs. Participants completed
sleep logs during a 2-week pretreat-
ment baseline, the treatment phase it-
self, a 2-week posttreatment assess-
ment, and a 2-week follow-up 6 months
later. On arising, participants com-
pleted sleep log items about the previ-
ous night’s bedtime, rising time, sleep
onset latency, and both MWASO and
TWASO. Additionally, sleep logs elic-
ited respondents’ ratings of the qual-
ity (1 = extremely poor; 5 = excellent) of
each night’s sleep. Outcome measures
derived from logs included the esti-
mates of total sleep time, MWASO and
TWASO, sleep efficiency, and sleep
quality.

Outcome Questionnaires. Partici-
pants completed a 13-item Insomnia
Symptom Questionnaire (ISQ),35 a
9-item Self Efficacy Scale (SES),42 and
the Beck Depression Inventory (BDI)43
at baseline, midtreatment (ie, end of
third treatment week), posttreatment,
and the 6-month follow-up time points.
We used the ISQ to assess improve-
ments in subjective insomnia symp-
toms, the SES to detect changes in per-
ceived control over sleep, and the BDI
to assess changes in subtle PPI-related
mood disturbances.44-46 Each item on
the ISQ is accompanied by a 100-mm
horizontal line labeled “not at all” at its
left extreme and “very [confident]” at its
right extreme. The SES items include simi-
lar 100-mm analog scales labeled “not
at all [confident]” at their left ex-
tremes and “very [confident]” at their
right extremes. For both instruments,
respondents drew a vertical line through
the point on each item’s analog scale to
indicate their responses. The distance
from the left end of the line to the re-
sponse line reflects the item’s score and
the mean score across questionnaire
items represents the respondent’s over-
all score for that instrument. Inter-
item correlations derived from the base-
line administrations showed both the
ISQ (Cronbach α = .73) and SES (Cron-
bach α = .71) had acceptable internal
consistency. Research has also shown
that both measures reflect subjective
treatment-related improvements.35,42
Since the revised version of the BDI was
not available when this project began,
we used the original BDI, which has
well-established psychometric proper-
ties.47-49

Therapy Evaluation Question-
naire. Treatment credibility was as-
essed via responses (Likert ratings) to
the 7-item Therapy Evaluation Questi-
onnaire (TEQ).50 The TEQ’s first 5
questions assess perceived logic of and
confidence in a treatment, willingness
to repeat the treatment, and likeli-
hood the treatment will help others. The
final 2 items assess therapist warmth
and competence. Participants com-
pleted the initial 5 TEQ items after their
first treatment session and all 7 items
after their last session. Inter-item cor-
relations based on posttreatment re-
sponses suggest the TEQ has high in-
ternal consistency (Cronbach α = .79).

Therapists and Treatments
One male (aged 30 years) and 1 fe-
nale (aged 29 years) beginning-level
clinical psychologists, naive to behav-
ioral insomnia therapy, served as the
project’s therapists. Before treating
study participants, they were required
to review the project’s treatment manual
and audio recordings demonstrating
treatments, and then show compe-
tence with each treatment via role-
play sessions with the first author.
Throughout the project, therapists pro-
vided their assigned participants 6 weekly, 30- to 60-minute individual ses-
sions of their respective treatments. The first author jointly supervised the ther-
pists every 8 to 12 weeks throughout the study to ensure their adherence to
treatment protocol and to counter any emerging suspicions about the hypoth-
eses or placebo condition. Once all enrollees completed treatment, ther-
pists were debriefed about study hypotheses and placebo treatment.

The CBT recipients were first pre-
sented a standardized audio-cassette
cognitive therapy module designed to
correct misconceptions about sleep re-
quirements and the effects of aging, cir-
cadian rhythms, and sleep loss on sleep/
wake functioning. They were then given
Bootzin37 stimulus control instruc-
tions to (1) establish a standard
wake-up time; (2) get out of bed dur-
ing extended awakenings; (3) avoid sleep-incompatible behaviors in the
bed/bedroom; and (4) eliminate day-
time napping. Additionally, they each received an initial time in bed prescrip-
tion equal to their average sleep times
(from baseline logs) plus 30 minutes
(ie, normal sleep latency and brief
awakenings). With the established ris-
ing time, this prescription designated
the earliest retiring time allowed each
night. Sessions 2 through 6 entailed re-
viewing instructions and adjusting time
in bed. The time in bed was increased by 15 minutes each week the patient
showed a mean SE of 85% or higher,
but reported continued daytime sleepi-
ness. The time in bed was decreased by
15 minutes each week the patient
showed a mean sleep efficiency of less
than 80%. Otherwise, time in bed was
held constant.

The RT assignees received progres-
sive muscle RT,31 introduced as a
method for overcoming the “condi-
tioned arousal” that perpetuates noc-
turnal wakefulness. Over 6 sessions, RT
recipients first learned to alternately
tense and relax 16 major skeletal muscle
groups, and then to use progressively
more efficient tensing-relaxing and pas-
sive relaxation exercises. After their sec-
ond session, they were encouraged to use
their relaxation skills to help them re-
turn to sleep on awakening at night.
Each week, the RT recipients received an
instructional audio-cassette tape
locked in a tape player equipped with a
mechanism used for covert monitoring
of their intersession practice. They were
instructed to practice the exercise once
each day between sessions only with the
assistance of this tape and tape player but
they remained uninformed about the
monitoring of their practice. However,
they were discouraged from using the
taped instructions in bed because “op-
erating the recorder at night could pro-
long awakenings.”

The patients assigned to PT re-
ceived a quasi-desensitization treat-
ment,52 presented as a means of elimi-
nating the “conditioned arousal,” which
prolongs nocturnal awakenings. Ther-
pists helped each PT recipient de-
velop a chronological 12-item hierar-
chy of common activities he/she did on
awakening at night (eg, opening eyes,
clock watching). Therapists also helped
them develop 6 imaginal scenes of
themselves engaged in neutral activi-
ties (eg, reading the newspaper). Each
session, PT recipients were taught to
pair neutral scenes with items on the
12-item hierarchy so, by the end of the
sixth session, all hierarchy items had
been practiced with therapist assist-
ance. Each session, the exercise was
tape recorded and the patient was given

<table>
<thead>
<tr>
<th>Table 1. Demographic Characteristics and Therapist Assignment for the 3 Treatment Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristic</strong></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Insomnia, mean (SD), y</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>Men</td>
</tr>
<tr>
<td>Education, mean (SD), y</td>
</tr>
<tr>
<td>Marital status</td>
</tr>
<tr>
<td>Married</td>
</tr>
<tr>
<td>Not married</td>
</tr>
<tr>
<td>Current hypnotic use</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>&lt;1 time/wk</td>
</tr>
<tr>
<td>1-4 times/wk</td>
</tr>
<tr>
<td>&gt;4 times/wk</td>
</tr>
<tr>
<td>Therapist assignment</td>
</tr>
<tr>
<td>Total for male therapist</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>Men</td>
</tr>
<tr>
<td>Total &lt;55 y</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>Men</td>
</tr>
<tr>
<td>Total ≥55 y</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>Men</td>
</tr>
<tr>
<td>Total for female therapist</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>Men</td>
</tr>
<tr>
<td>Total &lt;55 y</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>Men</td>
</tr>
<tr>
<td>Total ≥55 y</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>Men</td>
</tr>
</tbody>
</table>
this tape locked in a player like the device provided to the RT recipients. The patients assigned to PT were told to practice their exercises at home once each day, no less than 2 hours before bedtime, but to avoid using the tape or exercise during sleep periods.

After their posttreatment assessments, CBT and RT recipients were asked to return for their final outcome assessment 6 months later. Given their time already invested in the study, the PT patients were not asked to complete the additional 6-month follow-up before receiving active treatment. Instead, they were debriefed and immediately offered active treatment with their previously assigned therapist. Those who accepted were randomized to 6-week courses of CBT (3 women, 6 men) or RT (4 women, 2 men) but their subsequent data were not considered in any of the statistical comparisons conducted. To maintain their blinding, therapists were told that PT recipients were offered a second, more tested treatment, because their initial treatment was a new therapy that had not yet received sufficient testing to justify its isolated use. They were also told that the PT was a promising treatment deserving of the scrutiny provided by this project.

**RESULTS**

**Treatment Attendance and Follow-up**

Seventy enrollees completed all scheduled sessions of their initial treatment. One PT assignee completed only 2 sessions and 1 RT recipient completed only 3 sessions; neither completed the midtreatment assessment. Three others (2 women receiving CBT and 1 man receiving RT) completed at least 4 sessions and midtreatment measures before withdrawing. Of those initially assigned to CBT or RT, 32 (16 CBT and 16 RT) completed questionnaires and 29 (14 CBT and 15 RT) completed sleep logs at follow-up. Comparisons showed married participants were more likely to return for follow-up than were unmarried individuals ($P=.04$); otherwise those who accepted and declined follow-up were demographically similar (Table 1). Marital status was not significantly related to treatment outcomes and no significant demographic differences were found between the CBT and RT subgroups who accepted or declined follow-up.

**Treatment Credibility and Compliance**

The TEQs showed no significant between-group differences (all $P>.47$) in regard to how credible and effective the patients initially believed their assigned treatments to be. At the conclusion of treatment, PT recipients reported significantly less willingness to recommend their treatment to others ($F_{2,65}=5.90; P=.004$) and significantly less confidence that their treatment would be effective for others ($F_{2,64}=5.63; P=.006$) than did CBT and RT recipients. Nonetheless, posttreatment ratings of therapist warmth and competence did not differ across groups ($P=.09$ for both).

The CBT compliance was assessed using sleep log measures of participants’ average nightly times in bed and their within-subject SDs of daily rising times during baseline, each in-treatment week, and during the posttreatment assessment. The CBT recipients were expected to show more marked baseline-to-treatment phase decreases in their average time in bed and their rising time variability than the RT and PT recipients. Figure 2 shows group averages of these measures during baseline, all treatment weeks, and the posttreatment assessment. Analyses of covariance (ANCOVA) adjusted for baseline levels showed the CBT group spent sig-
significantly less time in bed each treatment week and after treatment than did the other 2 groups (P=.001). Kruskal-Wallis tests with Bonferroni adjustment showed the CBT group had significantly less (P=.02) rising time variability than the RT or PT groups during treatment weeks 1, 2, and 5, although Figure 2 shows trends in this direction during and after treatment. Thus, these indices reflected reasonable CBT treatment compliance.

We assessed RT and PT compliance via the covert practice-monitoring data. Figure 3 shows RT participants had the expected pattern of longer practice sessions initially and briefer practices as treatment progressed. The PT recipients showed the expected 10 to 15 minute daily practice sessions throughout treatment. These data suggested acceptable levels of treatment compliance for these 2 groups. Moreover, the mean (SD) weekly practice times for RT of 83.9 (55.1) minutes and 74.5 (37.4) minutes for PT did not differ significantly (P=.49)

Treatment Purity
All therapy sessions were tape recorded and a randomly selected subset (12 CBT, 10 RT, and 7 PT) were selected for scrutiny. Using a checklist designed for this project, a blinded judge reviewed these tapes and identified treatment-specific instructions presented therein. This reviewer observed a mean (SD) of 3.5 (2.3) appropriate instructions during the CBT sessions, 3.8 (1.2) during RT sessions, and 2.7 (2.1) during PT sessions; these means were not statistically different (F2,27=0.68, P=.52). Furthermore, all sessions were rated 100% pure; none of the sessions contained elements from more than 1 treatment.

Treatment Comparisons
Analyses of variance showed no significant preintervention differences among the treatment groups on any of the outcome measures. However, visual inspection of these means (Table 2) suggested the RT group had slightly more disturbed sleep (logs and polysomnogram) and pathological scores on the outcome questionnaires at baseline than did CBT assignees. Thus, ANCOVA, which adjusted for pretreatment levels of outcome measures, was used for all planned treatment comparisons.

We first compared the 3 treatment groups across all posttreatment outcome measures. An initial set of these analyses showed no significant therapist effects so a 1-factor ANCOVA was used for these comparisons. The ANCOVA was conducted first excluding dropouts, and then with all participants using an intention-to-treat approach. The last in-treatment sleep logs and midtreatment questionnaires served as projected end points for those who withdrew prior to the posttreatment assessment. However, using relevant pretreatment predictors and data from those who actually completed posttreatment assessment, we used recommended regression methods to estimate posttreatment sleep log (1 PT), questionnaire (1 RT and 1 PT), and polysomnography (2 CBT, 1 RT, and 4 PT) data for those lacking/declining these posttreatment measures. Resulting regression models were significant (all P=.02) and showed an acceptable mean (SD) prediction by R2 analysis of posttreatment sleep log of 0.58 (0.19), questionnaire of 0.54 (0.16), and polysomnography of 0.61 (0.19).

ANCOVA with and without dropouts showed similar results so only the more conservative intention-to-treat analyses are presented. Table 3, which summarizes these comparisons, shows

![Figure 3. Relaxation Training and Placebo Therapy Compliance Assessment](https://example.com/figure3)

Data were obtained from the covert monitoring device used to monitor participants’ home practice of assigned relaxation training and placebo therapy compliance exercises. Error bars represent SE values.

### Table 2. Baseline Comparisons of Treatment Groups Across All Outcome Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Cognitive Behavioral Therapy</th>
<th>Relaxation Training</th>
<th>Placebo Therapy</th>
<th>F2,72</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total sleep time, min</td>
<td>348.1 (61.7)</td>
<td>315.1 (56.6)</td>
<td>347.1 (68.0)</td>
<td>2.28</td>
<td>.11</td>
</tr>
<tr>
<td>Sleep logs</td>
<td>361.6 (81.8)</td>
<td>342.2 (59.5)</td>
<td>352.5 (77.1)</td>
<td>.44</td>
<td>.25</td>
</tr>
<tr>
<td>Polysomnography</td>
<td>55.0 (25.3)</td>
<td>52.8 (32.3)</td>
<td>60.6 (32.7)</td>
<td>.44</td>
<td>.11</td>
</tr>
<tr>
<td>Middle wake time after sleep onset, min</td>
<td>220.8 (38.6)</td>
<td>45.1 (44.6)</td>
<td>63.0 (50.6)</td>
<td>1.40</td>
<td>.25</td>
</tr>
<tr>
<td>Sleep logs</td>
<td>43.8 (33.6)</td>
<td>49.5 (45.6)</td>
<td>50.6 (36.5)</td>
<td>.28</td>
<td>.76</td>
</tr>
<tr>
<td>Polysomnography</td>
<td>9.6 (12.4)</td>
<td>16.5 (26.1)</td>
<td>16.2 (28.6)</td>
<td>.69</td>
<td>.51</td>
</tr>
<tr>
<td>Sleep efficiency, %</td>
<td>73.7 (11.4)</td>
<td>70.1 (12.9)</td>
<td>71.6 (11.6)</td>
<td>.39</td>
<td>.68</td>
</tr>
<tr>
<td>Sleep logs</td>
<td>80.3 (10.5)</td>
<td>78.3 (10.4)</td>
<td>74.8 (13.4)</td>
<td>1.47</td>
<td>.24</td>
</tr>
<tr>
<td>Polysomnography</td>
<td>2.87 (0.52)</td>
<td>2.83 (0.41)</td>
<td>2.83 (0.52)</td>
<td>.06</td>
<td>.94</td>
</tr>
<tr>
<td>Questionnaires</td>
<td>54.4 (12.4)</td>
<td>58.5 (11.2)</td>
<td>51.7 (14.0)</td>
<td>1.85</td>
<td>.16</td>
</tr>
<tr>
<td>Insomnia Symptom Questionnaire</td>
<td>43.5 (14.0)</td>
<td>43.0 (16.4)</td>
<td>51.0 (14.0)</td>
<td>2.28</td>
<td>.11</td>
</tr>
<tr>
<td>Beck Depression Inventory</td>
<td>4.9 (2.7)</td>
<td>6.6 (4.5)</td>
<td>4.9 (3.8)</td>
<td>1.79</td>
<td>.17</td>
</tr>
</tbody>
</table>

*Sleep quality ratings vary between 1 (poor) and 5 (excellent); Insomnia Symptom Questionnaire and Self Efficacy Scale scores may range from 0 to 100. High scores on the Insomnia Symptom Questionnaire and low scores on the Self Efficacy Scale are pathological. Beck Depression Inventory scores range from 0 (no depression) to 63 (severe depression).*

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the CBT group had higher mean polysomnogram and sleep log measures of sleep efficiency, and lower mean sleep log values of MWASO than did the RT and PT groups. They also had significantly higher posttreatment sleep quality ratings than did RT recipients. Most other measures showed significantly more favorable outcomes for CBT recipients than for PT assignees, whereas the RT and PT groups generally did not differ significantly. Only PT comparisons of BDI scores showed RT had more favorable results than CBT.

To compare patients’ short-term and longer-term effects in the CBT and RT groups, we used a 2 (CBT vs RT) × 2 (accepted vs declined follow-up) × 2 (time: posttreatment vs follow-up) ANCOVA model in the analyses of data provided by these patients at both posttreatment and follow-up time points. All ANCOVAs were adjusted for baseline values and used actual or estimated posttreatment data as estimates of missing follow-up measures. Both treatments produced statistically similar improvements in sleep time (P = .90), BDI (P = .50), ISQ (P = .12), and SES scores (P = .83), and nonsignificant main effects for time (P = .17) in all analyses suggested posttreatment outcomes persisted during follow-up. Figure 4 shows that CBT produced significantly larger improvements in sleep log WASO and efficiency across both time points than RT. Although both groups were averaging slightly more than 6 hours of sleep per night by the follow-up, the CBT group also showed an average MWASO of 26.6 minutes and an average sleep efficiency of 85.1% at this time point. In contrast, RT-treated patients showed an average MWASO of 43.3 minutes and an average sleep efficiency of 78.8% during the follow-up assessment. The single significant interaction (F1,45 = 5.93; P = .02) showed CBT assignees who declined follow-up had higher posttreatment quality ratings than did those who returned, whereas the RT group showed an opposite trend. The sole remaining finding showed those patients who declined follow-up (mean [SE], 4.9 [0.8]) had higher (F1,45 = 7.17; P = .01) BDI scores than did those returning for follow-up (mean [SE], 3.1 [0.6]).

We assessed the clinical significance of our results by computing the proportion of each group achieving at least a 50% reduction in pretreatment WASO (MWASO and TWASO) by the end of treatment. Sleep logs showed 64% (16/25) met this criterion for CBT, 12% (3/25) for RT, and 8% (2/25) for PT (χ² = 24.2; P = .001). Cognitive behavioral therapy was significantly superior to RT (P = .001) and PT (P = .001). Using polysomnogram data, 40% (10/25) of the CBT group, 28% (7/25) of the RT group, and 12% (3/25) of the PT group met this criterion (χ² = 5.0; P = .08). Additionally, we computed the proportions in each group having posttreatment ISQ scores of 41 or less, a cut point score with 92% sensitivity and 64% specificity for normal sleepers. Eliminating those below this cut-off at study entry, we found 59.1% (13/22) for CBT, 29.2% (7/24) for RT, and 4.8% (1/21) for PT went below this normative ISQ score on study completion (χ² = 14.8; P = .001). The CBT group differed (P = .001) from PT by this criterion whereas the RT group did not (P > .05).

Table 3. Adjusted Results for Posttreatment Comparisons*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Cognitive Behavioral Therapy (CBT)</th>
<th>Relaxation Training (RT)</th>
<th>Placebo Therapy (PT)</th>
<th>F2,71</th>
<th>P Value</th>
<th>Post-hoc Tests‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total sleep time, min</td>
<td>336.8</td>
<td>360.0 (8.4)</td>
<td>362.0 (8.6)</td>
<td>361.0 (8.4)</td>
<td>0.01</td>
<td>.99</td>
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<tr>
<td>Sleep logs</td>
<td>352.1</td>
<td>372.4 (10.6)</td>
<td>337.9 (10.6)</td>
<td>334.0 (10.6)</td>
<td>3.96</td>
<td>.02</td>
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<tr>
<td>Polysomnography</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Middle wake time after sleep onset, min</td>
<td>56.2</td>
<td>28.1 (4.2)</td>
<td>44.4 (4.2)</td>
<td>47.1 (4.2)</td>
<td>6.06</td>
<td>.004</td>
</tr>
<tr>
<td>Sleep logs</td>
<td>50.8</td>
<td>30.1 (8.9)</td>
<td>50.6 (8.9)</td>
<td>66.4 (9.0)</td>
<td>4.12</td>
<td>.02</td>
</tr>
<tr>
<td>Polysomnography</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Terminal wake time after sleep onset, min</td>
<td>47.7</td>
<td>21.1 (6.4)</td>
<td>36.2 (6.3)</td>
<td>47.0 (6.3)</td>
<td>4.19</td>
<td>.02</td>
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<tr>
<td>Sleep logs</td>
<td>14.1</td>
<td>4.2 (2.0)</td>
<td>10.2 (2.0)</td>
<td>12.4 (2.0)</td>
<td>4.39</td>
<td>.02</td>
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<td>Polysomnography</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Sleep efficiency, %</td>
<td>72.0</td>
<td>84.3 (1.7)</td>
<td>78.1 (1.6)</td>
<td>76.2 (1.6)</td>
<td>6.64</td>
<td>.002</td>
</tr>
<tr>
<td>Sleep logs</td>
<td>77.8</td>
<td>85.5 (1.9)</td>
<td>78.1 (1.9)</td>
<td>75.7 (2.0)</td>
<td>6.80</td>
<td>.002</td>
</tr>
<tr>
<td>Polysomnography</td>
<td>2.8</td>
<td>3.4 (0.1)</td>
<td>2.9 (0.1)</td>
<td>3.1 (0.1)</td>
<td>4.00</td>
<td>.02</td>
</tr>
<tr>
<td>Sleep quality (logs)</td>
<td>54.9</td>
<td>41.9 (2.5)</td>
<td>47.6 (2.6)</td>
<td>52.9 (2.6)</td>
<td>4.73</td>
<td>.01</td>
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<tr>
<td>Questionnaires</td>
<td>45.8</td>
<td>62.8 (2.8)</td>
<td>60.6 (2.8)</td>
<td>52.9 (2.6)</td>
<td>3.35</td>
<td>.04</td>
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<tr>
<td>Insomnia Symptom Questionnaire</td>
<td>5.5</td>
<td>4.0 (0.5)</td>
<td>2.9 (0.5)</td>
<td>4.8 (0.5)</td>
<td>3.66</td>
<td>.03</td>
</tr>
<tr>
<td>Self Efficacy Scale</td>
<td>4.0 (0.5)</td>
<td></td>
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<tr>
<td>Beck Depression Inventory</td>
<td>4.0 (0.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*NA indicates no post-hoc tests were performed.
†Analysis of covariance was used.
‡Significant differences found in Bonferroni-corrected paired comparisons.
COMMENT
Cognitive behavioral therapy produced the largest effects on measures of sleep fragmentation. On average, CBT recipients reported a 54% reduction in WASO by the end of treatment whereas the patients receiving RT and PT, respectively, reported only 16% and 12% reductions in this key measure. Although polysomnography suggested CBT produced somewhat more modest WASO improvements, those patients receiving RT and PT, on average, showed virtually no changes in their polysomnographic WASO measures. Likewise both sleep logs and polysomnography showed that CBT produced substantially greater short-term sleep efficiency improvements than did the other treatments. Furthermore, sleep log estimates of these 2 parameters as well as quality ratings favored CBT over RT across the 6-month follow-up period. In contrast, the effects of CBT on subjective sleep time (sleep logs) were more modest and not significantly different from the effects of other treatments. Polysomnography reflected even smaller sleep time improvements for CBT recipients, but the other 2 groups failed to show objective sleep time increases. Hence, only the CBT group showed both subjective and objective sleep time increases through treatment. In a broader context, the group receiving CBT, had increased sleep time, which suggests a moderate effect size that is similar to the more efficacious behavioral treatments but smaller than that typically reported for short-term pharmacotherapy. Nonetheless, the modest effect of CBT on sleep time appears enduring through follow-up whereas pharmacotherapy's long-term effect on sleep time has yet to be documented.

The clinical significance of symptom changes is reflected by our improvement criteria as well as by the average performances of participants in each treatment group. Almost two thirds of the CBT group reduced their initial sleep log WASO by 50% or more but only 12% of RT recipients and 8% of PT recipients achieved similar results. polysomnographic data, though less impressive, showed a similar trend. On ending their participation, the average CBT recipient reported (sleep logs) a MWASO of less than 30 minutes, a level regarded as normal. Neither of the other treatment groups reached normative levels for this measure. Furthermore, assuming a pathological pretreatment mean sleep time of about 5.5 hours, the average CBT-treated participant could expect to achieve a mean subjective sleep time of slightly over 6 hours (Figure 4) which, given what is known about human sleep requirements, appears minimally normative/sufficient. Finally, CBT appeared superior to the other treatments in normalizing ISQ scores which reflect perceived sleep/wake functioning.

Figure 4. Cognitive Behavioral Therapy vs Relaxation Training After Treatment and at Follow-up: Sleep Log Data

Analysis of covariance was used for adjusted means (SEs). The x-axis in each part represents the adjusted baseline mean. Asterisk indicates a treatment effect of $F_{1,45}=3.77; P=0.05$. Dagger indicates a treatment effect of $F_{1,45}=8.77; P=0.005$. WASO indicates wake time after sleep onset. Double dagger indicates a treatment effect of $F_{1,45}=4.24; P=0.05$. Section symbol indicates a treatment effect of $F_{1,45}=9.10; P=0.004$; the subgroup treatment effect (interaction of treatment multiplied by subgroups, such as completed vs declined follow-up) was $F_{1,45}=5.93; P=0.02$. Data plotted are from the 29 (14 cognitive behavioral therapy and 15 relaxation training) who completed and the 21 (11 cognitive behavioral therapy and 10 relaxation training) who did not complete sleep logs at follow-up.
Admittedly this trial would have benefited by a larger study sample and more extensive use of objective outcome measures. Also, although our enrollees reported no hypnotic use during the trial, random urine screens to rule out occult benzodiazepine use may have been useful. Finally, our highly selected sample may limit generalization of our findings. Nonetheless, our results deserve serious consideration since a majority of chronic insomnia patients present sleep maintenance complaints, yet disproportionate numbers of pharmacologic and nonpharmacologic trials have targeted sleep-onset insomnia. Furthermore, insomnia remains undertreated and behavioral interventions are underused.21,22 Given our results, CBT may have a deserving and important niche in the clinical management of PPI patients with sleep maintenance difficulties.

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