INSOMNIA

Dose-Response Effects of Cognitive-Behavioral Insomnia Therapy: A Randomized Clinical Trial

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Subject Objective: To determine the optimal number of therapist-guided Cognitive-Behavioral Insomnia Therapy (CBT) sessions required for treating primary sleep-maintenance insomnia.

Design and Setting: Randomized, parallel-group, clinical trial at a single academic medical center. Outpatient treatment lasted 8 weeks with final follow-up conducted at 6 months.

Participants: 86 adults (43 women; mean age 55.4±9.7 years) with primary sleep-maintenance insomnia (nightly mean wake time after sleep onset [WASO] = 93.4±44.5 minutes).

Interventions: One (week 1), 2 (weeks 1 and 5), 4 (biweekly), or 8 (weekly) individual CBT sessions scheduled over an 8-week treatment phase, compared with an 8-week no-treatment waiting period (WL).

Measurement: Sleep diary and actigraphy measures of total sleep time, onset latency, WASO, total wake time, and sleep efficiency, as well as questionnaire measures of global insomnia symptoms, sleep related self-efficacy, and mood.

Results: Statistical tests of subjective/objective sleep measures favored the 1- and 4-session CBT doses over the other CBT doses and WL control. However, comparisons of pretreatment data with data acquired at the 6-month follow-up showed only the 4-session group showed significant long-term improvements in objective wake time and sleep efficiency measures. Additionally, 58.3% of the patients receiving 4 CBT sessions met criteria for clinically significant improvement by the end of treatment compared to 43.8% of those receiving 1 CBT session, 22.2% of those provided 2 sessions, 35.3% of those receiving 8 sessions, and 9.1% of those in the control condition.

Conclusion: Findings suggest that 4 individual, biweekly sessions represents the optimal dosing for the CBT intervention tested. Additional dose-response studies are warranted to test CBT models that contain additional treatment components or are delivered via group therapy.

Keywords: Cognitive-behavioral therapy, primary insomnia

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INTRODUCTION

PRIMARY INSOMNIA (PI) IS A PREVALENT AND SERIOUS HEALTH CONCERN THAT PREDICTS THE ONSET OF CLINICAL DEPRESSION AND ADVERSELY AFFECTS quality of life for millions worldwide.5,6 Pharmacotherapy with benzodiazepine receptor agonists (BZRAs) and cognitive-behavioral therapy (CBT) currently represent the most viable and efficacious treatment options for PI.6,6 Given its ease of administration and variety of BZRA’s with proven efficacy for PI, pharmacotherapy remains the most common first-line therapy provided to PI patients who present for treatment.6,8 However, medication side effects, concerns about oversedation, and potential adverse interactions with other medications taken for comorbid conditions may argue against the use of BZRAs with selected patients.3,10 Moreover, many PI sufferers prefer nonmedicinal approaches for addressing their sleep difficulties.11,12 Thus, CBT may represent the favored therapy for a sizeable subgroup of those PI patients who seek treatment.

Although few comparisons of CBT and BZRAs have been conducted, meta-analytic and other systematic reviews suggest that outcomes achieved with CBT often equal or exceed those achieved with pharmacotherapy.13,14 CBT models involving, 1, 2, 4, 6, or 8 treatment sessions have all proven efficacious for PI sufferers,15-17 but little is known about the relationship between treatment dosing and outcomes with CBT. Despite the ample number of exemplary dose-response curve studies extant in the pharmacological literature,20 research specifically designed to determine the optimal dosing of CBT has yet to be conducted. Hence, it is not currently possible to offer evidenced-based guidelines concerning the amount of CBT considered optimal for treating PI. The lack of such guidelines may be problematic to patients in the current managed care environment in which health insurance administrators authorize and limit access to specialists such as those trained in CBT on the basis of such information. Given PI’s morbidity, research leading to evidence-based dosing guidelines for CBT would seem beneficial for insomnia patients and to the health care market at large.

Studies of CBT dose-response effects differ in focus from pharmacotherapy dose-response studies. For therapies like CBT, studies of the so-called dose-response curve may assess the number of treatment sessions and/or the amount of time in therapy required to achieve optimal outcomes. These options involve comparing the outcomes for varying numbers of treatment sessions/therapist contacts delivered within a fixed time period or for varying intersession intervals given a set number of treatment sessions/therapist contacts. For this initial dose-response study, we chose the former of these design options. Specifically, we compared the short- and longer-term outcomes of 1, 2, 4, and 8 CBT sessions delivered over a standardized 8-week period. The

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This was not an industry supported study. Dr. Edinger has received research support from Respiromedics, Inc. and Helicor, Inc.; and has received honorarium from Sepracor for manuscript preparation. Dr. Radtke has received research support from GlaxoSmithKline; has participated in speaking engagements supported by GlaxoSmithKline, UCB, Novartis, Ortho-McNeil; and has received honoraria from GlaxoSmithKline, UCB, and Novartis. Dr. Carney has received research support from Respironics, Inc. and Helicor, Inc.; and has received honorarium from Sepracor for manuscript preparation. Dr. Radtke has received research support from Respironics, Inc. and Helicor, Inc.; and has received honorarium from Sepracor for manuscript preparation.
specific CBT “doses” chosen for testing were selected since they spanned the range of CBT doses most frequently reported in the literature for treating primary insomnia, and they represented a logical dosing sequence resulting from the successive doubling of treatment sessions in a stepwise fashion. We decided that an 8-session CBT model would be the highest treatment dose tested since our clinical experience suggested that few patients require more than 8 sessions to achieve maximal benefits from the form of CBT tested. For the purposes of this study, we adopted “a more is better” assumption and hypothesized that the 8-session CBT intervention would lead to larger improvements in sleep, subjective insomnia symptoms, and mood status than would the more abbreviated treatments.

METHODS

Design

This study used a double-blinded, randomized, parallel group design. Participants were randomly assigned to a waiting list (WL) or to treatment consisting of 1, 2, 4, or 8 CBT sessions with a study therapist. Participants assigned to active treatment were initially kept blind to the number of therapy sessions they would receive. Likewise, the 2 study therapists were initially blinded to the number of treatment sessions they would eventually deliver to each participant. This blinding was designed to encourage maximum use of the initial CBT session, but both therapists and participants became unblinded to the treatment condition as therapy progressed. The Duke University Medical Center’s Institutional Review Board approved the protocol, and all candidates signed the study consent form. Participants were reimbursed for study-related parking expenses and were not charged for research evaluation/therapy procedures. The WL participants were provided a $100.00 honorarium for collecting data for an initial 10 weeks without receiving treatment.

Participants

Recruitment occurred primarily via newspaper advertisements between October 1998 and August 2002. Screening included structured sleep and psychiatric interviews conducted by a licensed PhD-level clinical psychologist (WKW), a medical examination conducted by the study physician (RAR), a sleep diary (1 week), and a diagnostic polysomnogram (PSG). Included were individuals between the ages of 40 and 75 years with sleep maintenance complaints who: (1) met the diagnostic criteria for PI as described in the 4th edition of the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders;22 (2) had a nightly mean wake time after sleep onset (WASO) > 60 minutes on the screening sleep diary; (3) had suffered insomnia > 6 months with onset after age 10; and (4) reported one or more poor sleep hygiene practices (e.g., taking 3 or more naps/week, varying bed/rising times by > 2 hours from day to day). The following led to study exclusion: (1) pregnancy; (2) a medical condition (e.g., rheumatoid arthritis) that compromises sleep; (3) Structured Clinical Interview (SCID)22 findings suggesting a major psychiatric disorder; (4) a score < 27 on the Folstein Mini Mental Status Exam;24 (5) habitual substance abuse or unwillingness to abstain from sleep medications during the study; (6) current use of anxiolytics or antidepressants; (7) periodic limb movements during sleep associated with > 15 arousals per hour or an apnea/hypopnea index > 15 on diagnostic PSG; (8) structured sleep interview findings suggesting a primary sleep disorder other than or in addition to PI; or (9) PSG measured sleep time ≥ 2 times higher than sleep time estimated by the patient for the PSG night.

A total of 205 candidates were screened to enroll 86 (43 women) who qualified and then underwent a pretreatment assessment conducted by a research assistant (RA). Subsequently, the RA randomly assigned them to treatment x therapist “cells” within sex and age (< 55 vs > 55 years) strata, using a computerized randomization program provided by a consulting statistician. The computer randomization program was specifically designed to limit assignment to the waitlist control condition. Hence, with the computer algorithm employed, 8 out of every 9 enrollees were initially assigned to an active CBT treatment. The randomization program was structured to assign approximately 60% of the CBT recipients to therapist 1 (WKW) and the remaining 40% to therapist 2 (JDE). Accordingly, 43 enrollees in the final study sample were randomized to therapist 1 and the remaining 32 were assigned to therapist 2. During and after treatment, the RA collected all outcome measures from enrollees. Figure 1 shows participant flow through the study, and Table 1 provides descriptive characteristics for those enrolled. Statistical comparisons (ANOVA, Fisher’s Exact test) showed no difference among the treatment groups in age, sex, ethnic composition, or mean baseline values of total sleep time and WASO. The proportions of study participants treated by each therapist were not significantly different across the 4 CBT conditions.

### Table 1—Descriptive Characteristics of Study Sample

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<th>Variable</th>
<th>Wait List</th>
<th>1 CBT Session</th>
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<th>4 CBT Sessions</th>
<th>8 CBT Sessions</th>
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<td>360.1±37.6</td>
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<td>Baseline WASO (min.)</td>
<td>83.1±34.9</td>
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<td>82.3±28.0</td>
<td>101.6±49.1</td>
<td>87.7±38.9</td>
<td>93.4±44.5</td>
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</table>

Table Caption: TST = total sleep time; WASO = wake time after sleep onset. Descriptions of Therapist #1 and therapist # 2 are provided in the text.

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MEASURES

Polysomnography (PSG)

Those meeting initial selection criteria completed screening PSG conducted in their homes with an 8-channel Oxford Medilog® analogue recorder. PSG monitoring included electroencephalography (2 channels), submental EMG, bilateral electro-oculography, nasal/oral airflow, and bilateral anterior tibialis EMG. Findings used for screening were the apnea-hypopnea index (i.e., # of apneas and hypopneas per hour of sleep) and PLM arousal index (i.e., number of PLM-related EEG arousals per hour of sleep). Although PSG typically includes additional respiratory measures (respiratory effort, oximetry), it was felt that airflow monitoring along with interview screening would provide reasonable likelihood of excluding sleep apnea sufferers.

Sleep Diary

Participants completed sleep diaries each morning during one

Figure 1—Study Flow Chart
screening week, a 2-week baseline, the 8-week treatment phase, and during 2-week periods 3 and 6 months following treatment. Diaries included queries about each night’s bed and rising times, sleep onset latency (SOL), and WASO (all time awake between initial sleep onset and final AM rising time). Measures derived from diaries included total sleep time (TST), SOL, WASO, total wake time (TWT = SOL + WASO), and sleep efficiency (SE = [TST / Time in Bed] x 100%). Diary values of WASO and SE served as primary outcome measures and the remaining diary measures were considered secondary outcome measures.

**Actigraphy**

Actitracs® actigraphs (IM Systems, Baltimore, MD) were used to assess objective sleep improvements. The Actitrac monitors movement/activity, interfaces with a PC computer, and uses MS Windows®-style software to derive estimates of common sleep parameters such as TST, TWT, SOL, and SE. Recent research has shown that Actitrac sleep and wake time estimates derived from insomnia patients correlate moderately well (Rs = .52 to .71) with analogous measures derived from PSG, and they are sufficiently sensitive to detect sleep improvements resulting from behavioral insomnia therapy. Participants wore an actigraph nightly on their nondominant wrists throughout baseline, the 8-week treatment, and the 2 follow-up assessments. The manufacturer’s sleep scoring algorithm was used to derive estimates of TST, TWT, SOL, and SE for each night of monitoring. Primary outcome measures derived from actigraphy included TWT and SE, and TST and SOL served as secondary outcome measures.

**Outcome Questionnaires**

Participants completed the Insomnia Symptom Questionnaire (ISQ), Beck Depression Inventory (BDI), State-Trait Anxiety Inventory (STAI), Profile of Mood States (POMS), and the sleep related Self-Efficacy Scale (SES) at baseline, mid-treatment (i.e., end of treatment week 4), the end of treatment (i.e., end of week 8) and at each of the 2 follow-up points. The BDI, STAI, POMS are all well-validated, widely used instruments. The 13-item ISQ (Cronbach’s alpha = 0.73) and 9-item SES (Cronbach’s alpha = 0.71) are psychometrically sound instruments with proven utility for detecting subjective improvements in response to insomnia treatment. Mean item scores on the ISQ and SES, total scores on the BDI and POMS, and the Trait score from the STAI served as outcome measures in this trial. For the purposes of this study, the ISQ served as the primary questionnaire outcome measure, and scores on the remaining questionnaires served as secondary outcome measures.

**Therapy Evaluation Questionnaire (TEQ)**

Credibility of varying CBT therapy “doses” was assessed via 7-point Likert ratings to the 7 items on this scale. The first 5 items assess treatment credibility; the final 2 items assess therapist warmth/competence. CBT recipients completed the initial 5 TEQ items after their first therapy session prior to knowing how many therapy sessions they were to receive. They again completed these initial 5 TEQ items as well as the final 2 items to rate therapist warmth/competence at the end of the 8-week treatment when they were no longer blind to the number of sessions they were provided.

**Treatments**

Two licensed male clinical psychologists provided CBT guided by the study’s treatment manual. When the study commenced, therapists 1 (age 34) and 2 (age 47) respectively had 5 and 17 years of experience with sleep-disordered patients. Therapists delivered CBT in a standard fashion via individual therapy sessions. The first session for all CBT recipients lasted 45-60 minutes, and the subsequent sessions provided to those receiving more than one CBT session lasted 15-30 minutes. Depending upon their treatment assignment, participants randomized to CBT met with their assigned therapists on 1 (week 1 only), 2 (weeks 1 and 5), 4 (weeks 1, 3, 5 & 7), or 8 (weekly) occasions during the study’s 8-week treatment phase.

All CBT assignees received an initial therapy session that included education to correct dysfunctional beliefs about sleep and a behavioral regimen to correct sleep-disruptive habits. Each CBT recipient first listened to an audiocassette recording that included education about sleep needs and the effects of aging, circadian rhythms, and sleep loss on sleep/wake functioning. The therapist then provided verbal and written (pamphlet) stimulus control instructions encouraging: (a) a standard rising time; (b) exiting bed during extended awakenings; (c) using the bedroom only for sleep and sex; and (d) avoiding daytime naps. Additionally, an initial time in bed (TIB) prescription set at the average baseline sleep time (from diaries) + 30 minutes was also provided to each CBT recipient. Finally, each participant was provided instructions for modifying these prescriptions throughout treatment as a function of the sleep performance achieved. For those receiving additional treatment sessions, such sessions consisted of therapist guidance in modifying TIB prescriptions as well as therapist encouragement of treatment adherence.

In contrast, those in the WL group received no treatment but continued to complete diaries, actigraphy, and questionnaires at the above-mentioned time points throughout the 8 weeks following baseline assessment. Subsequently, they received compensation for their data collection, and were randomized to a 2, 4, or 8-session CBT protocol. Data obtained from these individuals after entry into CBT was not considered in study analyses.

**RESULTS**

**Treatment Credibility/Therapist Ratings**

TEQ item ratings obtained after the first therapy session showed that each CBT group rated their CBT treatment very positively regardless of the dose they received. Likewise, posttreatment ratings of the therapists were uniformly positive across the 4 CBT groups. Statistical comparisons of the 4 CBT groups showed no significant group differences (all P values > 0.19) at the beginning and end of treatment for any of these ratings. Hence, participants in each of the CBT treatment conditions rated the therapies and therapists similarly.

**Treatment Attendance and Adherence**

Figure 1 details study attrition. Eleven of the 86 who completed baseline and were randomized to experimental conditions withdrew before the end of the treatment phase. Slightly over 50% (39 of 69) of the CBT assignees who completed treatment returned and completed some or all of the assessment procedures.
at the 6-month follow-up. The proportions of all CBT-assigned participants who did and did not return for follow-up did not differ across CBT groups (Fisher’s Exact $P = 0.25$).

During treatment, CBT recipients received instructions to standardize their sleep schedules, whereas those assigned to the WL received no such instructions. CBT recipients were thus expected to reduce their time in bed variability upon entry into the study’s treatment phase, and the WL-assigned participants were not. To test for this group difference in treatment enactment, a within-subject standard deviation of nightly time in bed (TIB) was calculated for each participant at baseline and for the first and final weeks of the 8-week treatment using actigraphy and sleep diary data. ANOVAs with subsequent Bonferroni-corrected pair-wise comparisons showed that none of the CBT groups differed significantly from the WL group on actigraphy or diary variability indices derived from the baseline data. Subsequent ANCOVAs that adjusted for baseline values showed a significant group effect for the actigraphy ($F_{5,46} = 4.16$, $P = 0.005$) and diary ($F_{5,46} = 4.62$, $P = 0.002$) TIB variability indices. Figure 2 shows the adjusted group mean values of these indices averaged across the 2 in-therapy time points for the WL and various CBT groups. Bonferroni-corrected pair-wise comparisons showed that each of the CBT groups differed from the WL group on the actigraphic variability index. Similar comparisons with the diary-based indices showed that all but the one-session CBT group differed from the WL. The one-session condition did show a trend towards lower TIB variability than did the WL, but the post hoc test for this difference did not reach the Bonferroni-corrected alpha required for significance. Overall, these findings confirm the expected differences in treatment enactment between the CBT and WL groups.

Sleep Data

Descriptive and inferential statistics for the sleep measures taken from sleep diaries and actigraphy were computed using SAS 9.1 statistical software. An alpha = 0.05 (two-tailed) was used to assign significance for all inferential tests. The primary analyses were based on a split-plot, group (5 treatment conditions) by time (pretreatment, week 8 of treatment, 3-month follow-up, and 6-month follow-up) randomized design. Linear mixed models, using the SAS PROC MIXED procedure, were used to analyze each sleep measure. All available data, including those from participants who subsequently discontinued the study, were used for the longitudinal analyses. This statistical approach is well suited to manage missing observations, even when missing data points are planned (e.g., as in the case of WL patients who were not asked to complete follow-up before receiving CBT). The methods used to estimate mixed-effects parameters yield unbiased estimates of model parameters when outcomes are missing at random.

Treatment and time main effects, and treatment by time interactions were assessed using F-tests wherein denominator degrees of freedom where computed using Satterwhaite’s approximation. Preplanned within-group tests of simple effects and pair-wise comparisons were conducted to determine the nature of any noted interaction effects by setting up the appropriate contrast within the linear mixed model. In all of these post hoc tests, common statistical corrections (i.e., Bonferroni correction, Dunnett’s adjustment) to alpha levels were made to account for multiple group comparisons. In the first step, we set up contrasts to assess change during treatment (baseline to week 8) that each group showed in the diary and actigraphic measures. Our second step was to compare in-treatment changes in sleep measures between each treatment group and the waitlist group. In addition, we set up contrasts to assess changes during follow-up (week 8 to 6-month) and throughout the total study (baseline to 6-month) each group showed in these measures. Although no specific contrasts were effected to assess change at the 3-month follow-up, data obtained from the 3-month time point were used in our statistical model to enhance prediction of missing follow-up values and for error term estimation. Finally, we compared changes for both the follow-up period and total study period between treatment groups.

Table 2 provides the means and standard deviations for all diary and actigraphic measures collected. No significant group main effects (all $P$ values > 0.05) were found for any of these measures. Significant time effects were noted for diary measures of TST ($F = 5.89, P = 0.002$), SOL ($F = 3.03, P = 0.04$), WASO, ($F = 20.93, P = 0.0001$), TWT ($F = 22.90, P = 0.0001$), and SE% ($F = 18.96, P = 0.0001$). In general, diary measures of TST and SE% increased significantly from pretreatment to follow-up, whereas diary measures of SOL, WASO and TWT decreased significantly. For actigraphy, significant time effects were noted for SOL ($F = 5.18, P = 0.004$), TWT ($F = 7.23, P = 0.0006$), and SE% ($F = 3.16, P = 0.03$), and the general changes in these measures were similar in direction to analogous measures derived from diaries. In addition, significant treatment x time interactions were found for diary measures of TST ($F = 2.48, P = 0.02$), WASO, ($F = 2.58, P = 0.01$), TWT ($F = 2.61, P = 0.01$), and SE% ($F = 2.63, P = 0.01$); and for actigraphic measures of TST ($F = 2.68, P = 0.02$), TWT ($F = 2.19, P = 0.04$), and SE% ($F = 2.28, P = 0.03$).

The data presented in Table 2 show the group trends contributing to these interactions for diary and actigraphic TST, TWT, and SE. We found that the groups receiving 1 and 4 CBT sessions displayed significant increases in diary SE and significant decreases in diary WASO and both diary and actigraphic TWT during treatment. The 1- and 4-session groups respectively showed mean diary SE changes of $+12\% (t = 4.76, P = 0.0001)$ and $+10\% (t = 5.16, P = 0.0001)$; mean diary WASO changes of $-53.6$ minutes ($t = -5.56, P = 0.0001$) and $-52.4$ minutes ($t = -5.56, P = 0.0001$); mean diary TWT changes of $-64.3$ minutes ($t = 4.88, P = 0.0001$) and $-58.5$ minutes ($t = -5.39, P = 0.0001$); and mean actigraph TWT changes of $-21.3$ minutes ($t = -2.85, P = 0.006$) and $-29.9$ minutes.
Those in the 4-session CBT condition also showed a significant increase in actigraphic SE (Mean = +4.7%; t = 3.38, P = .001) during this phase. The 4-session CBT group additionally showed significantly greater change than the WL group in diary WASO (Mean difference = -42.5 min.; t = -2.44, P = 0.017) and actigraphic TWT (Mean difference = -30.3 min.; t = 2.35, P = 0.020) during treatment. No other CBT-to-WL group comparisons of in-treatment changes were significant. We also found that none of the CBT groups showed significant changes in their sleep measures during the follow-up period. However, our Bonferroni-corrected post hoc tests showed the groups receiving 1, 2, and 4 CBT sessions displayed significant increases in diary TST and SE and significant decreases in diary TWT from baseline to the final follow-up. Only those who received 4 CBT sessions showed significant increases in SE and significant decreases in TWT on actigraphy through this time period. The 8-session CBT group showed a significant decrease in actigraphic TST from baseline to 6-month follow-up.

Outcome Questionnaire Data

The methods of statistical analyses conducted with the questionnaire measures were similar to those conducted with the sleep measures. Table 3 shows the means and standard deviations for all questionnaire measures. No significant group main effects (all P values > 0.05) were found for these measures. Significant time main effects were noted for total scores on the ISQ scores (F = 20.06, P = .0001), BDI (F = 4.94, P = 0.004), POMS (F = 3.37, P = .048).
Table 3—Means and Standard Deviations for Questionnaire Measures Across Study Time Points

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</tbody>
</table>

ISQ = Insomnia Symptom Questionnaire; BDI = Beck Depression Inventory; Trait Anxiety Score is taken from the Trait portion of the State-Trait Anxiety Inventory; POMS = Profiles of Moods States questionnaire; SES = Self Efficacy Scale. The n values shown indicate the number of participants completing each questionnaire properly at each time point. Variability in n values across time points is due both to incomplete questionnaires at the various time points and participant attrition from the study. § (P) connotes a primary outcome measure. † = a significant within-group change from baseline by post-hoc test. The week 8 values that are underlined suggest a significantly greater change from baseline than shown within the waitlist control group.

Clinical Significance

We compared the performance of each CBT group against that shown by the WL group using 2 indices of clinically significant improvement. The first of these used mean diary measures of WASO taken from the 2-week baseline and the final week (week 8) of treatment. Patients were classified as “improved” if they showed at least a 50% reduction in their mean values of WASO from baseline to treatment week 8; the remainder was classified as “unimproved.” A single data imputation (i.e., last value carried forward) was used to estimate week 8 values of WASO for all participants who withdrew before week 8 of treatment. Last value carried forward is an ad hoc method with strong assumptions. The assumption of a constant profile seems reasonable in this case because of the short treatment time frame (i.e., 8 weeks). Classification results showed 1 (9.1%) of 11 in the WL group, 7 (43.8%) of 16 who received one CBT session, 4 (22.2%) of 18 who received 2 sessions, 14 (58.3%) of 24 who received 4 sessions, and 6 (35.3%) of 17 in the 8-session condition were rated improved by the end of treatment. Fisher’s Exact Test showed the proportions of improved patients differed across groups (P = 0.0355). Bonferroni-corrected pair-wise comparisons showed only the 4-session CBT group had a significantly (P = 0.0095) higher improvement rate by this criterion than did the WL group.

In our second test of clinical significance, patients were classified as improved if they showed: (a) a 50% reduction in their total ISQ scores from baseline to week 8 of treatment; or (b) an ISQ score in the pathological range (i.e., > 41) at baseline and a score in the normal range (i.e., < 41) at the week 8 assessment. Those not meeting either of these conditions were classified as unimproved. Once again, an intent-to-treat data imputation (i.e., last value carried forward) was used to estimate week 8 ISQ scores for all participants who withdrew from the study prematurely. Results showed that none of the WL group, 9 (56.3%) of 16 who received 1 CBT session, 4 (22.2%) of 18 who received 2 sessions, 14 (58.3%) of 24 who received 4 sessions, and 5 (29.4%) of 17 in the 8-session condition were rated improved by the end of treatment (Fisher’s Exact Test P = 0.0021). Bonferroni-corrected pair-wise comparisons showed that both the 1-session (P = 0.003) and 4-session (P = 0.0009) CBT groups had significantly higher improvement rates than did the WL group. The ISQ improvement rates shown by the remaining 2 CBT and WL groups were not significantly different.
DISCUSSION

This study compared the efficacy of varying “doses” of CBT for the treatment of middle-aged and older adult patients with sleep-maintenance insomnia. Within the specific paradigm used in this investigation, treatment “dose” was defined as the number of CBT sessions delivered during a standard 8-week intervention period. Assuming that higher “doses” of CBT would be better than lower “doses,” we hypothesized that our 8-session CBT intervention would prove more efficacious than no treatment and/or treatments with fewer CBT sessions. Contrary to this prediction, the results obtained from sleep diaries, actigraphy, and a global insomnia symptom questionnaire suggested that our 4-session CBT intervention appeared to be the optimal treatment tested. This condition showed the most consistent subjective/objective improvements in nocturnal sleep/wake time and global insomnia symptoms. The indices of clinical improvement also favored the 4-session CBT intervention. Our 1-session model performed relatively well, although not quite as well as the 4-session intervention when all outcome measures are considered. In contrast, the 2- and 8-session models performed more poorly and generally were not better than the WL condition on most outcome measures. Moreover, for most measures, neither of these CBT “doses” showed any gradual or notable improvements during the follow-up period. Thus, within the experimental paradigm chosen for this study, the 4-session CBT intervention appeared to represent the optimal “dosing” of the particular form of CBT tested.

Although reasons that the 4-session CBT intervention appeared optimal cannot be determined from the data collected, it is possible to speculate about the strengths and weakness of each CBT model tested. The 4-session model, with treatment sessions scheduled biweekly, may provide an optimal balance between therapist guidance and patient independence. Since success with CBT is dependent on patients implementing prescribed behavioral changes and developing self-sufficiency in managing their sleep problems, it may be that a minimal inter-session interval of 2 weeks is needed to optimize this change process. Checking in with the therapist every 2 weeks may help reinforce this self-sufficiency for some and serve to quickly “right the ship” for others whose efforts at treatment implementation go awry. CBT models that provide fewer therapist contacts may offer greater opportunity to develop self-sufficiency but at the expense of therapist assistance when needed. The weekly sessions provided in the 8-session CBT model tested may not foster sufficient independence to facilitate self-sufficiency and consequent treatment adherence. Given these speculations, future CBT dose-response studies may benefit by the inclusion of measures (e.g., ratings by significant others and/or objective indices derived from 24-hour actigraphy) to monitor treatment implementation so that the effects of varying therapy doses on treatment enactment can be directly ascertained.

Results did not suggest a graduated, linear relationship between therapist contact and treatment outcome since our 1-session CBT model performed much better than our 2-session model. In fact, our 1-session CBT condition was clearly our second best treatment “dose” of the 4 protocols tested. Once again it is difficult to ascertain the reasons for such findings from the data obtained. Those who received only one CBT session were required to take what they learned from this session and become proficient in CBT strategies independent of subsequent therapist guidance. In the absence of additional therapist assistance, patients may have developed individualistic CBT implementation strategies to maximize their results. As such, the one session model may offer maximum opportunity for self-sufficiency while allowing for highly idiosyncratic methods of treatment implementation. Our results concerning the efficacy of a single CBT session seem to fit with previous reports indicating the efficacy of abbreviated behavioral insomnia interventions.15,38,39 Hence, additional studies of such abridged treatments seem warranted.

Surprisingly, those receiving 2 CBT sessions showed a disappointing treatment response. Like the participants assigned to 1-session CBT, those in the 2-session condition initially had opportunity for independent and idiosyncratic treatment implementation over the first 4 weeks of treatment. However, they then were provided another therapist visit. For many such patients, any therapist “corrective action” provided after 4 weeks of independent treatment enactment may have derailed the treatment course. Since no study patients were told how many CBT sessions they would eventually receive, providing those in the 2-session condition a single, and likely unexpected, follow-up therapist contact 4 weeks after the initial visit may have been particularly disruptive to many assigned to this specific CBT protocol. Nonetheless, we17 previously found a 2-session CBT model to be highly efficacious when therapist contacts were scheduled biweekly and patients were informed of the timing of these contacts before beginning therapy. Thus, both the timing of treatment and the subject blinding in this study may explain the relatively poor performance of the 2-session CBT protocol.

Designing dose-response experiments to test psychological and behavioral treatments is a complex and challenging task. In retrospect, it is apparent that the study paradigm we selected is one of several options that could be used in a study of this nature. In the current study, the forcing of 1, 2, 4, or 8 sessions into a standard 8-week treatment period resulted in a confound between number of sessions and the pace (i.e., inter-session interval) at which CBT was delivered. Both the number of treatment sessions and the length of the inter-session interval are factors worthy of investigation. Studies designed to test the effects of varying one of the factors would require holding the other factor constant. For example, the pace of therapy could be held constant (e.g., biweekly sessions) to allow testing different numbers of sessions delivered at this pace. Alternately, a set number of treatment sessions could be delivered at varied intervals to separately determine the optimal pacing of treatment. Both the pace of therapy and number of sessions delivered could be manipulated systematically in the same experiment, but such an approach would require a sizable study sample. Such a study may ultimately be needed to ascertain the optimal CBT dosing paradigm for insomnia treatment.

Given the noted design limitations, a degree of caution is warranted when generalizing these findings to clinical practice. This study represents an initial overture toward the ultimate understanding of the CBT dose-response curve. Whereas, our findings suggest the relative merits of 4 biweekly CBT sessions, different findings may have been obtained had we included CBT paradigms consisting of 6, 8, or even 10 biweekly CBT sessions. Furthermore, the CBT approach tested included only sleep education, stimulus control, and sleep restriction therapies, and omitted the formal cognitive restructuring, relaxation training, and sleep hygiene therapy included in many multicomponent CBT regimens. It is possible that higher treatment “doses” and more comprehensive CBT therapies will ultimately prove optimal for insomnia.
management. Although additional studies will be required to confirm this assumption, the results of at least one previous meta
analysis found positive associations between treatment duration and outcome.

In addition to the various limitations noted in regard to our study design, this investigation had several other limitations that
merit consideration. Only middle-aged and older adults with primary
sleep-maintenance insomnia enrolled, so our findings may
not generalize to younger age groups, those with exclusively sleep
onset complaints, or those with comorbid medical/psychiatric
conditions. The CBT model tested was delivered via individual
therapy sessions. We might have obtained different findings with
group treatment models or individual treatment sessions supple-
mented by programmed self-help or interactive internet-based
interventions. Our screening PSG lacked the full respiratory mon-
tage commonly used to identify sleep disordered breathing. Hence,
some enrollees may have had occult sleep disordered breathing
that confounded their treatment responses. Furthermore, whereas
we collected actigraphic sleep measures, no PSG confirmation of
these measures was obtained. Finally, our follow-up data suffered
from a high rate of attrition, likely due to a lack of participant incen-
tives for completing any of the assessment procedures. Nonethe-
less, this study has merit, since it provides some initial insights
into the effects of varying dosing protocols with the most com-
monly used CBT strategies.

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