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Original Article

ORIGINAL ARTICLE

Telemedicine versus face-to-face delivery of cognitive behavioral therapy for insomnia: a randomized controlled noninferiority trial

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Abstract

Study Objectives: In a randomized controlled noninferiority trial, we compared face-to-face and telemedicine delivery (via the AASM SleepTM platform) of cognitive-behavioral therapy (CBT) for insomnia for improving insomnia/sleep and daytime functioning at posttreatment and 3-month follow-up. A secondary objective compared the modalities on treatment credibility, satisfaction, and therapeutic alliance.

Methods: A total of 65 adults with chronic insomnia (46 women, 47.2 ± 16.3 years of age) were randomized to 6 sessions of CBT for insomnia delivered individually via AASM SleepTM (*n* = 33, CBT-TM) or face-to-face (*n* = 32, CBT-F2F). Participants completed sleep diaries, the Insomnia Severity Index (ISI), and daytime functioning measures at pretreatment, posttreatment, and 3-month follow-up. Treatment credibility, satisfaction, and therapeutic alliance were compared between treatment modalities. The ISI was the primary noninferiority outcome.

Results: Based on a noninferiority margin of four points on the ISI and, after adjusting for confounders, CBT-TM was noninferior to CBT-F2F at posttreatment (β = 0.54, *SE* = 1.10, 95% CI = 1.64 to 2.72) and follow-up (β = 0.34, *SE* = 1.10, 95% CI = 1.83 to 2.53). Daytime functioning measures, except the physical composite scale of the SF-12, were significantly improved at posttreatment and follow-up, with no difference between treatment formats. CBT-TM sessions were, on average, nearly 10 min shorter, yet participant ratings of therapeutic alliance were similar to CBT-F2F.

Conclusions: Telemedicine delivery of CBT for insomnia is not inferior to face-to-face for insomnia severity and yields similar improvements on other sleep and daytime functioning outcomes. Further, telemedicine allows for more efficient treatment delivery while not compromising therapeutic alliance.

Clinical Trial Registration Number: NCT03293745

Statement of Significance

Telemedicine is increasingly an option for delivery of healthcare services, but its efficacy and acceptability for delivering cognitive behavioral therapy (CBT) for insomnia have not been adequately tested. In this randomized controlled noninferiority trial, we showed that benefits from telemedicine-delivered CBT for insomnia were not inferior to gold-standard individual face-to-face delivery for insomnia severity and daytime functioning in people with chronic insomnia. Telemedicine also allowed for more efficient treatment delivery without impacting the therapist–patient working relationship. Future studies should evaluate potential cost savings of telemedicine-delivered CBT for insomnia, how this modality best fits among treatment delivery options, and which people with chronic insomnia are most likely to benefit from this delivery format.

Key words: insomnia; face-to-face; telemedicine; noninferiority trial

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Introduction

Chronic insomnia is highly prevalent and has been linked to reduced quality of life, decrements in perceived health, increased risk for new mood and substance use disorders, and exacerbation of co-occurring health conditions [1–8]. It may occur as an independent disorder, but more commonly presents comorbid with other psychiatric and medical disorders [5]. In addition to its adverse impacts on the individual, chronic insomnia exacts a significant economic burden, with the vast majority of costs attributable to increased work absences and reduced on-the-job productivity [9–11]. Multiple controlled trials indicate that cognitive-behavioral therapy (CBT) for insomnia benefits 70%–80% of individuals with chronic insomnia [12–14], that 40%–50% achieve remission from insomnia posttreatment [15, 16], and that initial treatment gains are well-maintained over time [17–19]. These findings have led several professional organizations to recommend CBT for insomnia as the first-line treatment for chronic insomnia [20–22].

Despite its demonstrated efficacy and safety, widespread implementation of CBT as a first-line therapy for chronic insomnia has not occurred for various reasons, including the perception that it costs more than pharmacotherapy, patient burden associated with receiving treatment (e.g. multiple clinic visits), and a lack of available services at the most common point-of-care (primary care) and outside of urban settings. One of the approaches to increasing uptake of CBT for insomnia has been to develop treatment modalities other than face-to-face that could reduce patient burden and increase access. Several different modalities have been studied in recent years, such as therapist-delivered via telephone [23, 24] and self-help via television and video [25, 26], written materials with and without telephone consultation [27–32], mobile phone apps [33], and other digital media [34–39]. The efficacy of self-help modalities for CBT for insomnia delivery is supported by recent meta-analyses [40–44], but one meta-analysis that included multiple treatment modalities found that effects on sleep outcomes were lower for self-help than for face-to-face treatments [44]. In addition, effect sizes are consistently larger for self-help studies that include greater degrees of clinician involvement [40, 41].

Videoconferencing delivery of health care services (i.e. telemedicine) has emerged in recent years, including for sleep medicine [45, 46], but it has received only limited testing as a delivery modality for CBT for insomnia [47–51]. Relative to other available formats, telemedicine has the potential to offer the best compromise between maximizing treatment efficacy and minimizing patient burden and cost. In addition, telemedicine allows for real-time communication of both verbal and nonverbal information and, because patient and therapist can see each other, real-time demonstration of different therapy skills. To date, only two controlled studies of telemedicine delivery of CBT for insomnia have been conducted. In the first, Scogin and colleagues [50] assessed the efficacy of a 10-session telehealth-delivered CBT for both depression and insomnia to usual care in 40 rural-dwelling adults with depression and insomnia. Participants receiving the treatment showed greater improvement in insomnia but not depression symptoms at posttreatment and 3-month follow-up [50]. The second study directly compared 6 weeks of internet to telehealth delivery of CBT for insomnia in 73 adults with chronic insomnia. Participants assigned to internet delivery received treatment from home, while telehealth participants had to travel to one of 40 telehealth sites (mean 31.2 km from home) to receive treatment. Global measures of insomnia severity, fatigue, and work and social impairment improved equally in both groups, but treatment adherence and format preference were higher for the internet treatment [48]. Overall, these findings suggest promise for telemedicine delivery of CBT for insomnia, but more randomized trials of this delivery modality are needed, particularly direct comparisons to gold-standard face-to-face delivery.

The primary objective of this study was to compare the efficacy of telemedicine-delivered (via the AASM SleepTM platform) to individual face-to-face-delivered CBT for insomnia in a randomized controlled noninferiority trial. A secondary objective was to compare the two treatment modalities on measures of treatment credibility, satisfaction, and therapeutic alliance. Our main hypothesis was that reductions in insomnia severity for telemedicine participants, as measured by the Insomnia Severity Index, would not be inferior to face-to-face participants after 6 weeks of treatment and at 3-month posttreatment follow-ups. We further hypothesized that treatment credibility and satisfaction would not differ significantly between the delivery formats, but that therapeutic alliance would be higher for participants who received individual face-to-face CBT.

Methods

Study design

The study was a randomized, controlled, single-site parallel noninferiority trial of CBT for insomnia delivered individually either via telemedicine (CBT-TM, American Academy of Sleep Medicine SleepTM, AASM SleepTM) or face-to-face (CBT-F2F), using a 2 (CBT-TM vs. CBT-F2F) × 3 (pretreatment, posttreatment, and 3-month posttreatment follow-up) mixed factorial design. Eligible participants (n = 65) were block randomized (block size of 6) in a 1:1 ratio to CBT-F2F (n = 32) or CBT-TM (n = 33), stratified by sex (see Figure 1 for study flow chart). Participants were blinded to the study hypotheses and allocation to condition occurred after participants had met all study eligibility, including confirmation of three or more nights/week of insomnia symptoms on a 2-week baseline daily sleep diary. CBT for insomnia was delivered in six weekly manualized sessions by the same expert clinician (D.A.C.) with identical content delivered in both conditions. Treatment sessions were audiotaped and treatment fidelity measures were completed by trained research staff on a randomly selected 10% of sessions in each condition.

Participants completed self-report measures of insomnia and daytime functioning before and after treatment. Treatment credibility was assessed after the first session, participant satisfaction with treatment was evaluated at posttreatment, and therapeutic alliance was assessed at the end of each treatment session. Insomnia and daytime functioning measures were also completed at 3-month posttreatment follow-up. Daily sleep diaries were completed starting 2 weeks before treatment through 2 weeks posttreatment and then repeated for two consecutive weeks at 3-month posttreatment follow-up.

Participants

Participants were recruited from November 2017 to June 2019 via advertisements, clinical referrals, and from patients presenting for treatment to sleep clinics. Individuals who were

18 years of age or older and met ICSD-3 [52] criteria for chronic insomnia disorder were eligible to participate. Exclusion criteria included: (1) suspicion of or inadequately treated sleep disorder other than insomnia; (2) presence of Axis I psychiatric disorders for which CBT for insomnia may be contraindicated (e.g. bipolar disorder, psychotic disorder, and active substance use disorder); (3) unstable chronic medical condition directly related to insomnia onset and course (e.g. chronic pain condition); (4) routine overnight shift work; and (5) previous failed adequate trial of CBT for insomnia. Eligibility was confirmed by medical chart review, in-person clinical interview administered by one of the study team members (J.T.A. or D.A.C.), and a home sleep apnea test for participants who had not undergone sleep testing previously. Study procedures were approved by the Michigan Medicine Institutional Review Board and participants provided written informed consent.

Treatment

CBT for insomnia was delivered over six, 30–60 min sessions by one of the co-authors (D.A.C.), who has more than 20 years of sleep medicine experience and is a Diplomate of Behavioral Sleep Medicine. Consistent with current clinical practice guidelines for CBT for insomnia [53], treatment content included sleep hygiene education, behavioral therapy (sleep restriction [54] and stimulus control [55]), cognitive therapy, counter-arousal strategies (relaxation strategies and constructive worry), and relapse prevention.

Outcome measures

Insomnia/sleep

The Insomnia Severity Index (ISI) [56] was the primary outcome for evaluating noninferiority of the treatment conditions. Based on empirical studies [57, 58] and previous noninferiority trials of CBT for insomnia [59, 60], we set our noninferiority margin at four points on the ISI. Secondary ISI outcomes were the percentage of participants achieving treatment response (change score from baseline > 7) [58] and treatment remission (posttreatment absolute ISI score ≤ 7).

Daily sleep/wake diaries [61] also provided secondary measures of sleep quality. Diary outcomes included sleep latency (SL), wake after sleep onset (WASO), total sleep time (TST), and sleep efficiency (SE). The 16-item Dysfunctional Beliefs and Attitudes About Sleep Scale (DBAS-16) [62] was also included to provide a measure of unhelpful beliefs related to sleep.

Daytime functioning

Daytime functioning was assessed with the following self-report measures: (1) Multidimensional Fatigue Inventory (MFI-20) [63], a 20-item scale designed to measure five dimensions of fatigue: general fatigue, physical fatigue, mental fatigue, reduced motivation, and reduced activity. We evaluated the general fatigue subscale, ranging from 4 to 20, with higher scores indicating greater fatigue; (2) Patient Health Questionnaire (PHQ-9) [64], a 9-item assessment consisting of the DSM-IV symptoms of major depression with scores ranging from 0 to 27, with scores of 5, 10, and 15, respectively, indicating mild, moderate, and severe depression; (3) GAD-7 [65], a 7-item measure ranging from 0 to 21 that assesses symptom criteria for generalized anxiety disorder; scores of 5, 10, and 15 are used as cutoffs for mild, moderate, and severe anxiety, respectively; (4) Work and Social Adjustment Scale (WSAS) [66], a 5-item validated scale designed to measure perceived functional impairments, with scores less than 10 indicating no impairment, 10–20 significant impairment, and above 20 moderate to severe impairment [67]; and (5) 12-item Short-Form Health Survey (SF-12) [68], which computes physical and mental composite scale scores ranging from 0 to 100, with higher scores indicative of better quality of life (mean = 50.0, standard deviation = 10.0).

Treatment credibility, satisfaction, and therapeutic alliance

The five-item version of the Therapy Evaluation Questionnaire (TEQ) [69], which assesses perceived logic, confidence, and success of the treatment and participant willingness to take part, was completed after the first treatment session to assess treatment credibility. Scores range from 5 to 35, with higher scores indicating greater perceived treatment credibility. Satisfaction was assessed after the last treatment session with the Client Satisfaction Questionnaire (CSQ-8) [70], an 8-item measure designed to assess the perceived value of treatment services. Scores range from 8 to 32, with higher scores indicative of greater satisfaction. Finally, we assessed for differences in therapeutic alliance after each treatment session with the Working Alliance Inventory–Short Revised (WAI-SR), a 12-item measure that evaluates three aspects of therapeutic alliance—agreement on therapy goals and tasks, and development of an affective bond. Scores on the Goal, Task, and Bond domains range from 5 to 20, with higher scores indicating better alliance. We evaluated both the WAI-SR total score and scores on the three subscales.

Statistical analyses

Power analyses

A priori power analyses were conducted to determine the sample size needed for the primary noninferiority study hypothesis using the ISI results from existing CBT for insomnia noninferiority trials [59, 60]. Consistent with these prior noninferiority trials, we chose a noninferiority margin of four points on the ISI, corresponding to half of the score required for a clinically significant change [58]. With a noninferiority margin of 4 units and standard deviation of 8, we initially determined that we required 50 subjects per condition at a 5% level of significance (two-group t-test) and 80% power to conclude noninferiority. However, a second power analysis conducted after 40 participants in response to a sponsor request indicated that only 28 participants/group were required to be fully powered to test noninferiority on the ISI (noninferiority margin of 4 units and standard deviation of 5). We, therefore, adjusted our ascertainment goal to recruit 32 subjects/group to account for a 10% drop out in both conditions.

Descriptive analyses were carried out using graphical and numerical summarization of key variables. Treatment groups were initially compared on pretreatment sociodemographic and clinical variables using t-tests, chi-square tests, and Fisher's exact tests as appropriate. Analyses of study outcomes were conducted with an intent-to-treat approach using SAS Version 9.4M6 (SAS Institute Inc., Cary, NC, USA). To test our primary hypothesis of noninferiority between CBT-TM and CBT-F2F, we used a linear mixed model with the ISI score as the outcome, subject-specific random intercept, adjusting for Condition (CBT-TM vs. CBT-F2F), Visit (baseline, posttreatment,

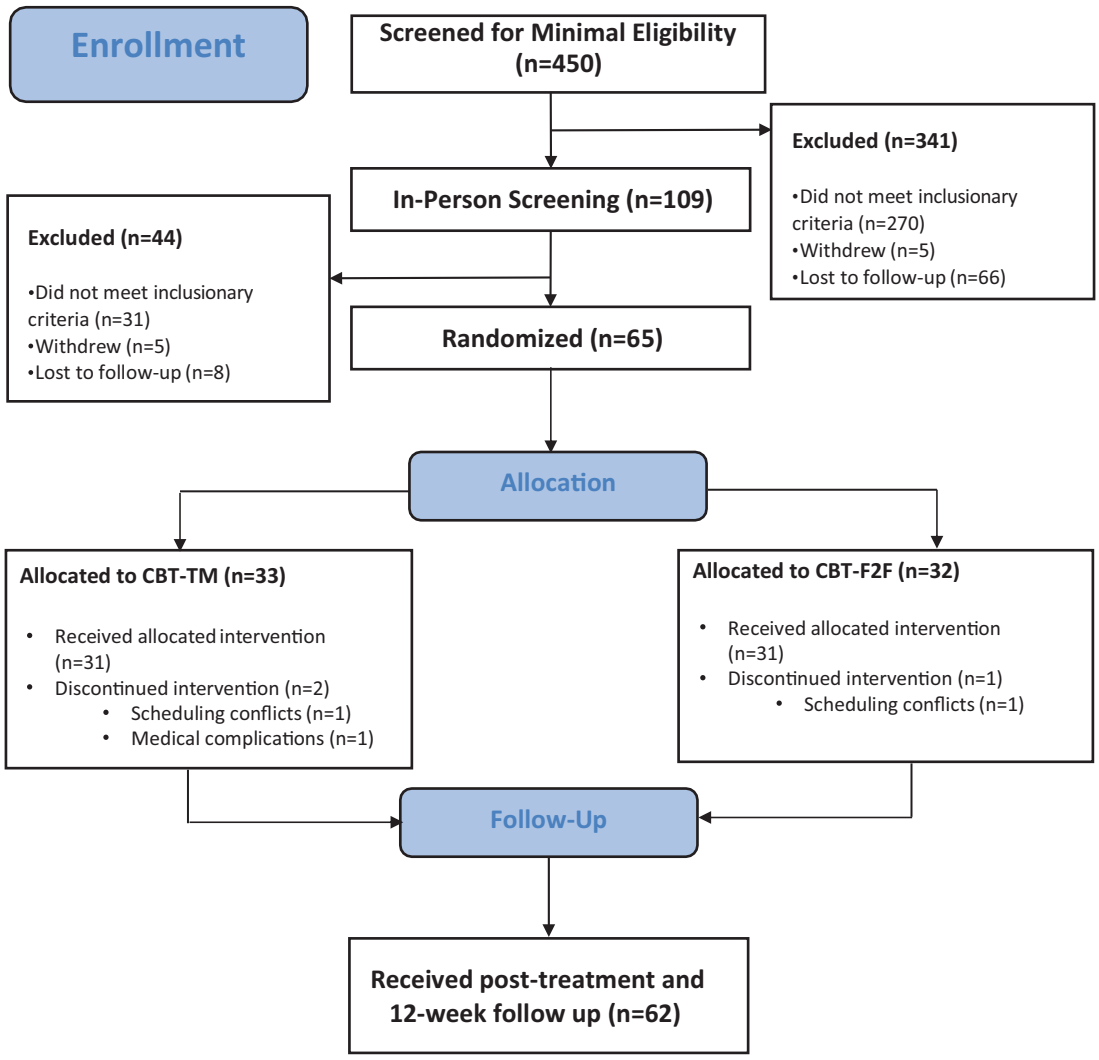

Figure 1. CONSORT flow diagram.

and 3-month follow-up), the Condition by Visit interaction, age, gender, and any sociodemographic and/or clinical variables that differed between the conditions at baseline. The criterion for determining noninferiority was if the lower boundary of the 95% CI for the regression coefficient corresponding to the Condition by Visit interaction at posttreatment and follow-up was less than four points. The proportions of treatment responders and remitters in each condition at posttreatment and follow-up were compared with logistic regressions, controlling for confounding variables. Since there are no established equivalence limits in the literature for the secondary sleep/wake diary and daytime functioning outcomes, we carried out superiority tests to compare these outcomes across the two delivery modalities with similar statistical models as for our primary analysis. We also used similar statistical models to evaluate our treatment credibility, satisfaction, and therapeutic alliance outcomes.

Results

Recruitment and retention

A CONSORT diagram of participant flow through the protocol is shown in Figure 1. Overall, 65 participants were randomized to CBT-TM (n = 33) or CBT-F2F (n = 32) and 62 (95.3%) completed

Table 1. Sociodemographic and clinical characteristics for randomized participants

Variable	Telemedicine (CBT-TM, *n* = 33)	Face-to-face (CBT-F2F, *n* = 32)	Total (*n* = 65)	*P* value*
	Mean (*SD*)	Mean (*SD*)		
Age	43.7 (17.4)	50.9 (14.5)	47.2 (16.3)	0.076
	N (%)	N (%)	N (%)	
Gender				0.847
Female	23 (69.7)	23 (71.9)	46 (70.8)	
Male	10 (30.3)	9 (28.1)	19 (29.2)	
Marital status				0.024
Never married	14 (42.4)	3 (9.4)	17 (26.2)	
Married	12 (36.4)	19 (59.4)	31 (47.7)	
Live-in-partner	3 (9.1)	5 (15.6)	8 (12.3)	
Divorced	4 (12.1)	4 (12.5)	8 (12.3)	
Widowed	0 (0)	1 (3.1)	1 (1.5)	
Education				0.143
High school	3 (9.1)	3 (9.4)	6 (9.2)	
Associates degree	1 (3.0)	2 (6.3)	3 (4.6)	
Bachelors degree	17 (51.5)	7 (21.9)	24 (36.9)	
Masters degree	8 (24.2)	13 (40.6)	21 (32.3)	
PhD or MD	4 (12.1)	7 (21.9)	11 (16.9)	
Employment status				0.060
Full time	13 (39.4)	18 (56.3)	31 (47.7)	
Part time	4 (12.1)	8 (25.0)	12 (18.5)	
Retired	7 (21.2)	4 (12.5)	11 (16.9)	
Unemployed	9 (27.3)	2 (6.3)	11 (16.9)	
Income				0.014
$0–49,999	13 (39.4)	7 (21.9)	20 (30.8)	
$50,000–$99,999	13 (39.4)	7 (21.9)	20 (30.8)	
$100,000 or more	7 (21.2)	18 (56.3)	25 (38.5)	
Ethnicity				0.363
Hispanic/Latino	2 (6.1)	0 (0)	2 (3.1)	
Not Hispanic or Latino	30 (90.9)	32 (100)	62 (95.4)	
Unknown	1 (3.0)	0 (0)	1 (1.5)	
Race				0.263
White/Caucasian	28 (84.9)	24 (75.0)	52 (80.0)	
Non-White/more than one race/unknown	5 (15.2)	8 (25.0)	13 (20.0)	
Comorbidity				
Medical	18 (54.5)	14 (43.8)	32 (49.2)	0.460
Psychiatric	21 (63.6)	16 (50.0)	37 (56.9)	0.321
Sleep medications/aids				
Prescription	13 (39.4)	14 (43.8)	27 (41.5)	0.804
Over-the-counter	13 (39.4)	11 (34.4)	24 (36.9)	0.798

*p value from t-test for continuous variables, Chi-square test for gender, and Fisher's exact tests for all other categorical variables comparing the two conditions.

posttreatment and 3-month follow-up assessments. Two participants (one from each condition) discontinued treatment due to scheduling conflicts and one participant (CBT-TM group) dropped out due to a medical complication unrelated to the study.

Descriptive data for all randomized subjects are summarized in Table 1. The majority of participants were middle-aged, white, educated, and employed women, consistent with residents of the study catchment area. In addition, the majority had a diagnosed mental health disorder, nearly half had at least one chronic medical condition for which they were receiving treatment, and roughly 40% in each group used prescription and/or over-the-counter sleep aids.

Noninferiority analyses

ISI scores at posttreatment and 3-month follow-up are presented in Table 3 and results of the noninferiority analyses are shown in Figure 2. Compared to baseline, the CBT-TM group showed a reduction of 8.80 (*SE* = 0.78, $t[120] = 11.31$, $p < 0.001$) points on the ISI at posttreatment compared to a 9.34 (*SE* = 0.78, $t[120] = 11.96$, $p < 0.001$) point reduction for the CBT-F2F group, but the Condition by Visit interaction was not significant ($p = 0.63$). At posttreatment, ISI scores were on average 0.54 (*SE* = 1.10) points higher (worse) for the CBT-TM compared to the CBT-F2F condition, but the confidence interval lower boundary for the difference between CBT-TM and CBT-F2F in posttreatment reduction of ISI fell below 4 points (95% CI: −1.64 to 2.72), supporting noninferiority.

At a 3-month follow-up, ISI scores were on average 0.34 (*SE* = 1.10) points higher for the CBT-TM condition, but the confidence interval for the interaction term again was within the noninferiority margin of 4 points (95% CI: −1.83 to 2.53). There was evidence of robust within-condition changes in ISI scores relative to baseline for both conditions (CBT-TM: −8.67 ± 0.78 points, $p < 0.001$; CBT-F2F: −9.02 ± 0.78, $p < 0.001$), with minimal

changes from posttreatment to 3-month follow-up (CBT-TM: 0.13 ± 0.78 points; CBT-F2F: 0.32 ± 0.78 points), suggesting that initial treatment gains were well maintained.

These noninferiority findings at posttreatment and 3-month follow-up did not change when controlling for baseline mental health status, mental health symptom severity, and sleep medication use.

Treatment responder and remitter analyses

The clinical significance of the changes in the ISI by treatment condition was evaluated using published response and remission threshold criteria [58]. Thus, ISI scores at posttreatment and follow-up that changed by > 7 points from the pre-treatment score defined a moderate clinical improvement (treatment response), while a raw ISI score ≤ 7 at posttreatment and follow-up indicated insomnia remission. We conservatively characterized any drop-out as a nonresponder/non-remitter. Response and remission rates by condition at posttreatment and follow-up are shown in Table 2. At posttreatment, there were no differences by condition in the odds of participants achieving treatment response (OR = 0.45, 95% CI: 0.13 to 1.50, p = 0.19) or treatment remission (OR = 0.64, 95% CI: 0.20 to 2.03, p = 0.45). Similarly, the odds of being classified as a treatment responder (OR = 0.64, 95% CI: 0.20 to 2.03, p = 0.45) or treatment remitter (OR = 0.95, 95% CI: 0.31 to 2.92, p = 0.94) did not differ by condition at 3-month follow-up.

Effects of treatment modality on self-reported sleep and daytime functioning outcomes

We evaluated changes in other sleep and daytime outcomes with superiority analyses, since no equivalence limits exist to define noninferiority (Table 3). Linear mixed models revealed no significant Condition by Visit interactions, but diary-rated SL and WASO were lower and TST and SE were higher for both conditions at posttreatment and follow-up (all ps < 0.001). Compared to baseline, TST increased overall by 23.4 ± 14.4 min at posttreatment (p = 0.10) and by 34.1 ± 14.6 min at follow-up (p = 0.02). SE improved by 13.9 ± 1.6% at posttreatment (p < 0.001) and by 11.9 ± 1.6% at follow-up (p < 0.001) compared to baseline. No within-condition changes in diary variables were found from posttreatment to follow-up, except that TST increased significantly in the CBT-TM condition (t [118] = 3.1, p < 0.002). Secondary analyses of the weekly sleep diary data collected during treatment similarly demonstrated no significant interactions, suggesting that there was also no difference in the rate of change on any of the sleep outcomes between the CBT-TM and CBT-F2F conditions. DBAS-16 scores showed significant improvement at posttreatment and follow-up (p < 0.001), with no differences between conditions.

Similar to the other sleep outcomes, no Condition by Visit interactions were found for any of the daytime functioning outcomes, but main effects of Visit were found for all outcomes except the SF-12 Physical composite score (Table 3). Thus, scores on the MFI-20 General Fatigue subscale, PHQ-9, GAD-7, WSAS, and the SF-12 Mental composite scale were significantly improved at posttreatment and follow-up for both the CBT-TM and CBT-F2F conditions. Moreover, there were no significant differences between posttreatment and 3-month follow for any daytime outcome (all ps > 0.05), suggesting maintenance of initial treatment gains.

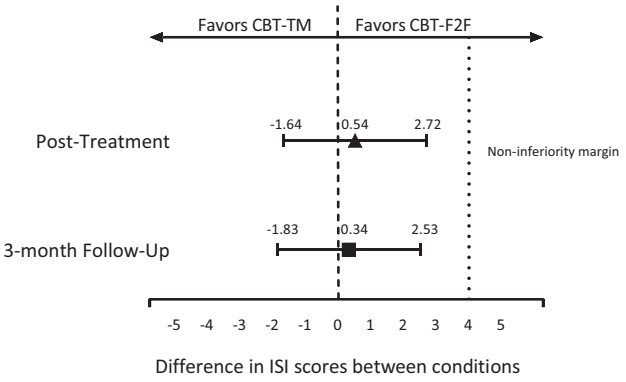

Figure 2. Summary of noninferiority analysis results on the Insomnia Severity Index (ISI) at posttreatment and 3-month follow-up.

Treatment credibility, satisfaction, and therapeutic alliance

At baseline, participant ratings of treatment credibility on the TEQ were not different by condition (CBT-TM: 25.32 ± 1.08, CBT-F2F: 24.03 ± 0.91, F[8,53] = 0.78, p = 0.62). Both treatment modalities were rated highly on the CSQ by participants at posttreatment (28.48 ± 0.74 for CBT-TM vs. 29.87 ± 0.43 for CBT-F2F, F[8,53] = 0.59, p = 0.78). The WAI-SR was administered following each of the six treatment sessions and no significant differences emerged by condition over the sessions for the total score or for any of the three subscales. Participant ratings also did not change across sessions for the total score or the Bond or Goal domains, but ratings increased significantly across treatment sessions for the Task domain (F[5, 315] = 2.64, p < 0.02).

Treatment fidelity

No differences between conditions were found for the number of treatment sessions received (CBT-TM: 5.73 ± 1.10, CBT-F2F: 5.84 ± 0.89, t[63 = 0.47, p = 0.64) or for the length of time to

Table 2. Response and remission rates (n [%]) by condition

	Telemedicine (CBT-TM, n = 33)		Face-to-Face (CBT-F2F, n = 32)		Total (n = 65)	
Outcome	Posttreatment	3-month follow-up	Posttreatment	3-month follow-up	Posttreatment	3-month follow-up
Response	20 (60.6)	19 (57.8)	21 (65.6)	20 (62.5)	41 (63.1)	39 (60.0)
Remission	14 (42.4)	14 (42.4)	16 (50.0)	15 (46.9)	30 (46.2)	29 (44.6)

Response was defined as a change of > 7 points on the Insomnia Severity Index at posttreatment and follow-up, relative to baseline. Remission was defined as an Insomnia Severity Index score ≤ 7 at posttreatment and follow-up.

Table 3. Means (*SD*) for insomnia/sleep and daytime symptom outcomes by condition and visit

	Telemedicine (CBT-TM, *n* = 33)			Face-to-face (CBT-F2F, *n* = 32)				
Outcome	Baseline	Posttreatment	3-month follow-up	Baseline	Posttreatment	3-month follow-up	Condition*Visit interaction (*F*-value)	Visit effect (*F*-value)
ISI	17.5 (3.7)	8.6 (5.5)	8.8 (5.1)	17.2 (3.4)	7.9 (3.4)	8.3 (4.0)	0.12	176.74**
Other sleep outcomes								
Diary SL (min)	49.2 (25.3)	22.8 (12.9)	26.0 (15.3)	48.9 (36.8)	22.0 (14.8)	24.3 (20.0)	0.09	43.68**
Diary WASO (min)	104.8 (49.1)	49.3 (30.0)	53.2 (30.5)	88.4 (48.1)	46.9 (27.4)	55.7 (30.0)	1.73	56.09**
Diary TST (h)	6.0 (1.2)	6.4 (1.0)	7.2 (2.1)	6.0 (1.4)	6.4 (0.9)	6.6 (1.3)	1.88	12.49**
Diary SE (%)	69.3 (11.3)	83.8 (7.7)	83.7 (8.1)	70.8 (11.0)	84.8 (5.8)	83.0 (6.7)	0.25	87.95**
DBAS-16	5.2 (1.6)	2.5 (1.8)	2.3 (1.5)	5.3 (1.2)	2.2 (1.5)	2.8 (2.0)	1.54	102.24**
Daytime symptom outcomes								
MFI General	14.4 (3.9)	11.1 (3.6)	11.6 (3.4)	14.9 (3.3)	11.4 (4.0)	11.9 (3.6)	0.10	53.21**
PHQ-9	8.2 (4.2)	4.1 (3.0)	4.2 (3.0)	9.5 (5.1)	4.7 (3.6)	5.2 (4.7)	0.54	68.65**
GAD-7	5.5 (4.8)	2.5 (2.4)	2.6 (2.5)	6.0 (4.9)	3.3 (3.6)	4.2 (5.0)	0.63	27.11**
WSAS	10.2 (9.5)	5.8 (7.4)	5.8 (7.8)	14.0 (10.4)	7.7 (8.3)	6.0 (8.1)	2.65	32.87**
SF-12 PCS	48.7 (9.3)	49.9 (9.0)	50.7 (9.6)	47.2 (8.4)	50.4 (8.8)	48.6 (9.0)	1.26	2.84
SF-12 MCS[†,‡]	45.6 (10.4)	50.0 (9.0)	48.4 (9.4)	42.1 (12.7)	45.9 (11.3)	47.1 (11.2)	0.93	8.60*

SL, sleep latency; WASO, wake after sleep onset; TST, total sleep time; SE, sleep efficiency; ISI, Insomnia Severity Index; DBAS-16, 16-item Dysfunctional Beliefs and Attitudes About Sleep scale; MFI General, General Fatigue subscale of the Multidimensional Fatigue Inventory; PHQ-9, Patient Health Questionnaire 9-item scale; GAD-7, Generalized Anxiety Disorder 7-item scale; WSAS, Work and Social Adjustment Scale; SF-12 PCS, Physical Composite Scale of the SF-12; SF-12 MCS, Mental Composite Scale of the SF-12.

[†]Conditions are different ($p < 0.05$) at baseline.

[‡]Conditions are different ($p < 0.05$) at post-tx.

*$p < 0.01$.

**$p < 0.001$.

complete treatment (45.24 ± 13.5 vs. 48.19 ± 9.78 days for CBT-TM and CBT-F2F, respectively, $t[63] = 1.00$, $p = 0.32$). The average session duration was, however, nearly 10 min longer in the CBT-F2F condition (52.29 ± 5.57 vs. 42.90 ± 6.68 min, $t[63] = 6.14$, $p < 0.001$).

Treatment sessions were audiotaped and 20 sessions from each condition (~10%) were randomly selected for treatment fidelity review. Each taped session was evaluated by trained raters against a checklist of each content area to be covered in each session (range 10–16 content areas). The mean percentage of content areas covered in the CBT-TM (97.21 ± 0.046%) and CBT-F2F (98.26 ± 0.039%) conditions was not significantly different.

Discussion

The findings from this randomized controlled noninferiority trial indicate that telemedicine-delivery of CBT for insomnia is not inferior to gold-standard face-to-face. Specifically, we found equivalent posttreatment improvements on our primary outcome of insomnia severity among participants who received treatment via telemedicine versus face-to-face, with initial treatment gains maintained in both conditions at 3-months posttreatment. Superiority analyses of secondary daytime functioning measures found robust improvements in fatigue, depression and anxiety symptoms, sleep-related cognitions, and quality of life; these improvements did not differ between conditions and were sustained at follow-up. Participant ratings of treatment credibility and satisfaction with assigned treatment modality were also high and not different between conditions. Finally, we unexpectedly found that therapeutic alliance ratings were similar to whether participants received treatment via telemedicine or face-to-face.

To the best of our knowledge, this study is the first direct comparison of telemedicine and face-to-face delivery of CBT for insomnia in an adequately powered randomized controlled trial. Our primary study hypothesis was supported since the lower limit of the 95% CI of the Condition by Visit regression coefficient for the ISI fell below our noninferiority margin of 4 points at both posttreatment (–1.64 to 2.72) and follow-up (–1.83 to 2.53). Mean changes on the ISI from baseline to posttreatment in both conditions were consistent with moderate clinical improvement [58], and remained stable through a 3-month follow-up. Moreover, response and remission rates were consistent with or exceeded rates in previous randomized controlled trials of face-to-face CBT [15, 71, 72], with nearly 50% of participants in both groups achieving remission from insomnia at posttreatment and follow-up. Our findings are in line with the two previous controlled studies that found improvements in insomnia with telemedicine delivery of CBT for insomnia compared to control [48, 50], but we expand on these earlier studies by showing that the magnitude of posttreatment and follow-up improvements for telemedicine did not differ from gold-standard face-to-face. In contrast to Scogin et al. [50], we found improvements in depression symptoms with a CBT for insomnia-focused intervention, although we did not select participants with depression specifically. In addition, telemedicine study participants in our study could receive treatment in their home environment, rather than traveling to another location as was the case for telehealth participants in the study by Holmqvist et al. [48]. Our primary finding that outcomes from telemedicine delivery were not inferior to face-to-face is also consistent with prior research directly comparing these modalities for other CBT treatments, including for panic disorder with agoraphobia [73] and posttraumatic stress disorder [74, 75].

Our study also adds to the broader literature on delivery modalities for CBT for insomnia. Although direct comparisons are lacking, the few studies conducted to date have found that sleep and daytime functioning outcomes are more favorable for individual face-to-face than for either video-based (60-min animated video plus six booklets) [26] or internet [76, 77] modalities. The latter two studies found that CBT for insomnia improved sleep more for internet delivery compared to control, but effect sizes were consistently larger for face-to-face than internet at posttreatment and follow-up. Two studies directly comparing face-to-face with written material and telephone support found no differences at posttreatment, but treatment gains were better maintained at follow-up for the face-to-face condition [28, 29]. In contrast, our study found that effect sizes were comparable between telemedicine and face-to-face delivery for insomnia and daytime symptom measures at posttreatment and follow-up. It would be premature to conclude that telemedicine is superior to these other non-face-to-face modalities as replication of our findings is required in larger and fully powered samples and in direct comparison to these other modalities. It should also be noted that three of these head-to-head studies were conducted in specific insomnia subgroups, namely active duty military personnel [77], breast cancer survivors [26], and people with alcohol use disorders [29]. While it remains to be determined where telemedicine might fit into a stepped-care model of insomnia treatment, the encouraging findings from this study suggest that it could fill a current void that exists between minimally intensive interventions, such as the internet and written materials without therapist involvement, and the most resource-intensive in-person face-to-face modality.

Findings on our primary outcome were further reflected in robust improvements in secondary diary-rated sleep outcomes and daytime functioning measures for both conditions at posttreatment and follow-up. Diary-measured SL and WASO improved by nearly 50%, SE improved by about 15%, and TST improved by 30–60 min at posttreatment and follow-up, consistent with previous trials of CBT for insomnia [44, 78, 79]. CBT for insomnia also produced robust improvements in unhelpful sleep-related cognitions, which has been shown in other studies [80]. Consistent with previous studies, we also found hypothesized improvements with CBT for insomnia on measures of fatigue [81, 82], depression/anxiety symptoms [40, 44, 83], and quality of life [84]. While our sample was treatment-seeking and the majority had a comorbid psychiatric/medical condition and/or were taking sleep medications, it is notable that baseline scores on the depression and anxiety scales, in particular, were in the mild range. The findings from our study may therefore not translate to people with insomnia and more symptomatic comorbid psychiatric disorders.

A secondary aim of this study was to compare telemedicine and face-to-face CBT for insomnia on measures of treatment credibility, satisfaction, and therapeutic alliance. It is perhaps not surprising that ratings of the treatment credibility were high overall and did not differ by condition since all participants received CBT for insomnia. Treatment satisfaction was high in both conditions at posttreatment and not significantly different, although variability was higher in the telemedicine condition. It is possible that, despite high satisfaction overall, some telemedicine participants perceived that something was lost with this modality of therapy. Understanding which treatment modalities work best for which patients is an important area of future study.

The overall high satisfaction ratings for telemedicine were further bolstered by the somewhat unexpected finding that participant-rated therapeutic alliance was not different whether treatment was delivered via telemedicine or whether subjects came to the office. None of the previous studies directly comparing face-to-face CBT for insomnia to a less intensive modality with therapist involvement (e.g. telephone consultations) evaluated working alliance; however, a recent meta-analysis of 12 studies comparing working alliance for face-to-face and videoconferencing CBT psychotherapy found that, while symptom reduction was noninferior between the two modalities, working alliance was inferior for videoconferencing CBT [85]. The promising findings from our study, therefore, require replication, but direct comparisons of various therapist-involved CBT for insomnia modalities should routinely include ratings of therapist alliance, ideally from multiple sources, given that it is consistently related to treatment outcome in several meta-analyses [86–88]. Our treatment fidelity analyses further indicated that treatment delivery was more efficient via telemedicine (sessions were on average 10 min shorter), even though the exact same content was covered in each session. This more efficient delivery may stem from the tendency for more focused and directed delivery of the session material with less “small talk”; alternatively, sessions may have been longer on average in the face-to-face condition because participants felt more comfortable sharing information in that environment. Further studies are needed to evaluate the specific reasons for any discrepancies in delivery efficiency between face-to-face and telemedicine and to determine participant-level factors that might lead to better outcomes with one format over another. The lack of difference in therapeutic alliance and more efficient delivery of telemedicine raise the possibility that cost savings may be realized with telemedicine delivery of CBT for insomnia, although direct comparisons of costs associated with telemedicine and face-to-face delivery are needed.

Strengths of this trial included the use of gold-standard in-person face-to-face CBT as the active comparison treatment in the noninferiority design, a 95% retention rate of participants throughout the 3-month follow-up period, and adherence to CONSORT procedures for conducting the randomized controlled trial. Limitations include the lack of diversity with respect to race and education, although a significant proportion of our sample had co-occurring medical or mental health disorders and a substantial percentage were taking prescription and/or over-the-counter sleep aids. These demographic and clinical factors are both reflective of the patient population seeking insomnia treatment at the primary recruitment site, which comprised the vast majority of participants in the sample. While the trial was powered to evaluate noninferiority on our primary outcome of insomnia severity, it is conceivable that it was underpowered to find differences in the secondary outcomes, particularly the daytime functioning outcomes. Thus, further studies with larger, more diverse, and fully powered samples are needed. Our study design also did not include a no treatment or wait list control condition, but the magnitude of changes on our primary and secondary outcomes in both treatment conditions were in accordance with multiple randomized controlled trials. Our study tested one specific telemedicine system—AASM SleepTM—so it is possible that our results may not generalize to other telemedicine systems, although we purposefully did not maximize the use of the SleepTM functionality to narrow the comparison to a

delivery system only (i.e. telemedicine vs. face-to-face). Finally, our study therapist had more than 20 years of clinical experience in sleep medicine, thus the findings on our primary and secondary study outcomes may not generalize to settings where less experienced therapists deliver CBT for insomnia.

In summary, we found that telemedicine delivery of CBT for insomnia was not inferior to face-to-face delivery for improving insomnia severity at posttreatment and follow-up, and yielded similar improvements in other sleep and daytime symptom outcomes associated with insomnia. We additionally showed that telemedicine delivery allowed for more efficient treatment delivery and did not hamper the therapeutic alliance between therapist and participant, a critical ingredient to treatment outcomes. Our findings support the use of telemedicine as an effective modality for delivery of CBT for insomnia, but future work is needed to evaluate potential cost savings of this delivery format and determine where it best fits in a stepped-care model of insomnia. Additional head-to-head comparisons of various CBT for insomnia modalities against face-to-face are needed to develop valid dissemination algorithms for maximizing the reach of CBT for insomnia. Future studies should also focus on evaluating patient and clinical characteristics that moderate response to different delivery modalities to optimize patient treatment outcomes.

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