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Randomized Noninferiority Trial of Telehealth Delivery of Cognitive Behavioral Treatment of Insomnia Compared to In-Person Care

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ABSTRACT

Objective: Insomnia is prevalent and is associated with a range of negative sequelae. Cognitive behavioral treatment for insomnia (CBT-I) is the recommended intervention, but availability is limited. Telehealth provides increased access, but its efficacy is not certain. The objective of this study was to compare the efficacy of CBT-I delivered by telehealth to in-person treatment and to a waitlist control.

Methods: Individuals with *DSM-5* insomnia disorder ($n = 60$) were randomized to telehealth CBT-I, in-person CBT-I, or 8-week waitlist control. CBT-I was delivered over 6–8 weekly sessions by video telehealth or in-person in an outpatient clinic. Follow-up assessments were at 2 weeks and 3 months posttreatment. The Insomnia Severity Index (ISI) was the primary outcome. Change in ISI score was compared between the CBT-I group in an intent-to-treat, noninferiority analysis using an a priori margin of -3.0 points. All analyses were conducted using mixed-effects models. Data collection occurred from November 2017–July 2020.

Results: The mean (SD) change in ISI score from baseline to 3-month follow-up was -7.8 (6.1) points for in-person CBT-I, -7.5 (6.9) points for telehealth, and -1.6 (2.1) for waitlist, and the difference between the CBT-I groups was not statistically significant ($t_{28} = -0.98$, $P = .33$). The lower confidence limit of this between-group difference in the mean ISI changes was greater than the a priori margin of -3.0 points, indicating that telehealth treatment was not inferior to in-person treatment. There were significant improvements on most secondary outcome measures but no group differences.

Conclusions: Telehealth CBT-I may produce clinically significant improvements in insomnia severity that are noninferior to in-person treatment. CBT-I is also associated with significant gains across a range of domains of functioning. Telehealth is a promising option for increasing access to treatment without loss of clinical gains.

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Population-based studies suggest that about 30% of the general population complains of insomnia symptoms, while approximately 10–15% has associated symptoms of daytime functional impairment consistent with the diagnosis of insomnia disorder.¹ In a primary care setting, 69% of patients reported clinically significant insomnia symptoms, with 50% reporting occasional insomnia and 19% reporting chronic insomnia.² Insomnia disorder negatively impacts multiple domains including interpersonal and vocational functioning.³ Insomnia also has a significant financial impact on society exceeding \$100 billion annually in the US.⁴

Cognitive behavioral therapy for insomnia (CBT-I) has demonstrated efficacy for the treatment of insomnia.^{5,6} Widespread implementation of CBT-I is limited by the lack of clinicians who are trained in this treatment. There is a need for strategies to increase access, particularly for patients in areas with few health care providers. Telehealth offers a technological means of providing treatment without the patient and provider needing to be in the same location. In the past year, there has been an explosion in the use of telehealth due to restriction related to the COVID-19 pandemic. The rapid deployment of telehealth interventions did not allow time to assess this approach in a controlled manner. A concern with telehealth is that communication via technological means may reduce the efficacy of treatment, with the associated belief that in-person treatment is superior. There are a number of studies that have demonstrated comparable outcomes for psychotherapeutic treatments delivered by telehealth compared to in-person treatment.^{7–9} However, there is limited evidence of the efficacy of CBT-I delivered by telehealth. One study compared telehealth CBT-I to web-based delivery and found comparable outcomes.¹⁰ A recent study was the first to compare telehealth CBT-I to in-person treatment and found that telehealth delivery was noninferior,¹¹ although it did not contain a control group for superiority comparisons.

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Clinical Points

- Telehealth provides a mean of increasing access to treatments such as cognitive behavioral treatment for insomnia (CBT-I), but it is not clear if there is a loss of efficacy in using this modality.
- These results suggest that CBT-I can be delivered via telehealth without sacrificing treatment outcomes.

The goal of this study was to build on this foundation by further comparing telehealth and in-person delivery of CBT-I. Unlike prior work, this study also included a waitlist control condition to permit both noninferiority and superiority comparisons. The primary hypothesis was that telehealth CBT-I would be noninferior to in-person treatment. This hypothesis is based on the past literature cited above consistently demonstrating noninferiority of telehealth treatments across forms of psychotherapy. Secondary hypotheses were that both CBT-I groups would be superior to a waitlist control for improving insomnia severity and several domains of functioning.

METHODS

Participants

Participants were males and females aged 21–60 years recruited from the greater Philadelphia metropolitan area using flyers, brochures, and online advertisements. Eligibility criteria were as follows: meet *DSM-5* criteria for insomnia disorder as determined by clinical interview; Insomnia Severity Index (ISI) score > 11, with self-reported duration of insomnia > 3 months; able to read and speak English; own a personal computer with a high-speed internet connection. Individuals were excluded for the following reasons: obstructive sleep apnea or other sleep disorder other than insomnia; clinically unstable medical condition as defined by a new diagnosis or change in medical management in the previous 2 months; use of prescribed medications or over-the-counter products that affect sleep; alcohol or substance abuse/dependence, bipolar disorder, delirium, dementia, amnesic disorder, schizophrenia, and other psychotic disorders as determined by the Mini-International Neuropsychiatric Interview for *DSM-5*; visual, hearing, or cognitive impairment; and prominent current suicidal or homicidal ideation. The study was approved by the Institutional Review Board of the University of Pennsylvania and registered on ClinicalTrials.gov (NCT03328585). Data were collected from November 2017 to July 2020.

Study Protocol

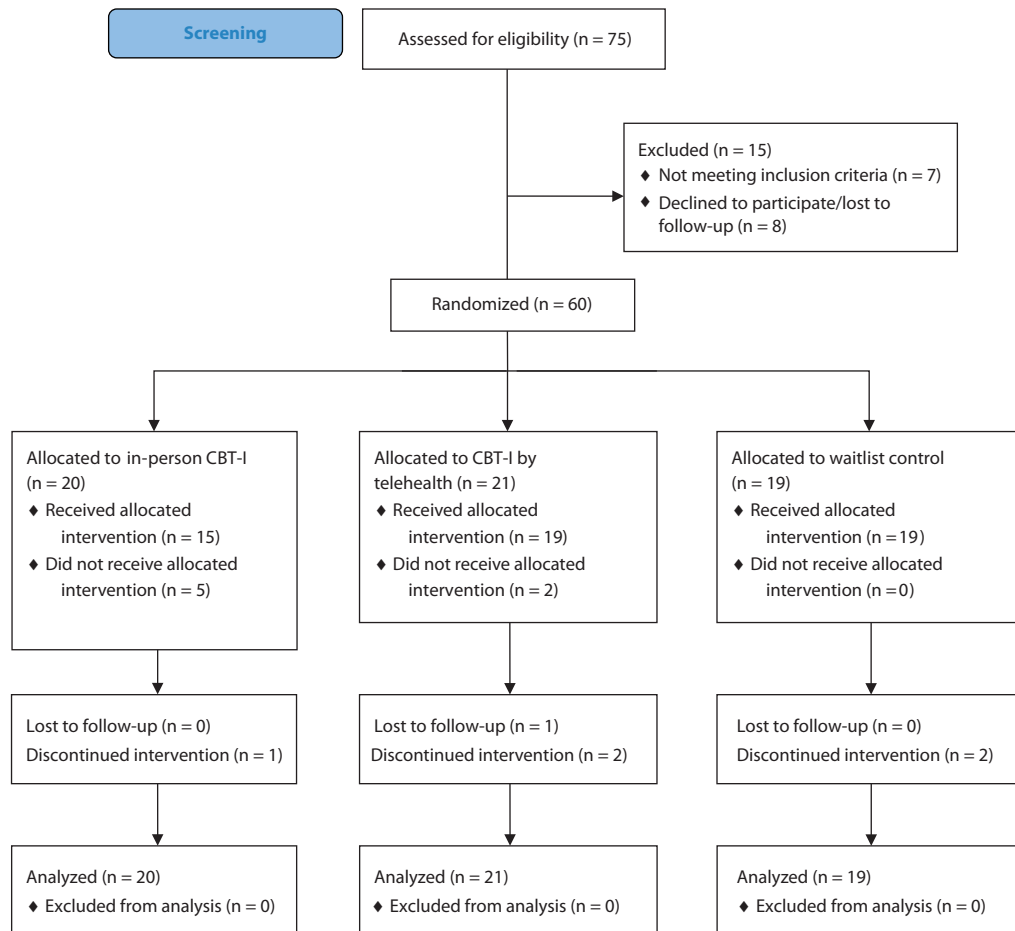
Individuals interested in participating were scheduled for a screening interview, at which time they provided written informed consent and were assessed for eligibility. Subjects completed the following self-report measures: demographics information, Insomnia Severity Index, Patient Health Questionnaire depression scale (PHQ-9), Generalized Anxiety Disorder Scale (GAD-7), Work and

Social Adjustment Scale, and Medical Outcomes Study Short Form-12 (SF-12). All subjects were provided with a home unattended sleep study with a Type 3 portable monitor to identify those individuals with sleep apnea. Subjects were instructed on how to apply the sensors at home prior to their usual bedtime and to remove them in the morning. They returned the device either at their next study visit or by mail. Individuals with untreated moderate to severe sleep apnea, defined as an apnea-hypopnea index > 15 events/h were not eligible to participate in the study and were referred to a sleep center for evaluation.

Subjects who met all eligibility criteria were randomized to one of 3 groups in a 1:1:1 ratio: in-person CBT-I, telehealth CBT-I, or waitlist control. A randomization sequence was generated in SAS PROC PLAN in blocks of 12 subjects. Subjects in the CBT-I groups received weekly treatment sessions over the course of 6–8 weeks and completed follow-up assessments at 2 weeks and 3 months posttreatment. CBT-I was delivered by 10 individuals with at least a master's degree in psychology who were trained and supervised by a licensed clinical psychologist with extensive CBT-I expertise and Diplomate of the Board of Behavioral Sleep Medicine (Dr Findley). Each therapist provided CBT-I in both treatment modalities. Treatment was delivered in a manualized, but flexible, format that allowed individual tailoring of treatment components and length of treatment. The protocol consisted of standard CBT-I components: stimulus control, sleep restriction therapy, dearousal techniques (eg, relaxation exercises, winding down time before bed), sleep hygiene, and cognitive therapy strategies. Throughout treatment, subjects completed daily sleep diaries each morning through the online database platform REDCap, which was used for all assessments over the course of the study. For the telehealth group, treatment was delivered over the SleepTM platform. SleepTM is a HIPAA-compliant telehealth platform developed by the American Academy of Sleep Medicine for use by sleep medicine professionals and includes features such as screen sharing for reviewing sleep diaries and therapy materials during sessions and file sharing for securely transferring materials to patients. Subjects in the waitlist group completed a follow-up assessment 8 weeks after their baseline assessment. These subjects were then offered CBT-I, although their treatment data are not included in these analyses. The waitlist group did not have a 3-month follow-up in order to avoid further delays to treatment.

All CBT-I sessions were audio recorded. An independent assessor, who is an expert in CBT-I, reviewed a random sample (15%) of audiotapes drawn from each of the therapy conditions and rated them for fidelity to the manual. A fidelity rating scale was created as a checklist of expected content in each session, so the rater indicated whether this content occurred as an indication of fidelity. A session was considered as having high fidelity if each of the necessary elements for that session was covered. Fidelity ratings were compared between groups to ensure that any differences in outcomes are not due to differential implementation quality.

Figure 1. CONSORT Diagram



Abbreviation: CBT-I=cognitive behavioral treatment for insomnia.

Assessments

The following measures were completed at each assessment timepoint:

Insomnia Severity Index.¹² The ISI is a 7-item (0–4 Likert scale) measure with a total score of 28. The norms for the scale are as follows: 0–7 represents no clinically significant insomnia, 8–14 represents subthreshold insomnia, 15–21 represents clinical insomnia (moderate severity), and 21–28 represents clinical insomnia (severe). The Insomnia Severity Index was used as the primary outcome measure.

Patient Health Questionnaire depression scale.¹³ The PHQ-9 is a 9-item measure of depression that is one component of the broader Patient Health Questionnaire. The scale purports to measure severity of depressive symptoms and is based on *DSM* criteria for major depression.

Generalized Anxiety Disorder Scale.¹⁴ The GAD-7 is a brief, 7-item measure that yields a total anxiety score. The scale purports to assess symptoms of generalized anxiety disorder and to serve as a sensitive and specific screen.

Work and Social Adjustment Scale.¹⁵ The Work and Social Adjustment Scale is a simple 5-item (all on 0-to-8 scales) patient self-report measure that assesses the impact

of a person's health difficulties on their ability to function in terms of work, home management, social leisure, private leisure, and personal or family relationships.

Multidimensional Fatigue Inventory.¹⁶ The Multidimensional Fatigue Inventory is a 20-item self-report scale designed to measure 5 dimensions of fatigue: general fatigue, physical fatigue, mental fatigue, reduced motivation, and reduced activity.

Medical Outcomes Study Short Form-12.¹⁷ The SF-12 is a 12-item self-administered health-related quality of life questionnaire, with established reliability and validity, providing summary information on physical and mental health status.

Home unattended sleep study. Home unattended sleep studies were performed with a Type 3 portable monitor (ZMachine, General Sleep Inc.) to screen individuals for obstructive sleep apnea. The monitor records the following signals: airflow by nasal pressure, rib cage and abdominal movement, oxygen saturation, heart rate, snoring, body position, and single-channel electroencephalogram. The portable monitor recordings were manually scored with the aid of computer software and interpreted by Dr Gehrman.

Table 1. Baseline Demographic and Clinical Characteristics of the Study Sample (Mean \pm SD)

	In-person (n = 20)	Telehealth (n = 21)	Waitlist control (n = 19)	Overall (N = 60)
Age, mean \pm SD, y	33.70 \pm 10.58	33.14 \pm 10.00	31.21 \pm 8.70	32.72 \pm 9.70
Race, n (%)				
Asian	3 (15)	3 (14)	1 (5)	7 (12)
Black or African American	5 (25)	5 (24)	1 (5)	11 (18)
White	11 (55)	13 (62)	16 (84)	40 (67)
Preferred not to answer	1 (5)	0 (0)	1 (5)	2 (3)
Non-Hispanic n (%)	18 (90)	21 (100)	19 (100)	58 (97)
Female, n (%)	13 (65)	13 (62)	13 (68)	39 (65)
Marital status, n (%)				
Single—never married	13 (65)	17 (81)	15 (79)	45 (75)
Married	6 (30)	3 (14)	4 (21)	13 (22)
Divorced	1 (5)	0 (0)	0 (0)	1 (2)
Widowed	0 (0)	1 (5)	0 (0)	1 (2)
Employment, n (%)				
Working, full-time	10 (50)	13 (62)	10 (53)	33 (55)
Working, part-time	5 (25)	2 (10)	3 (16)	10 (17)
Not currently employed	4 (20)	1 (5)	4 (21)	9 (15)
Student	1 (5)	5 (24)	2 (11)	8 (13)
Education, n (%)				
Completed high school or GED	1 (5)	1 (5)	1 (5)	3 (5)
1–3 years of college	7 (35)	2 (10)	0 (0)	9 (15)
Completed college	5 (25)	11 (52)	10 (53)	26 (43)
Postgraduate college	7 (35)	7 (33)	8 (42)	22 (37)
Insomnia Severity Index score, mean \pm SD	16.2 \pm 2.7	17.9 \pm 3.9	17.1 \pm 4.3	17.0 \pm 3.7
PHQ-9 score, mean \pm SD	8.1 \pm 3.7	8.5 \pm 4.2	9.1 \pm 3.2	8.5 \pm 3.7
GAD-7 score, mean \pm SD	6.9 \pm 4.1	5.3 \pm 4.1	7.3 \pm 3.8	6.5 \pm 4.0
Multidimensional Fatigue Inventory score, mean \pm SD	53.2 \pm 13.0	55.7 \pm 14.6	55.1 \pm 11.9	54.7 \pm 13.1
WSAS score, mean \pm SD	15.8 \pm 7.7	18.2 \pm 8.4	14.3 \pm 7.7	16.2 \pm 8.0
SF-12 physical score, mean \pm SD	51.3 \pm 5.0	51.1 \pm 5.8	51.6 \pm 4.6	51.3 \pm 5.1
SF-12 mental score, mean \pm SD	28.7 \pm 8.5	30.7 \pm 10.9	31.1 \pm 8.5	30.2 \pm 9.3

Abbreviations: GAD-7 = Generalized Anxiety Disorder Scale, GED = General Educational Development, PHQ-9 = Patient Health Questionnaire depression scale, SF-12 = Medical Outcomes Study Short Form-12, WSAS = Work and Social Adjustment Scale.

Statistical Analyses

Descriptive statistics were computed for all study measures, and baseline differences among the 3 groups were examined using analysis of variance. The primary aim of this study was to demonstrate that the efficacy of CBT-I delivered via video teleconferencing is not clinically inferior relative to in-person delivery. All subsequent analyses were conducted using mixed effects models in SAS PROC MIXED to allow all subjects to be included even with missing data and differing number of timepoints (3 in the CBT-I groups and 2 in the waitlist group). In the primary analysis, baseline ISI scores were included as a covariate. The primary measure of efficacy was change in ISI score from pretreatment baseline to 3 months post completion of CBT-I. The primary noninferiority hypothesis for this study is $H_0: \Delta T - \Delta P \geq \delta$ vs $H_1: \Delta T - \Delta P < \delta$, where ΔT and ΔP are the mean ISI change scores from baseline to 3 months in the telehealth (T) and in-person (P) groups, respectively, and where a negative change score indicates improvement. That is, the null hypothesis was that the improvement among telehealth participants compared to the in-person group would be less than or equal to the prespecified noninferiority margin, δ . Based on preliminary data from our clinical telehealth work, the mean (SD) of the pre-post change in ISI scores was -6.0 . We therefore set $\delta = -3.0$ based

on the reasoning that a loss of efficacy $> 50\%$ would provide evidence of inferiority. This implies that the mean change in ISI in the video teleconferencing group must be no more than 3 points lower than that of the in-person group. To test this difference, planned post hoc comparisons were conducted comparing the 3-month ISI scores between the in-person and telehealth groups. The primary analysis used an intent-to-treat approach so that all individuals who were randomized to treatment were included in the analyses. The analysis was repeated using only subjects who completed at least 6 sessions of CBT-I in a per-protocol analysis.

Following the primary noninferiority comparison, additional mixed-effects models were performed for each outcome measure. The mixed models included main effects of group and time as well as the interaction effect. Significant effects were followed up with post hoc comparisons using a Tukey correction to account for potential Type I error due to multiple comparisons. Separate models were run for the ISI and all secondary measures.

RESULTS

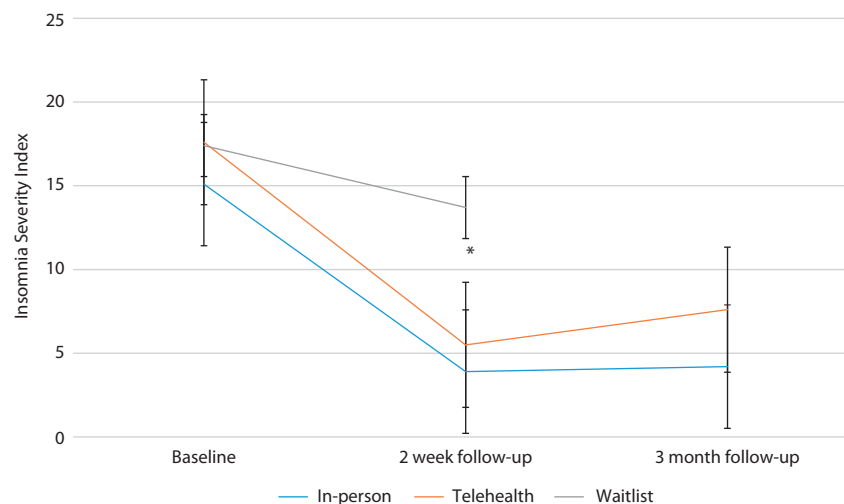
A total of 60 participants were randomized to in-person CBT-I (n = 20), telehealth CBT-I (n = 21), or waitlist control (N = 19). A CONSORT diagram showing the flow of subjects

Table 2. Primary and Secondary Outcomes at Follow-up Assessments

	ISI	GAD-7	PHQ-9	MDI	WSAS	SF-12 mental	SF-12 physical
Score, mean (SD)							
Baseline							
In-person	16.2 (2.7)	6.9 (4.1)	8.1 (3.7)	53.2 (13.0)	15.8 (7.7)	51.3 (5.0)	28.7 (8.5)
Telehealth	17.9 (3.9)	5.3 (4.1)	8.5 (4.2)	55.7 (14.6)	18.2 (8.4)	51.1 (5.8)	30.7 (10.9)
Waitlist	17.1 (4.3)	7.3 (3.8)	9.1 (3.2)	55.1 (11.9)	14.3 (7.7)	51.6 (4.6)	31.1 (8.5)
2 Week follow-up							
In-person	4.3 (4.0)	4.7 (5.0)	2.7 (2.4)	39.8 (8.8)	4.4 (4.9)	39.4 (12.1)	54.7 (4.0)
Telehealth	5.5 (3.7)	3.7 (2.6)	4.1 (2.6)	45.8 (11.0)	7.1 (4.3)	37.6 (6.4)	52.7 (3.6)
Waitlist	13.9 (3.2)	5.5 (2.6)	6.5 (11.6)	52.4 (11.6)	12.5 (5.0)	34.7 (8.4)	51.9 (3.7)
3 Month follow-up							
In-person	4.2 (4.1)	4.3 (5.2)	2.8 (2.9)	41.6 (8.9)	3.4 (4.6)	37.6 (13.6)	52.6 (5.5)
Telehealth	7.6 (6.1)	3.8 (3.4)	4.7 (3.9)	48.4 (18.6)	8.1 (8.4)	34.5 (13.1)	52.4 (4.4)
Significance (<i>P</i> value) ^a							
Baseline–2 week follow-up							
In-person vs waitlist	<.01	.91	.08	.07	.03	.15	.11
Telehealth vs waitlist	<.01	.80	.08	.04	<.01	.08	.26
In-person vs telehealth	.28	.71	.93	.86	.26	.80	.58
Baseline–3 month follow-up							
In-person vs telehealth	.61	.82	.54	.69	.65	.38	.74

^aLinear contrast *P* values are shown for comparisons between baseline and each follow-up assessment between groups. Abbreviations: GAD-7=Generalized Anxiety Disorder Scale, ISI=Insomnia Severity Scale, MDI=Multidimensional Fatigue Inventory, PHQ-9=Patient Health Questionnaire depression scale, SF-12=Medical Outcomes Study Short Form-12, WSAS=Work and Social Adjustment Scale.

Figure 2. Insomnia Severity Index Total Scores by Group and Timepoint



*Waitlist significantly different from both groups receiving cognitive behavioral treatment for insomnia.

through the study is presented in Figure 1. There were 6 subjects in the in-person CBT-I group, 5 in the telehealth CBT-I group, and 2 in the waitlist control for whom there are not complete data. Demographic characteristics of the groups are provided in Table 1, which also contains baseline values for all outcome measures. There were no statistically significant differences among the groups on any demographic variables. The mean (SD) baseline ISI scores were 16.2 (2.7) for the in-person group, 17.9 (3.9) for the telehealth group, and 17.1 (4.3) for the waitlist control group ($P=.34$), which places the sample at the moderate range of insomnia severity, on average.

Of the subjects in the CBT-I conditions, 15 (75.0%) in the in-person group and 16 (76.2%) in the telehealth group completed at least 6 treatment sessions. There was not a

significant difference in dropout between the 2 treatment groups. In the waitlist control, 2 (10.5%) dropped out of the study before their post-waitlist assessment. While all 60 subjects were included in the primary intent-to-treat analyses, only 47 with complete data were included in the per-protocol analyses. Data on primary and secondary measures at each timepoint are shown in Table 2. Ratings of treatment fidelity by an independent rater indicated that 100% of treatment sessions were adherent to the treatment manual.

In the primary noninferiority analyses, the mean (SD) difference between groups on ISI total score at the 3-month follow-up, controlling for the baseline score, was -1.80 (1.5) ($t_{28} = -0.98$, $P=.33$) (see Figure 2 and Table 2). The lower confidence limit of this between-group difference in

the mean ISI changes was greater than the a priori margin of -3.0 points, indicating that telehealth treatment was not inferior to in-person treatment. At the posttreatment assessment, the difference was even smaller at 0.7 (1.6). In the per-protocol analyses, the mean (SD) change in ISI total score from baseline to 3-month follow-up was -11.1 (3.9) points for in-person CBT-I and -10.1 (5.9) for telehealth CBT-I. The difference in change scores of 1.0 points is within the specified a priori margin of 3.0 points, leading to the same conclusion of noninferiority of telehealth treatment. The mean (SD) change in ISI scores over the waitlist period was -1.6 (2.1) and -2.4 (2.1) in the ITT and per-protocol analyses, respectively.

In the mixed effects model that included the waitlist control group, there was a significant interaction between group and time ($F_{3, 62} = 17.5$, $P < .0001$). Analyses of simple effects using Tukey-Kramer adjusted P values revealed that both CBT-I groups had significantly lower ISI scores at the 2-week follow-up than the waitlist control ($P < .0001$). At the 3-month follow-up, the ISI score in the telehealth group was not significantly different than the in-person group. As such, both CBT-I conditions produced significant decreases in insomnia severity that were maintained at 3 months, while the waitlist control was associated with only minor improvements.

For the secondary questionnaire analyses, additional fixed effects models were examined. There was a significant group \times time interaction for the Work and Social Adjustment Scale ($F_{3, 62} = 5.9$, $P = .0013$). In follow-up simple effects with Tukey-Kramer adjusted P values, there were no differences among the 3 groups at any timepoint, but there were significantly lower scores for both CBT-I groups at the follow-up timepoints compared to baseline ($t_{62} = 5.0$ and 6.5 , $P < .0001$ for the in-person group simple effects and $t_{62} = 6.5$ and 5.4 , $P < .0001$ for the telehealth group simple effects). There were significant main effects of time for the GAD-7 ($F_{2, 62} = 5.95$, $P = .0043$), PHQ-9 ($F_{2, 62} = 30.29$, $P < .0001$), Multidimensional Fatigue Inventory ($F_{2, 62} = 5.95$, $P = .0043$), and SF-12 mental health scale ($F_{2, 62} = 11.11$, $P \leq .0001$) but not for the SF-12 physical health scale. In all cases, scores improved from baseline to follow-up but not between follow-up assessments. Finally, there was a significant effect of group on the PHQ-9 ($F_{2, 57} = 3.71$, $P = .031$), with scores in the waitlist group being significantly higher than in the in-person group.

DISCUSSION

The results of this study suggest that CBT-I delivered by video telehealth produces clinical improvements that are not clinically inferior to in-person treatment and that are superior to a waitlist control. This suggests that the benefits of telehealth, including increased access and reduced travel time, do not come with a cost of reduced efficacy. Telehealth treatment was also not associated with a greater rate of dropout from treatment or a reduction in treatment fidelity. These findings are consistent with the results of a recent,

similar noninferiority study that was conducted in parallel to this investigation¹¹ and add to the growing literature on the efficacy of telehealth delivery of psychotherapeutic interventions.

There were significant improvements in a range of secondary outcome measures related to mood/anxiety and daytime functioning, consistent with our secondary hypotheses and a recent meta-analysis that found CBT-I to produce small-to-moderate improvements in daytime functioning.¹⁸ Some of the strongest effects were for the Work and Social Adjustment Scale, indicating that CBT-I was associated with important improvements in the ability to carry out work and social responsibilities. However, for most other measures the improvements seen over time were not significantly different between the CBT-I and control groups. The participants in this study were relatively healthy and did not have significant comorbidities other than insomnia, but they were still able to experience daytime improvements. Further work is needed to examine the impact of telehealth CBT-I on daytime functioning in more complicated patients with comorbidities that commonly co-occur with insomnia disorder.

This study was conducted prior to the current COVID-19 pandemic, which has led to a dramatic increase in the use of telehealth to provide health care.^{19,20} Once the pandemic began and telehealth became the norm, it was not feasible to conduct randomized trials comparing telehealth to in-person treatment given the questionable ethics of requiring subjects to come in for face-to-face care. Controlled studies, such as this one, are essential for assessing the quality of care provided over video technology. The results underscore that the use of telehealth during the pandemic is not a “necessary evil” but rather a means of providing high quality care while reducing risks of exposure.

Beyond implications for telehealth in general, these results are also important specifically with regard to treatment of insomnia during the pandemic. There have been significant global mental health consequences of the pandemic and associated lockdown, including significant increases in rates of insomnia, depression and anxiety.²¹ Clinical guidelines have recommended the use of CBT-I to address the high prevalence of insomnia at this time.²² Further, CBT-I has also been found in numerous studies, including this one, to be associated with reductions in depressive and anxious symptoms.²³ If the results of this study are confirmed in larger trials, there is tremendous potential for widespread implementation of telehealth CBT-I to address these common mental health sequelae of the pandemic.

Finally, these results also have important implications for addressing disparities in health care. There is growing evidence that disparities in sleep health vary by race/ethnicity, socioeconomic status, and sex.²⁴ One major contributor to health disparities is the lack of health care providers in underserved and rural communities. The access problem can be especially true for CBT-I given the overall lack of providers trained in this treatment.²⁵ Low socioeconomic status patients in urban settings may also find it difficult to

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take time off from work and travel to weekly appointments. Telehealth provides a means of increasing access to health care providers for underserved communities, which can reduce both sleep-specific and overall health disparities. While participation in this study required a desktop computer and high-speed internet connection, which may not be accessible to some individuals, treatment can also be delivered via video on mobile phone, which is more widespread.

The results of this study significantly advance our understanding of the efficacy of sleep-focused treatments delivered by telehealth. However, the study also has limitations that need to be taken into consideration. As described above, the participants in this study were generally healthy and well educated. More work needs to

be done to extend these findings to individuals who have more complicated health or socioeconomic difficulties. It will also be important to examine the efficacy of telehealth CBT-I delivered over mobile devices. The sample size for this study is modest, and results will need to be confirmed in a larger study. Lastly, the individuals in this study chose to participate in telehealth treatment, so the results may not be generalizable to all patients with insomnia. There are likely other individuals who do not want to receive treatment this way or who may not fare well with this modality. Future work is needed to identify who is most likely to benefit from telehealth treatment versus those who would respond better in person. These and other research questions will need to be further addressed in larger clinical trials as telehealth becomes more integral to health care delivery.

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Potential conflicts of interest: Dr Gehrman has research funding from Merck, Inc., is a consultant to WW, and serves on the scientific advisory board of Eight Sleep. The topic of this study is not related to these activities. Mr Gunter and Drs Findley, Frasso, Weljie, Kuna, and Kayser have no conflicts to disclose.

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