https://doi.org/10.5664/jcsm.9280

JCSM | Journal of Clinical Sleep Medicine

SCIENTIFIC INVESTIGATIONS

A population health approach to insomnia using internet-based cognitive behavioral therapy for insomnia

Stephen F. Derose, MD, MSHS[1,2]; Emily Rozema, MPH[1]; Aiyu Chen, MPH[1]; Ernest Shen, PhD[1]; Dennis Hwang, MD[3]; Prasanth Manthena, MD[1,3]

[1]Department of Research and Evaluation, Kaiser Permanente Southern California, Pasadena, California; [2]Baystate Health, Springfield, Massachusetts; [3]Department of Neurology and Sleep Medicine, Kaiser Permanente Southern California, Los Angeles, California

Study Objectives: To determine if a population health approach to insomnia using internet-based cognitive behavioral therapy for insomnia (ICBT-I) affects dispensed medications and provider encounters compared with usual care.

Methods: A pragmatic hybrid study design was used to evaluate both the implementation strategy and the long-term effects of ICBT-I on health care utilization in an integrated health system. Adult members with insomnia (a diagnosis or insomnia medication dispensation) or at high risk of insomnia (a diagnosis of depression or anxiety) were randomized to receive information on either an ICBT-I program (intervention arm) or in-person classes on insomnia (usual-care arm). Outcomes included dispensed insomnia medications and provider encounters over 12 months. The effectiveness of our implementation of ICBT-I on the target population was determined by an intention-to-treat analysis and by regression models comparing those who engaged in ICBT-I with matched usual-care arm controls.

Results: A total of 136,630 participants were randomized. Six hundred thirty-eight (0.96%) accessed the ICBT-I program while 431 (0.66%) attended 1 or more usual-care insomnia classes. Dispensed insomnia medications and provider encounters were no different in the ICBT-I arm vs the usual-care arm (intention-to-treat) or among those who engaged in ICBT-I vs matched usual-care arm controls.

Conclusions: Since ICBT-I program engagement was low, additional strategies to improve engagement should be explored. ICBT-I did not result in a reduction in several measures of health care utilization; nevertheless, it offers an alternative and accessible approach to managing population insomnia.

Clinical Trial Registration: Registry: ClinicalTrials.gov; Name: Trial of Internet-Based Cognitive Behavioral Therapy for Insomnia in Patients Prescribed Insomnia Medications; URL: https://clinicaltrials.gov/ct2/show/NCT03313466; Identifier: NCT03313466

Keywords: insomnia, cognitive behavioral therapy, hybrid study design, pragmatic study

Citation: Derose SF, Rozema E, Chen A, Shen E, Hwang D, Manthena P. A population health approach to insomnia using internet-based cognitive behavioral therapy for insomnia. *J Clin Sleep Med.* 2021;17(8):1675–1684.

BRIEF SUMMARY

Current Knowledge/Study Rationale: Chronic insomnia is common and contributes to both mental and physical health problems, and internet-based cognitive behavioral therapy for insomnia has shown to be an effective treatment. This study evaluated a population health approach to insomnia using internet-based cognitive behavioral therapy.

Study Impact: Few patients opted to enroll in a program to treat insomnia when offered access using a population health approach. Insomnia medication use and health care visits were not affected. Future population health approaches to insomnia should attempt to reach high-risk patients when they are more likely to engage in internet-based cognitive behavioral therapy.

INTRODUCTION

Chronic insomnia with daytime symptoms is very common, with approximately 10% of the general population affected at any given time, depending on the classification system used.[1] Insomnia often coexists with mental health disorders, medical conditions, medication side effects, psychological stressors, environmental factors, unhealthy sleep habits, and other sleep disorders. For example, insomnia and short sleep duration are closely linked to hypertension and diabetes, and potentially to cardiovascular disease events.[2] Substantial overlap exists between insomnia symptoms and mental disorders.[1] National surveys in the United States have shown a strong association between insomnia or trouble sleeping and coexisting anxiety and mood disorders.[3,4] In fact, insomnia appears to be predictive of future depressive and anxiety disorders.[5–7] Insomnia is associated with increased accidents,[8,9] reduced work productivity,[10,11] decreased health-related quality-of-life outcomes,[12] and increased health care costs.[13–15] Given the high prevalence and its association with poor health, reduced quality of life, and societal costs, insomnia represents a significant public health problem that may benefit from a population health approach to clinical services.

While chronic insomnia is commonly treated with sedating hypnotic medications, cognitive behavioral therapy for insomnia (CBT-I) has become the recommended treatment option. CBT-I is considered to be standard of care and first-line therapy given its superior sustained long-term effectiveness and

reduced risk of side effects or adverse events (eg, falls) when compared with pharmacologic treatment.[16–19] Unfortunately, access to treatment is challenging due to the paucity of trained therapists and the labor-intensive nature of delivering CBT-I, which is often structured as multiple hour-long sessions. Internet CBT-I (ICBT-I) programs utilizing digital algorithms have been developed to deliver components of CBT in an automated and interactive process and is also an evidence-based approach to CBT delivery.[20,21]

ICBT-I has the advantage of providing near-limitless access (merely requiring access to a digital device that connects to the internet) and enables more frequent (eg, daily) patient engagement with therapy. As a result, this technology is amenable to being applied as part of a population health approach in which ICBT-I can be a systemwide offering with open recruitment and not limited to individual provider-prescribed therapy. As a population health offering, ICBT-I can be the primary treatment, a component of a tiered insomnia management care pathway, or an adjunctive treatment.

This study aimed to determine the effects on health care utilization of implementing a population-based approach that offered open access to ICBT-I for members with insomnia or at high risk of insomnia in a large, integrated health system.

METHODS

Study design, setting, and data sources

A pragmatic trial with a hybrid study design[22] was used to evaluate both an implementation strategy and the long-term effectiveness of ICBT-I on health care utilization in clinical practice. The purpose of the design was to optimize rapid translation of a population approach to insomnia management into health system practices.

Adult participants were identified from a large integrated health care system (Kaiser Permanente Southern California) with over 4 million patients of diverse characteristics at 13 medical centers. The integrated nature of the health care system enables near-comprehensive collection of patient enrollment data, inpatient and outpatient services delivered, pharmacy utilization, and other patient data through the health care system electronic health record (EHR) platform (Epic Systems, Inc., Verona, WI) and claims databases for emergency services at non-system facilities. Approximately 98% of members have a pharmacy benefit enabling the ability to accurately capture pharmacy utilization. All membership and health care utilization study data were passively gathered. Self-reported data on sleep were available for patients who accessed the ICBT-I program. Providers were notified of the research initiative but not of particular patient enrollment. The study was approved by the Institutional Review Board of Kaiser Permanente Southern California.

Study arms

Intervention arm: access to ICBT-I

The intervention group was offered access to an ICBT-I program through population outreach. The Sleepio ICBT-I program (by Big Health, San Francisco, CA) was chosen for the study. Sleepio provides a personalized, interactive experience in a stepwise process using a computer or smartphone interface. The program collects patient-reported data related to sleep behaviors and delivers standard CBT-I components in a guided course that can be completed at the user's own pace. Members randomized to this arm were given a code that allowed them free access to the program. Patients had up to 6 months to activate the code and could access the program for up to 12 weeks after activation. The Sleepio program does not provide management of sleep-related medications. Subjects in this arm could access other health system resources for insomnia at their own initiative or by referral from their clinician, including the Sleep Well, Live Well program described below.

Comparison arm: optimized usual care

The comparison group had their usual care "optimized" by population outreach to inform members of the health system's existing insomnia program. The Sleep Well, Live Well program is formatted as a series of 4 weekly 1-hour group classes provided through the health education department at each medical center. Therapy is delivered by trained health educators (usually social workers or marriage and family therapists, sometimes RNs or MPHs) who teach about sleep, sleep hygiene, and components of CBT-I, which include stimulus control, sleep restriction, relaxation techniques, and attitudes about sleep. The therapy is not directed toward an individual patient's specific problems and thus it is up to the attendee to apply the lessons to themselves. The program does not provide initiation or management of sleep-related medications. Participants in this arm were not informed about or given access to the ICBT-I program described above.

Implementation strategy overview

The study was structured to mimic potential future health system implementation of a sustainable, population-based ICBT-I program for persons diagnosed with insomnia or at high risk of insomnia. Typically, patients enroll into CBT-I programs after clinician referral. Targeted population health outreach is a systematic approach to efficiently offer services to individuals who may benefit from specific interventions, and is often part of a broader population health program. The goals of implementing a population outreach approach in this study include reaching at-risk patients quickly, economically, and without potential bottlenecks in clinician referral. A potential disadvantage of the population approach is lower patient enrollment rates than seen when the patient is referred at the point-of-care during a clinical encounter with an insomnia complaint. We expected that if the ICBT-I intervention proved to be effective among individuals targeted in population outreach, then it would also be effective among those referred by clinicians.

Case-identification criteria

At-risk persons were prospectively identified using EHR data. Potential participants were identified if they met 1 of the following inclusion criteria: (1) an outpatient prescription in the

past 14 days for any of a predetermined list of medications to treat insomnia; (2) an outpatient diagnosis code in the past 14 days for (a) insomnia, (b) depression, or (c) anxiety. Exclusion criteria included the following: (1) age < 18 years, (2) membership in the health plan for < 365 days, (3) self-reported lack of proficiency in English, or (4) no registration for secure email communication (17% of total adult members).

Measures

Passively collected

Patients with insomnia, anxiety, or depression were identified using *International Classiciation of Diseases* (ICD) codes (see **Study Methods Details** in the supplemental material). Data were collected on enrollment in ICBT-I (Sleepio) and on attendance to the Sleep Well, Live Well program, as well as the number of sessions attended for each. Insomnia, depression, and anxiety medication dispensations were identified (see **Study Methods Details**). For patients dispensed an insomnia medication that is not specific to the treatment of insomnia (eg, doxepin, trazodone, temazepam, triazolam), an encounter with an insomnia diagnosis code within the prior 30 days was required. Available refills are generally filled by the patient without provider contact. Outpatient and inpatient encounters were gathered, including remote outpatient encounters by telemedicine. Outpatient encounters were further categorized by the specialty of the provider. All these measures were also gathered up to 1 year before the case identification date for use as pre-existing, baseline covariates.

Self-reported

Sleep-quality metrics collected by the Sleepio program were used to compare short-term changes in sleep quality among those who engaged in Sleepio with similar data on ICBT-I as reported in the literature.[23]

Outcomes

Implementation: population reach

Program engagement was defined as the proportion of patients who (1) accessed (redeemed their code to sign in) ICBT-I, (2) attended at least 1 ICBT-I session, or (3) attended at least 1 Sleep Well, Live Well session. Since patients in the ICBT-I arm were each given a unique code to access the program, enrollment rates and utilization could be tracked. Attendance and nonattendance to the Sleep Well, Live Well sessions were obtained from the EHR.

ICBT-I effectiveness

This study did not attempt to modify provider behavior (eg, prescribing) but was expected to influence patients' prescription and care-seeking behavior. Primary study outcomes included (1) total days' supply of dispensed insomnia medications per month until 12 months of follow-up, disenrollment, or death (used for sample size calculation); (2) total days' supply of insomnia medications, antidepressants, and antianxiety agents; (3) primary care encounters; and (4) sleep medicine and psychiatry encounters, each indexed per month for up to 12 months of follow-up. Secondary outcomes were self-reported measures of sleep quality (eg, sleep-onset latency, total sleep time, wake after sleep onset) among those who engaged in Sleepio.

Study enrollment and population outreach

We tested our implementation processes prior to the start of the study and excluded these individuals from analyses. The series of steps leading to patient enrollment and outreach is shown in **Figure 1**. The study team identified eligible patients, randomized patients to study pathways, and submitted participant information to the health care system Population Outreach team to deliver access information to either ICBT-I or the Sleep Well, Live Well program. All study participant contact materials are shown in the **Recruitment Materials** in the supplemental material.

Enrollment and randomization

Study enrollment was done in batches every 2 weeks as newly eligible patients were identified from EHR data by the research team. Randomization into ICBT-I vs usual-care study arms was performed using a random-number generator.

Outreach process

The Population Outreach team used existing automated outreach systems to deliver the study interventions to both study arms. Prior to outreach, a standard population outreach quality-assurance process removed members who should not be contacted (eg, due to terminal illness, recent death, on a do-not-contact for research list, etc). Initial outreach to each study arm was by an automated telephone call informing the patient that they were invited to participate in a sleep health program and would soon receive a message with more information. This was followed the next day by a more detailed email to their health system member-secured email account. Reminders were sent via email 13 days after the initial invitation.

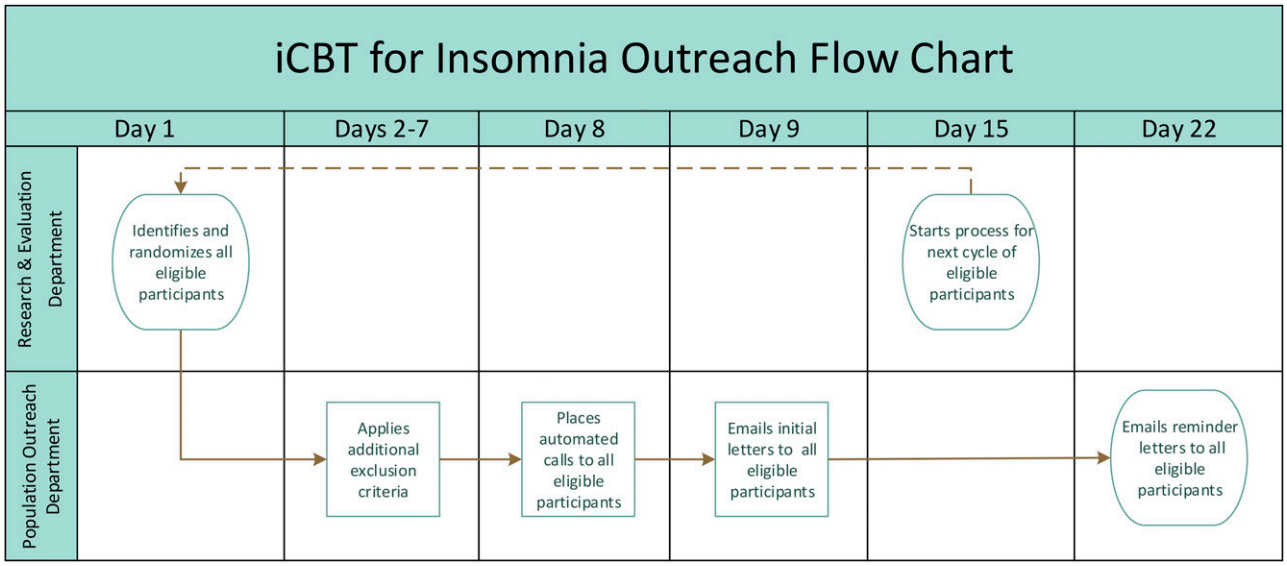
Informed consent

A Research Study Informational Sheet was provided to ICBT-I study arm participants. An Informational Sheet was not provided in the usual-care arm. The Information Sheet indicated that participation in Sleepio was voluntary and would include them in a research study gathering self-reported data on sleep and investigating the long-term effects of ICBT-I. A telephone number was provided in case participants had questions or to report concerns.

Outreach scripts and materials

Invitation via automated telephone calls utilized scripts with standard population outreach language prompting members to check their email account within the next few days for a message with information about a sleep-improvement program (either Sleepio or Sleep Well, Live Well). The initial and reminder messages sent to the ICBT-I study arm contained information regarding ICBT-I, the Research Study Informational Sheet, and a code that allowed them to access the ICBT-I program for free. Each access code was unique to each study participant to allow tracking of Sleepio access. A colorful flyer advertising Sleepio was included. The initial and reminder messages sent to the

Figure 1—Enrollment process.



Flowchart detailing the study's recruitment and enrollment cycle. The cycle was repeated until enough participants were accumulated. iCBT = internet cognitive behavioral therapy.

usual-care arm contained information regarding the Sleep Well, Live Well class.

Sample size

We estimated effect size among participants who engaged in the programs rather than among all those randomized to the study arms. Total days' supply of insomnia medications was used to calculate sample size. An examination of available data indicated that the average supply of insomnia medications was approximately 23 days per year among adults dispensed these medications. We assumed a clinically relevant reduction in insomnia medication days' supply of 7–10 days (a typical prescription supply) for those who engaged in Sleepio compared with those under usual care. Power was fixed at 0.9 and type I error at 0.025. Based on these assumptions, a sample size of 100 per group allowed for detecting a rate ratio of, at most, 0.577, which translated to a minimum detectable difference of 7.6 days' supply. We thus aimed to have at least 100 patients who engaged in the Sleepio intervention arm for a matched analysis or, for a direct comparison of programs, at least 100 who engage in the Sleep Well, Live Well class usual-care arm to have sufficient power for analysis. Further details on sample size assumptions and calculations are shown in the **Study Methods Details**.

Analytic methods

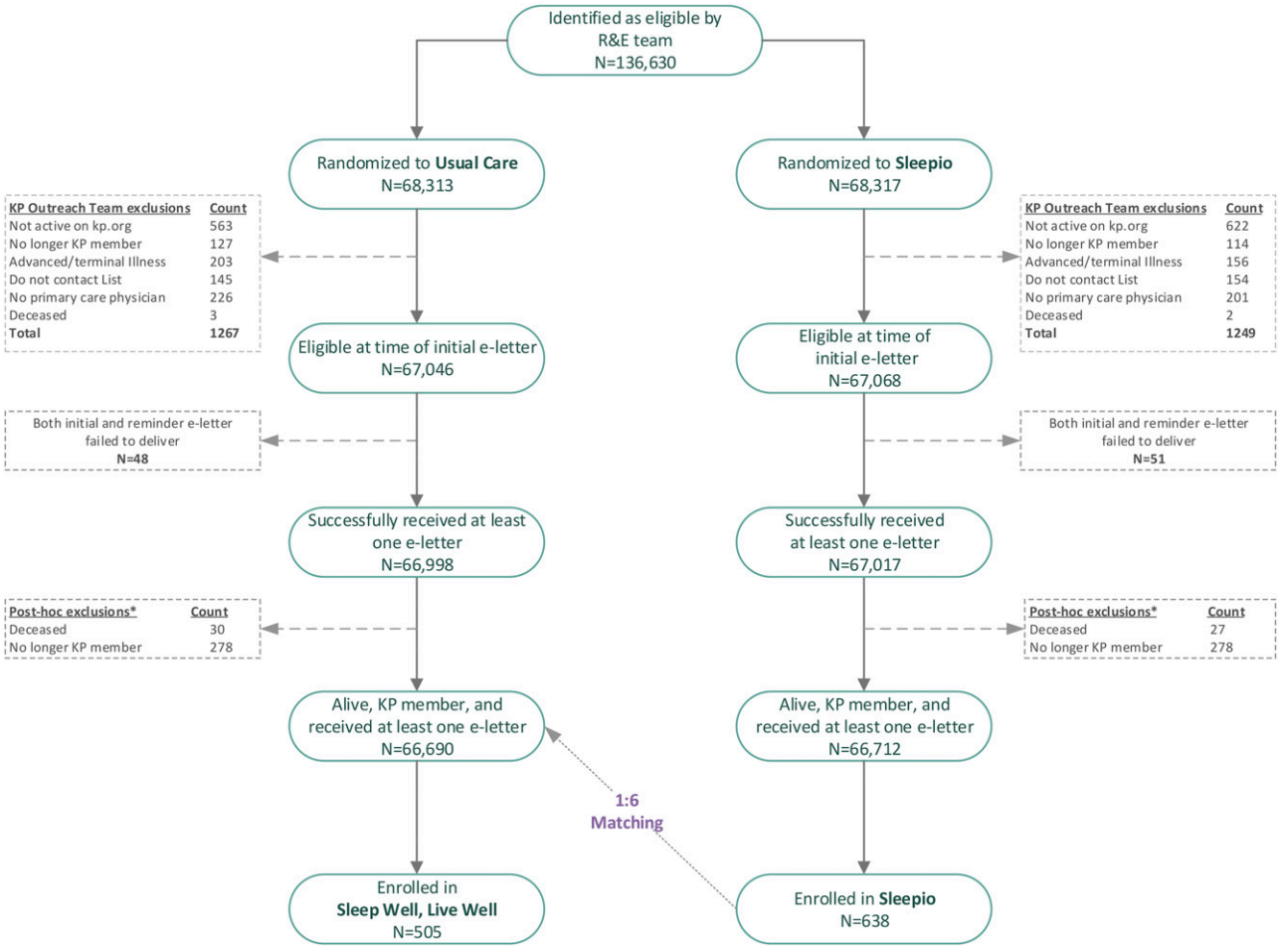
The implementation strategy was evaluated by the proportion of patients accessing 1 or more ICBT-I or Sleep Well, Live Well sessions. Preliminary testing estimated that ICBT-I enrollment would be 1–2%, while historical enrollment after population outreach for Sleep Well, Live Well classes was typically approximately 1%. Demographic characteristics and baseline utilization were compared between study arms and in those who enrolled vs did not enroll into ICBT-I and Sleep Well, Live Well using standardized differences.

The effectiveness of our implementation of ICBT-I in the eligible population was determined by an intention-to-treat analysis. ICBT-I effectiveness among those who chose to access ICBT-I was determined by a matched analysis. All participants who accessed Sleepio were matched to participants from the usual-care arm in a 1:6 ratio based on age, sex, race/ethnicity, and study inclusion criteria. We used a greedy matching algorithm with equal weight for each matching factor. Matched usual-care participants who attended a Sleep Well, Live Well class were given priority for inclusion. Regression models were performed using generalized estimating equations with a negative binomial distribution to estimate the effect of the intervention (ICBT-I) vs usual care on count data outcomes. In some cases, a zero-inflated model was used. Models accounted for correlation between matched pairs when this correlation was not negligible. Regression analyses were conducted with and without inclusion of covariates. These covariates included the following: (1) count of the outcome in the preceding 365 days, (2) number of ICBT-I and Sleep Well, Live Well sessions completed, and (3) a prior diagnosis of insomnia or dispensed insomnia medications in the preceding 365 days. Preliminary analyses examined outcomes at 6 months (data not shown). In secondary analyses, *t* tests were used to assess change in self-reported sleep metrics in those who engaged in Sleepio. Analyses were conducted in SAS version 9.4 (SAS Institute, Cary, NC).

RESULTS

The study enrolled patients from March 13 through June 19, 2018. Enrollment details are shown in the study flowchart

Figure 2—Enrollment flowchart.



Flowchart detailing study randomization, exclusions, recruitment reach, enrollment, and analyses. *Death records and membership take several weeks to update; these exclusions were discovered after outreach. KP = Kaiser Permanente, R&E = research and evaluation department.

(**Figure 2**). A total of 314,594 patients met 1 of the 4 inclusion criteria. After the application of all exclusion criteria, there were 133,402 participants (66,712 in the ICBT-I arm and 66,690 in the usual-care arm). Total enrollment was 2.9% of the active population. The characteristics of these members are shown in **Table 1**. In the ICBT-I arm, 638 participants (0.96%) redeemed their access code to access the ICBT-I program within 8 weeks of outreach. In the usual-care arm, 505 participants (0.76%) attended 1 or more Sleep Well, Live Well sessions within the same time frame.

The outcomes in each study arm are shown in **Table 1** as "Follow-up count per month" in medication days' supply and in visits. In the intention-to-treat analyses of the effectiveness of population outreach, there were no differences in health care utilization between ICBT-I and the usual-care arm, as shown by the very small standardized differences (imbalance defined as absolute value > 0.20).

The characteristics of participants who engaged in ICBT-I, as well as the results of matching, are shown in **Table 2**. Of 505 participants who accessed a Sleep Well, Live Well class, 424 were matched to ICBT-I participants. A comparison of **Table 1** and **Table 2** reveals that those who self-selected to engage in ICBT-I tended to be slightly older, non-Hispanic White, or Asian; have a recent insomnia diagnosis or sleep-related medication dispensed (55.3% vs 36.0%, comparing **Table 2** and **Table 1**); and had more medications and provider visits during the preceding year.

ICBT-I effectiveness among those who accessed ICBT-I vs usual care (with varying access to Sleep Well, Live Well) is shown in **Table 3**. In these models, participants who accessed ICBT-I were compared with matched participants from the usual-care arm with control for baseline utilization (eg, insomnia medication use in the preceding year) and the number of ICBT-I and Sleep Well, Live Well sessions attended. Model 1 shows no significant difference in the relative risk (RR) of insomnia medication dispensation (1-day supply/month) in participants who accessed ICBT-I vs usual care (RR: 1.03; 95% confidence interval: 0.91, 1.17). Similarly, no difference was found in our combined medication outcomes or provider visits (**Table 3**). In model 2, we examined whether the number of ICBT-I and Sleep Well, Live Well class sessions attended modified the risk of the outcomes. No differences were found,

Table 1—Patient characteristics.

Characteristics	ICBT-I	Usual Care	Total	Standardized Difference*
n	67,068	67,046	134,114	
Age, mean (SD), y	52.5 (17.92)	52.3 (17.91)	52.4 (17.92)	0.01188
Sex				0.00550
Female	46,133 (68.8)	46,135 (68.8)	92,268 (68.8)	
Male	20,933 (31.2)	20,910 (31.2)	41,843 (31.2)	
Other	1 (0.0)	0 (0.0)	1 (0.0)	
Unknown	1 (0.0)	1 (0.0)	2 (0.0)	
Race/ethnicity				0.00933
White	36,127 (53.9)	35,955 (53.6)	72,082 (53.7)	
Black	4,892 (7.3)	4,926 (7.3)	9,818 (7.3)	
Hispanic	18,648 (27.8)	18,858 (28.1)	37,506 (28)	
Asian/Pacific Islander	4,547 (6.8)	4,535 (6.8)	9,082 (6.8)	
Other	1,253 (1.9)	1,214 (1.8)	2,467 (1.8)	
Missing	1,601 (2.4)	1,558 (2.3)	3,159 (2.4)	
Marital status				0.00820
Married/partnered	32,129 (47.9)	32,266 (48.1)	64,395 (48.0)	
Single/separated	24,760 (36.9)	24,787 (37)	49,547 (36.9)	
Widowed	3,628 (5.4)	3,531 (5.3)	7,159 (5.3)	
Other	55 (0.1)	56 (0.1)	111 (0.1)	
Missing	6,496 (9.7)	6,406 (9.6)	12,902 (9.6)	
Study entry criteria				
Had insomnia medication order in the past 14 days	7,392 (11.0)	7,365 (11.0)	14,757 (11.0)	0.00117
Had insomnia diagnosis in the past 14 days	13,023 (19.4)	12,837 (19.1)	25,860 (19.3)	0.00687
Had depression diagnosis in the past 14 days	27,766 (41.4)	27,953 (41.7)	55,719 (41.5)	−0.00594
Had anxiety diagnosis in the past 14 days	39,631 (59.1)	40,006 (59.7)	79,637 (59.4)	−0.01178
Had insomnia diagnosis/medication at baseline[a]	24,125 (36.0)	24,016 (35.8)	48,141 (35.9)	0.00314
Number of sessions completed				0.03685
0	66,627 (99.3)	66,540 (99.2)	133,167 (99.3)	
1	233 (0.3)	163 (0.2)	396 (0.3)	
2+	208 (0.3)	343 (0.5)	551 (0.4)	
Baseline count per month, mean (SD)[b]				
Insomnia medication days' supply	3.7 (9.10)	3.7 (9.73)	3.7 (9.42)	−0.00355
Insomnia/depression/anxiety medication days' supply	23.5 (25.00)	23.6 (25.29)	23.5 (25.14)	−0.00380
Primary care visits	0.9 (0.79)	0.8 (0.79)	0.9 (0.79)	0.00934
Psychiatry/sleep medicine visits	0.6 (1.11)	0.6 (1.09)	0.6 (1.10)	0.00483
Follow-up count per month, mean (SD)[c]				
Insomnia medication days' supply	3.7 (9.39)	3.7 (9.39)	3.7 (9.39)	−0.00435
Insomnia/depression/anxiety medication days	24.1 (27.33)	24.1 (26.64)	24.1 (26.99)	0.00000
Primary care visits	0.8 (0.86)	0.8 (0.86)	0.8 (0.86)	0.00734
Psychiatry/sleep medicine visits	0.6 (1.23)	0.5 (1.20)	0.6 (1.22)	0.00508

Continuous data are presented as mean ± SD; categorical variables are presented as n (%). Characteristics of ICBT-I arm and usual-care arm: intention-to-treat cohort. *Standardized difference = difference in means or proportions divided by standard error; imbalance defined as absolute value > 0.20 (small effect size). [a]Had an insomnia diagnosis or any of the insomnia medication 12 months prior to outreach. [b]12 months prior to outreach. [c]12 months after outreach. ICBT-I = internet cognitive behavioral therapy for insomnia.

with the exception of an increased risk of sleep medicine and psychiatry visits among those who accessed ICBT-I vs usual-care participants who did not access any Sleep Well, Live Well classes (RR: 1.30; 95% confidence interval: 1.07, 1.57). In model 3, we examined whether the presence of an insomnia diagnosis or medication at baseline modified the risk of the

Table 2—Matched cohort characteristics.

Characteristics	ICBT-I	Usual Care	Total	Standardized Difference*
n	638	3,825	4,463	0.00101
Age, mean (SD), y	54.5 (15.13)	54.5 (15.13)	54.5 (15.13)	
Sex				0.00051
Female	446 (69.9)	2,673 (69.9)	3,119 (69.9)	
Male	192 (30.1)	1,152 (30.1)	1,344 (30.1)	
Race/ethnicity				0.00492
White	453 (71)	2,718 (71.1)	3,171 (71.1)	
Black	30 (4.7)	180 (4.7)	210 (4.7)	
Hispanic	102 (16.0)	612 (16.0)	714 (16.0)	
Asian/Pacific Islander	29 (4.5)	174 (4.5)	203 (4.5)	
Other	8 (1.3)	48 (1.3)	56 (1.3)	
Missing	16 (2.5)	93 (2.4)	109 (2.4)	
Marital status				0.12799
Married/partnered	301 (47.2)	2037 (53.3)	2338 (52.4)	
Single/separated	235 (36.8)	1,252 (32.7)	1,487 (33.3)	
Widowed	30 (4.7)	146 (3.8)	176 (3.9)	
Other	2 (0.3)	5 (0.1)	7 (0.2)	
Missing	70 (11)	385 (10.1)	455 (10.2)	
Study entry criteria				
Had insomnia medication order in the past 14 days	106 (16.6)	725 (19)	831 (18.6)	−0.06122
Had insomnia diagnosis in the past 14 days	216 (33.9)	1,276 (33.4)	1,492 (33.4)	0.01051
Had depression diagnosis in the past 14 days	246 (38.6)	1,412 (36.9)	1,658 (37.1)	0.03390
Had anxiety diagnosis in the past 14 days	320 (50.2)	2,014 (52.7)	2,334 (52.3)	−0.04997
Had insomnia diagnosis/medication at baseline[a]	353 (55.3)	1,886 (49.3)	2,239 (50.2)	0.12079
Number of sessions completed				
0	197 (30.9)	3,401 (88.9)	3,598 (80.6)	1.48211
1	233 (36.5)	136 (3.6)	369 (8.3)	
2+	208 (32.6)	288 (7.5)	496 (11.1)	
Baseline count per month, mean (SD)[b]				
Insomnia medication days' supply	5.3 (10.83)	5.1 (10.59)	5.1 (10.62)	0.02199
Insomnia/depression/anxiety medication days' supply	29.0 (27.41)	25.7 (26.86)	26.1 (26.96)	0.12354
Primary care visits	1.0 (0.95)	0.9 (0.83)	0.9 (0.85)	0.12890
Psychiatry/sleep medicine visits	0.8 (1.42)	0.5 (1.09)	0.6 (1.14)	0.17548
Follow-up count per month, mean (SD)[c]				
Insomnia medication days' supply	5.1 (10.39)	5.1 (10.92)	5.1 (10.84)	0.00256
Insomnia/depression/anxiety medication days	29.9 (28.56)	25.9 (28.08)	26.5 (28.18)	0.13805
Primary care visits	1.0 (1.02)	0.9 (0.92)	0.9 (0.93)	0.09927
Sleep medicine or psychiatry visits	0.8 (1.44)	0.6 (1.26)	0.6 (1.29)	0.18278

Continuous data are presented as mean ± SD; categorical variables are presented as n (%). Characteristics of participants who accessed ICBT-I and matched participants in usual care: matched cohort. Matched participants who accessed ICBT-I (Sleepio) to usual-care participants with a 1:6 ratio based on race/ethnicity, sex, age, Sleep Well, Live Well class participation, and study entry criteria. *Standardized difference = difference in means or proportions divided by standard error; imbalance defined as absolute value > 0.20 (small effect size). [a]Had an insomnia diagnosis or any of the insomnia medication 12 months prior to outreach. [b]12 months prior to outreach. [c]12 months after outreach. ICBT-I = internet cognitive behavioral therapy for insomnia.

outcomes in those who accessed ICBT-I vs usual care. The only difference was an increased risk of sleep medicine and psychiatry visits among patients without an insomnia diagnosis or medication at baseline (RR: 1.38; 95% confidence interval: 1.11, 1.72).

Among ICBT-I users, statistically significant ($P < .05$ after session 2) improvements were detected for sleep-onset latency (eg, reduced by 14 minutes), total sleep time (increased by 30 minutes), wake after sleep onset (reduced by 9 minutes),

Table 3—Model results.

	ICBT-I Group (n) vs Comparison Group (n)	Relative Risk (95% CI)			
		Insomnia Medications[a]	Insomnia, Depression, Anxiety Medications[a]	Primary Care Visits[b]	Sleep Medicine or Psychiatry Visits[b]
Model 1: Adjusted	ICBT-I (Sleepio) vs usual care (all)	1.03 (0.91, 1.17)	1.03 (0.95, 1.12)	0.97 (0.89, 1.06)	1.11 (0.90, 1.36)
Model 2: adjusted with session completion interaction	Sleepio 0 sessions vs Sleep Well, Live Well 0 sessions	1.08 (0.85, 1.37)	1.02 (0.89, 1.18)	1.06 (0.93, 1.22)	1.27 (0.94, 1.72)
	Sleepio 1 session vs Sleep Well, Live Well 1 session	1.07 (0.77, 1.47)	1.02 (0.82, 1.25)	0.91 (0.73, 1.12)	1.01 (0.64, 1.58)
	Sleepio 2+ sessions vs Sleep Well, Live Well 2+ sessions	0.95 (0.72-1.25)	1.06 (0.88, 1.26)	0.88 (0.74, 1.05)	0.94 (0.57, 1.57)
	Sleepio 1+ sessions vs Sleep Well, Live Well 0 sessions	0.92 (0.81, 1.05)	1.04 (0.96, 0.13)	1.05 (0.97, 1.13)	1.30 (1.07, 1.57)
Model 3: adjusted with insomnia interaction	Sleepio insomnia vs usual-care insomnia	0.94 (0.84, 1.06)	1.01 (0.93, 1.11)	0.98 (0.90, 1.07)	1.13 (0.90, 1.43)
	Sleepio non-insomnia vs usual-care non-insomnia	1.38 (0.99, 1.92)	1.06 (0.96, 1.17)	1.10 (1.00, 1.21)	1.38 (1.11, 1.72)

Results of all models, matched analyses. Matched participants who accessed ICBT-I (Sleepio) to usual-care participants with a 1:6 ratio on race/ethnicity, sex, age, and study entry criteria. Model 1 is adjusted for 1-year baseline count and number of sessions completed. Model 2 is adjusted for 1-year baseline count, number of sessions completed, and the interaction between number of sessions and treatment. Model 3 is adjusted for 1-year baseline count, baseline insomnia status (diagnosis or medication for insomnia up to 1 year prior to case identification), and the interaction between baseline insomnia status and treatment. [a]Days' supply of medications. Zero-inflated negative binomial model. Correlation among matched pairs is negligible and therefore not accounted for in the model. [b]Primary care visits, sleep medicine/psychiatry visits. GEE model with negative binomial distribution, considering correlation between matched pairs. CI = confidence interval, GEE = generalized estimating equation, ICBT-I = internet cognitive behavioral therapy for insomnia.

and thus sleep efficiency (improved by 8%). For details of these self-reported measures, see **Analyses of Self-Reported Measures of Sleep Quality Among ICBT-I Users** in supplemental material.

DISCUSSION

CBT-I is a primary treatment for insomnia, but access to trained therapists is limited. ICBT-I has the advantage of ready access from any location and thus lends itself to a population-based approach to treatment. Using this approach, patients with insomnia or at high risk are informed of and provided access to services in a proactive way: delays for appointments with busy primary care providers are avoided and additional workload is alleviated. We undertook this study to implement a population health program for insomnia using ICBT-I and targeting known patients with insomnia as well as high-risk patients. Our study design was pragmatic with no disruption in the usual-care arm and minimal differences between the intervention arm and any future implementation (ie, a study information sheet).

While we hoped for higher participation in ICBT-I, Sleepio enrollment was low (~1%) using our population outreach processes. This participation rate was not substantially different from Sleep Well, Live Well class engagement, which was itself typical of enrollment in other health education classes after population outreach through mailings and public notices in our health system. Given that proportionally more participants with insomnia accessed the ICBT-I program, a strategy to increase program engagement, albeit by limiting outreach, is to focus on patients with active insomnia rather than other at-risk populations. Anecdotal feedback from about a dozen patient phone calls to the research study participant help-line involved practical questions on how to access the program or clinical questions regarding stopping medications, with just 1 question related to the research itself. Program uptake thus may be potentially improved by providing more guidance to patients about program access.

Given the low engagement in ICBT-I, the measured effectiveness of the intervention in the exposed population is reduced proportionally with compliance.[24] Nevertheless, with a large number of participants per study arm, we had the ability to detect small differences. Although participation was very low in ICBT-I, the intention-to-treat estimate still provides a real-world measure of effectiveness while maintaining the properties of randomization (ie, eliminating bias due to measured and unmeasured confounders), and using alternative estimators to assess effectiveness (eg, as-treated, per-protocol) would have posed additional challenges due to the skewed distribution of the compliance classes.[24,25] The final result was no detectable difference in population effect between ICBT-I and optimized usual care for the study outcomes at 6 months (data not shown) and at 1 year.

We performed analyses with matched controls from the usual-care arm in order to obtain an estimate of program effectiveness among those who chose to access ICBT-I, thus moving toward an estimate of ICBT-I intervention efficacy vs usual care. A limitation of this approach is that participants who accessed ICBT-I also agreed to allow additional sleep-related data to be collected for research. We have no equivalent

knowledge of which matched controls would have enrolled in ICBT-I if offered it. To the extent that this difference in self-selection between groups is associated with unmeasured factors that influence our study outcomes, bias may be introduced. We attempted to adjust for this bias by controlling for demographic characteristics, baseline utilization, and self-selection into Sleep Well, Live Well class attendance. Acknowledging this limitation, we found no difference in medication utilization among those who accessed ICBT-I compared with usual care, regardless of attendance to Sleep Well, Live Well classes or prior insomnia diagnosis or medications. In some comparisons (those who did not access Sleep Well, Live Well and those without an insomnia diagnosis or medications), ICBT-I access was associated with an increase in sleep and psychiatry visits, perhaps reflecting underlying mental health risks in these populations.

We chose to measure the long-term effects of ICBT-I on key measures of health care utilization because they represent patient health outcomes and reflect health care costs. The effect of ICBT-I on medication use is particularly relevant since medications are risky in some patients (eg, falls in the elderly), are potentially more expensive than ICBT-I in the long term, and can be habit-forming and difficult to withdraw after chronic use. To the extent that an ICBT-I program can be designed to safely delivery medication discontinuation therapy, a greater change in medication utilization might be observed. Some prior studies have reported a decline in self-reported medication use, although missing data may have affected results.[26–28] Other studies did not find a change in medication use.[29] We found only 1 prior study that measured health care encounters, and no effect of ICBT-I on provider visits was observed.[27] Although we did not observe changes in insomnia medication dispensations or a reduction in provider visits, we did observe typical self-reported improvement in measures of sleep quality among patients undertaking at least 2 sessions of ICBT-I. This fact anchors our result in the prior literature and underscores the success of our ICBT-I implementation among program users. Both CBT-I and ICBT-I are clearly associated with improved self-reported measures of sleep quality, even many months after program completion.[20,21,23,30–33]

Our study's estimate of the long-term effects of ICBT-I were potentially affected by the hybrid study design, as discussed above. A similar study in other health systems and populations may produce different results. Our study's advantages for generalizability include the following: a defined population with high data capture, which established the entire clinical population who were eligible for the study, and a diverse patient population, similar to that of Southern California, with Medicaid and Medicare recipients. We did not test our program in non-English speakers, and results in those populations may vary. ICBT-I is not always readily available in a variety of languages. We do not know what proportion of eligible participants were truly bothered by insomnia or would have accessed traditional one-on-one therapist-delivered CBT-I.

There are broad frameworks to consult when designing and testing a population health program and help ensure implementation.[34] Barriers to implementation and sustainability are many (cost, time, expertise, resources, etc) and vary by setting.[35] In an integrated health system such as Kaiser Permanente Southern California, systems exist for automated outreach for population health, substantially lowering the effort and costs associated with implementing new programs. Our health system leaders identified cost-neutrality as a particular concern for sustainability of the ICBT-I program. Given competition for health care resources among various conditions (such as cancer, obesity, mental health), new programs are more easily implemented and sustained when resources are simultaneously saved. In our ICBT-I program, population reach is not critical for sustainability when a low-cost, automated outreach process is available and the incremental cost of the program is on a per-person basis.

Our study suggests that a population-based approach to insomnia using ICBT-I can be implemented, but potentially with low engagement. Additional strategies may be necessary to improve population reach, such as better targeting of patients with symptoms through a focus on recent insomnia diagnoses or automated EHR note analyses, more intensive outreach to patients, identifying potential individual barriers such as concern over side effects and the time involved, and developing effective strategies to enhance patient engagement such as spousal involvement. Providers might be most easily involved by making an electronic referral to an automated program possible, triggering tailored outreach, and automated reports on progress to providers. Developers of automated insomnia programs might also consider how to provide and test automated guidance for insomnia medication discontinuation. Although "hard" measures of utilization were not improved by our implementation of ICBT-I compared with optimized usual care with information provided about insomnia classes, we nevertheless feel that improving sleep quality is sufficient for offering access to an ICBT-I program.

ABBREVIATIONS

CBT-I, cognitive behavioral therapy for insomnia
EHR, electronic health record
ICBT-I, internet cognitive behavioral therapy for insomnia
RR, relative risk

REFERENCES

1. Ohayon MM, Reynolds CF 3rd. Epidemiological and clinical relevance of insomnia diagnosis algorithms according to the DSM-IV and the International Classification of Sleep Disorders (ICSD). *Sleep Med*. 2009;10(9):952–960.
2. Khan MS, Aouad R. The effects of insomnia and sleep loss on cardiovascular disease. *Sleep Med Clin*. 2017;12(2):167–177.
3. Pearson NJ, Johnson LL, Nahin RL. Insomnia, trouble sleeping, and complementary and alternative medicine: analysis of the 2002 national health interview survey data. *Arch Intern Med*. 2006;166(16):1775–1782.
4. Roth T, Jaeger S, Jin R, Kalsekar A, Stang PE, Kessler RC. Sleep problems, comorbid mental disorders, and role functioning in the national comorbidity survey replication. *Biol Psychiatry*. 2006;60(12):1364–1371.
5. Baglioni C, Battagliese G, Feige B, et al. Insomnia as a predictor of depression: a meta-analytic evaluation of longitudinal epidemiological studies. *J Affect Disord*. 2011;135(1-3):10–19.

6. Hertenstein E, Feige B, Gmeiner T, et al. Insomnia as a predictor of mental disorders: a systematic review and meta-analysis. *Sleep Med Rev.* 2019;43: 96–105.
7. Morin CM, Drake CL, Harvey AG, et al. Insomnia disorder. *Nat Rev Dis Primers*. 2015;1(1):15026.
8. Kessler RC, Berglund PA, Coulouvrat C, et al. Insomnia, comorbidity, and risk of injury among insured Americans: results from the America Insomnia Survey. *Sleep*. 2012;35(6):825–834.
9. Koski K, Luukinen H, Laippala P, Kivelä SL. Risk factors for major injurious falls among the home-dwelling elderly by functional abilities: a prospective population-based study. *Gerontology*. 1998;44(4):232–238.
10. Kessler RC, Berglund PA, Coulouvrat C, et al. Insomnia and the performance of US workers: results from the America insomnia survey. *Sleep*. 2011;34(9): 1161–1171.
11. Daley M, Morin CM, LeBlanc M, Grégoire JP, Savard J. The economic burden of insomnia: direct and indirect costs for individuals with insomnia syndrome, insomnia symptoms, and good sleepers. *Sleep*. 2009;32(1):55–64.
12. Kyle SD, Morgan K, Espie CA. Insomnia and health-related quality of life. *Sleep Med Rev.* 2010;14(1):69–82.
13. Sarsour K, Kalsekar A, Swindle R, Foley K, Walsh JK. The association between insomnia severity and healthcare and productivity costs in a health plan sample. *Sleep*. 2011;34(4):443–450.
14. Anderson LH, Whitebird RR, Schultz J, McEvoy CE, Kreitzer MJ, Gross CR. Healthcare utilization and costs in persons with insomnia in a managed care population. *Am J Manag Care*. 2014;20(5):e157–e165.
15. Léger D, Bayon V. Societal costs of insomnia. *Sleep Med Rev.* 2010;14(6): 379–389.
16. Qaseem A, Kansagara D, Forciea MA, Cooke M, Denberg TD; Clinical Guidelines Committee of the American College of Physicians. Management of chronic insomnia disorder in adults: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2016;165(2):125–133.
17. Riemann D, Baglioni C, Bassetti C, et al. European guideline for the diagnosis and treatment of insomnia. *J Sleep Res*. 2017;26(6):675–700.
18. Wilson S, Anderson K, Baldwin D, et al. British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders: an update. *J Psychopharmacol*. 2019;33(8):923–947.
19. Morgenthaler T, Kramer M, Alessi C, et al; American Academy of Sleep Medicine. Practice parameters for the psychological and behavioral treatment of insomnia: an update. An American Academy of Sleep Medicine report. *Sleep*. 2006;29(11):1415–1419.
20. Trauer JM, Qian MY, Doyle JS, Rajaratnam SM, Cunnington D. Cognitive behavioral therapy for chronic insomnia: a systematic review and meta-analysis. *Ann Intern Med*. 2015;163(3):191–204.
21. van Straten A, van der Zweerde T, Kleiboer A, Cuijpers P, Morin CM, Lancee J. Cognitive and behavioral therapies in the treatment of insomnia: a meta-analysis. *Sleep Med Rev.* 2018;38:3–16.
22. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. 2012;50(3): 217–226.
23. Zachariae R, Lyby MS, Ritterband LM, O'Toole MS. Efficacy of internet-delivered cognitive-behavioral therapy for insomnia—a systematic review and meta-analysis of randomized controlled trials. *Sleep Med Rev.* 2016; 30:1–10.
24. Sommer A, Zeger SL. On estimating efficacy from clinical trials. *Stat Med*. 1991; 10(1):45–52.
25. Bang H, Davis CE. On estimating treatment effects under non-compliance in randomized clinical trials: are intent-to-treat or instrumental variables analyses perfect solutions? *Stat Med*. 2007 Feb 28;26(5):954–964.
26. Kaldo V, Jernelöv S, Blom K, et al. Guided internet cognitive behavioral therapy for insomnia compared to a control treatment—a randomized trial. *Behav Res Ther.* 2015;71:90–100.
27. Luik AI, Marsden A, Emsley R, et al. Long-term benefits of digital cognitive behavioural therapy for insomnia: follow-up report from a randomized clinical trial. *J Sleep Res*. 2020;29(4):e13018.
28. Blom K, Jernelöv S, Rück C, Lindefors N, Kaldo V. Three-year follow-up of insomnia and hypnotics after controlled internet treatment for insomnia. *Sleep*. 2016;39(6):1267–1274.
29. van Straten A, Emmelkamp J, de Wit J, et al. Guided internet-delivered cognitive behavioural treatment for insomnia: a randomized trial. *Psychol Med*. 2014;44(7): 1521–1532.
30. Geiger-Brown JM, Rogers VE, Liu W, Ludeman EM, Downton KD, Diaz-Abad M. Cognitive behavioral therapy in persons with comorbid insomnia: a meta-analysis. *Sleep Med Rev.* 2015;23:54–67.
31. Seyffert M, Lagisetty P, Landgraf J, et al. Internet-delivered cognitive behavioral therapy to treat insomnia: a systematic review and meta-analysis. *PLoS One*. 2016;11(2):e0149139.
32. Ritterband LM, Thorndike FP, Ingersoll KS, et al. Effect of a Web-based cognitive behavior therapy for insomnia intervention with 1-year follow-up: a randomized clinical trial. *JAMA Psychiatry*. 2017;74(1):68–75.
33. Vedaa Ø, Hagatun S, Kallestad H, et al. Long-term effects of an unguided online cognitive behavioral therapy for chronic insomnia. *J Clin Sleep Med*. 2019;15(1): 101–110.
34. Lobb R, Colditz GA. Implementation science and its application to population health. *Annu Rev Public Health*. 2013;34(1):235–251.
35. Glasgow RE, Emmons KM. How can we increase translation of research into practice? Types of evidence needed. *Annu Rev Public Health*. 2007; 28(1):413–433.

ACKNOWLEDGMENTS

The authors acknowledge Big Health for donating access to Sleepio for this study and the Sleepio team at Big Health for contributing to our understanding of ICBT-I and the workings of Sleepio.

SUBMISSION & CORRESPONDENCE INFORMATION

Submitted for publication November 6, 2020
Submitted in final revised form March 23, 2021
Accepted for publication March 24, 2021
Address correspondence to: Stephen F. Derose, MD, MSHS, Department of Research and Evaluation, Kaiser Permanente Southern California, 100 S. Los Robles, Pasadena, CA 91101; Email: stephen.derose@baystatehealth.org

DISCLOSURE STATEMENT

All authors have reviewed and approved this manuscript. Work for this study was performed at Kaiser Permanente Southern California, Department of Research and Evaluation, Pasadena, California. This study was funded internally by Kaiser Permanente. The authors report no conflicts of interest.