Short-Term Efficacy of Digital Cognitive Behavioral Therapy for Insomnia With Different Types of Coaching: A Randomized Controlled Comparative Trial

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Abstract

Background: Digital cognitive behavioral therapy for insomnia (dCBTi) is a scalable and effective intervention for treating insomnia. The findings regarding its efficacy compared to face-to-face CBTi are inconclusive but suggest that dCBTi might be inferior. The lack of human support and low treatment adherence are believed to be barriers to dCBTi achieving its optimal efficacy. However, there has yet to be a direct comparative trial of dCBTi with different types of coaching support.

Objective: The present study examined whether adding virtual and human coaching would improve dCBTi's efficacy and treatment adherence.

Methods: 129 participants (76% women; age = 34.09 ± 12.05) who had clinically significant insomnia symptoms (Insomnia Severity Index (ISI) ? 10) were recruited. A randomized controlled comparative trial with five arms was conducted: dCBTi with virtual coaching and therapist support (dCBTi-therapist), dCBTi with virtual coaching and research assistant support (dCBTi-assistant), dCBTi with virtual coaching only (dCBTi-virtual), dCBTi without any coaching (unguided-dCBTi), and digital sleep hygiene and self-monitoring control (dSH). Participants completed measures of insomnia (ISI, the Sleep Condition Indicator [SCI]), mood disturbances, fatigue, daytime sleepiness, quality of life, dysfunctional beliefs about sleep, and sleep-related safety behaviors, at baseline, post-treatment, and 4-week follow-up. Treatment adherence was measured by the completion of video sessions and sleep diaries. Intention to treat analysis was conducted using linear mixed models. Fisher's exact tests was conducted to evaluate differences in treatment adherence across conditions.

Results: Significant condition-by-time interaction effects showed that recipients of dCBTi, regardless of having any coaching or not, had greater improvements in insomnia measured by the SCI (Cohen's d=.45), depressive symptoms (Cohen's d=-.62), anxiety (d=-.40), fatigue (d=-.35), dysfunctional beliefs about sleep (d=-.53), and safety behaviors related to sleep (d=-.50), than those of dSH. The addition of virtual coaching and human support did not improve treatment efficacy. However, adding human support promoted greater reductions in fatigue (d=-.33), and sleep-related safety behavior (d=-.30) than dCBTI-virtual at 4-week follow-up. In particular, dCBTi-therapist promoted a greater reduction in fatigue than dCBTi-assistant at follow-up (d=-.41). As expected, dCBTi-therapist had the highest video and diary completion rates compared to other conditions (video: 60+% in dCBTi-therapist vs. <25% in dCBTi-unguided), indicating greater treatment adherence, especially in later treatment sessions.

Conclusions: The present findings support the efficacy of a fully automated, standalone dCBTi in treating insomnia, reducing thoughts and behaviors that perpetuate insomnia, reducing mood disturbances, fatigue, and improving quality of life. Adding virtual coaching and human support did not significantly improve dCBTi's efficacy at post-treatment. Still, it may improve long-term efficacy given its effects on increasing treatment adherence and incremental benefits on reducing fatigue and behaviors that could perpetuate insomnia. Clinical Trial: ClinicalTrials.gov NCT05136638

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Abstract

Background: Digital cognitive behavioral therapy for insomnia (dCBTi) is a scalable and effective intervention for treating insomnia. The findings regarding its efficacy compared to face-to-face CBTi are inconclusive but suggest that dCBTi might be inferior. The lack of human support and low treatment adherence are believed to be barriers to dCBTi achieving its optimal efficacy. However, there has yet to be a direct comparative trial of dCBTi with different types of coaching support. **Objective:** The present study examined whether adding virtual and human coaching would improve dCBTi's efficacy and treatment adherence.
Methods: 129 participants (76% women; age = 34.09 ± 12.05) who had clinically significant insomnia symptoms (Insomnia Severity Index (ISI) ≥ 10) were recruited. A randomized controlled comparative trial with five arms was conducted: dCBTi with virtual coaching and therapist support (dCBTi-therapist), dCBTi with virtual coaching and research assistant support (dCBTi-assistant), dCBTi with virtual coaching only (dCBTi-virtual), dCBTi without any coaching (unguided-dCBTi), and digital sleep hygiene and self-monitoring control (dSH). Participants were blinded to the condition assignment and study hypotheses, and the outcomes were self-assessed using questionnaires administered online. The outcomes included measures of insomnia (ISI, the Sleep Condition Indicator [SCI]), mood disturbances, fatigue, daytime sleepiness, quality of life, dysfunctional beliefs about sleep, and sleep-related safety behaviors, at baseline, post-treatment, and 4-week follow-up. Treatment adherence was measured by the completion of video sessions and sleep diaries. Intention to treat analysis was conducted using linear mixed models. Fisher's exact tests were conducted to evaluate differences in treatment adherence across conditions.
Results: Significant condition-by-time interaction effects showed that recipients of dCBTi, regardless of having any coaching or not, had greater improvements in insomnia measured by the SCI (Cohen's d=.45) but not the ISI (Cohen's d=-.28), depressive symptoms (Cohen's d=-.62), anxiety (d=-.40), fatigue (d=-.35), dysfunctional beliefs about sleep (d=-.53), and safety behaviors related to sleep (d=-.50), than those of dSH. The addition of virtual coaching and human support did not improve treatment efficacy. However, adding human support promoted greater reductions in fatigue (d=-.33), and sleep-related safety behavior (d=-.30) than dCBTI-virtual at 4-week follow-up. In particular, dCBTi-therapist promoted a greater reduction in fatigue than dCBTi-assistant at follow-up (d=-.41). As expected, dCBTi-therapist had the highest video and diary completion rates compared to other conditions (video: 60+% in dCBTi-therapist vs. <25% in dCBTi-unguided), indicating greater treatment adherence, especially in later treatment sessions.
Conclusions: The present findings support the efficacy of a fully automated, standalone dCBTi in treating insomnia, reducing thoughts and behaviors that perpetuate insomnia, reducing mood disturbances, fatigue, and improving quality of life. Adding virtual coaching and human support did not significantly improve dCBTi's efficacy at post-treatment. Still, it may improve long-term efficacy given its effects on increasing treatment adherence and incremental benefits on reducing fatigue and behaviors that could perpetuate insomnia.
Trial Registration: ClinicalTrials.gov NCT05136638

Keywords: insomnia; cognitive behavioral therapy; digital intervention; mhealth; virtual coaching; human support

Introduction

Insomnia disorder is the most common sleep-wake disorder characterized by difficulty initiating or maintaining sleep despite having adequate opportunities to sleep or having non-restorative sleep, not explained by other sleep disorders [1,2]. The prevalence of insomnia disorder ranges from 2.3% to 25.5% globally [3] and was heightened during the COVID-19 pandemic affecting as many as one-third of the general population [4–6]. Insomnia is associated with high societal and economic costs resulting from healthcare utilization, work absenteeism, and lost productivity [7,8]. It is estimated to cost as much as 100 billion USD per year in the United States [9] and a loss of annual gross domestic product of 19.6 billion in Canada, 41.4 billion in the United Kingdom, and 19.2 billion in Australia [10]. The cost of untreated insomnia outweighs the cost of treating insomnia, with cognitive behavioral therapy for insomnia (CBTi) achieving greater cost-effectiveness than pharmacological treatments [11]. Technology-aided delivery of CBTi may have even greater cost-effectiveness given its high scalability and reduced demands for human resources compared to face-to-face CBTi [12].

CBTi is an evidence-based and the first-line treatment of insomnia disorder recommended by health organizations around the world [13,14]. It targets the cognitive and behavioral mechanisms perpetuating sleep difficulties, namely compromised sleep drive, disturbed circadian rhythm, and/or hyperarousal, especially hyperarousal associated with the sleeping environment or sleep per se [15–17]. Integrating multiple treatment techniques, CBTi aims to preserve sleep drive, stabilize circadian rhythm, and reduce hyperarousal; it is typically delivered in six-to-eight hourly sessions by a trained mental health professional [18]. CBTi effectively improves sleep quality and reduces insomnia symptoms across populations, including populations with medical and psychiatric comorbidities. On average, CBTi leads to 20-30-minute reductions in both sleep onset latency and wake after sleep onset and approximately 10% increases in sleep efficiency at the end of treatment [19] with less consistent effects on total sleep time [20]. CBTi also improves mood, fatigue, and quality of life, indirectly through sleep improvements or directly through changes in behavior and cognition [21,22]. Despite its strong evidence base, CBTi is not consistently delivered to most people due to various implementation obstacles, notably the lack of mental health workers trained in delivering CBTi and limitations in time and resources required for delivering and receiving CBTi [23].

Digital CBTi (dCBTi) is a promising alternative mode of delivery of CBTi, given its high scalability and low demands for human resources. Meta-analyses have found comparable efficacy estimates of dCBTi compared to face-to-face CBTi [24,25]. However, a direct comparative trial found dCBTi less efficacious than face-to-face CBTi [26]. Notably, fully automated dCBTi is the most cost-effective treatment of insomnia, followed by group CBTi and individual CBTi [27]. Of the different types of dCBTi, dCBTi with therapist support is found to have the highest efficacy compared to other dCBTi without therapist support [28]. Indeed, CBTi recipients attribute treatment success to the working alliance with the therapist and they perceive therapist-assisted support, such as the provision of personalized feedback, motivational enhancement, and accountability, to be critical for increasing engagement with dCBTi [23]. Nonetheless, the need for therapist support hinders the scalability and accessibility of dCBTi, the core benefits of dCBTi over face-to-face CBTi.

Non-therapist guidance to dCBTi is a lower-cost alternative. Although it may be limited in delivering expert advice and addressing challenging motivational or emotional barriers, non-

therapist support can provide personalized feedback, motivational enhancement, and accountability. Non-therapist support has been found to improve treatment outcomes of self-help CBTi [29]. With technological advancements, a virtual conversational agent designed to mimic patient-therapist interactions and provide personalized content and feedback, also known as virtual coaching or e-coaching, is made possible [30]. Non-therapist and virtual support require no therapist and preserve the core benefit of dCBTi over face-to-face CBTi. Meta-analyses have found mixed results regarding the effect sizes of dCBTi with different types of coaching support, and a direct comparative trial is nonexistent.

Low treatment adherence and high attrition rates are the major challenges in implementing dCBTi and even face-to-face CBTi [31,32]. On average, half of the dCBTi recipients do not adhere to treatment [33], compared to 14-44% in face-to-face CBTi [34]. While dCBTi offers greater potential for scalability, if engagement and treatment adherence is low, its impact on population health will remain minimal. Adding human or virtual guidance to dCBTi is one of the most discussed solutions to improving engagement [31,33]; however, empirical support for its effects on treatment adherence is still being determined.

In sum, dCBTi is undoubtedly a promising intervention for insomnia that could have a major impact at the population level. Nevertheless, more research on how to optimize its benefits is needed. In particular, adding human or virtual coaching has been frequently regarded as a useful strategy to improve treatment efficacy. However, a direct comparative trial of dCBTi with different types of coaching compared to unguided dCBTi has yet to be conducted. Furthermore, the effects of different types of coaching on treatment adherence have not been evaluated.

The present study is the first empirical evaluation of the efficacy of dCBTi with different types of coaching. Moreover, we aim to evaluate if different coaching types improve treatment adherence along with treatment outcomes. Specifically, in a five-arm randomized controlled comparative trial, we evaluate whether (1) a fully-automated mobile dCBTi has superior efficacy to an active digital sleep hygiene education control, (2) adding coaching, regardless of types, will enhance treatment adherence and efficacy compared to unguided dCBTi, (3) dCBTi with human support will enhance treatment adherence and efficacy compared to dCBTi with virtual support, and (4) support from a therapist is superior to support from non-therapists. We hypothesized that (1) dCBTi, regardless of the presence of coaching, would be efficacious for improving insomnia symptoms compared to dSH control; (2) dCBTi with coaching would promote greater improvements in insomnia symptoms and greater treatment adherence than unguided dCBTi; (3) dCBTi with human coaching would promote greater improvements in insomnia symptoms and treatment adherence than dCBTi with virtual coaching; and, (4) dCBTi with therapist coaching will promote greater improvements in insomnia symptoms and greater treatment adherence than dCBTi with assistant coaching.

Methods

Study Design

The study is a five-arm, parallel, participant-blinded, randomized, controlled comparative trial. The five conditions include dCBTi with virtual coaching and therapist support (dCBTi-therapist), dCBTi with virtual coaching and research assistant support (dCBTi-assistant), dCBTi with virtual coaching only (dCBTi-virtual), dCBTi without any coaching (unguided-dCBTi), and

digital sleep hygiene and self-monitoring control (dSH). The study protocol was pre-registered on ClinicalTrials.gov (ID: NCT05136638).

Ethical Considerations

This study was approved by the Human Research Ethics Committee at the University of Hong Kong before data collection (Ref#: EA210458). Electronic informed consent was obtained from each participant prior to study participation. Each participant was informed that participation was entirely voluntary and they could withdraw from the study at any point without negative consequences. All data were kept confidential in a password-protected drive. Only the research team has access to the data. All personal identifying information was removed from the research data and will be kept separately from the research data for three years after the publication of the main study findings to ensure that there are no problems with consent, fabrication, and falsification, Anonymous data will be kept indefinitely. Each participant was compensated HKD$ 60 (~USD$8) for completing research measures at each time point.

Randomization and Blinding

Simple randomization with equal chances of assigning a participant to one of the five conditions was conducted using the randomization function implemented in *Sleep Sensei*, a mobile application developed with the MobileCoach platform [35,36] specifically for the present study. Participants were informed that they were assigned to one of the intervention conditions. However, they were not informed about the conditions nor the condition to which they were assigned. They were not informed of the study hypothesis either. Because all participants were given access to *Sleep Sensei*, we considered them blinded to the condition assignment and study hypothesis. The therapists and assistants who provided coaching support were not blinded to the assignment. The assessments of treatment outcomes were all self-administered using Qualtrics.

Participants

The inclusion criteria were: (a) have a score on Insomnia Severity Index (ISI) ≥ 10 indicating clinically significant insomnia [37], (b) aged 18 to 65, (c) have access to a smartphone and a local phone number, and (d) able to understand written Chinese and spoken Cantonese, the languages used in *Sleep Sensei*. The exclusion criteria were: (a) self-reported sleep apnea or high risk of sleep apnea identified using the Berlin Questionnaire [38], (b) self-reported acute, untreated mental or medical illnesses that would interfere with participation, (c) suicidal ideation suggested by a score ≥ 1 on the Patient Health Queationnaire-9 (PHQ9) and confirmed by a follow-up interview by clinical psychology trainees, (d) unstable medication use that can affect sleep, (e) currently receiving psychotherapy for insomnia, and, (f) other conditions that prevent the adherence to CBTi recommendations such as shift work. Participants who did not complete baseline research assessments were also excluded. Eligible participants showed sufficient digital literacy to be able to complete the online screening survey and use the mobile application.

An a priori power analysis was conducted to determine the sample size required for detecting significant time by group interaction effects if there were clinically meaningful differences in the primary outcome, which is a 4-point difference in the ISI total score [39], in patterns

specified in the four hypotheses. A simulation-based power analysis was performed using R package *mixedpower* [40]. We simulated a database using the means and standard deviations of ISI from a local sample for another insomnia trial as the baseline values [41] as these data were most likely the closest estimates of baseline ISI values in the present sample. For hypothesis 1, we simulated a database with post-treatment ISI values to be 4 point lower than the baseline in the experimental conditions. For hypotheses #2-4, we simulated a database with post-treatment ISI values to be 4 point lower than the baseline and 4 point lower than the comparison group. Based on these simulations, a sample size of 120 would be required for detecting significant results with statistical power > 95%, >80%, > 90%, and >80% for hypotheses #1-4, respectively.

Procedures

Participants were recruited using mass emails sent to students, staff, and affiliates of the University and social media advertisements with the institutional affiliation displayed. Inclusion and exclusion criteria were evaluated based on their responses to the screening survey, followed by phone interviews as needed by the authors SHCL & AKMC, who were clinical psychology trainees under the supervision of lead author WSC, a licensed clinical psychologist. Eligible participants then downloaded *Sleep Sensei* for free. All conditions were delivered via *Sleep Sensei*. They were given access to modules and functions according to the condition to which they were assigned (see **Table 1**). They had access to *Sleep Sensei* from baseline to follow-up. Assessments of outcomes were administered at baseline, post-intervention, and 4-week follow-up using Qualtrics. **Figure 1** presents the CONSORT diagram and **Figure 2** presents the attrition diagram.

Table 1. Intervention components in each treatment condition

Treatment Components	dCBTi-therapist	dCBTi-assistant	dCBTi-virtual	dCBTi-unguided	dSH
Video lessons	✓	✓	✓	✓	✓ (sleep hygiene only)
Resource library	✓	✓	✓	✓	✓ (sleep hygiene only)
Daily diary entry and visualization	✓	✓	✓	✓	✓
Automatic customized sleep schedule suggestions	✓	✓	✓	✓	
Weekly goal setting and action planning entries	✓	✓	✓	✓	
Virtual coaching	✓	✓	✓		
Assistant support		✓			
Therapist support	✓				

Interventions

Sleep Sensei

Sleep Sensei was developed specifically for the present study and hence was customized to deliver the five conditions with differing combinations of content and functionalities. *Sleep Sensei* employed the talk-and-tools user-interface paradigm, which comprised a "talk" system enabling text-based chat interactions between the user and a conversational agent, i.e., a virtual coach, and a "tools" system allowing the user to observe and manipulate the objects in the interface [30]. Before launching the application, *Sleep Sensei* underwent three rounds of usability testing with six volunteers.

In *Sleep Sensei*, the core CBTi treatment components were implemented using the tools system, which consisted of 1) six video lessons providing psychoeducation and the rationale for each treatment recommendation, delivered chronologically in the order described in the next section, 2) a resource library storing and presenting video lesson content in written format and additional resources such as relaxation recordings, 3) daily diary entries and visualization of diary data, 4) automatic, individually-tailored weekly sleep schedule suggestions, and 5) weekly goal setting and action planning entries. Appendix 1 presents screenshots of *Sleep Sensei* interface.

CBTi Core Treatment Components

CBTi is a multi-component intervention that combines behavioral techniques (sleep restriction, stimulus control, relaxation) and cognitive therapy [42]. The core treatment components of CBTi include sleep restriction, stimulus control, sleep hygiene, psychoeducation about sleep, relaxation, and cognitive therapy. Sleep hygiene is included in CBTi but is not considered CBTi alone. It is often used as an active control condition for clinical trials of CBTi [43].

Sleep restriction is a technique to improve one's sleep efficiency by restoring a high sleep drive via limiting time in bed, specifically to match one's current sleep needs. It is achieved by tailoring time in bed (TIB) to match one's average total sleep time (TST). Once adequate sleep efficiency is achieved, time in bed can gradually extend until optimal sleep duration is reached. In the present study, the rationale and procedures for sleep restriction are presented in video lesson #1. If the participant's previous-week sleep diary data show that their sleep efficiency equals to or is greater than 85% and they indicated that they were not sleep deprived by answering a yes/no question, they will be asked to maintain their TIB with consistent wake time and bedtime. If their sleep efficiency equals to or is greater than 85% and they indicated that they were sleep deprived, the app would recommend a TIB with a 20-min increase. If their sleep efficiency is below 85%, the app would recommend a range of TIBs, from the minimum TST (equivalent to the previous week's average TST based on diary data but no fewer than five hours) to 20 minutes less than the previous week's TIB. The participant will be asked to specify a consistent wake time suitable for them and choose a bedtime that will result in a TIB within the suggested range. This implementation of the sleep restriction procedures enables the participant to choose either to restrict TIB more aggressively or gradually by 20 minutes each week, allowing for greater flexibility and potentially greater adherence.

Sleep hygiene refers to daily habits that influence sleep drive, circadian rhythm, or arousal associated with the sleeping environment. They include keeping the sleeping environment dark, quiet, and cool; having a consistent sleep schedule, especially a consistent wake time; maintaining adequate light exposure and activity levels; reducing stimulating activities before bedtime such as eating too much, intense exercise, alcohol or nicotine consumption, and screen time; and setting up a relaxation routine before bedtime. The rationale and procedures for sleep hygiene are presented in video lesson #2.

Stimulus control refers to re-conditioning the sleep environment to be a place only for sleep and to reduce conditioned arousal. The procedures include ensuring one enters the sleeping environment only when they feel ready to fall asleep, leaving the sleeping environment if one cannot fall asleep or stay asleep for more than approximately 20 minutes by estimation, and going back to bed only when they feel sleepy. The distinction between feeling fatigued and sleepy is also discussed. The rationale and procedures for stimulus control are presented in video lesson #3.

Relaxation includes practices of progressive muscle relaxation and visual imagery exercises that can be used to reduce hyperarousal. Its rationale and procedures are presented in video lesson #4. Participants are guided to practice relaxation during the video lesson and told that recordings of relaxation guidance could be accessed in the resource library. Additionally, another clinical technique targeting excessive worry is also introduced in this lesson—setting up worry time, referring to setting aside a 30-minute period each day (not close to bedtime) for worrying and limiting worrying only to this time to restrict the impact of worrying on mental health and sleep.

Cognitive therapy refers to a set of techniques to identify and reframe thoughts and beliefs that may promote and sustain sleep difficulties such as thoughts that lead to heightened worries and frustration about the consequences of not having good sleep or thoughts that reduce motivation and treatment adherence. Its rationale and procedures are presented in video lessons #5 and #6.

Virtual Coaching

The virtual coaching element was delivered using the “talk” system via a series of logic-based pre-programmed conversational turns created by WSC, SHCL, and AKMC with the goal to simulate therapeutic interactions. These text-based conversations covered several areas: 1) post-video summary and quiz—the virtual coach guided the participants to reflect on what they learned from the video lessons and facilitated them to apply the learned strategies to their own situations; 2) weekly goal setting and action planning—the participants were guided to set up goals and action plans to implement the treatment recommendations during the week; 3) positive feedback and reflection—encouraging messages were sent to participants when they completed daily sleep diaries and achieved their weekly goals; and 4) problem-solving—when the participants did not complete daily diaries or achieve weekly goals, the virtual coach guided them to think about different solutions to remove the barriers to implement the treatment recommendations.

Assistant Support

Assistant support was provided to participants in dCBTi-assistant at the end of sessions 1, 3, and 6 by two undergraduate research interns who had no prior experience in counseling or CBTi. They

were trained by WSC to provide supportive contact including expressing appreciation for their time and effort in using the app, encouraging them to continue using the app and complete daily diaries, and asking if they encountered any technical issues that needed support. If the participant asked sleep/CBTi-related questions, the assistants would direct the participant to review the CBTi materials on the app. The contact time was restricted to 20 to 30 minutes. The numbers of phone calls completed were 20 (74.1%), 9 (33.3%), and 8 (29.6%) for sessions 1, 3, and 6, respectively.

Therapist Support

Therapist support was provided to participants in dCBTi-therapist at the end of sessions 1, 3, and 6 by two postgraduate clinical psychology trainees (SHCL & AKMC) who had received at least one year of clinical psychology training and training in a CBTi protocol. The support included reinforcing the understanding of the intervention materials, providing sleep/CBTi-related expert advice, reviewing treatment progress, identifying, and resolving barriers to implementing CBTi treatment strategies, and addressing any motivational issues. Similar to the dCBTi-assistant condition, the contact time was restricted to 20 to 30 minutes. The numbers of phone calls completed were 21 (84.0%), 19 (76.0%), and 17 (68.0%) for sessions 1, 3, and 6, respectively.

Measures

The assessments were all electronic questionnaires administered using Qualtrics. The electronic questionnaires had been tested by research assistants before distributing to the participants. The questionnaires were distributed through email and were instructed to complete it within one week. The order of the questions was the same for each participant. All questions were mandatory.

Primary Outcome

The Insomnia Severity Index (ISI)

The ISI is a widely used self-report questionnaire assessing insomnia symptoms in the previous two weeks [44]. It consists of seven items asking the participants to rate the severity of their insomnia symptoms on a 4-point Likert scale from 0 to 4, with higher scores indicating greater insomnia severity. The composite score ranges from 0 to 28, with a score of 10 or above indicating clinical insomnia. The validated Chinese version was used in the present study [45]. The ISI showed acceptable to excellent internal consistencies across the three time points with Cronbach's αs in the range of .77-.90.

Secondary Outcomes

The Sleep Condition Indicator (SCI)

The SCI is a newer measure of insomnia symptoms developed based on the DSM-5 diagnostic criteria [1], the research diagnostic criteria [46], and recommended quantitative parameters [47]. It consists of eight items assessing the severity of sleep difficulties and daytime impairment during the past month. Four items assess insomnia symptoms on 5-point scales with quantitative anchors, i.e., frequency or duration. For instance, item 1 asks "How long does it take for you to fall asleep" and the participants respond on a scale of 0 (0-15 mins), 1 (16-30 mins), 2 (31-45 mins), 3 (45-60 mins), and 4 (over 60 mins). The other four items assess insomnia symptoms on 5-point scales with qualitative anchors. For instance, item 4 asks "How do you rate your sleep quality" on a

scale from 0 (very good) to 4 (very bad). The SCI has been validated against the ISI and showed good reliability and convergent validity. The validated Chinese version of the Sleep Condition Indicator was used in the present study [48]. The total score ranges from 0 to 32; higher scores indicate lower levels of insomnia and a score of 16 or below indicates insomnia disorder. In the present study, the SCI had acceptable to good internal consistency with Cronbach's αs in the range of .70-.88.

The Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9 was used to assess depressive symptoms [49]. The PHQ-9 consists of nine items asking participants to rate the frequency of their depressive symptoms in the past two weeks on a 4-point Likert scale from 0 (not at all) to 4 (nearly every day). The total score ranges from 0 to 27; higher scores indicate higher levels of depressive symptoms, with a PHQ-9 cutoff score of 10 or above indicating depressive disorder. The validated Chinese version was used in the present study [50]. The PHQ-9 showed good internal consistencies across the three time points with Cronbach's αs in the range of.81 -.88.

The Generalized Anxiety Disorder 7-item Scale (GAD-7)

The GAD-7 was used to measure anxiety symptoms [51]. The GAD-7 consists of 7 items asking participants to rate the frequency of their anxiety symptoms in the past two weeks on a 4-point Likert scale from 0 (not at all) to 4 (nearly every day). The composite score ranges from 0 to 21; higher scores indicate higher levels of anxiety symptoms, with a GAD-7 cutoff score of 8 or above indicating anxiety disorders. The validated Chinese version was used in the present study [52]. The GAD-7 showed excellent internal consistencies across the three time points with Cronbach's αs in the range of .92 -.95.

The Fatigue Assessment Scale (FAS)

The FAS was used to assess fatigue [53]. The FAS consists of 10 items asking participants to rate the frequency of their fatigue symptoms on a 5-point Likert scale from 0 (never) to 5 (always). The total score ranges from 10 to 50, with higher scores indicating higher levels of fatigue. The validated Chinese version was used in the present study [54] In the present study, the FAS had good internal consistencies across the three time points with Cronbach's αs in the range of .88-.90.

The Epworth Sleepiness Scale (ESS)

The validated Chinese version of the ESS was used to assess daytime sleepiness [55]. The ESS consists of 8 items asking participants to rate the chance of dozing in different situations on a 4-point Likert scale, ranging from 0 (never) to 3 (high chance). The composite score ranges from 0 to 24, higher scores indicate greater daytime sleepiness and an ESS score of 11 or above indicates excessive or clinically significant daytime sleepiness. The ESS showed good internal consistencies across the three time points with Cronbach's αs in the range of .82-.83.

The Satisfaction with Life Scale (SWLS)

The SWLS was used to measure general psychological well-being [56]. The SWLS asks the participants to rate their agreement with 5 statements of life satisfaction on a 7-point Likert scale from 0 (strongly disagree) to 7 (strongly agree). The total score ranges from 5 to 35; higher scores

indicate greater psychological well-being. The validated Chinese version was used in the present study [57]. The SWLS showed good internal consistencies across the three time points with Cronbach's αs in the range of .90-.92.

Mechanistic Outcomes

The Dysfunctional Beliefs and Attitudes About Sleep Scale-16 (DBAS-16)

The DBAS-16 measures one's endorsement of dysfunctional thoughts and beliefs that could elevate anxiety and frustration about sleep difficulties, leading to the perpetuation of insomnia [58]. For example, one of the items is "I need 8 hours of sleep to feel refreshed and function well during the day". The DBAS-16 asks the participants to rate how much they believe the 16 statements about sleep on an 11-point Likert scale from 0 (strongly disagree) to 10 (strongly agree). The total score ranges from 0 to 160; higher scores indicate stronger dysfunctional beliefs about sleep. The validated Chinese version was used in the present study [59]. The DBAS-16 showed good to excellent internal consistencies across the three time points with Cronbach's αs in the range of .85-.95.

The Sleep-Related Behavior Questionnaire (SRBQ)

The SRBQ measures one's engagement in sleep-related safety behaviors, behaviors that aim to alleviate the distress and consequences of insomnia but inadvertently perpetuate insomnia [60]. For instance, preoccupation with sleep such as "I spend time considering ways to improve sleep" and reduced daytime engagement to preserve energy such as "I take on fewer social commitments." The validated Chinese version of the SRBQ consisting of 20 statements was used [61]. Participants rated these statements on a 5-point Likert scale from 0 (almost never) to 4 (almost always). The composite score ranges from 0 to 80; higher scores indicate greater engagement in sleep-related safety behavior. The SRBQ had good to excellent internal consistencies across the three time points with Cronbach's αs in the range of .85-93.

Treatment Adherence

Video completion and sleep diary completion for each dCBTi session were used as the indicators of treatment adherence in the current study, which are common global indicators of treatment adherence used in other CBTi and dCBTi trials [62].

Statistical Analysis

Analyses were performed with R (Version 4.0.2). All tests for significance were two-sided and a *P*-value of less than 5% was considered statistically significant. Intention-to-treat analyses were conducted using linear mixed models with restricted maximum likelihood (REML) method for handling missing data. The REML incorporate the observed data and model covariance structure to estimates the variance parameters in the model with missing data [63] The models included treatment groups (dCBTi-therapist, dCBTi-assistant, dCBTi-virtual, dCBTi-unguided, and dSH), time (baseline, post-treatment, and follow-up), and the group-by-time interaction as fixed effects. Participant IDs were included as the random effect in the model. Planned contrasts were specified in the models to test the four hypotheses. Hypothesis 1: all dCBTi conditions compared to dSH. Hypothesis 2: all guided dCBTi conditions compared to unguided dCBTi. Hypothesis 3: dCBTi with

human support compared to dCBTi-virtual. Hypothesis 4: dCBTi-therapist compared to dCBTi-assistant. Cohen's *d* was calculated from the mean differences between conditions at post-treatment to indicate the effect size of each significant effect. Fisher's exact tests were conducted to evaluate if the percentages of participants who completed the video and sleep diary for each session were different across conditions. Additionally, we conducted chi-square tests on remission rates to evaluate the differences in remission rates across conditions at posttreatment. Remission was defined as having an ISI < 10 or SCI > 21. We also conducted analysis on the percentages of participants achieving clinically meaningful reduction in depressive symptoms (5-point reduction in the PHQ-9), anxiety symptoms (4-point reduction in the GAD-7), fatigue (4-point reduction in the FAS), and daytime sleepiness (2-point reduction in the ESS).

Results

Descriptives

Out of 819 individuals who completed the screening survey, 690 participants were not eligible, declined to participate, or did not complete the baseline measures. The final sample consisted of 129 participants (mean age = 34.09, SD of age = 12.05). The sample was primarily female (76.0%), never married (67.4%), completed tertiary education (80.6%), and employed full-time (59.7%). There were no significant differences in age, marital status, education level, employment status, and monthly household income across treatment conditions (see **Table 2**). **Table 3** presents the mean values and standard deviations of each outcome at three time points. No significant differences were observed in all outcomes at baseline. Significant differences in the ISI, SCI, PHQ-9, GAD-7, DBAS-16, and SRBQ across conditions were observed at post-treatment, favoring the treatment conditions over the control.

Table 2. Demographic characteristics of participants at baseline

Variables	Groups	dCBTi-therapist (*n* = 25)	dCBTi-assistant (*n* = 27)	dCBTi-virtual (*n* = 26)	dCBTi-unguided (*n* = 21)	dSH (*n* = 30)	Full sample (*N* = 129)	*F*/ Chi-square	*P*
Age in years, *M* (SD)		34.28 (12.18)	34.22 (13.62)	35.58 (12.23)	30.76 (10.45)	34.83 (11.68)	34.09 (12.05)	0.52	.72
Gender, *n* (%)									
	Female	18 (72.0)	21 (77.8)	21 (80.8)	11 (52.4)	27 (90.0)	98 (76.0)	10.23	.04
	Male	7 (28.0)	6 (22.2)	5 (19.2)	10 (47.6)	3 (10.0)	31 (24.0)		
Marital status, *n* (%)									
	Never married	16 (64.0)	20 (74.1)	14 (53.8)	18 (85.7)	19 (63.3)	87 (67.4)	17.11	.15
	Cohabiting	2 (8.0)	0 (0.0)	3 (11.5)	0 (0.0)	0 (0.0)	5 (3.9)		
	Married	5 (20.0)	5 (18.5)	9 (34.6)	2 (9.5)	10 (33.3)	31 (24.0)		
	Divorced / Separated	2 (8.0)	1 (7.4)	0 (0.0)	1 (4.8)	1 (3.3)	6 (4.7)		
Highest educational level, *n* (%)									
	Secondary	4 (16.0)	2 (7.4)	4 (15.4)	0 (0.0)	2 (6.7)	12 (9.3)	12.10	.15
	Tertiary (Non-degree)	3 (12.0)	3 (11.1)	1 (3.8)	0 (0.0)	6 (20.0)	13 (10.1)		
	Tertiary (Degree)	18 (72.0)	22 (81.5)	21 (80.8)	21 (100.0)	22 (73.3)	104 (80.6)		
Employment, *n* (%)									
	Full-time	15 (60.0)	15 (55.6)	19 (73.1)	13 (61.9)	15 (50.0)	77 (59.7)	13.85	.84
	Part-time	1 (4.0)	3 (11.1)	0 (0.0)	1 (4.8)	4 (13.3)	9 (7.0)		
	Unemployed	1 (4.0)	2 (7.4)	1 (3.8)	1 (4.8)	2 (6.7)	7 (5.4)		
	Retired	1 (4.0)	1 (3.7)	2 (7.7)	0 (0.0)	1 (3.3)	5 (3.9)		
	Homemaker	1 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.7)	3 (2.3)		
	Student	6 (24.0)	6 (22.2)	4 (15.4)	6 (28.6)	6 (20.0)	28 (21.7)		
Monthly household income, *n* (%)									
	< HK$ 15,000	7 (28.0)	9 (33.3)	4 (15.4)	4 (19.0)	9 (30.0)	33 (25.6)	12.33	.71
	HK$15,000 – HK$24,999	5 (20.0)	4 (14.8)	4 (15.4)	6 (28.6)	7 (23.3)	26 (20.2)		
	HK$25,000 – HK$39,999	6 (24.0)	6 (22.2)	11 (42.3)	5 (23.8)	5 (16.7)	33 (25.6)		
	HK$40,000 –	3 (12.0)	4 (14.8)	3 (11.5)	2 (9.5)	1 (3.3)	13 (10.1)		

Variables	Groups	dCBTi-therapist (*n* = 25)	dCBTi-assistant (*n* = 27)	dCBTi-virtual (*n* = 26)	dCBTi-unguided (*n* = 21)	dSH (*n* = 30)	Full sample (*N* = 129)	*F*/ Chi-square	*P*
	HK$59,999								
	> HK$60,000	4 (16.0)	4 (14.8)	2 (7.7)	4 (19.0)	7 (23.3)	21 (16.28)		

Table 3. Measures of outcomes by time points

Variables	Time points	dCBTi-therapist (n = 25)	dCBTi-assistant (n = 27)	dCBTi-virtual (n = 26)	dCBTi-unguided (n = 21)	dSH (n = 30)	Full sample (N = 129)	*F*	*P*
		M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)		
ISI[a]									
	Baseline	14.96 (3.65)	13.70 (3.86)	14.50 (4.96)	15.76 (5.17)	16.30 (4.39)	15.05 (4.44)	1.47	.22
	Post-treatment	9.10 (4.23)[j]	9.00 (4.59)[k]	9.42 (4.44)	9.64 (5.00)	13.22 (5.07)[jk]	10.28 (4.92)	3.66	.01
	Follow-up	9.26 (4.85)	7.55 (4.86)	10.00 (5.32)	6.88 (4.67)	12.06 (6.20)	9.36 (5.43)	2.28	.07
SCI[b]									
	Baseline	11.88 (4.22)	13.48 (5.28)	12.81 (5.21)	12.81 (5.01)	11.70 (4.62)	12.51 (4.85)	0.62	.65
	Post-treatment	19.86 (4.90)[j]	18.30 (5.80)	19.16 (6.48)[k]	19.43 (7.55)	13.96 (6.03)[jk]	17.80 (6.41)	3.81	.01
	Follow-up	21.00 (6.38)	20.40 (7.00)	19.00 (6.11)	22.75 (4.71)	15.67 (8.13)	19.45 (7.00)	2.23	.07
PHQ-9[c]									
	Baseline	11.60 (5.32)	9.52 (4.59)	10.16 (4.61)	12.86 (6.33)	10.38 (5.36)	10.80 (5.28)	1.50	.21
	Post-treatment	7.10 (5.35)	6.35 (5.02)[j]	7.16 (3.86)	8.07 (5.41)	10.92 (6.36)[j]	8.04 (5.51)	2.77	.03
	Follow-up	6.74 (5.43)	6.40 (5.50)	7.47 (4.66)	7.86 (4.74)	9.44 (6.24)	7.51 (5.44)	0.87	.48
GAD-7[d]									
	Baseline	9.52 (5.55)	7.44 (5.06)	8.92 (4.56)	11.95 (5.67)	9.69 (5.86)	9.40 (5.46)	2.16	.08
	Post-treatment	6.10 (3.99)	5.35 (5.01)[j]	6.05 (4.56)	8.79 (6.28)	9.54 (6.04)[j]	7.16 (5.40)	2.82	.03
	Follow-up	7.42 (6.09)	6.05 (4.95)	6.87 (5.25)	9.43 (7.50)	7.33 (5.98)	7.13 (5.69)	0.48	.75
FAS[e]									
	Baseline	32.24 (7.23)	28.74 (7.07)	28.04 (7.20)	30.81 (7.40)	31.00 (7.61)	30.15 (7.36)	1.42	.23
	Post-treatment	25.81 (6.27)	25.61 (5.61)	26.74 (8.09)	27.64 (8.58)	30.54 (8.52)	27.38 (7.56)	1.77	.14
	Follow-up	25.47 (8.20)	25.75 (6.89)	27.87 (7.37)	27.57 (7.02)	28.56 (6.96)	26.89 (7.27)	.61	.66
ESS[f]									
	Baseline	9.32 (4.63)	10.59 (4.76)	10.24 (4.38)	11.86 (4.61)	8.55 (5.10)	10.12 (4.77)	1.75	.14
	Post-treatment	8.57 (4.51)	8.57 (4.53)	10.47 (4.23)	9.36 (5.68)	8.23 (5.22)	8.94 (4.80)	0.71	.59
	Follow-up	7.16 (5.21)	8.30 (4.43)	10.67 (3.70)	11.29 (5.94)	7.33 (4.43)	8.52 (4.78)	2.13	.08
SWLS[g]									
	Baseline	14.64 (6.25)	17.26 (6.17)	18.00 (6.43)	13.48 (5.20)	17.34 (5.25)	16.28 (6.04)	2.63	.04

Variables	Time points	dCBTi-therapist (n = 25)	dCBTi-assistant (n = 27)	dCBTi-virtual (n = 26)	dCBTi-unguided (n = 21)	dSH (n = 30)	Full sample (N = 129)	*F*	*P*
	Post-treatment	18.29 (7.24)	19.74 (6.05)	18.00 (6.72)	15.86 (6.31)	17.54 (5.46)	18.04 (6.32)	0.88	.48
	Follow-up	19.16 (8.39)	20.00 (5.67)	19.47 (6.15)	19.43 (6.58)	18.17 (5.76)	19.23 (6.47)	0.19	.94
DBAS-16[h]									
	Baseline	6.22 (1.23)	5.94 (1.71)	6.09 (1.20)	6.04 (1.18)	6.20 (1.68)	6.10 (1.42)	0.17	.95
	Post-treatment	2.51 (2.27)[j]	3.33 (2.14)[k]	3.50 (2.57)[l]	2.73 (2.54)[m]	5.55 (2.74)[jklm]	3.63 (2.68)	6.67	<.001
	Follow-up	2.55 (2.53)	2.57 (2.43)	2.99 (2.81)	1.87 (2.77)	3.30 (3.02)	2.71 (2.73)	0.96	.43
SRBQ[i]									
	Baseline	37.68 (9.21)	32.85 (11.50)	36.20 (9.46)	34.43 (10.40)	36.47 (10.30)	35.55 (10.21)	0.89	.47
	Post-treatment	28.05 (11.11)	27.13 (10.15)[j]	29.11 (11.36)	30.57 (14.66)	38.73 (15.62)[j]	31.08 (13.32)	3.30	.01
	Follow-up	24.11 (14.36)	25.00 (11.97)	30.53 (11.72)	29.38 (11.71)	34.44 (13.69)	28.39 (13.22)	1.97	.11

[a]ISI = Insomnia Severity Index
[b]SCI = Sleep Condition Indicator
[c]PHQ-9 = Patient Health Questionnaire-9 (PHQ-9)
[d]GAD-7 = Generalized Anxiety Disorder 7-item Scale
[e]FAS = Fatigue Assessment Scale
[f]ESS = Epworth Sleepiness Scale
[g]SWLS = Satisfaction With Life Scale
[h]DBAS-16 = Dysfunctional Beliefs and Attitudes About Sleep Scale
[i]SRBQ = Sleep-Related Behavior Questionnaire-29
[jklm] indicates significant differences between treatment groups in post-hoc multiple comparisons

Treatment Efficacy

Hypothesis 1: All dCBTi conditions compared to dSH

As shown in **Table 4**, the condition-by-time interaction effects on the SCI, PHQ-9, GAD-7, FAS, DBAS-16, and SRBQ were significant at post-treatment, indicating that participants who received dCBTi had greater improvements in insomnia symptoms measured by the SCI, greater reductions in fatigue, depressive symptoms, anxiety symptoms, dysfunctional thoughts about sleep, and safety behaviors related to sleep than participants who received dSH (see **Figure 2**). At follow-up, significant condition-by-time interaction effects were observed on the SCI, FAS, PHQ-9, SWLS, and SRBQ (see **Table 4**), indicating greater improvements in these outcomes experienced by dCBTi than dSH recipients (see **Figure 2**). Additionally, as shown in **Table 5**, the remission rate based on the ISI was 58.4% in the dCBTi conditions, significantly greater than that in dSH (22.2%). The remission rate based on the SCI was 36.4% in the dCBTi conditions, significantly greater than that in dSH (7.4%). No significant differences were observed for the rates of achieving clinically meaningful differences in the PHQ-9, GAD-7, FAS, and ESS.

Hypothesis 2: All guided dCBTi compared to unguided dCBTi

No significant interaction effects were found on all outcomes at post-treatment and follow-up when comparing guided dCBTi and unguided dCBTi (see **Table 4**), suggesting that adding virtual coaching and human support did not improve treatment efficacy. Similarly, the rates of remission of insomnia and the rates of achieving clinically meaningful changes in the secondary outcomes did not differ significantly between guided dCBTi and unguided dCBTi (see **Table 5**).

Hypothesis 3: dCBTi with human support compared to dCBTi-virtual

Significant condition-by-time interaction effects were observed on the FAS and SRBQ at follow-up (see **Table 4**), indicating that participants who received dCBTi with either therapist or assistant support experienced greater reductions in fatigue and sleep-related safety behaviors than those who received dCBTi with virtual coaching only (see **Figure 2**). The rates of remission of insomnia and the rates of achieving clinically meaningful changes in the secondary outcomes did not differ significantly between dCBTi with human support and dCBTi-virtual (see **Table 5**).

Hypothesis 4: dCBTi-therapist compared to dCBTi-assistant

A significant condition-by-time interaction effect was observed on the FAS at follow-up (see **Table 4**), indicating that participants who received dCBTi-therapist experienced greater reductions in fatigue than those who received dCBTi-assistant (see **Figure 2**). Additionally, the rate of achieving clinically meaningful changes in the GAD-7 was significantly greater in dCBTi-therapist than in dCBTi-assistant (see **Table 5**).

Table 4. Linear mixed models results[a]

Outcome measures	Assessment time points	Interaction effects for dCBTi conditions vs. dSH		Interaction effects for guided-dCBTi conditions vs. dCBTi-unguided		Interaction effects for dCBTi with human support vs. dCBTi-virtual		Interaction effects for dCBTi-therapist vs. dCBTi-assistant	
		Estimate (*P*)	Cohen's *d* (95% CI)	Estimate (*P*)	Cohen's *d* (95% CI)	Estimate (*P*)	Cohen's *d* (95% CI)	Estimate (*P*)	Cohen's *d* (95% CI)
ISI[b]									
	Post-treatment	**-2.01 (.06)**	**-0.28 (-0.42, -0.14)**	0.24 (.86)	0.02 (-0.08, 0.13)	-0.30 (.81)	-0.03 (-0.15, 0.08)	-1.16 (.41)	-0.12 (-0.22, -0.02)
	Follow-up	-1.89 (.12)	-0.22 (-0.34, -0.11)	2.57 (.12)	0.22 (0.13, 0.30)	-1.54 (.26)	-0.16 (-0.27, -0.06)	0.26 (.86)	0.03 (-0.07, 0.12)
SCI[c]									
	Post-treatment	**3.83 (.003)**	**0.45 (0.33, 0.56)**	-0.20 (.90)	-0.02 (-0.11, 0.07)	-0.08 (.96)	-0.01 (-0.10, 0.09)	2.94 (.08)	0.26 (0.17, 0.34)
	Follow-up	**3.51 (.02)**	0.35 (0.24, 0.45)	-1.03 (.60)	-0.07 (-0.14, -0.002)	2.25 (.17)	0.20 (0.11, 0.29)	2.54 (.15)	0.21 (0.13, 0.29)
PHQ-9[d]									
	Post-treatment	**-4.12 (< .001)**	**-0.62 (-0.77, -0.47)**	0.75 (.55)	0.09 (-0.03, 0.21)	-0.40 (.74)	-0.05 (-0.18, 0.08)	-1.47 (.26)	-0.17 (-0.29, -0.06)
	Follow-up	**-4.00 (< .001)**	**-0.52 (-0.65, -0.39)**	1.65 (.31)	0.15 (0.06, 0.24)	-1.44 (.26)	-0.17 (-0.29, -0.05)	-2.16 (.11)	-0.24 (-0.35, -0.13)
GAD-7[e]									
	Post-treatment	**-2.56 (.01)**	**-0.40 (-0.56, -0.25)**	-0.10 (.93)	-0.01 (-0.13, 0.11)	0.33 (.77)	0.04 (-0.09, 0.17)	-1.57 (.21)	-0.19 (-0.31, -0.07)
	Follow-up	-1.70 (.12)	-0.23 (-0.37,	1.14 (.46)	0.11 (0.01,	-0.58 (.63)	-0.07 (-0.19,	-1.06 (.42)	-0.12 (-0.24,

			-0.09)		0.20)		0.05)		-0.01)
FAS[f]									
	Post-treatment	**-2.87 (.02)**	**-0.35 (-0.47, -0.23)**	-1.05 (.50)	-0.10 (-0.20, -0.004)	-2.15 (.14)	-0.22 (-0.32, -0.12)	-2.93 (.07)	-0.28 (-0.37, -0.18)
	Follow-up	**-4.01 (.01)**	**-0.42 (-0.53, -0.33)**	1.43 (.47)	0.11 (0.03, 0.18)	**-3.47 (.03)**	**-0.33 (-0.43, -0.24)**	**-4.56 (.01)**	**-0.41 (-0.50, -0.32)**
ESS[g]									
	Post-treatment	-0.81 (.35)	-0.14 (-0.31, 0.03)	0.20 (.85)	0.03 (-0.11, 0.16)	-1.47 (.16)	-0.21 (-0.36, -0.07)	0.83 (.47)	0.11 (-0.02, 0.24)
	Follow-up	-0.88 (.38)	-0.13 (-0.28, 0.02)	0.73 (.61)	0.08 (-0.03, 0.18)	-1.48 (.18)	-0.20 (-0.33, -0.06)	-0.15 (.90)	-0.02 (-0.15, 0.11)
SWLS[h]									
	Post-treatment	2.14 (.07)	0.27 (0.14, 0.39)	0.40 (.79)	0.04 (-0.06, 0.14)	1.94 (.17)	0.20 (0.10, 0.31)	1.30 (.40)	0.13 (0.03, 0.22)
	Follow-up	**3.02 (.03)**	**0.33 (0.22, 0.43)**	-1.88 (.33)	-0.14 (-0.22, -0.07)	2.55 (.10)	0.25 (0.15, 0.35)	1.75 (.28)	0.16 (0.07, 0.25)
DBAS-16[i]									
	Post-treatment	**-2.41 (<.001)**	**-0.53 (-0.75, -0.31)**	0.34 (.62)	0.06 (-0.12, 0.25)	-0.58 (.39)	-0.11 (-0.30, 0.08)	-1.09 (.16)	-0.18 (-0.34, -0.02)
	Follow-up	-0.68 (.24)	-0.15 (-0.37, 0.07)	0.79 (.25)	0.15 (-0.04, 0.33)	-0.42 (.53)	-0.08 (-0.27, 0.11)	-0.30 (.70)	-0.05 (-0.21, 0.11)
SRBQ[j]									
	Post-treatment	**-7.74 (.001)**	**-0.50 (-0.57, -0.43)**	-3.64 (.21)	-0.18 (-0.23, -0.13)	-0.90 (.74)	-0.05 (-0.10, 0.01)	-2.30 (.45)	-0.11 (-0.16, -0.06)
	Follow-up	**-8.71 (.001)**	**-0.49 (-0.54,**	-2.17 (.54)	-0.09 (-0.13,	**-5.93 (.05)**	**-0.30 (-0.35,**	-5.70 (.07)	-0.27 (-0.32,

			-0.43)		-0.05)		**-0.25)**		-0.22)

[a]dCBTi conditions refers to dCBTi-therapist, dCBTi-assistant, dCBTi-virtual, and dCBTi-unguided conditions. Guided-dCBTi conditions refer to dCBTi-therapist, dCBTi-assistant, and dCBTi-virtual conditions. dCBTi with human support refers to dCBTi-therapist and dCBTi-assistant conditions.
[b]ISI = Insomnia Severity Index
[c]SCI = Sleep Condition Indicator
[d]PHQ-9 = Patient Health Questionnaire-9 (PHQ-9)
[e]GAD-7 = Generalized Anxiety Disorder 7-item Scale
[f]FAS = Fatigue Assessment Scale
[g]ESS = Epworth Sleepiness Scale
[h]SWLS = Satisfaction With Life Scale
[i]DBAS-16 = Dysfunctional Beliefs and Attitudes About Sleep Scale
[j]SRBQ = Sleep-Related Behavior Questionnaire-29

Table 5. Comparison of the Rates of Remission/Clinically Meaningful Changes Across Conditions at Posttreatment

Outcome	Comparison between dCBTi conditions vs. dSH			Comparison between guided-dCBTi conditions vs. dCBTi-unguided			Comparison between dCBTi with human support vs. dCBTi-virtual			Comparison between dCBTi-therapist vs. dCBTi-assistant		
	dCBTi, *n* (%)	dSH, *n* (%)	X^2 (*P*)	Guided-dCBTi , *n* (%)	dCBTi-unguided , *n* (%)	X^2 (*P*)	dCBTi with human support, *n* (%)	dCBTi-virtual , *n* (%)	X^2 (*P*)	dCBTi-therapist, *n* (%)	dCBTi-assistant, *n*(%)	X^2 (*P*)
ISI[b]	**45 (58.44)**	**6 (22.22)**	**9.09 (.003)**	37 (58.73)	8 (57.14)	<0.01 (1.00)	26 (59.09)	11 (57.89)	<0.01 (1.00)	13 (61.90)	13 (56.52)	<0.01 (.96)
SCI[c]	**28 (36.36)**	**2 (7.41)**	**6.82 (.01)**	22 (42.86)	6 (34.92)	0.06 (.80)	15 (34.09)	7 (36.84)	<0.01 (1.00)	8 (38.10)	7 (30.43)	0.05 (.83)
PHQ-9[d]	28 (36.84)	4 (16.00)	2.87 (.09)	21 (33.87)	7 (50.00)	0.68 (.41)	17 (38.64)	4 (22.22)	0.89 (.35)	10 (47.62)	7 (30.43)	0.74 (.39)
GAD-7[e]	25 (32.89)	5 (20.00)	0.94 (.33)	20 (32.36)	5 (35.71)	<0.01 (1.00)	13 (29.55)	7 (38.89)	0.17 (.68)	**10 (47.62)**	**3 (13.04)**	**4.75 (.03)**
FAS[f]	35 (46.05)	8 (32.00)	1.00 (.32)	30 (48.39)	5 (35.71)	0.32 (.57)	22 (50.00)	8 (44.44)	0.01 (.91)	13 (61.90)	9 (39.13)	1.46 (.23)
ESS[g]	33 (43.42)	6 (24.00)	2.23 (.14)	28 (45.16)	5 (35.71)	0.12 (.73)	22 (50.00)	6 (33.33)	0.84 (.36)	10 (47.62)	12 (52.17)	<0.01 (1.00)

[a]dCBTi conditions refers to dCBTi-therapist, dCBTi-assistant, dCBTi-virtual, and dCBTi-unguided conditions. Guided-dCBTi conditions refer to dCBTi-therapist, dCBTi-assistant, and dCBTi-virtual conditions. dCBTi with human support refers to dCBTi-therapist and dCBTi-assistant conditions.

[a]ISI = Insomnia Severity Index. Criterion of remission = ISI score < 10.

[b]SCI = Sleep Condition Indicator. Criterion of remission = SCI score > 21.

[c]PHQ-9 = Patient Health Questionnaire-9 (PHQ-9). Criterion of reaching clinically meaningful difference = 5-point change.

[d]GAD-7 = Generalized Anxiety Disorder 7-item Scale. Criterion of reaching clinically meaningful difference = 4-point change.

[e]FAS = Fatigue Assessment Scale. Criterion of reaching clinically meaningful difference = 4-point change.

[f]ESS = Epworth Sleepiness Scale. Criterion of reaching clinically meaningful difference = 2-point change.

Treatment Adherence

Table 6 presents the results of treatment adherence across conditions. As expected, participants in dCBTi-therapist and dCBTi-assistant completed significantly more video sessions than participants in dCBTi-guided. They also completed more weeks of sleep diaries than participants in dSH. The significant differences in treatment adherence were observed especially in later sessions, with more participants in dCBTi-therapist completing sleep diaries during sessions 4-6 compared to dCBTi-unguided and dSH.

Table 6. Video Completion and Sleep Diary Completion across Conditions

Variables	dCBTi-therapist (*n* = 25)	dCBTi-assistant (*n* = 27)	dCBTi-virtual (*n* = 26)	dCBTi-unguided (*n* = 21)	dSH (*n* = 30)	*F* values / Fisher's exact test *P*-values
Total no. of video sessions completed, M(SD)	4.24 (1.83)[c]	3.37 (2.50)[d]	2.69 (2.24)	1.48 (2.02)[cd]	NA	6.58, *P*<.001
Session[a] 1	20 (80.0)[c]	18 (66.7)	15 (55.7)	10 (47.6)[c]	NA	.03
Session 2	19 (76.0)	18 (66.7)	14 (53.8)	9 (42.9)	NA	.09
Session 3	21 (84.0)[cd]	17 (63.0)	12 (46.2)[d]	6 (28.6)[c]	NA	< .001
Session 4	18 (72.0)	14 (51.9)	12 (46.2)	5 (23.8)	NA	.10
Session 5	16 (64.0)[c]	14 (51.9)	10 (38.5)	5 (23.8)[c]	NA	.01
Session 6	16 (64.0) [cd]	13 (48.1)[e]	8 (30.8)[d]	3 (14.3) [ce]	NA	< .001
Total no. of weeks of diaries completed, M(SD)	5.32 (1.55)[a]	4.74 (1.87)	3.96 (2.57)	3.81 (2.18)	3.60 (2.33)[a]	2.95, *P* =.02
Week[b] 1	24 (96.0)	24 (88.9)	21 (80.8)	19 (90.5)	27 (90.0)	.57
Week 2	21 (84.0)	25 (92.6)	19 (73.1)	17 (81.0)	22 (73.3)	.31
Week 3	22 (88.0)	21 (77.8)	17 (65.4)	14 (66.7)	18 (60.0)	.15
Week 4	22 (88.0)[c]	21 (77.8)	16 (61.5)	12 (57.1)	15 (50.0)[c]	.02
Week 5	22 (88.0)[cd]	18 (66.7)	16 (61.5)	10 (47.6)[c]	14 (46.7)[d]	.01
Week 6	22 (88.0)[cd]	19 (70.4)	14 (53.8)	8 (38.1)[c]	12 (38.7)[d]	.001

[a]Indicates the percentage of participants completing the specific video session

[b]Indicates the percentage of participants completing the specific week of sleep diaries

[cde]Numbers denoted with the same superscript in the same row are significantly different from each other based on post-hoc comparisons with adjustments for multiple tests

Discussion

Main Findings

This work presents the first randomized controlled comparative trial that evaluates the effects of virtual coaching and human support on the treatment efficacy of and adherence to dCBTi. We found that participants who received dCBTi had greater improvements in insomnia symptoms measured by the SCI, mood disturbances, fatigue, life satisfaction, and reductions in dysfunctional beliefs and safety behaviors related to insomnia than those who received the dSH, with medium effect sizes comparable to previous studies of dCBTi. Most improvements in the dCBTi conditions were sustained at 4-week follow-up. Surprisingly, adding virtual coaching and human support did not significantly improve treatment effects on insomnia. Nonetheless, adding human support, especially therapist support, promoted greater improvements in fatigue and the reduction in safety behavior related to sleep. Adding virtual coaching and human support also improved some indicators of treatment adherence.

Does fully automated unguided dCBTi work?

Supporting hypothesis 1, dCBTi delivered by a fully automated mobile application is efficacious for improving insomnia, mood disturbances, fatigue, and psychological well-being in adults with insomnia, with effect sizes comparable to those of other tested versions of dCBTi [64-67]. Recipients of dCBTi, regardless of having coaching or not, achieved an average of 12.0% increase in sleep efficiency at post-treatment, from 75.4% to 87.4%, noting that ≥85% sleep efficiency is considered in remission [68]. The remission rate reached 58.4% in dCBTI conditions compared to 22.2% in the control dSH. The present study was one of the few randomized control trials of dCBTi conducted in non-Western populations and the only mobile application of CBTi implemented in Cantonese with published efficacy. The present study also extended upon previous findings by showing that dCBTi was also efficacious for reducing dysfunctional beliefs about sleep and maladaptive behavior related to sleep—the mechanisms theorized to bring about the treatment effects in CBTi. This finding provided even stronger support for dCBTi by showing that it did work in the way consistent with the theory.

Unexpectedly, a greater reduction in insomnia symptoms in the dCBTi group was only reflected by the SCI, but not the ISI. The SCI differs from the ISI in that its ratings on sleep difficulties are based on the recommended quantitative criteria from the DSM-5 as opposed to qualitative impressions of insomnia symptom severity. The inconsistent results reflected by the two scales might suggest that quantitative anchors are more sensitive in detecting changes in insomnia symptoms. Nevertheless, the absence of a treatment effect of dCBTi on the ISI in the present study differed from the findings of previous studies [64,67,69]. These previous studies employed more stringent participant inclusion criteria. For instance, in addition to scoring 10 or above on the ISI, participants had to meet the duration (≥ 3 months) and frequency (≥ 3 days/week) diagnostic criteria of insomnia disorder. Participants in these studies might have had more chronic and severe insomnia to begin with and hence experienced greater improvements. Indeed, the ISI scores were 17 [67] and 19 [64] in prior studies and 15 in our sample. The present sample might have also included individuals with acute insomnia. As acute and subclinical insomnia could

predict chronic insomnia and depressive episodes [70,71], the evidence for the efficacy of dCBTi for this group of participants with a potentially wider range of symptom duration and severity adds confidence for the impact of dCBTi at the population level where people with differing symptom duration and severity could benefit from dCBTi.

Does adding virtual coaching and human support improve dCBTi?

Partially consistent with hypothesis 2, adding coaching support improved treatment adherence to dCBTi, but not efficacy. Our findings suggested that both human-assisted guidance and virtual coaching were useful strategies to enhance engagement in middle and late stages of dCBTi. The treatment adherence rates in the guided-dCBTi conditions were double of that of unguided-dCBTi. Among all types of guided dCBTi, adding therapist coaching resulted in the highest adherence rate, followed by assistant coaching and virtual coaching. However, increased adherence rates did not improve efficacy. Consistent with previous meta-analyses [72-74] showing that dCBTi was not inferior to face-to-face CBTi for alleviating insomnia, the present study did not find any meaningful differences (> 4 points in the ISI total score) between guided CBTi conditions and unguided CBTi. The present study was the first direct comparison of guided and unguided CBTi with different types of guidance and provided primary evidence indicating that adding either therapist support does not promote meaningfully greater treatment efficacy.

It is possible that the high degrees of personalization offered by dCBTi might have minimized the benefit of coaching support on treatment efficacy. For instance, in the unguided dCBTi condition, participants still received a tailored sleep schedule suggestion based on their diary-reported sleep in the previous week. They were also prompted to set up individualized weekly goals and action plans. With mobile technology, even unguided dCBTi could deliver tailored treatment recommendations, which is one of the promising benefits of dCBTi. Furthermore, our sample might have included participants with acute insomnia, and insomnia symptoms experienced by these individuals might not necessitate coaching support. Additionally, the present sample is overrepresented by highly educated young adults with no psychiatric comorbidities. Coaching support may not be most needed for this population, as adding therapist support may be beneficial specifically for patients with psychiatric comorbidities [75]. Nevertheless, the differences in adherence between guided-and-unguided-CBTi reflected the utility of coaching support for enhancing engagement and potentially reducing early dropouts and motivational barriers.

Similarly, partially consistent with hypothesis 3, adding human support did not promote greater improvements in insomnia and most outcomes compared to virtual coaching alone. However, greater improvements in fatigue and greater reductions in safety behavior related to sleep were observed in dCBTi with human support compared to dCBTi with virtual coaching only. These incremental benefits might promote greater or more sustained improvements in sleep and well-being in the long term because reduced fatigue and safety behavior could potentially enhance the maintenance of positive changes resulting from CBTi, such as maintaining adequate daytime activities and inhibiting anxiety and frustration about sleep. Indeed, as shown in a previous study, adding human support to a self-help CBTi did not lead to greater improvements in insomnia symptoms at post-treatment and 4-week follow-up; however, the incremental improvements appeared later at 3-month follow-up [76].

Is support from a therapist better than that from an assistant?

Inconsistent with hypothesis 4, support from a therapist did not promote superior treatment efficacy for most outcomes nor treatment adherence than that from a non-therapist. While the current study was the first to directly compare human therapist support and assistant support in dCBTi, our results converged with a prior study on digital intervention for depression to suggest that treatment efficacy was comparable between therapist-guided and non-therapist-guided digital interventions [77]. However, it should be noted that the assistant phone call completion rate was much lower than the therapist phone call rate, suggesting that therapist support was much more welcomed by the participants in comparison. The lack of differences between these two conditions could be explained by the lack of statistical power for detecting smaller effects. There were no prior data on the expected effect size for the difference between therapist and assistant support. The present study could have missed smaller effects between these two conditions. Indeed, as shown in Table 4, differences between dCBTi-therapist and dCBTi-assistant amounting to small effect sizes were observed on the SCI, PHQ-9, GAD-7, FAS, and SRBQ. Future studies with larger sample sizes statistically powered to detect small effects are needed to further elucidate if therapist support promotes incremental treatment efficacy.

Limitations

The current findings need to be interpreted accounting for the following limitations. First, the current sample consisted of mostly highly educated young adults, thus the present findings may not be generalizable to other populations. While dCBTi was found to be effective across demographic groups [70], all studies were conducted in working-age adult samples [71]. It remains unclear whether older adults also respond as well to dCBTi. Second, although the present study was adequately powered for detecting meaningful differences in the ISI, it could not detect smaller effects, which might have existed in the comparison between dCBTi with different coaching types. Nonetheless, we argued that such differences would have limited practical and clinical implications. Third, the follow-up assessment was conducted four weeks after treatment, thereby limiting any conclusions to be drawn about long-term efficacy of the present intervention. In particular, although we did not find significant meaningful differences in the primary outcomes between dCBTi conditions with different types of coaching at short-term follow-up, dCBTi with coaching, especially therapist coaching, performed better than dCBTi without coaching on the mechanism of action, i.e., sleep-related safety behavior. Such a greater improvement in the mechanism of action may promote incremental benefits on the primary outcome that appear at a longer follow-up. Future studies with longer follow-up are necessary to fully evaluate the potential benefits of adding coaching to dCBTi. Finally, we did not collect data on participants' usage of strategies learned in dCBTi. Although adding therapist support improved video session and sleep diary completions, it remains unclear if the addition of such support increased participants' usage of the learned strategies in their daily lives. More detailed assessments of adherence would provide greater insights into the relationship between treatment adherence and efficacy or the lack thereof.

Conclusion

The present findings supported the efficacy of a fully automated dCBTi, *Sleep Sensei*, compared to an active control for treating insomnia, reducing mood disturbances, fatigue, and improving quality of life. Adding virtual coaching and human support did not significantly improve the

efficacy of *Sleep Sensei* for treating insomnia, but they may improve long-term efficacy given their effects on increasing treatment adherence and additional benefits on reducing fatigue and behaviors that could perpetuate insomnia. In sum, *Sleep Sensei* can be used as a standalone intervention for treating insomnia and is the only Cantonese mobile application of CBTi published with demonstrated efficacy.

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Data Availability
The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

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Conflicts of Interest
TK is affiliated with the Centre for Digital Health Interventions (CDHI), a joint initiative of the Institute for Implementation Science in Health Care, University of Zurich, the Department of Management, Technology, and Economics at ETH Zurich, and the Institute of Technology Management and School of Medicine at the University of St.Gallen. CDHI is funded in part by CSS, a Swiss health insurer, MavieNext (UNIQA), an Austrian care provider, and MTIP, a Swiss investor company. TK is also a cofounder of Pathmate Technologies, a university spin-off company that creates and delivers digital clinical pathways. However, neither CSS, Pathmate Technologies, MavieNext nor MTIP was involved in this research. Other authors have no conflict of interests.

Author Contributions
WSC contributed to conceptualization, methodology, formal analysis, resources, writing – original draft, writing -review & editing, supervision, and funding acquisition. WYC contributed to software, formal analysis, writing – review and editing, and visualization. SHCL and AKMC contributed to investigation and writing – review and editing. AKWL contributed to data curation, project administration, and writing – review and editing. ASYN contributed to writing – review and editing and visualization. TK contributed to resources and writing – review and editing.

Abbreviations
dCBTi: digital cognitive behavioral therapy for insomnia
dCBTi-therapist: dCBTi with virtual coaching and therapist support
dCBTi-assistant: dCBTi with virtual coaching and research assistant support
dCBTi-virtual: dCBTi with virtual coaching only
unguided-dCBTi: CBTi without any coaching
dSH: digital sleep hygiene and self-monitoring control
TIB: time in bed
TST: total sleep time
ISI: The Insomnia Severity Index
SCI: The Sleep Condition Indicator
PHQ-9: The Patient Health Questionnaire-9
GAD-7: The Generalized Anxiety Disorder 7-item Scale

FAS: The Fatigue Assessment Scale
ESS: The Epworth Sleepiness Scale
SWLS: The Satisfaction with Life Scale
DBAS-16: The Dysfunctional Beliefs and Attitudes About Sleep Scale-16
SRBQ: The Sleep-Related Behavior Questionnaire

References

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5). Arlington, VA: American Psychiatric Publishing; 2013. doi: 10.1176/appi.books.9780890425596
2. American Academy of Sleep Medicine. The International Classification of Sleep Disorders, Third Edition (ICSD-3). Darian, IL; 2014.
3. Aernout E, Benradia I, Hazo JB, Sy A, Askevis-Leherpeux F, Sebbane D, Roelandt JL. International study of the prevalence and factors associated with insomnia in the general population. Sleep Med. 2021 Jun 1;82:186–192. PMID:33957414
4. Lam CS, Yu BYM, Cheung DST, Cheung T, Lam SC, Chung KF, Ho FYY, Yeung WF. Sleep and Mood Disturbances during the COVID-19 Outbreak in an Urban Chinese Population in Hong Kong: A Longitudinal Study of the Second and Third Waves of the Outbreak. International Journal of Environmental Research and Public Health. 2021;18(16):8444. PMID:34444192
5. Morin CM, Bjorvatn B, Chung F, Holzinger B, Partinen M, Penzel T, Ivers H, Wing YK, Chan NY, Merikanto I, Mota-Rolim S, Macêdo T, De Gennaro L, Léger D, Dauvilliers Y, Plazzi G, Nadorff MR, Bolstad CJ, Sieminski M, Benedict C, Cedernaes J, Inoue Y, Han F, Espie CA. Insomnia, anxiety, and depression during the COVID-19 pandemic: an international collaborative study. Sleep Med. 2021 Nov 1;87:38–45. PMID:34508986
6. Meaklim H, Junge MF, Varma P, Finck WA, Jackson ML. Pre-existing and post-pandemic insomnia symptoms are associated with high levels of stress, anxiety, and depression globally during the COVID-19 pandemic. Journal of Clinical Sleep Medicine. 2021 Oct;17(10):2085–2097. PMID: 33985647
7. Streatfeild J, Smith J, Mansfield D, Pezzullo L, Hillman D. The social and economic cost of sleep disorders. Sleep Oxford Academic; 2021 Nov 12;44(11). PMID:34015136
8. Yan Chan JW, Lam SP, Li SX, Man Yu MW, Chan NY, Zhang J, Wing YK. The Economic Burden of Insomnia: Direct and Indirect Costs for Individuals with Insomnia Syndrome, Insomnia Symptoms, and Good Sleepers. Sleep Oxford Academic. 2009 Jan 1;32(1):55–64. PMID:24790269
9. Wickwire EM, Shaya FT, Scharf SM. Health economics of insomnia treatments: The return on investment for a good night's sleep. Sleep Med Rev. 2016 Dec 1;30:72–82. PMID:26874067
10. Hafner M, Romanelli RJ, Yerushalmi E, Troxel WM. The societal and economic burden of insomnia in adults: An international study. 2023. Available from: https://www.rand.org/content/dam/rand/pubs/research_reports/RRA2100/RRA2166-1/RAND_RRA2166-1.pdf [accessed Jul 31, 2023]
11. Natsky AN, Vakulin A, Chai-Coetzer CL, Lack L, McEvoy RD, Lovato N, Sweetman A, Gordon CJ, Adams RJ, Kaambwa B. Economic evaluation of cognitive behavioural therapy for insomnia (CBT-I) for improving health outcomes in adult populations: A systematic review. Sleep Med Rev. 2020 Dec 1;54:101351. PMID:32739824
12. Buntrock C, Lehr D, Smit F, Horvath H, Berking M, Spiegelhalder K, Riper H, Ebert DD. Guided Internet-Based Cognitive Behavioral Therapy for Insomnia: Health-Economic Evaluation From the Societal and Public Health Care Perspective Alongside a Randomized Controlled Trial. J Med Internet Res. 2021 May 24;23(5):e25609. PMID: 34028361
13. Edinger JD, Arnedt JT, Bertisch SM, Carney CE, Harrington JJ, Lichstein KL, Sateia MJ, Troxel WM, Zhou ES, Kazmi U, Heald JL, Martin JL. Behavioral and psychological treatments for chronic

insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine. 2021 Feb;17(2):255–262. PMID: 33164742

14. Riemann D, Baglioni C, Bassetti C, Bjorvatn B, Dolenc Groselj L, Ellis JG, Espie CA, Garcia-Borreguero D, Gjerstad M, Gonçalves M, Hertenstein E, Jansson-Fröjmark M, Jennum PJ, Leger D, Nissen C, Parrino L, Paunio T, Pevernagie D, Verbraecken J, Weeß HG, Wichniak A, Zavalko I, Arnardottir ES, Deleanu OC, Strazisar B, Zoetmulder M, Spiegelhalder K. European guideline for the diagnosis and treatment of insomnia. J Sleep Res. 2017 Dec 1;26(6):675–700. PMID:28875581
15. Spielman AJ, Caruso LS, Glovinsky PB. A Behavioral Perspective on Insomnia Treatment. Psychiatric Clinics of North America Elsevier; 1987 Dec;10(4):541–553. PMID: 3332317
16. Harvey AG. A cognitive model of insomnia. Behaviour Research and Therapy Pergamon. 2002 Aug 1;40(8):869–893. PMID:12186352
17. Riemann D, Spiegelhalder K, Feige B, Voderholzer U, Berger M, Perlis M, Nissen C. The hyperarousal model of insomnia: a review of the concept and its evidence. Sleep Med Rev. 2010 Feb;14(1):19–31. PMID:19481481
18. Morin CM. Cognitive-behavioral approaches to the treatment of insomnia. Journal of Clinical Psychiatry. 2004;65:33–40. PMID: 15575803
19. Trauer JM, Qian MY, Doyle JS, Rajaratnam SMW, Cunnington D. Cognitive Behavioral Therapy for Chronic Insomnia: A Systematic Review and Meta-analysis. Ann Intern Med Ann Intern Med. 2015 Aug 4;163(3):191–204. PMID:26054060
20. Chan WS, McCrae CS, Ng AS-Y. Is Cognitive Behavioral Therapy for Insomnia Effective for Improving Sleep Duration in Individuals with Insomnia? A Meta-Analysis of Randomized Controlled Trials. Ann Behav Med Ann Behav Med. 2022 Dec 3;57(6)428-441 PMID:36461882
21. Alimoradi Z, Jafari E, Broström A, Ohayon MM, Lin CY, Griffiths MD, Blom K, Jernelöv S, Kaldo V, Pakpour AH. Effects of cognitive behavioral therapy for insomnia (CBT-I) on quality of life: A systematic review and meta-analysis. Sleep Med Rev. 2022;64. PMID:35653951
22. Cipriani A, Hawton K, Stockton S, Geddes JR. The Direct Effect of Cognitive Behavioral Therapy for Insomnia on Depression Prevention and the Mediation Effect via Insomnia Remission. JAMA Psychiatry. 2022;79(5):514–515. PMID:23814104
23. Koffel E, Amundson E, Polusny G, Wisdom JP. “You’re Missing Out on Something Great”: Patient and Provider Perspectives on Increasing the Use of Cognitive Behavioral Therapy for Insomnia. Behavioral Sleep Medicine. 2020 May 3;18(3):358–371. PMID: 30907144
24. Soh HL, Ho RC, Ho CS, Tam WW. Efficacy of digital cognitive behavioural therapy for insomnia: a meta-analysis of randomised controlled trials. Sleep Med. 2020 Nov 1;75:315–325. PMID:32950013
25. 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 Sleep Med Rev. 2016 Dec 1;30:1–10. PMID:26615572
26. Kallestad H, Saksvik S, Vedaa Ø, Langsrud K, Morken G, Lydersen S, Simpson MR, Dørheim SK, Holmøy B, Selvik SG, Hagen K, Stiles TC, Harvey A, Ritterband L, Sivertsen B, Scott J. Digital cognitive–behavioural therapy for insomnia compared with digital patient education about insomnia in individuals referred to secondary mental health services in Norway: protocol for a multicentre randomised controlled trial. BMJ Open. 2021 Jun;11(6):e050661. PMID: 34183350
27. Darden M, Espie CA, Carl JR, Henry AL, Kanady JC, Krystal AD, Miller CB. Cost-effectiveness of digital cognitive behavioral therapy (Sleepio) for insomnia: a Markov simulation model in the United States. Sleep Oxford Academic. 2021 Apr 9;44(4). PMID:33151330
28. Hasan F, Tu YK, Yang CM, James Gordon C, Wu D, Lee HC, Yuliana LT, Herawati L, Chen TJ, Chiu HY.

Comparative efficacy of digital cognitive behavioral therapy for insomnia: A systematic review and network meta-analysis. Sleep Med Rev. 2022 Feb 1;61:101567. PMID:34902820

29. Ho FYY, Chung KF, Yeung WF, Ng THY, Cheng SKW. Weekly brief phone support in self-help cognitive behavioral therapy for insomnia disorder: Relevance to adherence and efficacy. Behaviour research and therapy Behav Res Ther. 2014 Dec 1;63:147–156. PMID:25461790
30. Beun RJ, Fitrianie S, Griffioen-Both F, Spruit S, Horsch C, Lancee J, Brinkman WP. Talk and Tools: the best of both worlds in mobile user interfaces for E-coaching. Pers Ubiquitous Comput Springer London. 2017 Aug 1;21(4):661–674. doi: 10.1007/S00779-017-1021-5/FIGURES/6
31. Luik AI, van der Zweerde T, van Straten A, Lancee J. Digital Delivery of Cognitive Behavioral Therapy for Insomnia. Curr Psychiatry Rep Current Medicine Group LLC 1; 2019 Jul 1;21(7):1–8. PMID:31161406
32. van Straten A, Lancee J. Digital cognitive behavioural therapy for insomnia: the answer to a major public health issue? Lancet Digit Health Lancet Digit Health. 2020 Aug 1;2(8):e381–e382. PMID:33328041
33. Horsch C, Lancee J, Beun RJ, Neerincx MA, Brinkman WP. Adherence to Technology-Mediated Insomnia Treatment: A Meta-Analysis, Interviews, and Focus Groups. J Med Internet Res. 2015;17(9):e214. PMID:26341671
34. Agnew S, Vallières A, Hamilton A, McCrory S, Nikolic M, Kyle SD, Fleming L, Crawford MR. Adherence to Cognitive Behavior Therapy for Insomnia: An Updated Systematic Review. Sleep Med Clin. 2021;16(1):155–202. PMID:33485527
35. Filler A, Kowatsch T, Haug S, Wahle F, Staake T, Fleisch E. MobileCoach: A novel open source platform for the design of evidence-based, scalable and low-cost behavioral health interventions: Overview and preliminary evaluation in the public health context. Wireless Telecommunications Symposium (WTS). 2015:1-6. doi: 10.1109/WTS.2015.7117255
36. Kowatsch T, Volland D, Shih I, Rüegger D, Künzler F, Barata F, Filler A, Büchter D, Brogle B, Heldt K, Gindrat P, Farpour-Lambert N, L'Allemand D. Design and evaluation of a mobile chat app for the open source behavioral health intervention platform mobilecoach. Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics) Springer Verlag; 2017;10243 LNCS:485–489. doi: 10.1007/978-3-319-59144-5_36
37. Morin CM, Belleville G, Bélanger L, Ivers H. The Insomnia Severity Index: Psychometric Indicators to Detect Insomnia Cases and Evaluate Treatment Response. Sleep. 2011 May;34(5):601–608. PMID: 21532953
38. Netzer NC, Stoohs RA, Netzer CM, Clark K, Strohl KP. Using the Berlin Questionnaire to Identify Patients at Risk for the Sleep Apnea Syndrome. Annals of Internal Medicine. 1999:131(7):458-491. PMID: 10507956
39. Yang M, Morin CM, Schaefer K, et al. Interpreting score differences in the insomnia severity index: using health-related outcomes to define the minimally important difference. Curr Med Res Opin. 2009;25(10):2487-2494. doi: 10.1185/03007990903250547.
40. Kumle L, L-H Võ M, Draschkow D. Estimating power in (generalized) linear mixed models: An open introduction and tutorial in R. Behav Res Methods. 2021;53:2528–2543. PMID: 33954914
41. Chung HKS, Louie K, Chan WS. Development and evaluation of a Chinese short-form of the Sleep-related Behaviors Questionnaire in Hong Kong Chinese adults using item response theory. J Health Psychol. 2023;13591053231195518. doi: 10.1177/13591053231195518.
42. Riemann D, Baglioni C, Bassetti C, Bjorvatn B, Dolenc Groselj L, Ellis JG, Espie CA, Garcia-Borreguero D, Gjerstad M, Gonçalves M, Hertenstein E, Jansson-Fröjmark M, Jennum PJ, Leger D,

Nissen C, Parrino L, Paunio T, Pevernagie D, Verbraecken J, Weeß HG, Wichniak A, Zavalko I, Arnardottir ES, Deleanu OC, Strazisar B, Zoetmulder M, Spiegelhalder K. European guideline for the diagnosis and treatment of insomnia. J Sleep Res. 2017 Dec 1;26(6):675–700. PMID:28875581

43. Kaldo V, Jernelöv S, Blom K, Ljótsson B, Brodin M, Jörgensen M, Kraepelien M, Rück C, Lindefors N. Guided internet cognitive behavioral therapy for insomnia compared to a control treatment - A randomized trial. Behaviour Research and Therapy Elsevier Ltd; 2015 Aug 1;71:90–100. PMID:26091917
44. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. Psychiatry Res. 1989;28(2):193–213. PMID: 2748771
45. Tsai PS, Wang SY, Wang MY, Su CT, Yang TT, Huang CJ, Fang SC. Psychometric evaluation of the Chinese version of the Pittsburgh Sleep Quality Index (CPSQI) in primary insomnia and control subjects. Quality of Life Research. 2005;14:1943–1952. PMID: 16155782
46. Edinger JD, Bonnet MH, Bootzin RR, Doghramji K, Dorsey CM, Espie CA, Jamieson AO, McCall WV, Morin CM, Stepanski EJ. Derivation of Research Diagnostic Criteria for Insomnia: Report of an American Academy of Sleep Medicine Work Group. Sleep.; 2004 Dec 1;27(8):1567–1596. PMID:15683149
47. Lichstein KL, Durrence HH, Taylor DJ, Bush AJ, Riedel BW. Quantitative criteria for insomnia. Behaviour Research and Therapy. 2003 Apr 1;41(4):427–445. PMID:12643966
48. Wong ML, Lau KNT, Espie CA, Luik AI, Kyle SD, Lau EYY. Psychometric properties of the Sleep Condition Indicator and Insomnia Severity Index in the evaluation of insomnia disorder. Sleep Med. 2017;33:76-81. doi: 10.1016/j.sleep.2016.12.011.
49. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9 Validity of a Brief Depression Severity Measure. Gen Intern Med. 2001;16(9):606-613. PMID: 11556941
50. Yu X, Tam WWS, Wong PTK, Lam TH, Stewart SM. The Patient Health Questionnaire-9 for measuring depressive symptoms among the general population in Hong Kong. Compr Psychiatry. 2012 Jan;53(1):95–102. PMID:21193179
51. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A Brief Measure for Assessing Generalized Anxiety Disorder The GAD-7. Arch Intern Med. 2006;166(10):1092-1097. PMID: 16717171
52. Tong X, An D, McGonigal A, Park SP, Zhou D. Validation of the Generalized Anxiety Disorder-7 (GAD-7) among Chinese people with epilepsy. Epilepsy Res. 2016 Feb 1;120:31–36. PMID:26709880
53. Michielsen HJ, De Vries J, Van Heck GL, Van de Vijver FJR, Sijtsma K. Examination of the Dimensionality of Fatigue: The Construction of the Fatigue Assessment Scale (FAS). European Journal of Psychological Assessment. 2004;20(1):39–48. doi: 10.1027/1015-5759.20.1.39
54. Ho LYW, Lai CKY, Ng SSM. Measuring fatigue following stroke: the Chinese version of the Fatigue Assessment Scale. Disabil Rehabil. 2021;43(22):3234–3241. PMID:32142618
55. Chen N-H, Johns MW, Li H-Y, Chu C-C, Liang S-C, Shu Y-H, Chuang M-L, Wang P-C. Validation of a Chinese version of the Epworth sleepiness scale. Qual Life Res. 2002;11(8):817-821. PMID: 12482165
56. Pavot W, Diener E. Review of the Satisfaction With Life Scale. Psychol Assess. 1993; 5(2): 164-172. doi: 10.1037/1040-3590.5.2.164
57. Wang KT, Yuen M, Slaney RB. Perfectionism, Depression, Loneliness, and Life Satisfaction: A Study of High School Students in Hong Kong. Couns Psychol 2009;37(2):249–274. doi: 10.1177/0011000008315975
58. Charles M. Morin;, Annie Vallières;, Hans Ivers. Dysfunctional Beliefs and Attitudes about Sleep (DBAS): Validation of a Brief Version (DBAS-16). Sleep. 2007;30(11):1547–1554. PMID: 18041487
59. Chung KF, Ho FYY, Yeung WF. Psychometric comparison of the full and abbreviated versions of the

dysfunctional beliefs and attitudes about sleep scale. Journal of Clinical Sleep Medicine. 2016;12(6):821–828. PMID:26857054

60. Ree MJ, Harvey AG. Investigating Safety Behaviours in Insomnia: The Development of the Sleep-related Behaviours Questionnaire (SRBQ). Behaviour Change. 2004;21(1):26-36. doi:10.1375/bech.21.1.26.35971
61. Chung K, Louiem K, Chan W. Development and Evaluation of a Chinese Short-form of the Sleep-Related Behaviors Questionnaire in Hong Kong Chinese Adults using Item Response Theory. J Health Psychol (in press).
62. Mellor A, Kavaliotis E, Mascaro L, Drummond SPA. Approaches to the assessment of adherence to CBT-I, predictors of adherence, and the association of adherence to outcomes: A systematic review. Sleep Med Rev. 2022;63:101620. PMID:35398650
63. Corbeil RR, Searle SR. Restricted maximum likelihood (REML) estimation of variance components in the mixed model. Technometrics. 1976;18(1):31-38. doi: 10.1080/00401706.1976.10489347.
64. Majd NR, Broström A, Ulander M, Lin CY, Griffiths MD, Imani V, et al. Efficacy of a theory-based cognitive behavioral technique app-based intervention for patients with insomnia: randomized controlled trial. J Med Internet Res. 2020;22(4):e15841. doi: 10.2196/15841.
65. Cheng P, Luik AI, Fellman-Couture C, Peterson E, Joseph CLM, Tallent G, Tran KM, Ahmedani BK, Roehrs T, Roth T, Drake CL. Efficacy of digital CBT for insomnia to reduce depression across demographic groups: A randomized trial. Psychol Med. 2019 Feb 1;49(3):491–500. PMID:29792241
66. Batterham PJ, Christensen H, Mackinnon AJ, Gosling JA, Thorndike FP, Ritterband LM, Glozier N, Griffiths KM. Trajectories of change and long-term outcomes in a randomised controlled trial of internet-based insomnia treatment to prevent depression. BJPsych Open Royal College of Psychiatrists; 2017 Sep;3(5):228–235. PMID:28959453
67. Kuhn E, Miller KE, Puran D, Wielgosz J, Williams SLY, Owen JE, Jaworski BK, Hallenbeck HW, Mccaslin SE, Taylor KL. A Pilot Randomized Controlled Trial of the Insomnia Coach Mobile App to Assess Its Feasibility, Acceptability, and Potential Efficacy ScienceDirect. Behav Ther 2022;53:440–457. PMID: 35473648
68. Edinger JD, Bonnet MH, Bootzin RR, Doghramji K, Dorsey CM, Espie CA, Jamieson AO, McCall WV, Morin CM, Stepanski EJ. Derivation of Research Diagnostic Criteria for Insomnia: Report of an American Academy of Sleep Medicine Work Group. Sleep. 2004 Dec 1;27(8):1567–1596. PMID:15683149
69. Horsch CHG, Lancee J, Griffioen-Both F, Spruit S, Fitrianie S, Neerincx MA, Beun RJ, Brinkman WP. Mobile phone-delivered cognitive behavioral therapy for insomnia: A randomized waitlist controlled trial. J Med Internet Res. 2017 Apr 1;19(4). PMID:28400355
70. Ellis JG, Cushing T, Germain A. Treating acute insomnia: A randomized controlled trial of a “single-shot” of cognitive behavioral therapy for insomnia. Sleep. 2015 Jun 1;38(6):971–978. PMID:25515106
71. Ellis JG, Gehrman P, Espie CA, Riemann D, Perlis ML. Acute insomnia: Current conceptualizations and future directions. Sleep Med Rev. 2012. p. 5–14. PMID:21596596
72. Soh HL, Ho RC, Ho CS, Tam WW. Efficacy of digital cognitive behavioural therapy for insomnia: a meta-analysis of randomised controlled trials. Sleep Med. 2020 Nov 1;75:315–325. PMID:32950013
73. van Straten A, Cuijpers P. Self-help therapy for insomnia: A meta-analysis. Sleep Med Rev. 2009. 13(1):61–71. PMID:18952469
74. Deng W, van der Kleij MJJ, Shen H, Wei J, Brakema E, Guldemond N, Song X, Li X, van Tol M, Aleman

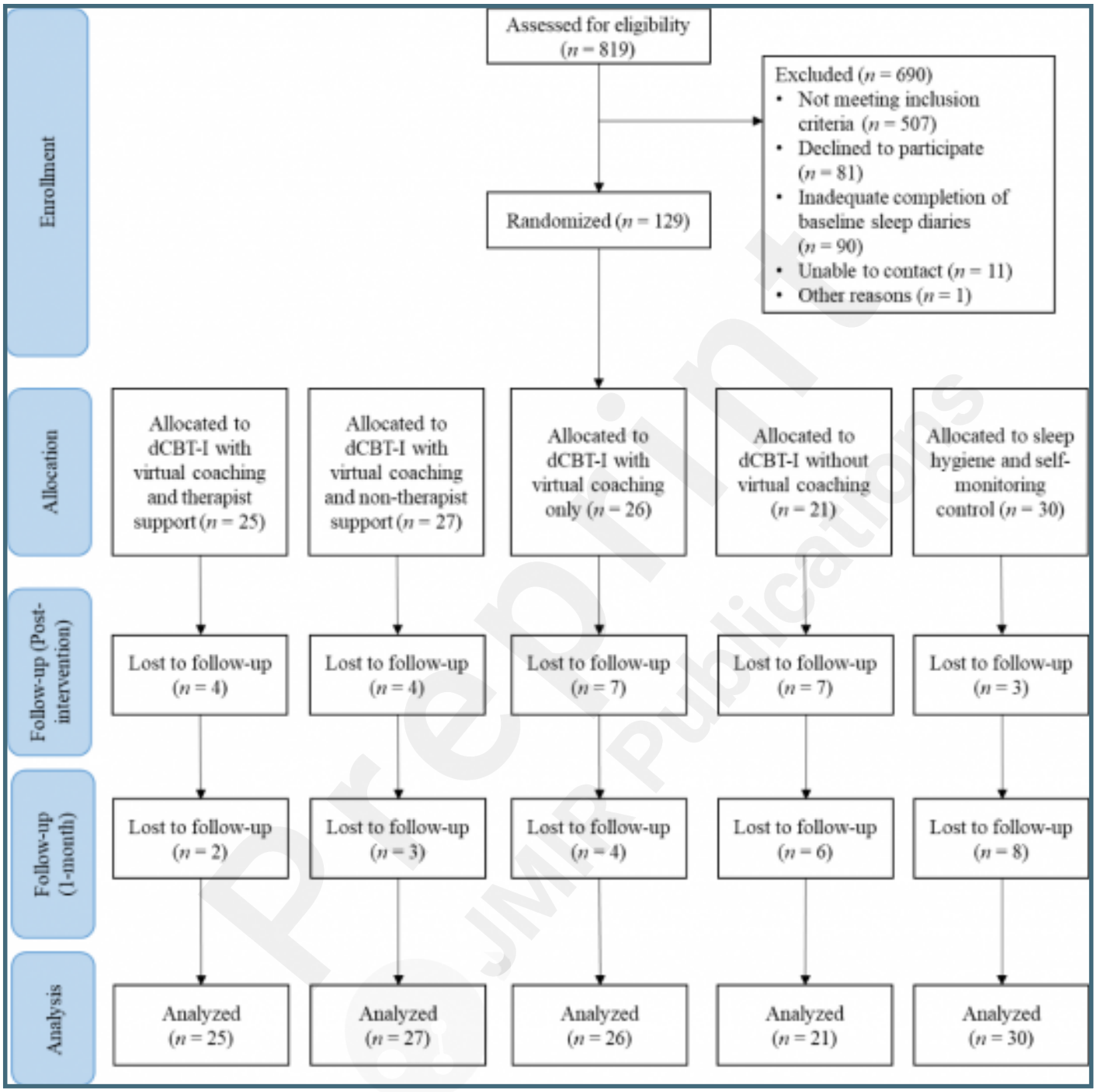
A, Chavannes N. eHealth-Based Psychosocial Interventions for Adults With Insomnia: Systematic Review and Meta-analysis of Randomized Controlled Trials. J Med Internet Res. 2023;25:e39250. doi: 10.2196/39250. URL: https://www.jmir.org/2023/1/e39250.

75. van der Zweerde T, Lancee J, Ida Luik A, van Straten A. Internet-Delivered Cognitive Behavioral Therapy for Insomnia: Tailoring Cognitive Behavioral Therapy for Insomnia for Patients with Chronic Insomnia. Sleep Med Clin. 2020;15(2)117–131. PMID:32386688
76. Ho FYY, Chung KF, Yeung WF, Ng THY, Cheng SKW. Weekly brief phone support in self-help cognitive behavioral therapy for insomnia disorder: Relevance to adherence and efficacy. Behaviour Research and Therapy. 2014 Dec 1;63:147–156. PMID:25461790
77. Titov N, Andrews G, Davies M, McIntyre K, Robinson E, Solley K. Internet treatment for depression: a randomized controlled trial comparing clinician vs. technician assistance. PLoS One. 2010;5(6):e10939. Published 2010 Jun 8. PMID: 20544030

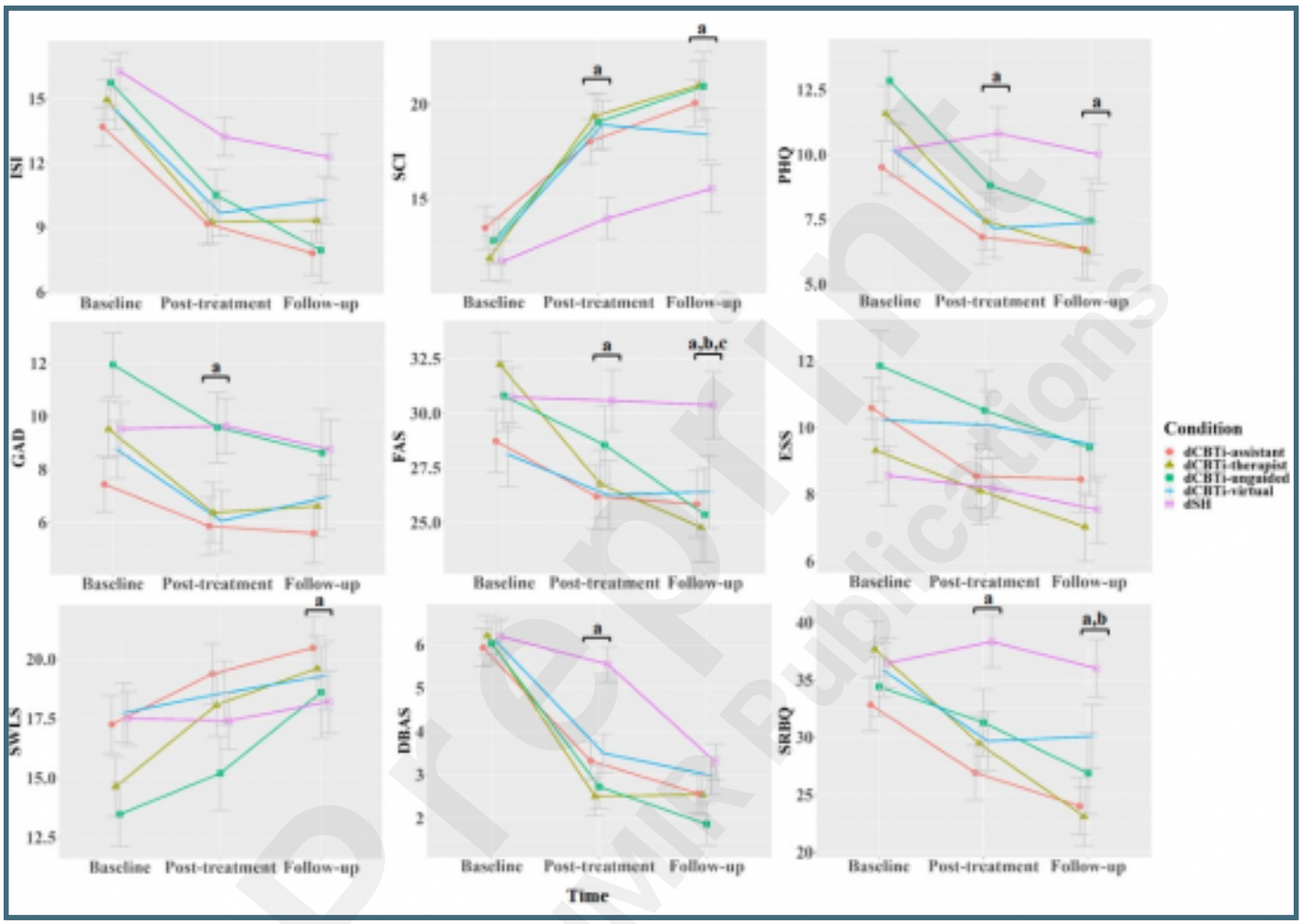
Supplementary Files

Figures

CONSORT Flowchart of Participants.



The linear prediction of outcomes. Error bars indicate the standard errors. ISI = Insomnia Symptom Index; SCI = Sleep Condition Indicator; PHQ = Patient Health Questionnaire-9; GAD = Generalized Anxiety Disorder 7-item Scale; FAS = Fatigue Assessment Scale; ESS = Epworth Sleepiness Scale; SWLS = Satisfaction with Life Scale; DBAS = Dysfunctional Beliefs and Attitudes About Sleep Scale; SRBQ = Sleep-Related Behavior Questionnaire-20. a indicates significant group-by-time effects of dCBTi versus dSH. b indicates significant group-by-time effects of dCBTi-human versus dCBTi-virtual. c indicates significant group-by-time effects of dCBTi-therapist versus dCBTi-assistant.



Multimedia Appendixes

Untitled.
URL: http://asset.jmir.pub/assets/00c0fb9d0bb601ec1e311c7cd2e8da15.pdf

CONSORT (or other) checklists

CONSORT-EHEALTH.
URL: http://asset.jmir.pub/assets/bc74d57718f26328885d9aeb1666749e.pdf