International Journal of Innovative Technologies in Social Science

e-ISSN: 2544-9435

Operating Publisher
SciFormat Publishing Inc.
ISNI: 0000 0005 1449 8214

2734 17 Avenue SW,
Calgary, Alberta, T3E0A7,
Canada
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ARTICLE TITLE	DIGITAL COGNITIVE-BEHAVIORAL THERAPY FOR INSOMNIA: SAFETY, LIMITATIONS, AND PATIENT-SPECIFIC CONTRAINDICATIONS
DOI	https://doi.org/10.31435/ijitss.1(49).2026.4925
RECEIVED	13 December 2025
ACCEPTED	23 January 2026
PUBLISHED	30 January 2026
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DIGITAL COGNITIVE-BEHAVIORAL THERAPY FOR INSOMNIA: SAFETY, LIMITATIONS, AND PATIENT-SPECIFIC CONTRAINDICATIONS

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ABSTRACT

Introduction & objective: Insomnia is a well-established clinical problem that places a burden on the healthcare system. Due to low accessibility to professional therapists, high costs, and geographical barriers, cognitive-behavioural therapy, which is a first-line treatment for insomnia, is rarely prescribed in clinical practice. The development of digital CBT-I was aimed at overcoming those issues. However, there is still limited data regarding the safety and implementation of dCBT-I in real-life settings. Our aim was to select a specific patient group in which the traditional approach to CBT-I is preferred/advised.
Review methods: This review is based on a non-systematic review of PubMed articles published between 2015 and 2026.
Brief description of state knowledge: In numerous studies, dCBT-I has been proven to be an effective alternative to face-to-face therapy. It can be delivered in several technological forms and may vary in the level of therapist oversight. Although each form of digital CBT-I is to some extent automated, fully automated platforms raise the greatest concerns regarding safety and patient outcomes. Thus, some research suggests that there are patients for whom face-to-face therapy would be advisable.
Summary: Digital CBT-I with therapist oversight may be particularly important for patients with psychiatric disorders, epilepsy, obstructive sleep apnea, safety-critical occupations, and older adults; however, limited real-world safety data highlight the need for further research to better define high-risk groups and refine clinical guidelines.

KEYWORDS

Cognitive Behavioral Therapy, Digital Cognitive-Behavioral Therapy, Insomnia, Safety, Contraindication, Automated, Cognitive-Behavioral Therapy for Insomnia

CITATION

Zofia Hałabuda, Kornelia Rynkiewicz. (2026) Digital Cognitive-Behavioral Therapy for Insomnia: Safety, Limitations, and Patient-Specific Contraindications. *International Journal of Innovative Technologies in Social Science*. 1(49). doi: 10.31435/ijitss.1(49).2026.4925

Introduction

Insomnia is a common health problem worldwide, with prevalence among adults ranging from 10% to 33%. It causes significant socioeconomic burdens, including reduced productivity and increased healthcare costs (Huang et al., 2026; Liang et al., 2022; Prather et al., 2025). The first-line non-pharmacological treatment for chronic insomnia is Cognitive Behavioural Therapy for Insomnia (CBT-I). Its proven efficacy and favourable safety profile compared to hypnotic medication make it a gold-standard approach when dealing with the disease. However, due to limited access, mostly because of a shortage of trained specialists and high treatment costs, fewer than 10% of patients receive this treatment (Prather et al., 2025; Riemann et al., 2023; Rosenberg et al., 2021). This situation raises an important question: how can CBT-I be scaled to improve accessibility while maintaining safety standards?

Digital CBT-I (dCBT-I), delivered through websites, mobile applications, or chatbots, is a solution for issues mentioned above, as it is cost-effective and scalable (Luik et al., 2017; Prather et al., 2025; Stern et al., 2025). The efficacy of dCBT-I has been proven in numerous studies, but its safety is not fully established. Fully automated or self-guided forms of therapy raise specific safety concerns. These include difficulty identifying adverse effects such as increased daytime sleepiness, complications in managing psychiatric emergencies, risks of inappropriate or insufficient intervention in vulnerable populations, and a lack of mechanisms to assess patient suitability or progress. The absence of clinical oversight creates challenges in managing these potential harms (Manber et al., 2023; Stanley et al., 2025; Stern et al., 2025). The aim of this review is to examine clinical limitations of digital therapeutics, highlight the importance of integrating dCBT-I safely within a stepped-care framework, and outline criteria for referral to specialist-led care.

Methods

This narrative review is based on a non-systematic search of PubMed articles published between 2011 and 2026; however, seminal theoretical works published earlier were also included to provide a conceptual context for cognitive behavioural therapy. The search strategy utilized the keywords: “dCBT-I”, “CBT”, “automated”, “therapist”, “insomnia”, “safety”, “limitations”, and “chronic insomnia disease.” Included sources comprised peer-reviewed clinical trials, meta-analyses, recent guidelines, systematic reviews, medical literature, and regulatory agency reports, all published in English and Polish. Relevance and methodological quality were assessed at the title, abstract, and full-text levels. No formal inclusion or exclusion criteria were applied.

The basis of Cognitive-Behavioral Therapy (CBT)

Cognitive behavioral therapy (CBT) is a well- known and studied method of psychological treatment used in a variety of psychological disorders. It is a model of aim-oriented psychological treatment focused on resolving a current issue, thereby improving patients’ current quality of life. In contrast to another leading psychological method, psychotherapy, it is not, at its core, focused on past events but rather on the present. CBT has been proven to be effective in both depression (Carney et al., 2007; Manber et al., 2008) and anxiety treatment (Curtiss et al., 2021). The idea of CBT is that thoughts, feelings, and behaviour are interconnected (Figure 1) and they inevitably influence one another.

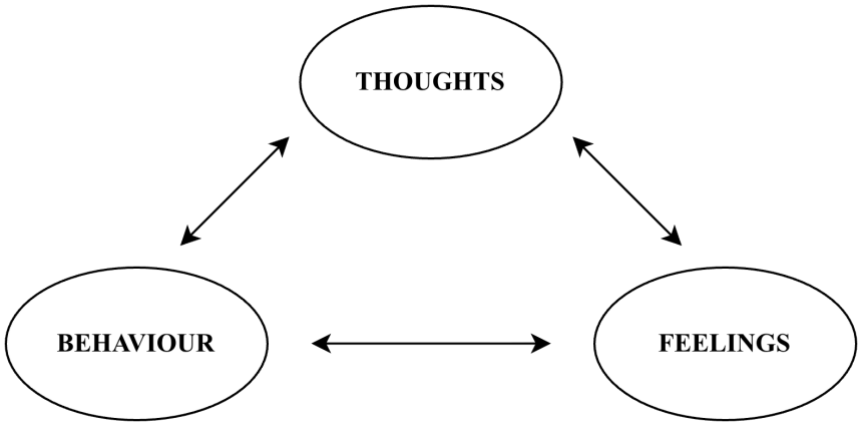

Fig. 1. *The foundation of Cognitive-Behavioral Therapy*

This figure illustrates the central concept of cognitive-behavioral therapy by presenting the connection between thoughts, emotions, and behaviors. Arrows represent the dynamic relationships among these three elements, showing how each aspect influences and shapes the others.

Sources: (Fenn & Byrne, 2013)

Figure credits: *Kornelia Rynkiewicz & Zofia Hałabuda*

The word "cognitive" derives from the Latin "cognoscere," meaning "to recognize." The cognitive component of CBT aims to develop the ability to understand one's thoughts, attitudes, and expectations clearly. This should result in recognizing and, when necessary, changing false and distressing beliefs. Thoughts that could have a negative impact are, e.g., “over-generalization” - creating a negative connotation based on one-time bad experience, or “catastrophizing”, when this one-time bad experience leads you to highly negative thoughts and outcomes. The behavioral component of CBT is based on “behaviorism”, which is rooted in the belief that human behavior is acquired and thus can be changed or modified. Behavioral therapy helps identify harmful behavioral patterns and aims to mediate by changing or stopping them.

Cognitive-behavioral therapy for insomnia generally comprises four components (**Figure 2**): sleep restriction therapy (SRT), stimulus control therapy (SCT), sleep hygiene (SH), and cognitive therapy (CT) (Walker et al., 2022). Relaxation is often included in the CBT-I process, constituting the fifth component. The duration of treatment may vary from patient to patient. In general, therapy lasts six to eight weeks. In some cases, positive effects may be observed after a few sessions, whereas others require more than a few months to show progress.

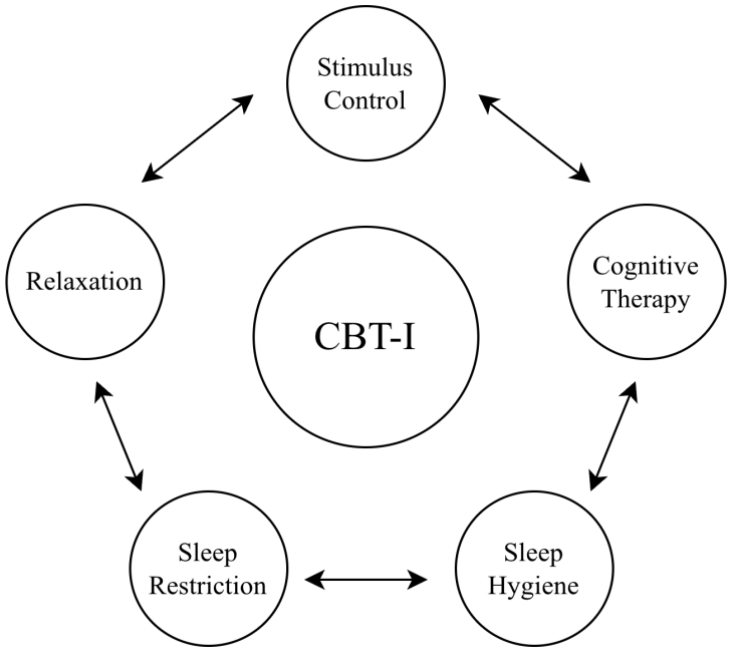

Fig. 2. *The principles of CBT-I*

This figure illustrates the key elements of cognitive-behavioral therapy for insomnia. Arrows indicate the significance of incorporating each CBT-I principle to achieve medical outcomes and ensure long-term effects.

Source: (Erten Uyumaz et al., 2021)

Credits: *Kornelia Rynkiewicz & Zofia Hałabuda*

SRT was introduced on the premise that sleep extension is a relevant factor in the development of insomnia (Spielman et al., 1987). Sleep extension is the tendency to compensate for lost sleep by increasing overall time in bed (Walker et al., 2022). This compensation can take the form of sleeping in on weekends, napping during the day, or going to bed earlier. This leads to a mismatch between sleep ability - the actual time spent on sleeping, and sleep opportunity- the exact time spent in bed. The preferred outcome of SRT is to eliminate the mismatch, in which sleep ability equals sleep opportunity (Walker et al., 2022). Nevertheless,

SRT could lead to such side effects as daytime sleepiness. The rise in daytime sleepiness increases the likelihood of earlier sleep. Still, if not well managed, it can become a burden for patients, especially in patient groups where maintaining daytime alertness is crucial. The second relevant component is stimulus control therapy. SCT is based on the idea that a specific stimulus may lead to a variety of outcomes (R.R. Bootzin, 1972). A desirable response to a stimulus, such as a bed or a bedroom, is somnolence that leads to sleep. In insomnia, the stimuli mentioned above are associated with activities other than sleep, such as reading or watching movies, thereby making it difficult to fall asleep (Perlis et al., 2011). The subsequent component is sleep hygiene, an educational process that informs patients about behaviors that may adversely affect sleep quality and quantity, thereby promoting better sleep practices (Rosch, 1994). It can be presented as a list of actions that negatively affect sleep (e.g., limiting caffeine and alcohol use before bedtime, napping, creating a comfortable sleeping environment, and exercising regularly) (Walker et al., 2022). An essential part of CBT-I is cognitive therapy, which aims to identify negative thoughts about sleep, analyze their accuracy, and modify them if necessary (Rosch, 1994). Common negative thinking patterns concerning insomnia are, e.g., “I have slept too little, because of that I will not be able to work properly tomorrow,” “I will lose my job because of it,” “I need to go to sleep.” These upsetting thoughts make the patient feel even more upset, making it harder to fall asleep. As a result, the more patients focus on sleep, the harder it is for them to fall asleep (Karol Grabowski, 2011). In therapy, the patient is encouraged by the therapist to consider alternative interpretations of sleep deprivation and its possible consequences. Relaxation, as a facultative element of CBT-I, can take the form of, e.g., progressive muscle relaxation (PMR). It is a technique of muscle tensing, followed by muscle relaxation. Relaxation methods improve sleep quality but do not affect the daytime consequences of poor sleep (Means et al., 2000).

Digital Cognitive-Behavioral Therapy (dCBT-I)

Digital Cognitive Behavioral Therapy for chronic insomnia (dCBT-I) was developed to address the low accessibility of traditional face-to-face therapy, primarily due to a shortage of professional therapists, high costs, and geographical barriers (Prather et al., 2025; Stanley et al., 2025). Its automated features enable patients to use it at any time and from any location, primarily at a low price. Digital CBT-I is delivered via technologies such as online platforms, mobile applications, and tablets (Luik et al., 2019). It uses a combination of strategies to address the psychological and behavioral factors that cause ongoing sleep problems. The core of dCBT-I is a structured framework that typically includes all CBT-I principles, namely stimulus control therapy (SCT), sleep restriction therapy (SRT), cognitive therapy, relaxation training, and sleep hygiene education. Treatment protocols may vary across applications, but typically full intervention is delivered over 4 to 9 weeks (Espie et al., 2019; Olsen et al., 2025).

Technologically, dCBT-I works through online sleep diaries, in which patients report daily data on sleep and wakefulness. The app tracks parameters such as sleep onset latency (SOL), wake time after sleep onset (WASO), and total sleep time (TST) (Maurer et al., 2025; Philip et al., 2022). Many of these platforms use an intelligent algorithm to process data, calculate sleep efficiency, and provide “sleep prescriptions” that tailor treatment recommendations, such as bedtime and wake time, based on the patient's ongoing progress (Chen et al., 2025; Ichikawa et al., 2017). This involves adjusting a user's “sleep window” weekly, which is a specific time an individual is permitted to be in bed, by measuring sleep efficiency. Sleep efficiency is defined as the ratio of total sleep time (TST) to total time spent in bed (TIB). If it reaches or exceeds 85%, the time allowed in bed increases, and if it falls below 80%, the time in bed is restricted (Olsen et al., 2025; Watanabe et al., 2023). Once behavioural habits are regulated, the app provides cognitive restructuring tools to challenge dysfunctional beliefs about sleep and sleep hygiene education to optimize the sleep environment (Luik et al., 2019; Rosenberg et al., 2021; Stern et al., 2025). Moreover, some applications offer relaxation training to reduce hyperarousal (Chiu et al., 2025; Olsen et al., 2025). The final stage focuses on maintaining long-term sleep health by inviting participants to create an individualised plan to prevent future relapse (Reesen et al., 2025).

Protocol implementation depends on the level of technical automation and the degree of human oversight. It can be delivered through fully automated programs, therapist-guided programs, or a hybrid model, in which non-responders to dCBT-I are “stepped up” to face-to-face specialist care (Cheng et al., 2019; Winter et al., 2025). Fully automated programs feature chatbots or virtual, animated therapists, whereas guided programs include oversight and feedback from a human professional (Luik et al., 2017, 2019). Newer apps also use passive smartphone sensors, such as GPS and accelerometers, and wearable devices to collect real-time data on user behaviour, enabling the app to suggest actions, such as “avoid naps,” or to adjust light exposure automatically (Huang et al., 2026; Stern et al., 2025).

Numerous applications are available on the market, but not all of them have undergone randomized controlled trials (RCTs). Due to demonstrated clinical efficacy, some are now approved by regulatory authorities and recognized as prescription digital therapeutics (PDTs), such as Sleepio (Big Health Ltd., London, UK) and Somryst (Pear Therapeutics, Inc., Boston, MA, USA). In **Table 1**, we compared available dCBT-I programs with respect to year of creation, device accessibility, therapy type, and regulatory approval.

Table 1. Applications for dCBT-I with scientific evidence (at least one RCT) (bold font indicates prescription digital therapeutics (PDTs)

App	Year of creation	Device accessibility	Type of therapy	Regulatory approval
Sleepio	2012	Web and mobile app	Fully automated (Animated virtual therapist)	Yes, by the FDA* and NICE**
Somryst	2009	Web and mobile app	Fully automated	Yes, by the FDA*
somnio (mementor GmbH, Leipzig, Germany)	2019	Web and mobile app	Fully automated (avatar “Albert”)	Yes, by the DiGA***
i-Sleep (Vrije Universiteit Amsterdam, Amsterdam, the Netherlands)	2014	Web platform	Therapist-Guided	
Sleep Ninja (Monash University, Melbourne, Australia)	2017	Smartphone app	Automated chatbot	
KANOPEE (Hospital and University of Bordeaux, Bordeaux, France)	2020	Smartphone app	Fully automated (Virtual agent “Louise.”	
SleepQ (Flinders University, Adelaide, Australia)	2023	Smartphone app	Fully automated	Yes by MFDS****
NUKKUAA (Flinders University, Adelaide, Australia)	2023	Smartphone app	Fully automated	

*FDA - Food and Drug Administration, **NICE - National Institute for Health and Care Excellence, ***DIGA - Digitale Gesundheitsanwendungen (Digital Health Applications), ****MFDS - Ministry of Food and Drug Safety in South Korea

Sources: (Espie et al., 2019; Hinterberger et al., 2024; Maurer et al., 2025; Philip et al., 2022, 2022; Reesen et al., 2025; Thorndike et al., 2024; Werner-Seidler et al., 2017)

Meta-analyses of dozens of randomized clinical trials (RCTs) involving thousands of participants confirm that dCBT-I has moderate-to-large and durable improvements in sleep quality, sleep efficiency (SE), sleep-onset latency (SOL), and wake time after sleep onset (WASO) (Li et al., 2025; Soh et al., 2020). When compared directly with face-to-face (F2F) therapy, F2F therapy often shows a slightly greater reduction in Insomnia Severity Index (ISI) scores (approximately 3.07 points more than digital). However, the difference typically falls within the four-point non-inferiority margin, indicating that the treatments are considered equally viable in clinical practice (Soh et al., 2020). However, some authors argue that a four-point margin on the ISI is too liberal, as a 4.6-point difference already indicates a clinically meaningful effect (Benz et al.,

2024). In **Table 2**, we compared the traditional CBT-I approach with its digital form across cost, accessibility, personalization, efficacy, adherence, and human support. While dCBT-I offers greater accessibility and cost-effectiveness than traditional methods, it faces challenges with personalized attention and adherence, underscoring the importance of practitioner guidance when choosing an appropriate therapy model.

Table 2. Comparison of traditional CBT-I and dCBT-I

	Traditional (face-to-face) cognitive-behavioural therapy	**Digital cognitive-behavioural therapy**
Costs	High	Cost-effective: lower labor costs and no travel expenses
Accessibility	Limited, restricted by clinician availability, clinic hours, and location	Highly available 24/7, overcomes geographic barriers and therapist shortages
Personalization	Clinician-driven, highly nuanced tailoring to complex patient needs and comorbidities	Algorithm-driven, tailored based on digital sleep diaries
Efficacy	Considered the "Gold Standard", it often gives slightly larger effects	Moderate-to-large effects
Adherence	Generally, higher adherence and completion rates are due to interpersonal accountability	Major challenge, high dropout rates, especially when unguided
Human support	Constant	Ranges from none (fully automated) to brief written/phone feedback

Sources: (Huang et al., 2026; Luik et al., 2017, 2019; Reesen et al., 2025; Rosenberg et al., 2021; Soh et al., 2020; Stanley et al., 2025)

The presence of human support is a significant determinant of effectiveness and adherence. Therapist-guided dCBT-I (with feedback or telephone support) is consistently found to be more effective than fully automated versions (Lee et al., 2023; Li et al., 2025). In cases of unguided or fully automated dCBT-I, dropout rates can exceed 50-80%. For example, an 80% dropout rate would turn 100 users who download applications into 20 who complete all modules. Therapist guidance often doubles adherence rates as the interpersonal bond provides accountability and motivation (Reesen et al., 2025; Stanley et al., 2025). To prevent high dropout rates in digital health, dCBT-i apps employ persuasive design elements (Gkintoni et al., 2025; So et al., 2026). These include automated push notifications, email reminders, visual progress charts, and a certificate at the end of the course to maintain user motivation (Erten Uyumaz et al., 2021; Fitrianie et al., 2021; Grotto et al., 2024).

To enhance adherence to dCBT-I, clinicians can schedule regular check-ins for personalized feedback and encouragement. Educating patients about the benefits of consistent engagement and integrating strategies such as app reminders and goal-setting can boost motivation and address barriers. A supportive environment and regular communication are key to optimizing the effectiveness of digital therapies.

The limitations of fully automated digital CBT-I

Studies show that CBT-I is effective in a variety of patients, from children (Ma et al., 2018) to adolescents (Mei et al., 2024) to elderly patients (Ritterband et al., 2025). The overall consensus is that there are no absolute contraindications to CBT. However, some suggest that severe personality disorders, such as antisocial personality disorders and lower intelligence competence, might enable patients to benefit from this form of therapy (Gautam et al., 2020). Moreover, patients suffering from severe psychological disorders might need medications or other forms of treatment before using CBT-I (Gautam et al., 2020). Given that cognitive-behavioral therapy is a well-established form of treatment, the question worth posing is the safety and limitations of digital CBT-I. Supporting this view is a recent study analyzing the rise in popularity of ChatGPT as a therapeutic intervention. The 2025 study found that users generally employed ChatGPT to simulate a

therapist, seek guidance, reenact distressing events, externalize thoughts, assist with real-life therapy, and disclose personal secrets (Luo et al., 2025). The researchers suggest that, in theory, nonjudgmental AI-based therapy appears promising; however, there are limitations, including potential errors, genAI biases, inconsistent advice, and a lack of clear accountability and regulatory oversight. Therefore, the question arises whether fully automated CBT-I has limitations and disadvantages as a therapeutic tool. It is crucial to note here that we are not comparing these two ideas, as CBT-I applications are structured explicitly around established therapeutic protocols for insomnia. In contrast, general AI chatbots can lack this therapeutic framework.

The potential biases inherent in AI-based therapy, such as algorithmic bias and a tendency to generate generic responses, can undermine the efficacy and safety of digital therapeutic interventions for complex sleep disorders. As research in this field is limited, it is worth analysing studies conducted in patients with specific comorbidities, not in terms of efficacy but in terms of safety. Sleep restriction is a core element of cognitive behavioral therapy for insomnia and is a reason for its high effectiveness. On the other hand, this high efficacy element may have adverse effects on certain patient groups and, when applied carelessly, may lead to adverse outcomes. Sleep deprivation is a common feature of the biannual change to summer or winter time. A 2018 study found that even a one-hour sleep restriction was associated with significantly higher rates of road accidents on the first and second days after daylight saving time, by 16% and 12%, respectively (Robb & Barnes, 2018). Sleep restriction in drivers lengthens the reaction time (RT), thereby increasing the risk of a car accident (Philip et al., 2005). In the case of unsupervised digital CBT-I, sleep restriction could pose a safety hazard for patients whose jobs require alertness and caution, e.g., driving mechanical vehicles (truck drivers), piloting, or jobs where focus and alertness are essential (e.g., heavy machine operators).

The treatment of insomnia in patients with coexisting diseases with episodes of aggressive or unpredictable behaviour may be a challenge with the use of digital CBT. CBT-I, meant for bipolar patients, is used in a modified form that includes interpersonal and social rhythm therapy, chronotherapy, and a motivational interview (Harvey et al., 2015). While CBT-I in patients with Bipolar Disease is associated with a low risk of hypomania or mania occurrence (Harvey et al., 2015), in some studies, moderate mood elevations can be observed in the context of sleep restriction (Kaplan & Harvey, 2013). In cases of poorly conducted therapy or during the first few weeks when sleep restriction is overly present, the patient's condition may worsen. In the studies that have proven the efficacy of CBT-I in bipolar patients, therapy is performed in the traditional form of face-to-face therapy. This raises the question of whether fully automated programmes yield similar outcomes. The only study that can, in some way, present the possible outcome of this type of therapy is a 2015 Swedish Single-Subject Design Pilot Study that examined the internet-based treatment of residual symptoms in patients with Bipolar Disorder Type II (Holländare et al., 2015). The study concerned a small group of seven participants, and applied such exclusion criteria as: having been diagnosed with a psychotic disorder or hospitalized within psychiatric care during the previous 12 months, previous suicide attempts, documented parasuicidal behavior or a score above three on item nine on the MADRS-S (Montgomery-Åsberg Depression Rating Scale - Self-assessment) —which would indicate suicidality—a history of mania, or ongoing psychotherapy. Therapy consisted of six online modules, with optional online contact with the therapist. Moreover, the therapists were supervised by a clinical psychologist with expertise in Internet-based treatment. The results were moderate: in most patients, insomnia severity decreased, whereas not all patients showed improvement. Although the CBT-I was delivered online, it was not a fully automated system, but rather a therapist-based therapy delivered online. Moreover, the exclusion criteria, such as lack of hospitalization or no previous suicide attempts, suggest that the concerned patients presented a stable mental state. Digital CBT-I could, in the case of unstable bipolar patients, end in a disease relapse, with mood instability resulting in life-threatening activities.

In the case of patients with psychosis, a 2015 study in patients with current psychotic experiences, which comprised very longstanding insomnia, delusions, and hallucinations, the overall sleep quality was improved through CBT intervention performed by clinical psychologists (Freeman et al., 2015). While the improvement in sleeping was observed, a series of adverse effects, such as aggressive behaviour and suicide attempts, were present. Interpersonal therapy was effective, yet it did not prevent adverse effects. In the case of digital therapy, the number of adverse effects could worsen, and the needed help in a life-threatening condition might not be delivered in time, leading to the patient’s death.

Schizophrenia is another disease in which, in its course, psychosis symptoms can occur. In 2021, a group of patients with diagnosed schizophrenia were recruited to a single- arm, uncontrolled study, where they were engaged with the seven- module programme via smartphone app for six weeks (Taylor et al., 2022). The

participant feedback indicated both quantitative and qualitative improvements in sleep, with an additional benefit of a reduction in clinician time per patient to an average of 107 min, compared with 240-480 min of therapist contact in the face-to-face approach (Freeman et al., 2015; Myers et al., 2011). Another challenge in using fully automated applications is the intellectual deficiency found in patients with schizophrenia. Intellectual deficiency may make it difficult to complete a nightly sleep diary, according to one study (Jeon et al., 2024). One answer to this is the development of an application specifically targeted at patients with schizophrenia, called SleepCather. It is still under development, and a 2024 original article published in a peer-reviewed journal described the algorithm and innovations used to improve the treatment, including mobile applications with sleep sensors that may aid in completing sleep diaries (Jeon et al., 2024). Both studies mentioned present the possibility of using digital CBT as a method among schizophrenia patients, yet worth mentioning is the emphasis on a therapist-guided digital CBT-I style therapy. Another solution that may help patients who fail to complete a sleep diary is a CBT-I application with an audio-sleep diary mode, which allows patients to record their sleep data. The collected data would then be processed by a therapist to propose the most suitable therapy, thereby potentially enhancing outcomes and preventing adverse effects.

As sleep quality and quantity worsen substantially with age, older adults may benefit from dCBT-I, though limitations such as device or internet accessibility may be particularly important in this group. Falls are common incidents among elderly adults (Hornbrook et al., 1994; Jeon et al., 2024; Sherrington et al., 2019), with multiple falls occurring in about 4% of the older population (Liu-Ambrose et al., 2019), being a common cause of disability and death. Studies suggest that reducing sleep time to less than 5 hours is associated with an increased risk of falls among older adults (Hausdorff et al., 2001); thus, sleep restriction, a key component of CBT-I, could increase the risk of falls, thereby compromising patients' safety.

Uncontrolled sleep restriction may also negatively influence patients with epilepsy. Epilepsy is a well-studied disorder characterized by recurring seizures caused by abnormal neuroelectrical activity. Sleep deprivation can provoke seizures; on the contrary, prolonged sleeping may lower seizure risk in focal epilepsy (Nobili et al., 2022). A 2021 review suggested that sleep deprivation provokes neuroinflammation and, together with brain seizure activity, can exacerbate neurodegeneration in the epileptic brain, thus indicating that adequate sleep hygiene helps manage seizures, improve quality of life, and prevent epilepsy-related mortality (Bonilla-Jaime et al., 2021).

The wide prevalence of insomnia among patients suffering from pulmonary diseases raises the question about therapeutic methods targeted at them. One of the more common respiratory diseases is obstructive sleep apnea (OSA), which is a sleep disorder characterized by repeated episodes of complete (apnea) or partial (hypopnea) upper airway collapse, resulting in oxygen desaturation and sleep fragmentation (Lv et al., 2023), which results in worsening daytime functioning. In Patients with Co-Morbid Insomnia and Sleep Apnea (COMISA), cognitive behavioral therapy could be a viable therapeutic method. Interestingly, sleep apnea was often an exclusion criterion in many studies examining CBT-I efficacy (Prather et al., 2025; Watanabe et al., 2023). A new 2025 review described digital CBT-I for patients with obstructive sleep apnea (Sweetman et al., 2025). Studies showed that sleep restriction exacerbated OSA symptoms in patients, likely by modulating upper airway muscle tone and altering the physiological response to airway collapse, thereby prolonging respiratory event duration (Sweetman et al., 2021). Moreover, bedtime restriction therapy was also associated with temporarily reduced sleep duration, increased symptoms of daytime sleepiness, and decreased attention/vigilance in people with COMISA (Qaseem et al., 2016; Sweetman et al., 2020). The researchers suggested that self-guided bedtime restriction therapy delivered via digital CBTi programs could result in temporarily increased severity of OSA, resulting in the raised risks of sleepiness and alertness failure in some patients. They suggested that patients with COMISA should be under supervision or referred to validated digital CBT-I applications specifically for COMISA patients. Another respiratory disorder, in which insomnia is commonly observed in patients, is chronic obstructive pulmonary disease (COPD) (Budhiraja et al., 2012).

One of the interventions used in COPD is COPD education (COPD-ED), which covers the physiology of the respiratory system, managing COPD and its complications, medications, and breathing techniques (Kapella et al., 2022). Interestingly, a 2022 randomized trial examined whether combining CBT-I and COPD-ED to elevate insomnia symptoms could lead to more effective outcomes. The common perception is that more advanced therapy yields greater benefits than fewer medical interventions. The results revealed that patients receiving both therapies simultaneously showed less effectiveness against fatigue, suggesting that when patients follow multiple treatment methods simultaneously, the overall efficacy may be reduced (Kapella et al., 2022). Considering that not all applications have a therapist's oversight and some patients might use them

without a medical order, fully digital applications operating CBT-I could interfere with their primary therapy, thus compromising their therapeutic progress.

Lastly, the issue worth analyzing is the safety of dCBT-I in patients with suicidal thoughts, which is a complex clinical issue, as insomnia is closely related to an increased risk of suicide (Li et al., 2025; Riemann et al., 2022). However, there are limited data on the safety of dCBT-I in these patients, primarily because they have typically been excluded from large-scale studies evaluating dCBT-I such as Sleepio, Somryst, and somnio (Espie et al., 2019; Vedaa et al., 2020). Expert guidelines suggest that patients with suicidal intention should be treated with face-to-face CBT-I due to a lack of professional therapists' supervision and immediate clinical control necessary for real-time risk assessment and intervention. On the other hand, the sources note that digital delivery is not entirely dissimilar to traditional therapy in this regard, as face–to–face therapists do not provide continuous patient care either. To manage risk, many dCBT-I programs implement safety and escalation protocols, such as screening with standardized tools and automated referrals to psychiatric services, emergency departments, or local suicide prevention lifelines (Luik et al., 2019; Tsai et al., 2022). Despite the risk, some authors have reported that insomnia remission acts as a "suicidolytic mechanism", with successful CBT-I results yielding significantly lower rates of suicidal ideation (Kalmbach et al., 2022).

The review of published studies in the field of CBT-I may lead us to identify patient groups in whom fully automated CBT-I therapy without therapist oversight should not be advised. (Table 3.) It comprises: psychiatric disease in which aggressive or psychosis symptoms can occur, patients with occupations where alertness and caution are key, and the lack of focus can lead to work and road-related accidents, e.g., drivers, pilots, heavy machine operators, epilepsy patients, and elderly patients. Also, overtherapisation can lead to unwarranted effects, as in the case of COPD patients, where surprisingly more means less, as undergoing two types of therapy simultaneously may in fact lower their efficacy. The limitations of digital CBT-I might also be general limitations of the CBT method, comprising patients with intellectual disability, or any neurocognitive or developmental disorder, and severe personality disorders, such as antisocial personality disorders. The situation regarding patients with suicidal thoughts is still uncertain. While treating insomnia in these individuals can have a "suicidolytic" effect, there are concerns about the lack of professional oversight in dCBT-I. The use of dCBT-I is not completely contraindicated, but it does require monitoring for any suicidal thoughts. Patients who actively have suicidal thoughts should be hospitalized and kept under constant supervision to ensure their safety.

Table 3. Groups of patients at risk of adverse reactions when using fully automated digital CBT-I

Groups of patients at risk of adverse reactions when using fully automated digital CBT-I
Schizophrenia
Bipolar disorder
Psychosis
Epilepsy
Obstructive sleep apnea
Patients with occupations where alertness and caution are key, e.g., drivers, pilots, heavy machine operators
Elderly people

Discussion

As Digital CBT-I is often offered to vulnerable populations, among whom access to therapy is generally limited, scientists emphasize the ethical necessity of providing clinical evidence to avoid unknown risks or potential harm (Luik et al., 2019). A significant concern is the limited clinical control in digital settings compared to face-to-face therapy, which poses significant risks for patients with specific mental health complaints. Worth noticing is the fact that in most studies concerning the above-mentioned psychiatric disorders, patients with severe states were not included in the trials, which leads us to believe that fully-automated digital CBT-I would not be advisable among them. Medical professionals should conduct a more thorough anamnesis in order to identify patients from the high-risk groups. For this reason, it would be helpful to perform initial screening (**Table 4**) when prescribing dCBT-I.

Table 4. Screening questions for identifying high-risk patients prior to dCBT-I

Risk domain	Clinical Concern	Screening questions
Risk of falls	Increased risk of falls is related to sleep restriction, nocturnal awakenings, or daytime sleepiness	How old are you? Have you experienced falls in the past? Do you suffer from osteoporosis?
Psychological vulnerability	Risk of symptom exacerbation during behavioral sleep interventions	Do you suffer from any psychological disorder? Have you noticed that your well-being has worsened during the last few weeks? Did you experience suicidal thoughts? Do you experience cognitive difficulties?
Seizure risk	Potential lowering of seizure threshold due to sleep deprivation	Do you suffer from epilepsy? Have you ever experienced an epileptic seizure?
Excessive daytime sleepiness	Risk of accidents during sleep restriction or transient sleep loss	Does your occupation entail activities that require alertness and caution, e.g., driving mechanical vehicles or operating heavy machinery?
Obstructive sleep apnea (OSA)	Sleep restriction may exacerbate symptoms and prolong apnea incidents	Do you snore loudly at night? Did your partner notice any episodes of heavy breathing or snoring at night? Do you experience any episodes of excessive somnolence during daytime activities?

Sources: (Hausdorff et al., 2001) (Harvey et al., 2015) (Nobili et al., 2022) (Sweetman et al., 2025) (Kaplan & Harvey, 2013)

Moreover, in addition to a detailed anamnesis, validated screening tools such as the MINI International Neuropsychiatric Interview for mental health assessment and the Epworth Sleepiness Scale for evaluating daytime sleepiness can be considered. Based on this diagnostic process, a suitable mobile application could be recommended, or the decision to pursue traditional face-to-face therapy could be made. With well-developed CBT-I protocols for specific patient groups, it would be possible to conduct CBT-I even in high-risk patients if the stability of patients' state were determined, and applications would include safety checks, e.g., limits on sleep reduction. By ensuring those features are in place, patients could be allowed to use the app without supervision. Moreover, upon discharge or during medical consultation, medical providers should provide patients with information on what to do if there is no noticeable improvement in insomnia management, increased fatigue, or worsening overall well-being. This advice could be as easy as contacting a primary care doctor or consulting the doctor managing the patient’s chronic disease. With technological advances and the

growing need for digital care for patients, more digital therapies will be used in the future; therefore, it is advisable to incorporate them into existing medical protocols. As there is still limited data on the safety and implementation of dCBT-I in real-life settings, future research must prioritize high-risk groups, specifically targeting those with severe psychiatric conditions, occupations requiring high alertness, and the elderly, and should focus on outcomes like safety, efficacy, and adherence in these populations. Such studies could include randomized adaptive trials, for example, targeting truck drivers subject to sleep restrictions or elderly patients with cognitive impairments. These trials would provide detailed insight into the safety and efficacy of fully automated CBT-I applications in real-world settings.

Limitations

This narrative review has several limitations. As this was a narrative rather than a systematic review, study selection may be subject to selection bias, publication bias, outcome reporting bias, confirmation bias, and interpretive bias. In addition, not all relevant publications may have been identified, and the included literature may emphasize studies reporting findings that support our incentive to identify high-risk group patients. The included literature comprises studies with varying designs, sample sizes, and clinical settings, potentially introducing heterogeneity in reported outcomes. Additionally, research on digital therapy in the mentioned patient group, who are already vulnerable, may be impossible to obtain, as implementing fully automated dCBT-I to test its limitations might impose negative effects and be unethical in light of already existing safer therapy methods. Despite this, the reviewed evidence consistently shows the limitations of digital CBT-I and the need to identify patient groups in whom a fully automated dCBT-I might lead to negative medical outcomes.

Conclusions

Over the decades, CBT therapy gained trust in dealing with a variety of psychological issues. CBT in the treatment of insomnia has been proven across multiple studies to have a high efficacy and safe profile. The development of technology has led to significant advances in digital CBT-I therapy. Various digital options include applications without psychological oversight, online therapy in the traditional sense, or a combination of both. Some countries already have CBT-I applications in their medical systems, proving their adaptability and efficacy. Research on this subject raises the question of whether fully digital applications can be promoted across all patient groups. After analyzing published studies, we identified sevenpatient groups for whom fully automated digital CBT may not be appropriate and for whom a more traditional CBT approach should be advised. The high-risk group of patients includes those with psychiatric disorders such as schizophrenia, bipolar disorder, or psychosis, epilepsy, obstructive sleep apnea, patients with occupations where alertness and caution are key, and the elderly. All proposed groups could have poor medical outcomes due to unsupervised over-sleep restriction, or some patients might fail following CBT-I therapy due to cognitive impairments. As there is still a need for studies of fully automated digital CBT-I in vulnerable patients, this topic warrants further investigation, which would, in the future, enable the development of suitable CBT-I protocols for high-risk groups.

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