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Digital Health Interventions for Insomnia: Turning Promise into Reality

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Abstract

Purpose of Review This article discusses existing research in internet-delivered cognitive behavioral therapy for insomnia (iCBT-I) and three domains that researchers identified as the critical gaps to be addressed in the next wave of clinical trials. Our focus is on iCBT-I interventions in which delivery of clinical content has been automated, rather than CBT-I-based telemedicine interventions involving synchronous clinician participation.

Recent Findings Despite its effectiveness and potential to revolutionize insomnia care, iCBT-I faces several challenges regarding real-world implementation.

Summary First, research into patient characteristics predicting treatment response may reveal novel patient trajectories and help clinicians match individuals to interventions. Second, optimizing iCBT-I treatments to be maximally effective while requiring minimum investment from patients may be vital to uptake. Lastly, an understanding of the cost-effectiveness of iCBT-I relative to other treatment modalities will support administrators and insurers in allocating financial resources to iCBT-I. Ultimately, widespread implementation of iCBT-I hinges upon how these questions are answered in the coming years.

Keywords Insomnia · Cognitive behavioral therapy for insomnia · mHealth · Digital health · Internet · Online

Introduction

Novel technological developments have opened new opportunities for the evaluation and treatment of health morbidities. The past several decades of innovation have seen the rise of several ground-breaking technological advances, particularly those in the realm of telemedicine. One domain which has received considerable attention is insomnia disorder, where researchers have embraced technology as a means to increase treatment accessibility.

Cognitive behavioral therapy for insomnia (CBT-I) is the first-line recommended treatment for insomnia, typically delivered in person over 6–8 weeks by a behavioral sleep medicine expert. The in-person delivery format is very effective for reducing insomnia severity [1] but puts a significant time demand for both the patients and providers. A lack of sufficiently trained sleep clinicians in the workforce means that for most adults with insomnia, access to in-person CBT-I treatment is limited [2]. This lack of access to evidence-based behavioral sleep treatment results in many individuals with insomnia not receiving treatment or receiving suboptimal treatments like sleep hygiene or hypnotic medications.

The potential for internet-delivered insomnia interventions to increase access to CBT-I has been a focus of sleep researchers, who have developed and disseminated several internet-delivered CBT-I (iCBT-I) programs. Multiple systematic reviews and meta-analyses provide support for the effectiveness of iCBT-I, with effect sizes similar to those achieved through traditional face-to-face approaches [3, 4]. iCBT-I has been shown to be appropriate for patients presenting with a wide range of physical and psychological comorbidities such as cardiovascular disease [5], cancer [6, 7], anxiety [8], and depression [9].

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Despite this level of empirical support, iCBT-I have not consistently replaced in-person treatment in practice. iCBT-I no longer needs to prove its effectiveness. Rather, the challenge is for iCBT-I to be designed and implemented in a manner that results in more widespread awareness and adoption. For this shift to occur, there are key barriers which have been consistently identified by researchers who have done the foundational work of establishing iCBT-I as a proven treatment strategy. This article reviews these topical issues in iCBT-I research, laying out a roadmap of key questions for researchers to consider in their future trials.

A literature review was conducted of all identified systematic reviews and meta-analyses of randomized controlled trials (RCTs) for insomnia treatment published between 2015 (the earliest year in which such a review was published) and 2022 that included at least one iCBT-I-based intervention. Additional sources were identified through searches of PubMed and PsycINFO databases using the search terms "internet," "CBT-I," "BBT-I," "online," and "insomnia," as well as a backward reference search from the published systematic reviews and meta-analyses. Authors independently reviewed the identified articles, with specific focus paid to the "limitations" and "future directions" sections of systematic reviews to spell out a roadmap for future iCBT-I research. We excluded studies of individuals aged 16 or younger. The main findings from these sources were summarized, and a list of potential gaps in the literature and future research directions were discussed and refined by the authors. To enhance our understanding of the particular issues we identified in the first pass, a second literature search was then conducted on the same databases using the original search terms in combination with "personalization," "precision," "components," "cost," "cost-effectiveness," "societal burden," "guided," "supported," and "automated."

Issues Identified in iCBT-I Research

Three main issues were consistently reported in the existing literature to be the most important for iCBT-I researchers to address in the coming years: (1) the personalization of iCBT-I treatment, (2) the optimization of iCBT-I components, and (3) the determination of cost-effectiveness of iCBT-I tools relative to their level of therapist support.

First, while automated iCBT-I treatments stand to greatly increase access to evidence-based insomnia treatment, it is not clear that a fully automated, "cookie cutter" approach will work for all patient groups. Research into the personalization of automated iCBT-I programs based on demographic, cultural, or clinical patient characteristics may increase patient adherence and engagement with these treatments, increasing their effectiveness.

Second, while iCBT-I is a multicomponent intervention, evidence suggests that some treatment components may not be necessary to deliver in most patients in order to achieve clinically significant improvement in insomnia symptoms [10, 11]. As adherence is generally higher for treatments that require less effort and engagement, and implementing each component in an automated treatment incurs additional development costs, researchers should seek to determine the optimal combination of iCBT-I components.

Lastly, iCBT-I treatments can differ in the degree to which the automated content is supplemented by support or guidance from a real-world clinician. While fully automated iCBT-I is the cheapest and easiest to scale for widespread dissemination, there is evidence suggesting that treatment effect sizes are increased with greater levels of therapist support. Researchers should conduct a cost-effectiveness analysis comparing fully automated and therapist-supported iCBT-I treatments to determine whether the additional costs of therapist support are justified by the potential increase in treatment effect sizes. Filling these gaps in the literature around iCBT-I treatments will set the stage for widespread implementation of these life-changing interventions, which will have a significant impact on the future of insomnia patient care.

Personalizing iCBT-I

The first of the three key issues is the personalization of iCBT-I. We need to better understand how digital tools can be optimized in terms of both the content and the treatment dose as it relates to the patient's personal and/or clinical characteristics. Personalized or precision medicine is designed to tailor treatments to the individual characteristics of a patient (e.g., genetic, cultural, environmental, lifestyle factors) in order to optimize treatment engagement and response. Personalized medicine differs from the standard one-size-fits-all approach and has been employed in domains such as weight management. Within the UK's National Health Service (NHS), individuals who are slightly overweight may receive dietary and physical activity education in the primary care setting to promote a healthy lifestyle, while those with morbid obesity may receive hospital-based treatment from a multidisciplinary team including specialist dieticians, psychological support, and potentially even bariatric surgery [12]. Personalized approaches are also progressively being applied to psychotherapeutic interventions for mental health conditions such as depression [13] and insomnia [14].

To reduce patient burden and increase treatment engagement, it may be fruitful to ascertain which individual patient characteristics can help determine the ideal combination of treatment components and dose to administer. Research into which patient characteristics are differentially associated

with treatment response to the various iCBT-I approaches (i.e., therapist-supported vs. fully automated, mobile app vs. webpage) will pave the way for the development of tailored approaches with improved effectiveness and reduced cost.

Existing Research

Several studies have explored personal characteristics as predictors of iCBT-I treatment response (Table 1). In this limited research, there is no consensus on how factors like baseline insomnia severity, culture, and age may affect response to iCBT-I. Greater insomnia severity at baseline, characterized by any or all of a high insomnia severity index (ISI) score, low total sleep time (TST), or low sleep efficiency (SE), is predictive of greater treatment response; however, this is likely a result of regression to the mean making this improvement easier to detect statistically [15, 16]. Similarly, lower baseline levels of insomnia were associated with a decreased likelihood of completing iCBT-I treatment [15]. Because it is reasonable for participants with lower baseline insomnia levels to discontinue adherence to treatment when they feel their sleep is "good enough," it is unclear whether dropout in this patient group is a result of symptom improvement or lack thereof. These issues will need to be addressed in order to best match patients to the most effective treatment options.

Table 1 Personal characteristics predicting iCBT-I treatment response

Study	Intervention(s)	Predictor(s)–personal characteristic(s) at baseline	Outcome(s)–treatment response	Results
Espie et al., 2014 [33]	Sleepio	SE	Change in SE	Lower baseline SE significantly predicts larger post-treatment improvement in SE
Yeung et al., 2015 [16]	6-week internet-based self-help CBT-I	TST, HADS[1], ISI	Treatment completion	Baseline TST > 6.82 h, HADS ≥ 9, and ISI ≤ 13 significantly predict treatment noncompletion. TST ≥ 5.92 h predicted early dropout (before 4th treatment session)
Zhou et al., 2022 [17]	SHUTi[2]; SHUTi-BWHS[3]; no treatment	Intervention received: SHUTi or SHUTi-BWHS	Change in ISI; treatment completion	Participants receiving either form of SHUTi had greater reductions in ISI from pre- to post-treatment More participants (78.2%) completed the culturally tailored SHUTi-BWHS program than completed the standard SHUTi program (64.8%)
Vincent and Walsh, 2013 [18]	Stepped care: Step 1: 6-week internet CBT-I Step 2: on-site consultation with psychologist Step 3: 6-week in-person group CBT-I Step 4: personalized psychotherapy	Age; employment status; SOL[4]; sleep quality	Proportion requiring more intensive care at each step	Older patients and unemployed patients had a higher likelihood of requiring more intensive care At step 1: higher sleep quality was associated with lower likelihood of requiring more intensive care At step 2: shorter SOL was associated with lower likelihood of requiring more intensive care

[1]Hospital Anxiety and Depression Scale

[2]Sleep Healthy Using the Internet (SHUTi; now "Somryst") was a 6-week iCBT-I intervention for insomnia treatment

[3]Sleep Healthy Using the Internet-Black Women's Health Study (SHUTi-BWHS) was an altered version of SHUTi tailored towards black women

[4]Sleep onset latency (SOL)

Recent studies have also investigated whether treatment effectiveness can be improved by tailoring iCBT-I treatment to the unique needs and preferences of certain patient groups. Treatment may be tailored to address common comorbidities of insomnia such as depression or cancer, or to meet the requirements of a particular cultural group. Zhou and colleagues showed that Black American women were more likely to complete a culturally tailored iCBT-I treatment, Sleep Healthy Using the Internet-Black Women's Health Study (SHUTi-BWHS) compared with the standard SHUTi program [17]. Treatment acceptance, adherence, and effectiveness may be higher when patients feel that a treatment addresses their unique needs.

Individual characteristics that are found to affect response to sleep treatment may also be used as part of the criteria for determining which patients should "step up" in a stepped care approach. Vincent and Walsh investigated a stepped care model for insomnia treatment and found that age and employment status to be associated with movement up the stepped ladder, with older patients and unemployed patients more likely to require treatment with on-site group CBT-I [18].

Recommendations

To address measurement issues regarding study attrition, future studies should strive to adopt consistent eligibility criteria, for example by using standardized scales with known cut-off scores (e.g., ISI scores of 15 or greater). In theory, this would reduce the number of participants who respond to treatment but drop out as a result of sleep becoming "good enough." Efforts should also be made to differentiate between "dropout" that results in the missing of a treatment session versus "dropout" that consists of a missed follow-up assessment after treatment completion. Researchers may also want to use a measure of treatment engagement that better captures whether participants are truly participating in the treatment, as session completion alone may be insufficient to produce insomnia improvements if recommendations are not understood or adhered to [15, 19]. Examples of engagement metrics could include the number of app/program logins, time spent actively engaging with the app/program, number of sleep diary entries completed, etc.

Attrition may be further reduced through the tailoring of iCBT-I programs to specific cultural or comorbid patient groups, as shown by Zhou and colleagues in their trial of SHUTi-BWHS [17]. These results show that tailoring of digital tools may significantly impact treatment adherence and engagement, a finding which has the potential to help address common health disparities in treatment if acted upon. Efforts are currently underway to tailor iCBT-I treatment to specific patient groups, notably patients with comorbid cardiovascular disease [20] and cancer [7, 21].

Lastly, incorporation of iCBT-I tools into stepped care models for insomnia treatment can be a cost-effective way of increasing access to evidence-based insomnia care. While more research is needed to confidently describe the relationships between factors like age, employment status, baseline sleep quality, and sleep onset latency with iCBT-I effectiveness, these findings show they may be useful in determining which patients should receive more intensive care and for whom less intensive care may be sufficient.

Optimizing iCBT-I

CBT-I consists of three main components (sleep restriction, stimulus control, cognitive restructuring) and two optional techniques (sleep hygiene and relaxation). While the efficacy of this combination of treatment components is well established [3, 4, 22], there is some evidence that not all treatment components are necessary in order to produce clinically significant improvements in insomnia symptoms [23]. As is the case with any novel intervention protocols, the initial stages of research have been focused on demonstrating effectiveness, which creates incentive to deliver a full dose of all treatment components to maximize the potential impact of the treatment on the disorder. Current versions of iCBT-I programs deliver a full CBT-I program, which has always been evaluated as a "package," with no way to separate the individual effects of its treatment components [23, 24]. The field has been investigating various protocols which do not include all CBT-I components as a means of reducing the burden required for patients and providers while preserving treatment efficacy. For example, brief behavioral treatment for insomnia (BBT-I) emphasizes the stimulus control and sleep restriction procedures but largely eliminates the cognitive restructuring and relaxation elements. Consequently, it is delivered over a shorter treatment period (4 sessions over 4 weeks) [25] with compelling data demonstrating its efficacy as well as durability of improvements [10, 11, 26].

Existing Research

As iCBT-I tools have only recently entered the market, there is very little existing research into optimizing iCBT-I components; however, researchers can look to other areas where attempts are being made to optimize the components of an online treatment. For example, MacDonell and colleagues published a protocol for the development of an internet-delivered intervention to promote adherence to HIV pre-exposure prophylaxis (PrEP) comprised of the optimal combination of treatment components identified during a Multiphase Optimization Strategy Trial (MOST) [27]. MOST is a framework aimed at optimizing multicomponent interventions to achieve the best expected outcome obtainable within key restrictions (i.e., resources, time,

money, participant burden) [28]. This approach has also been applied in the domain of weight management, where researchers conducted a MOST to optimize the components in BariFit, a digital intervention designed to promote physical activity following bariatric surgery [29]. Ultimately, a MOST for insomnia would result in an intervention that is not only optimized but economical (effective within budgetary constraints), efficient (avoids waste of resources/time), and scalable (able to be widely implemented with fidelity).

Recommendations

Given the effectiveness of in-person BBT-I treatments in improving insomnia symptoms and sleep diary indices, it may be worthwhile to invest in an internet-delivered version of BBT-I. This program would be shorter in duration and would require less engagement than a comparable iCBT-I program and could be offered to insomnia patients as a cheaper and less intensive first-line treatment. An online BBT-I program could be easily incorporated into a stepped care model as the lowest level of care, with iCBT-I acting as the next step for patients who require the additional cognitive components, followed by the more resource-intensive treatment options such as personalized therapy or in-person group therapy. An adaptive system that is able to match patients to one (or more, as necessary) of multiple treatment methods of varying intensity and mode of delivery would provide the best benefit to the insomnia patient population as a whole.

Alternatively, another possible direction would be to determine the optimal combination of iCBT-I components using an existing iCBT-I platform. In order to optimize iCBT-I treatment components and conserve both research and clinical resources, a MOST should be considered. A MOST consists of three phases: (1) a preparation phase in which a conceptual model is specified which details how each treatment component is theoretically expected to affect the desired outcome, (2) an optimization phase/trial in which the best combination of treatment components is identified in a factorial experiment based on four desiderata (effectiveness, efficiency, economy, and scalability), and (3) an evaluation phase, in which the optimized treatment is compared to standard of care in an RCT. Refining our understanding of each treatment component's effects both separate from and in combination with each other will allow us to improve evidence-based insomnia care and reduce the costs of delivering an effective intervention.

Understanding iCBT-I's Cost-Effectiveness

The trade-off between the cost of iCBT-I and its effectiveness is an important and pressing question. iCBT-I approaches differ in terms of their costliness, but one factor that may increase both the cost and the effect sizes of treatment is the extent to which an iCBT-I program is therapist-supported. iCBT-I interventions may be fully automated, requiring no clinician time at all, or they may be therapist-supported, meaning the automated content is supplemented by input from a real-world clinician who may review progress, provide feedback and encouragement, and advise on individual issues. Fully automated interventions are significantly less expensive in terms of their demand on clinical resources; however, researchers must still account for the initial investment cost of developing these programs, as well as the costs of maintenance, data stewardship, and technical support [19].

Given the limited availability of trained sleep clinicians, fully automated solutions are the easiest to scale for a large audience; however, some studies show that effect sizes can be increased by offering a higher degree of therapist support [4]. The degree to which levels of therapist support are cost-effective is a question which future researchers should strive to answer.

Existing Research

Zachariae and colleagues reviewed RCTs of iCBT-I interventions and identified three levels of therapist support: (1) fully automated interventions, (2) interventions that included the ability to contact clinical staff to receive individualized support, and (3) interventions wherein personal contact with a clinician/staff member was an integral part of the intervention [4]. This review found treatment effect sizes to be greater when participants are able to access a greater therapist support [4].

While no studies have directly investigated the cost-effectiveness of fully automated iCBT-I compared with therapist-supported iCBT-I to date, some researchers have compared the cost-effectiveness of these interventions with treatment as usual or face-to-face CBT-I. Baka and colleagues investigated the cost-effectiveness of a therapist-supported iCBT-I program (i-Sleep) compared with treatment as usual in 160 adults with insomnia. Therapist-supported iCBT-I was significantly more cost-effective than treatment as usual in producing improvements in insomnia severity, and there were no differences found in societal costs between the two groups [30]. These results are promising in that they illuminate the potential that iCBT-I holds to increase access to evidence-based insomnia care without substantially increasing the costs of treatment. Savard and colleagues performed a secondary analysis of an RCT which compared the cost-effectiveness of a 6-week face-to-face CBT-I program administered by a clinician against a fully automated video CBT-I program involving a 60-min video and 6 short booklets in a group of 161 women with breast cancer [31]. The researchers found no significant difference

in ISI reduction between the two treatments; however, total cost per patient was found to be 5.5 times higher with the face-to-face treatment ($1280.90 CAD/person) compared with fully automated video CBT-I ($234.36 CAD/person) [31]. Each 1-point reduction on the ISI was associated with a treatment cost that was significantly greater in the face-to-face group at both post-treatment (186.95 CAD vs. $44.87 CAD) and follow-up (154.76 CAD vs. $24.97 CAD) [31]. Despite its higher costs, face-to-face treatment was associated with a lower attrition rate of 22% and a slightly higher, though nonsignificant, reduction in insomnia severity compared with the video CBT-I group, which had 40% attrition. Given the lack of significant differences between treatment effects, these studies show the dramatic reductions in costs of CBT-I treatment that can be achieved by utilizing digital interventions alongside face-to-face approaches.

Recommendations

As shown by Zachariae and colleagues, effect sizes may be increased by using treatments that allow for a greater degree of therapist support [4]. However, it remains unclear whether the additional cost of therapist support is justified by this boost to treatment effectiveness. Moreover, the major advantage of internet delivery of CBT-I is that it can increase access to evidence-based sleep care for the large number of individuals who are unable to access care. The cost of therapist support scales linearly with the amount of patients who are treated, while fully automated interventions have the potential to service vast populations without substantial increases in cost. For these reasons, it is important to determine what the benefits of therapist support are relative to their costs and which patient groups may benefit from the additional support the most. Future studies should determine whether cost-effective treatment can be delivered by a trained allied health provider or staff member with supervision and support from a licensed sleep practitioner. A cost-effectiveness analysis must be conducted from both a patient perspective, looking for the lowest cost to achieve clinically significant improvement in symptoms, and a payee perspective, accounting for a reduction in societal costs associated with untreated insomnia (e.g., absenteeism, presenteeism, healthcare utilization).

Considering the large upfront investment cost for the development of both guided and fully automated iCBT-I interventions, the question of how these treatments will be funded is another important issue. While the main advantage of internet-delivered CBT-I is the potential audience size, real-world uptake of this treatment may be significantly hampered by requiring patients to pay for the service. Undoubtedly, widespread adoption of iCBT-I tools by the public, and therefore their impact in the realm of insomnia care, depends on their ability to be administered cheaply or without cost to the patient. However, even fully automated iCBT-I interventions will require a continual source of funding or income to support costs associated with system maintenance, including device support, technical updates, and answering user queries. Beyond securing institutional or private investors, one solution to this is to have an upfront cost for treatment that covers maintenance costs and is paid for by a patient's insurance.

The first digital therapeutics to hit the market for treating insomnia disorder are aiming to follow this approach, although the novelty of digital therapeutic tools in general may delay or prevent many insurance plans from providing coverage for some years. Big Health's flagship product Sleepio, the first digital therapeutic to receive approval from the UK's National Institute of Health and Care Excellence (NICE), is now available for download in both the USA and UK. Twelve months of access to the treatment (lessons, articles, sleep diary, and community) costs about $450 USD or £400, although this initial cost is being increasingly covered by US employer health care plans, as well as by the NHS in certain areas of the UK.

Like Sleepio, Somryst (Previously tested under the name SHUTi) has received a stamp of authorization as the first FDA-authorized prescription digital therapeutic indicated to treat insomnia. As Somryst is available by prescription only, patients will need to pay a fee for a consultation appointment to receive a prescription. Access to the full 9-week program is then granted at a cost (currently $900), which may be covered by some insurance plans, or paid for using funds from flexible savings accounts or health savings accounts. Unfortunately, the company which offered Somryst (Pear Therapeutics) filed for bankruptcy in 2023. Rights to Somryst were acquired by Nox Health, and there is no current knowledge of how patients will be able to access this treatment in the future.

One option is for users to download the Insomnia Coach app which is free of charge. Insomnia Coach was developed for veterans and service members by Stanford researchers along with the US Department of Veteran Affairs/Veterans Health Administration and the US Department of Defense but is available to everyone. A pilot study found Insomnia Coach to be an acceptable and feasible form of treatment in veterans with moderate insomnia symptoms [32]. This study also showed potential efficacy in treating insomnia disorder in veterans; however, fully powered RCTs will need to be conducted to confirm the significance of this findings. Given the large untreated population of insomnia patients, Insomnia Coach may represent a convenient and accessible option for self-guided insomnia intervention.

A clear idea of the cost-effectiveness between fully automated and therapist-supported iCBT-I programs will provide a foundation for decision-making about development of future interventions as well as administration of currently existing interventions. This line of research may also reveal associations between demographic factors and response to

either form of intervention, which can also be used to aid clinical decision-making.

Conclusion

With the speed that novel digital health approaches for insomnia are being developed and implemented, it is certainly an exciting time. The next decade promises the launch of several new iCBT-I programs across many different countries, in different languages, and tailored to different populations. By addressing the issues related to treatment optimization, personalization of treatment, and cost-effectiveness of different iCBT-I approaches, researchers can usher in a new era of insomnia care in which most patients are not only able to receive evidence-based care for their insomnia but are able to receive a first-line recommended behavioral treatment before resorting to second-line treatments like hypnotic medications. Given the effects of insomnia on physical and mental quality of life, as well as work productivity, absenteeism, and healthcare utilization, developing and increasing access to more effective insomnia treatments will have significant positive downstream impacts on the individual and society as a whole.

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Declarations

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