NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-HTE10068 Digital technologies delivering CBT for insomnia in adults

Final scope

1. Introduction

The technologies included in this NICE HealthTech evaluation are digital technologies delivering cognitive behavioural therapy for insomnia (dCBT-I). The technologies are proposed to be assessed for routine use. Routine use assessments consider HealthTech products that address a national NHS unmet need and may be suitable for routine widespread use in the NHS. Recommendations are based on assessment of clinical and cost effectiveness, or cost comparison. This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the previous version of the NICE HealthTech programme manual which was in place at the time this topic started scoping. This guidance will update and replace NICE's medical technologies guidance HTG624 (previously named MTG70) on Sleepio to treat insomnia and insomnia symptoms.

2. The condition

Insomnia is characterised by difficulties with sleeping, including difficulty with falling asleep, waking during the night, and waking up early. People with insomnia may experience 1 or more of the following symptoms:

- Fatigue/malaise
- Attention, concentration or memory impairment
- Impaired social, family, occupational or academic performance
- Mood disturbance or irritability

- Behavioural problems (for example, hyperactivity, impulsivity, aggression)
- Reduced motivation, energy or initiative
- Proneness for errors and or accidents
- Concerns about or dissatisfaction with sleep

Over a prolonged period, insomnia can impact health-related quality of life. Common triggers of sleep problems include stress, poor sleep habits, mental health conditions (such as anxiety disorders, depression, neurodiverse conditions and psychosis) and physical health conditions (such as chronic pain or diabetes). Some medications may also have a side effect of sleep problems (e.g. endocrine drugs). Riemann et al., 2023 reports comorbidities (simultaneously present conditions) and contributory factors to chronic insomnia. Examples include depressive disorders, cardiovascular disorders, obstructive sleep apnoea, neurodegenerative diseases and alcohol use.

It is reported that up to 10% of the adult population in Europe have insomnia (Riemann et al., 2023). Many people are believed to be living with undiagnosed insomnia, having not presented to healthcare services to receive a formal diagnosis of insomnia. Data has shown that self-reported insomnia symptoms were more common in females than males (de Lange et al., 2024), with insomnia prevalence also estimated to be higher in females than in males (statistically significant odds ratio of 1.58 reported in Zeng et al., 2020). It has been estimated that 40% to 60% of menopausal women report poor sleep quality and around 25% of menopausal women meet the criteria for an insomnia disorder (Ballot et al., 2017).

3. Current practice

3.1 Diagnosis

A diagnosis of insomnia is typically made following an initial assessment by a healthcare professional in primary care, or in secondary care if people are already being treated for a concurring condition. People in some areas may also be able to go down a self-referral route, through which triaging programmes may be used to diagnose insomnia. NICE's Insomnia clinical

knowledge summary (last revised 2025) recommends that assessment for suspected insomnia should include aspects such as an assessment of their symptoms and sleep history, review of any current medication, past and current medical history and substance use. Other investigations that may be considered include keeping a sleep diary. Where appropriate, screening for depression and anxiety may be done, or a physical examination to help identify co-occurring conditions. A referral to secondary care may be made for an assessment of co-occurring conditions or other sleep conditions which may mask as insomnia (e.g. circadian rhythm disorders, obstructive sleep apnoea or restless legs syndrome), if these are suspected. Some services may be able to screen for other sleep conditions using validated questionnaires, for example the STOP-BANG Score for sleep apnoea. GPs in primary care are, however, unlikely to be able to diagnose other sleep conditions, so onward referral may be necessary.

The European Insomnia Guideline (2023) notes that the following diagnostic criteria for insomnia are broadly aligned:

- International Classification of Diseases-11 (ICD-11)
- International Classification of Sleep Disorders (ICSD-3-TR, since 2023).
- Diagnostic and Statistical Manual of The American Psychiatric Association (DSM-5-TR, since 2022).

Other diagnostic criteria may still be in use in some areas. NICE's Insomnia clinical knowledge summary states that a diagnosis of insomnia should be made if despite adequate time and opportunity to sleep, the person has persisting difficulty in getting to sleep, difficulty maintaining sleep, or non-restorative sleep that results in impaired daytime functioning or wellbeing. Insomnia diagnosis is classed as short-term if the symptoms have been present for less than 3 months. Long-term (chronic) insomnia is diagnosed if symptoms occur on at least 3 nights per week for 3 months or more. Some people may be living with insomnia without having had a formal diagnosis. People may experience sleep related symptoms but not fulfil the diagnostic criteria for insomnia. NICE's Insomnia clinical knowledge summary states that

sleep difficulties without daytime impairment do not meet the diagnostic criteria for insomnia.

3.2 Treatment

For many people experiencing sleep problems, these may resolve within a few weeks with minimal to no intervention. For example, if sleep is disturbed due to a life situation/short-term stressor. For people living with insomnia, symptoms will not resolve naturally, so they may seek interventions. NICE's Insomnia clinical knowledge summary summarises the latest guidelines on managing insomnia in primary care, based on whether it is short term (less than 3 months) or long term (more than 3 months). It is understood that in practice treatment options for insomnia vary by region across the NHS. Many people with a diagnosis of insomnia do not have access to recommended insomnia treatment options in the order in which they are recommended, or at all. People may therefore turn to self-management techniques (e.g. over-the-counter medication, alcohol) to help manage their condition. The following sections outline the recommended treatment options for insomnia.

3.2.1 Sleep hygiene and Z drugs

Sleep hygiene aims to increase awareness of behavioural, environmental, and temporal factors that may be detrimental or beneficial to sleep. For example, noise, temperature, and light in the bedroom environment as well as comfort. Discussion about use of caffeine, nicotine, alcohol and medication, prescribed or non-prescribed, is also important. For short-term insomnia, NICE's Insomnia clinical knowledge summary recommends advice about sleep hygiene to be offered first. If this does not work and people are experiencing severe daytime impairment that is causing significant distress, a 3- to 7-day course of a non-benzodiazepine hypnotic medication (Z drugs) can be considered. Hypnotic medication should only be considered if symptoms are likely to resolve quickly (for example because of a short-term stressor), and long-term use is discouraged. However, experts have confirmed that long term use of Z drugs happens in practice. NICE's Insomnia clinical knowledge summary notes that treatment with Z drugs should be as short as possible

and should not exceed 4 weeks, including any period of tapering off. CBT-I (see section 3.2.2) during tapering of hypnotic medication is recommended and improves outcomes (Wilson et al. 2019).

3.2.2 Cognitive behavioural therapy for insomnia (CBT-I)

For short-term insomnia, NICE's Insomnia clinical knowledge summary recommends that cognitive behavioural therapy for insomnia (CBT-I) should be offered if sleep hygiene measures fail, daytime impairment is causing significant distress, and insomnia is not likely to resolve soon. For long-term insomnia, CBT-I is recommended as first-line treatment.

CBT-I includes aspects of sleep hygiene, in addition to other core components:

- Behavioural elements: for example, stimulus control to promote a strong association between the bed and sleep. Sleep scheduling (otherwise known as sleep restriction), which involves temporarily reducing the total time spent in bed to more closely match the actual average amount of time the person has been sleeping. Once sleep efficiency (the ratio of time asleep to time in bed) has consistently increased, the total time allowed in bed is gradually extended until an optimal duration is reached.
- Education elements: for example, sleep education and psychoeducation to understand the science of sleep and principles of behavioural change
- Cognitive elements: for example, cognitive restructuring attempts to change inaccurate or unhelpful thoughts about sleep, paradoxical intention to reduce the pressure and anxiety associated with attempts to fall asleep.
- Relaxation elements: for example, progressive muscle relaxation and breathing exercises.

Other components may also be offered as part of CBT-I, for example relapse prevention to promote long-term effects. The proportion of the different components, or sequence in which they are taken, may be tailored or adapted to meet a person's requirements or preferences.

CBT-I may be offered in different formats depending on local service capacity and provision:

- Therapist-led CBT-I that is delivered in-person/virtually by a trained professional (such as sleep specialist nurses, psychological wellbeing practitioners and CBT therapists). This may be on a one-to-one basis, or a group session.
- Digitally delivered CBT-I (dCBT-I), through which a person follows a series of online/digital resources. There may be a component of human oversight with some dCBT-I technologies.

CBT-I may be accessed following diagnosis of insomnia and referral by a healthcare professional, or through a self-referral platform which has a triaging software to identify people with insomnia for whom CBT-I may be offered. Before CBT-I is initiated, factors may be identified during assessment that require signposting, but do not automatically rule out CBT-I as a treatment option. This could include presence of other sleep conditions (e.g. sleep apnoea), mental health conditions, substance use, other medication or methods of self-management. For people who may be at higher risk of other sleep conditions, such as pregnant people or people with comorbidities, a medical assessment is needed before CBT-I is started. Some aspects of CBT-I are contraindicated for some patient groups, such as (but not limited to):

- Sleep scheduling: seizure disorders (e.g. epilepsy), bipolar, untreated sleep conditions
- Stimulus control: severe mobility issues or high fall risk could mean leaving bed during the night is unsafe

In some circumstances, a referral to secondary care may be made once suitability of CBT-I has been established (see section 3.2.4). Specialists can adapt CBT-I delivery to ensure an individualised approach. For example, complex cases of insomnia in which a person is experiencing other conditions.

In some regions, CBT-I may be available through NHS Talking Therapies, as part of the treatment of co-existing mental health problems. But NHS Talking

Therapies services are not commissioned to treat insomnia as a standalone condition and so these services may only offer CBT that features some sleep related components, rather than complete CBT-I. Clinical experts explained that this is less clinically effective and may leave people feeling frustrated, potentially dismissing any future offers of CBT-I. People may also be able to self-refer to dCBT-I interventions in some areas.

3.2.3 Other pharmacological interventions

Daridorexant is recommended by NICE for treating long-term insomnia in adults, only if CBT-I has been tried but not worked, or where CBT-I is unavailable or is unsuitable (see NICE's guidance on daridorexant). Treatment with daridorexant should be assessed within 3 months of starting and should be stopped in people whose long-term insomnia has not responded adequately. For people over 55 years of age with persistent insomnia, treatment with a prolonged-release melatonin may be considered. If treatment is continued, assessment of whether it is still working should be done at regular intervals. In some areas, other types of medication are believed to be prescribed off-label for the treatment/management of insomnia symptoms, such as the antidepressants mirtazapine, amitriptyline and trazodone. People may be receiving pharmacological interventions for other health conditions, which unintentionally improve (or in some cases, worsen) insomnia.

3.2.4 Referral to secondary care

Referral to secondary care (e.g. a sleep clinic, or specialist with expertise in neurology) should be considered if treatment in primary care has failed, or if there is doubt regarding the diagnosis. For example, if a person has symptoms of another sleep condition, such as narcolepsy or sleep apnoea. Initiation of CBT-I in people who have another underlying sleep condition may pose additional risk. As noted in 3.1, GPs are unlikely to be able to diagnose other sleep conditions (if suspected). A secondary care referral can ensure that the given diagnosis is accurate, and subsequent treatment is appropriate.

4. Unmet need

It is reported that 29% of people self-report experiencing insomnia symptoms, while only 6% of people have received an insomnia diagnosis in primary care (de Lange et al., 2024). It has been reported that there estimated to be around 14 million adults in the UK who are experiencing symptoms of insomnia but have not received a diagnosis (The Sleep Charity, 2024). Without a diagnosis of insomnia (or sometimes even with a diagnosis of insomnia), some people may not be accessing any treatment for their condition, or may instead find ways to self-manage their condition (that are potentially harmful if maintained long-term). Digital technologies delivering CBT for insomnia (dCBT-I) may increase treatment access for people who are living with insomnia but are not receiving any NHS treatment for their condition.

There is considerable variation in practice in the treatment of insomnia. This includes variation in terms of pharmacological treatments offered, with some centres prescribing alternative drugs such as antidepressants or sedating antihistamines. CBT-I is not always offered as first-line treatment for long-term insomnia, due to both lack of availability and lack of awareness of CBT-I and services offering it. In many areas, there is no dedicated CBT-I service so access to CBT-I in any form (therapist-led, group or digital) is limited or lacking. This may be because the number of trained healthcare professionals who can deliver CBT-I is minimal or lacking, and/or because no trust/ICB-level decision has been made to invest in CBT-I. This means many people who could benefit from CBT-I are unable to, with waiting lists for CBT-I of many months to years in some regions. Digital technologies delivering CBT-I may enable people with insomnia to access CBT-I earlier, through means of clinician and self-referral.

A lack of access to CBT-I interventions in some areas means that pharmacological treatments are being offered long-term, despite this not being advised and potentially costly to the NHS. Sometimes people who are taking sleeping pills can feel that they have become dependent on them or have

become tolerant to their effects. Sleeping pills can come with side effects including:

- periods of fatigue (e.g. early morning)
- difficulty concentrating
- constipation or diarrhoea
- falls on arising
- mood and appetite changes.

Digital technologies delivering CBT-I could increase availability of CBT-I options, potentially reducing existing waiting lists for CBT-I and CBT-I wait times for people diagnosed with insomnia in the future. There may be an improvement in NHS staff resource capacity for dealing with more severe or complex cases. Patient groups in geographically remote areas may also benefit from dCBT-I as they are able to access treatment remotely without needing to attend in-person appointments. Digital CBT-I may also reduce prolonged or inappropriate prescription of pharmacological treatments.

5. The technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions. The included technologies will only be assessed within their intended use in terms of target condition and population. Sections □ to 5.4 describe the 6 included technologies, with a summary of these technologies presented in .Table 1. NICE will consider digitally enabled therapies that:

- Deliver the core components of cognitive behavioural therapy for insomnia (CBT-I), with a substantial portion delivered through the technology (rather than being platforms to support therapist-led CBT-I), and
- have appropriate regulatory marking (CE or UKCA mark) where required. Products may also be considered if they are actively working towards the required CE or UKCA mark. And,

- are currently available (or are planned to be made available) for procurement in the NHS.

During scoping, the importance of escalation pathways within digital technologies delivering CBT-I was highlighted. Escalation pathways should ensure that people are able to access onward support/treatment when appropriate. For technologies with a fully automated mode of delivery that do not have a routine component of human oversight, escalation pathways within the technologies are important to ensure that any issues and risks when completing CBT-I programmes are identified and managed appropriately. For technologies with a hybrid mode of delivery, issues and risks may be identified and escalated by both the technology itself and the overseeing healthcare professional.

Table 1: summary of technologies included in the scope

Technology	Regulatory classification	Age indication	Mode of CBT-I delivery	Human component	Duration of access
Sleepful	Expected by March 2026	Adults	Fully-automated	-	Unlimited
Sleepio	Class I CE	Adults	Fully-automated (with algorithm tailoring)	-	1 year after completion
Sleepstation	Class I UKCA	Adults	Hybrid	Give tailored guidance, feedback and encouragement, refer patients directly and receive progress updates and summary reports to inform follow-up care.	1 year after completion
Somnio	Class IIa CE	Adults	Fully-automated (with algorithm tailoring)	-	90 days after registration
Space for Sleep	Class I CE	Adults	Hybrid	Guide users to relevant components, monitor symptom severity, regular check-ins.	1 year after completion
THIS WAY UP	Expected in 2026	Adults	Hybrid (fully-automated option currently only available in Australia)	Evaluating therapeutic effect of the program on the patient's symptoms over time, reviewing module progress.	1 year after completion

5.1 Sleepful (National Centre for Sport & Exercise Medicine/Loughborough University)

Sleepful is a digital structured self-help sleep improvement programme for adults with symptoms of insomnia disorder. The programme does not currently have a CE/UKCA mark, but this is expected by March 2026. The aim of the Sleepful programme is to improve subjective sleep quality by guiding users through evidence-based behavioural and cognitive techniques derived from cognitive behavioural therapy for insomnia (CBT-I). It delivers structured educational content and exercises covering sleep hygiene, stimulus control, sleep scheduling, the management of pre-sleep arousal, and maintaining healthy activity patterns. The programme includes 8 steps that are completed at the users preferred pace. The app provides automatically scored sleep and symptom questionnaires to help users understand the nature and severity of their sleep difficulties and assess whether the programme is likely to be suitable for their needs. Information, advice and guidance is provided using text, video and audio. Alarms and daytime prompts are available if required and a user-completed daily sleep diary provides continuous feedback on progress. The programme is self-managed and requires no clinical supervision or external agency input. The Sleepful programme is free of charge to download and use.

5.2 Sleepio (Big Health)

Sleepio is a CE-marked Class I digital sleep improvement program based on CBT-I. It is intended for the treatment of insomnia and insomnia symptoms in adults aged 18 and above. Sleepio delivers dCBT-I in a fully automated programme without input from a CBT-I-trained and certified therapist. Sleepio can be accessed through supported web browsers and on iOS or Android devices. Sleepio supports import of sleep data through FitBit devices. Course content can be tailored using Sleepio's algorithm, for example by using clinical characteristics and ongoing data from daily sleep diaries to recommend a personalized bed-time and wake-time, with adjustment over time to optimize

sleep efficiency. Access to dCBT-I through Sleepio is available 24/7, which enables those with work, academic, or caring responsibilities to access treatment beyond the typical therapist delivering services beyond business hours. Sleepio is typically used for between 2-6 weeks depending on the individual patient presentation and which treatment elements of dCBT-I they require. Patients are provided with 1 year of access, allowing them to re-engage with content techniques and continue to monitor their sleep with diaries, if needed.

5.3 Sleepstation (Born Digital Health)

Sleepstation is a UKCA marked Class I software intended to deliver digital cognitive behavioural therapy for insomnia (dCBT-I) to adults (18 year and over) for the improvement of sleep health and treatment of insomnia symptoms, insomnia and insomnia disorder. Content is delivered through an online platform consisting of recognised core components of CBT-I, with continuous human support. The full course of dCBT-I delivered through Sleepstation lasts 4 to 8 weeks, although the exact duration varies depending on individual progress and engagement. All users are screened at entry for risk factors and comorbidities, with escalation pathways to NHS services where appropriate. Trained sleep coaches monitor progress and wellbeing, with clinical oversight from senior practitioners. NHS patients access the programme online via self-referral or following referral from a GP, consultant, or NHS/community service. Clinicians can refer patients directly and receive progress updates and summary reports to inform follow-up care.

5.4 Somnio (Mementor)

Somnio is a CE marked Class IIa medical device for treating insomnia in adults. The programme is based on CBT-I and consists of 12 interactive modules which users follow with the guidance of an avatar. Users set individual goals and these are monitored and evaluated throughout the programme. A digital sleep diary is used to record and analyse sleep data such as information on sleep and wake times and general well-being. This sleep data is then used to tailor the programme to the individual user, with

continuous adjustment. After registration and entering the activation code patients gain access to Somnio's CBT-I program for 90 days. All modules, including the follow-up module, can be repeated as often as required by the patients until the end of the license period.

5.5 Space for Sleep (Silvercloud by Amwell)

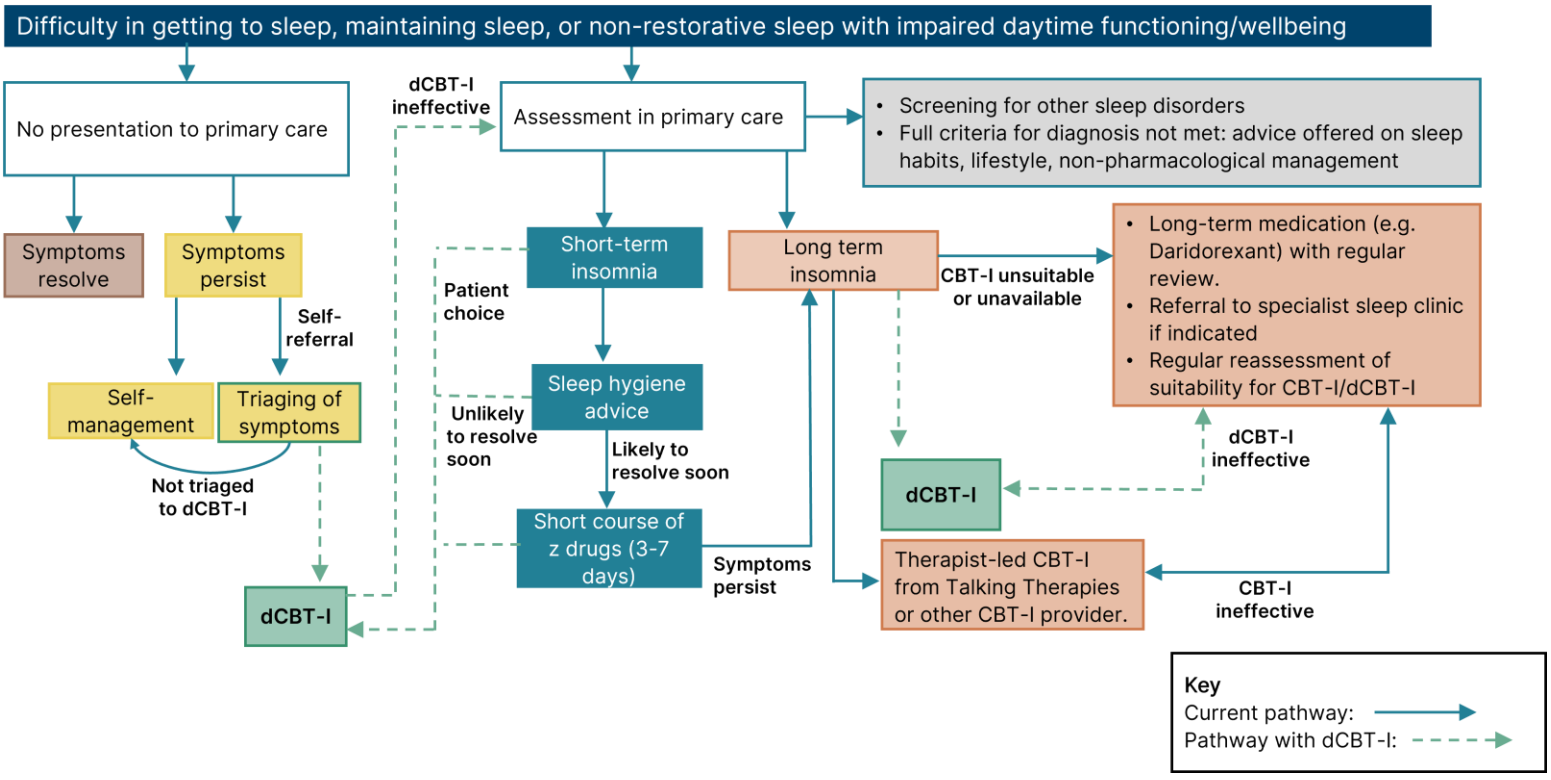
Space for Sleep is an online CBT-I program provided via the SilverCloud platform, that aims to improve the symptoms of insomnia. Each module takes roughly 40-60 minutes to complete, and the user is encouraged to try one module per week. For lower intensity treatment, 4 to 6 sessions are needed, with 8 to 12 sessions for a more intensive level. Typically, a mental health coach will support the user on their journey through the program, with regular check-ins to review their progress and offer guidance. The coach can tailor the program to better suit the needs of the user, for instance a module dealing with sleep scheduling can be unlocked for the user, if it is deemed relevant. The modules follow a robust structure, incorporating videos, informative content, quizzes, interactive activities, as well as homework suggestions and summaries. Throughout their use of the program users are encouraged to keep a sleep diary to monitor the amount and quality of their sleep, and to reflect on the impact the program is having on their daily life. After program completion, the platform enables users to move to a self-help mode so that they can continue to use the content and tools to practice and embed the learning from the treatment. This is usually for a year, but services can tailor this depending on their needs.

5.6 This Way Up (St Vincent's hospital)

THIS WAY UP's Insomnia Program provides online CBT for insomnia. It has been developed, owned and run by not-for-profit public hospital St Vincent's Hospital Sydney Ltd. The program does not currently have a CE/UKCA mark but the company states this is in progress and due to be in place in 2026. The program is delivered in 4 modules, with users able to decide when to engage with the platform and complete their modules (with the exception that users must wait 5 days between modules to give them time to practise the

techniques in each module). On completion of the course, users receive access to the course material for a further 12 months. The intervention is available in Australia entirely self-guided, or prescribed and supervised by a clinician. Currently, the intervention is only available in the UK when prescribed by a clinician, but in future it may also be made available as self-guided. To prescribe the intervention in the UK, registered healthcare professionals must register for an account with THIS WAY UP and agree to the Terms of Use. These terms include a responsibility of the healthcare professional to assess a person's suitability for the program, supervise and monitor progress as the patient completes the program, managing risk and escalating if necessary. The company states that as a standalone CBT-I intervention, there is no additional training required for prescribing healthcare professionals.

Figure 1 Overview of insomnia care pathway and position of dCBT-I technologies



5.7 The place of technologies in the care pathway

Digital technologies delivering CBT-I may be used to provide another option for people seeking treatment for insomnia, providing more patient choice.

Figure 1 provides a general overview of the insomnia care pathway and potential access routes to digital CBT-I technologies depending on whether people follow a self-referral pathway, or have a diagnosis established in primary care.

6. Comparator

Where therapist-led CBT-I is available, the comparator for this assessment is therapist-led CBT-I, which is indicated for short term insomnia after sleeping pills and sleep hygiene, and as first-line treatment for long-term insomnia. As outlined in section 4, therapist-led CBT-I is not widely available across the NHS. The comparator when therapist-led CBT-I is not available may include several options which reflect current NHS practice:

- No treatment: where a person is not receiving any NHS treatment for their insomnia.
- Sleep hygiene: indicated for short-term insomnia (see section 3.2.1).
- Sleeping pills (Z drugs): indicated for short-term insomnia (see section 3.2.1), but may also be offered long term in some areas (see section 4).
- Other pharmacological treatments (see section 3.2.3).

7. Patient issues and preferences

Some people may find different CBT-I technologies/services more effective and suitable for them. Fully automated dCBT-I may work well for people who prefer self-paced learning. Some people may have concerns about fully automated dCBT-I, instead preferring to have input from a healthcare professional as part of dCBT-I to motivate and support them in improving their sleep. People may find it easier (and prefer to) engage with or adhere to CBT-I of a certain delivery mode. Therefore, people may benefit from having a choice of dCBT-I technologies or therapist-led CBT-I services in order to find a solution that is most effective for them. People may also benefit from having a choice between different types of intervention (CBT-I and otherwise).

Some aspects of CBT-I may be challenging, such as sleep scheduling. For some people, leaving their bed during the night may not be possible. For

example, people who are at risk of falling, or those who experience mobility issues. For people who are able to do sleep scheduling, they may experience temporary side-effects, such as increased daytime sleepiness, headaches, fatigue, irritability and difficulty concentrating. These side effects may pose a larger risk to people in critical occupations, such as those operating machinery or driving long distances.

Experts have expressed the importance of digital technologies delivering CBT-I being usable for patients, with technical support available for users. This could improve both adherence to the technologies' CBT-I programmes and the benefits observed from the technologies.

8. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

8.1 Equality considerations related to the condition

- Insomnia is believed to be more common in women than men (de Lange et al., 2024). A prospective cohort study suggested 38% of pregnant women had insomnia, rising to 54% by the third trimester of pregnancy (Flacco et al., 2010).
- Insomnia may be present alongside a mental health condition (e.g. depression and anxiety, Riemann et al., 2023) or neurodevelopmental condition (e.g. autism). The lack of sleep associated with insomnia can contribute to heightened anxiety levels, making it challenging for people to manage stressors effectively.
- People with physical health conditions (e.g. cardiovascular conditions, diabetes, chronic pain and obstructive sleep apnoea) may also experience insomnia. Neurological conditions can also be present alongside insomnia (e.g. restless leg syndrome, multiple sclerosis, traumatic brain injury) (Riemann et al., 2023).

- Factors related to substance use may contribute to chronic insomnia (e.g. alcohol, nicotine, caffeine) (Riemann et al., 2023).
- Insomnia is more prevalent in prison populations than in the general public (Dewa et al., 2017).

8.2 Equality considerations related to the technologies

- Access to CBT-I is limited and varies between regions. Experts highlighted the postcode lottery in CBT-I provision with access generally limited to larger centres with specialist sleep/insomnia services. Digital CBT-I (dCBT-I) technologies could improve access by providing an option for patient groups who are otherwise unable to access CBT-I (e.g. people living in areas of socioeconomic deprivation). People who are unable to attend in-person CBT-I sessions (e.g. people with mobility issues) may benefit from being able to complete dCBT-I remotely, at a time/pace that is convenient for them.
- People may not have access to (or be confident with using) devices on which dCBT-I is delivered (e.g. smartphone, tablet or desktop). The usability of dCBT-I technologies and the level of available technical support may also be important considerations for some people. Some dCBT-I technologies may require an internet connection to enable full functionality, which not all people will have access to.
- Accessibility considerations of dCBT-I technologies include options for different languages, as well as features to promote usability for people with visual impairments, hearing or cognitive disabilities.
- Digital CBT-I technologies may be unsuitable for, or may need to be tailored to make them suitable for some patient groups. For example, people working shifts, people who have cognitive impairment or mental health conditions.

9. Guidance type

Digital technologies delivering CBT for insomnia are proposed to be assessed for routine use. This approach to guidance development is proposed because:

- the level of evidence on the assessed technologies means that some technologies may be suitable for routine widespread use in the NHS
- the assessed technologies (interventions) are not considered established practice in the NHS, so a comparator separate from the interventions can be defined (NICE HealthTech programme manual provides more detail on how established practice is determined)
- the technologies are potential transformative or disruptive innovations, as defined by the Department of Health and Social Care's medical technology innovation classification framework.

10. Decision problem

The key decision question for this assessment is:

- Are digital technologies delivering CBT for insomnia offering cost-effective use of NHS resources?

Table 2: Decision problem

Proposed type of assessment	Routine use
Population	Adults (aged 18 and over) who have insomnia and for whom CBT-I is suitable. If the evidence allows, the following subgroups may be considered: • People with physical comorbidities • People with mental comorbidities
Interventions	Digital technologies delivering CBT-I that have a hybrid delivery (with an element of human oversight) • Sleepstation • Space for Sleep • This Way Up Digital technologies delivering CBT-I that have an automated delivery (without any element of human oversight) • Somnio • Sleepful • Sleepio

Comparator	Current NHS practice may be comprised of several treatment options, with proportions varying depending on whether it is short-term or long-term insomnia, and by region. Current NHS practice includes: • Therapist-led CBT-I • No CBT-I available Where no CBT-I is available, current practice may include no NHS treatment being received, sleep hygiene and pharmacological treatments (see sections 3.2.1 and 3.2.3). See section 6 for more information on the comparator.
Setting	Primary care (e.g. GP practices, NHS Talking Therapies), specialist secondary care settings (e.g. sleep clinics), community settings
Outcomes and costs (may include but are not limited to)	**Intermediate outcomes:** • Uptake, adherence and acceptability of dCBT-I interventions • Time to intervention initiation • Change in use of pharmacological treatments **Clinical outcomes:** • Daytime functioning • Adverse events • Insomnia remission **Sleep related outcomes:** • Sleep quality • Sleep quantity • Total sleep time • Sleep efficiency • Reduction in sleep-onset latency • Reduction in wake after sleep onset • Sleep-related satisfaction and quality of life • Symptoms of comorbid health conditions (mental and physical) directly impacted by difficulty sleeping **Other patient-reported outcomes:** • Patient satisfaction • Health related quality of life measures **Costs and resource use:** • dCBT-I costs • Primary care appointments • Secondary care referrals • Prescription of pharmacological treatments • Service productivity, workforce utilisation, and operational efficiency

Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

11. Other issues for consideration

11.1 Support and maintenance

Sites procuring digital CBT-I technologies may require ongoing support from manufacturers, to ensure they can continue to adopt and implement them.

11.2 Outcome reporting

Outcome reporting from digital technologies delivering CBT-I could enable regulation and audit of their effectiveness.

NICE team

Sophie Harrison and Simon Webster (topic leads), Bernice Dillon

Technical team

Toni Gasse, Elaine Sale

Project team

January 2026