

Sleepio to treat insomnia and insomnia symptoms

Medical technologies guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guidance replaces MIB129.

1 Recommendations

- 1.1 Sleepio is recommended as a cost saving option for treating insomnia and insomnia symptoms in primary care for people who would otherwise be offered sleep hygiene or sleeping pills.
- 1.2 For people who may be at higher risk of other sleep disorder conditions, such as in pregnancy, or in people with comorbidities, a medical assessment should be done before referral to Sleepio.
- 1.3 More research or data collection is recommended on Sleepio for people who are eligible for face-to-face cognitive behavioural therapy for insomnia (CBT-I) in primary care. This is because there is limited clinical evidence to show how effective Sleepio is compared with face-to-face CBT-I. Find out more in the [further research section](#).

Why the committee made these recommendations

Usual treatment for people with sleep problems is advice about sleep hygiene. Sleeping pills may also be considered if insomnia symptoms are likely to resolve soon. If insomnia symptoms are not likely to resolve soon, best practice is to refer for face-to-face CBT-I, although its availability in the UK is limited. This clinical pathway is outlined in the [British Association for Psychopharmacology \(BAP\) consensus statement on insomnia](#). People who may be at higher risk of other sleep disorders including sleep apnoea should have a medical assessment before referral to Sleepio.

Sleepio is a digital self-help programme that includes CBT-I. It could therefore increase patients' access to CBT-I. It also increases the options available to GPs treating insomnia.

Clinical evidence shows that Sleepio reduces insomnia symptoms compared with sleep hygiene and sleeping pills. There is no direct evidence of its effectiveness compared with face-to-face CBT-I, so further research is recommended in this context.

At a price of £45 per person, Sleepio is cost saving compared with usual treatment in

primary care. This is based on an analysis of primary care resource use data before and after Sleepio was introduced in 9 GP practices. Healthcare costs were lower at 1 year, mostly because of fewer GP appointments and sleeping pills prescribed.

2 The technology

Technology

- 2.1 Sleepio (Big Health) is a self-help sleep improvement programme based on cognitive behavioural therapy for insomnia (CBT-I). It is primarily accessed through a website. There is a Sleepio app for iOS mobile and Android devices. The iOS app can be linked to a compatible wearable fitness tracker to monitor sleep (currently Fitbit and any other device that uses Apple's HealthKit). The Android app can be linked to Fitbit.
- 2.2 The programme is structured around a sleep test, weekly interactive CBT-I sessions and regular sleep diary entries. The sessions focus on identifying thoughts, feelings and behaviours that contribute to the symptoms of insomnia. Cognitive interventions aim to improve the way a person thinks about sleep and the behavioural interventions aim to promote a healthy sleep routine. The programme is designed to be completed in 6 weeks, but people have full access to the programme for 12 months from registration, including redoing sessions. They can also access electronic library articles, online tools and the online Sleepio user community. A daily sleep diary helps users track their progress and the programme tailors advice to individuals. Users can fill in the diary manually or the data can be automatically uploaded from a compatible wearable tracking device.

Care pathway

- 2.3 The British Association for Psychopharmacology (BAP) consensus statement on insomnia describes treatment options for adults with poor sleep, which depend on how long they have had insomnia symptoms. People are first offered advice about sleep hygiene. If this does not work and they are severely impaired during the day, and it is causing significant distress, a 3- to 7-day course of a non-benzodiazepine hypnotic medication can be considered. Hypnotic medication should only be considered if symptoms are likely to resolve quickly (for example

because of a short-term stressor). If symptoms are not likely to resolve soon, face-to-face or digital CBT-I should be offered. Currently, face-to-face CBT-I is not routinely available on the NHS for most people with insomnia. A short-term course of hypnotic medication can be offered in addition to CBT-I but should not be offered routinely. People should be offered follow-up consultations every 2 to 4 weeks to review their symptoms.

- 2.4 [NICE's clinical knowledge summary on insomnia](#) summarises the latest evidence on managing insomnia in primary care, based on whether it is short term (less than 3 months) or long term (more than 3 months). For both, the advice is to consider referral to a sleep clinic or neurology if the person has symptoms of another sleep disorder, and to address whatever might be causing the insomnia. It also advises making sure comorbidities such as anxiety and depression are managed. It gives the same advice on sleep hygiene, hypnotic medication and CBT-I as BAP.
- 2.5 People with insomnia often also have a mental health problem. [NICE's guideline on common mental health problems](#) recommends assessing people using the improving access to psychological therapies (IAPT) screening tools and validated scales. Treatment depends on symptom severity and includes education, monitoring, CBT and medication.

Innovative aspects

- 2.6 Sleepio uses an artificial intelligence (AI) algorithm to provide people with tailored digital CBT-I. There is also support available from a Sleepio community, which includes clinical experts and other people with insomnia.

Intended use

- 2.7 Sleepio is primarily intended as an alternative to usual treatment, which includes sleep hygiene education and hypnotic medication. People can get Sleepio through self-referral, or through primary care or IAPT services. People who have mental health conditions managed in routine care who are using Sleepio may benefit from having a healthcare

professional involved.

Training

- 2.8 The company offers primary care training on prescribing Sleepio, technical training and set up.

Costs

- 2.9 The cost of Sleepio is £45 (excluding VAT) per person who starts session 1 of the Sleepio programme. This price was proposed at consultation and differs from the previous cost models proposed by the company, which depended on regional uptake of Sleepio. The 2 previous cost models, the population-based and the tiered licence-based cost model, are outlined below.
- 2.10 The population-based cost model involved a cost per head per year depending on the size of the population within a region. This cost was independent of the number of people that used Sleepio. The larger the population, the lower the cost per head. Because a fixed price is paid by NHS organisations each year, increased uptake led to an increase in cost savings.
- 2.11 The tiered licence-based cost model was based on the number of people who had treatment with Sleepio. This was a tiered pricing system, so the cost per patient reduced as uptake increased beyond the number of people specified within each of the fixed tiers. For more details of these prices, see the [supporting documents for Sleepio on the NICE website](#).

For more details about the technology, see the [website for Sleepio](#).

3 Evidence

NICE commissioned an external assessment centre (EAC) to review the evidence submitted by the company. This section summarises that review. [Full details of all the evidence are in the project documents on the NICE website.](#)

Clinical evidence

The clinical evidence comprises 28 studies, 12 of which are randomised controlled trials

3.1 The EAC assessed 25 full text publications, an unpublished study and 2 abstracts. Twelve of the studies were randomised controlled trials (including 6 secondary analyses of randomised controlled trials). Six were non-randomised studies and there was 1 abstract. Also, the company provided the EAC with 2 unpublished, real-world evidence studies. For full details of the clinical evidence, see section 3 of the assessment report. Find the [assessment report in the supporting documents for Sleepio on the NICE website.](#)

The 12 randomised controlled trials are relevant to the decision problem and show that Sleepio reduces symptoms of insomnia

3.2 There is good quality evidence that Sleepio improves sleep in people with self-reported insomnia symptoms (according to DSM-5 [Diagnostic and Statistical Manual of Disorders 5], SCI [Sleep Condition Indicator] and ISI [Insomnia Severity Index] measures). The most robust evidence for Sleepio comprises 12 randomised controlled trials, 10 of which used intention-to-treat analyses to control for high drop-out rates. The studies are small relative to the potential reach of Sleepio but are adequately powered and well reported.

The UK population is well represented in the evidence for Sleepio

3.3 The UK population is well represented in the evidence base for Sleepio,

which includes 7 UK studies and 4 multinational studies that included UK populations. Four of the studies done in the UK were randomised controlled trials (Espie et al. 2012, Freeman et al. 2017, Denis et al. 2020 [pilot study], Kyle et al. 2020); all concluded that Sleepio was more effective in reducing insomnia symptoms than the comparator (standard care, waiting list, placebo or attention control).

The evidence is heterogenous

- 3.4 The studies included in the assessment varied in design, population, outcome measures and comparators. Study participants included people with difficulty sleeping with or without medical and mental health comorbidities, and different durations of insomnia. The comparator differed between studies and often the description of standard care lacked clarity. It was unclear whether standard care included aspects of cognitive behavioural therapy for insomnia (CBT-I), the hypnotic medication prescription, or both, and there was little information about what was offered as sleep hygiene education.

There is limited evidence comparing Sleepio with face-to-face CBT-I or other forms of digital CBT-I

- 3.5 The company acknowledged that the lack of evidence comparing Sleepio with face-to-face CBT or digital CBT-I was a limitation. It said that face-to-face CBT-I for insomnia is not routinely available on the NHS and is not scalable to the UK NHS population. There is a meta-analysis (Soh et al. 2020) that indicated that digital CBT-I is non-inferior to face-to-face CBT-I. A network meta-analysis (Hasan et al. 2022) compared various forms of digital CBT-I with face-to-face CBT-I. The authors concluded that web-based CBT-I with a virtual or real therapist offers better outcomes than other digital CBT-I approaches (web-based CBT-I without a therapist, telephone-based CBT-I and mobile app-based CBT-I). Sleepio includes a virtual therapist. The authors also reported that, although web-based CBT-I with a therapist resulted in reduced insomnia symptoms when compared with educational therapy, face-to-face CBT-I was superior to both these interventions. The authors said that the meta-analysis included relatively few studies that included face-to-face CBT-I and that the follow-up effects of digital CBT-I were

unavailable. There are currently no studies that compare Sleepio with other digital CBT-I technologies.

Cost evidence

The company used a single cohort spreadsheet model to compare the cost of Sleepio with treatment as usual and face-to-face CBT-I

- 3.6 The company submitted 12 economic studies relevant to the economic assessment. The EAC found 3 of them met the decision problem. The company's economic analysis modelled a population of adults with insomnia symptoms. The model compared Sleepio with 2 comparators: treatment as usual (which includes sleep hygiene and sleep medication) and face-to-face CBT-I. The model assumes that treatment with Sleepio is clinically equivalent to both comparators and so includes only the resource impact and no clinical outcomes. The company's analysis in the initial submission is based on the population-based price (see [section 2.10](#)).
- 3.7 The cost impact and proportion of patients using Sleepio are based on data from Sampson et al. (2021). The key costs were:
- Sleepio at £45 per adult who starts session 1 of the programme. This price was proposed at consultation. The [supporting documents for this guidance](#) describe the cost model results with the other prices mentioned in section 2.
 - Sleep hygiene at £0.
 - Face-to-face CBT-I at £492 (this was changed by the EAC to £542 to account for inflation) per adult.
 - Primary care resource use per user in years 1, 2 and 3 at £49.52, £43.52 and £42.05 respectively.

For full details of the cost evidence, see [section 4 of the assessment report in the supporting documents](#).

The EAC concluded that the statistical analysis in Sampson et al. (2021) is robust

3.8 The committee asked the EAC to review the statistical analysis described in Sampson et al. (2021) and explore if it was possible to link the NHS data with the data from Sleepio to better understand the outcomes associated with its use. Patient-level data was made available to the EAC, who replicated the multilevel generalised linear model described in the paper. It was not possible to link the NHS data to the data available from Sleepio users about usage and weekly sleep score. The EAC also investigated adding an individual patient level to the generalised linear model, the impact of seasonal adjustment, and relevant comorbidities. It found that the resource use saving results from the statistical model did not change significantly from those reported in the study (£6.64 compared with £5.53 per patient per year in the EAC model). It concluded that the Sampson et al. (2021) results are robust enough for use in the economic modelling for Sleepio.

The EAC's updates to the cost model make Sleepio cost saving compared with treatment as usual

3.9 After consultation, the EAC ran the cost model with the new price proposed at consultation. The base case shows that after 1 year, compared with treatment as usual, Sleepio is cost saving by £4.52 per person. If the results of resource savings at 1 year are extrapolated to 3 years, the cost savings are £90.08 per person. The EAC noted that with this price, the results do not depend on the uptake of the technology.

4 Committee discussion

Treatment pathway

Sleepio can be used to treat symptoms of insomnia after primary care referral

- 4.1 The evaluation considered Sleepio as a treatment for the symptoms of insomnia. The proposed patient population included people with symptoms or a diagnosis of insomnia. The committee accepted that this broad population was relevant and understood people could be referred to this technology by their GP or social prescriber if they live in a region where Sleepio is available. The committee accepted that insomnia symptoms are a common problem and that Sleepio has the potential to benefit many people.

The most relevant comparator is treatment as usual including sleep hygiene advice and short-term medication

- 4.2 Sleepio provides a sleep improvement programme based on cognitive behavioural therapy for insomnia (CBT-I) for people with clinically diagnosed insomnia or symptoms of insomnia. Clinical experts explained that the gold standard treatment for clinically diagnosed insomnia that is unlikely to resolve soon is face-to-face CBT-I, but its availability is limited in the NHS. Instead, they agreed that the most relevant comparator to treat clinically diagnosed insomnia and insomnia symptoms that are likely to resolve soon is 'treatment as usual', which includes sleep hygiene education and hypnotic medication. Several other digital technologies provide CBT-I or other support for people with clinically diagnosed insomnia and insomnia symptoms, but their uptake and use is limited. The committee concluded that the appropriate comparator for people with clinically diagnosed insomnia and insomnia symptoms that are likely to resolve soon is treatment as usual consisting of sleep hygiene advice and short-term medication.

Sleepio has the potential to provide another CBT-I option

- 4.3 Clinical experts explained that digital CBT-I, such as Sleepio and other digital CBT-I technologies, increases the options available to primary and secondary care practitioners when treating insomnia. They explained that the gold standard treatment for insomnia is face-to-face CBT-I, but its availability is very limited in the NHS. The committee considered that there is space in the care pathway for Sleepio. It concluded that Sleepio has the potential to provide another option for people who would benefit from access to CBT-I.

Clinical-effectiveness overview

Sleepio is effective at reducing insomnia symptoms compared with treatment as usual

- 4.4 The committee noted the large evidence base for Sleepio, and that the 28 studies in the evidence base included a range of patients who had a diagnosis or symptoms of insomnia. The external assessment centre (EAC) explained that changes in lifestyle are expected as part of treatment as usual, but it is unclear whether there was any explicit control for these factors in the evidence. The committee concluded that the evidence shows that Sleepio is more effective than treatment as usual in reducing symptoms of insomnia in adults.

The limited evidence comparing Sleepio with face-to-face CBT-I means it should not be prescribed to people who would be offered face-to-face CBT-I

- 4.5 The EAC explained that it did not identify any studies that compared Sleepio with other methods of delivering CBT-I directly (for example face-to-face or other digital methods) and had clinical outcomes. Clinical experts confirmed that other digital devices are available that also deliver digital CBT-I. They considered that the clinical effectiveness of Sleepio is likely to be comparable to other digital devices delivering CBT-I as well as face-to-face CBT-I, but recognised that there are some advantages to the latter. The committee noted that, although the Sleepio

programme includes a virtual therapist, a real therapist is not present during any of the sessions. The EAC also highlighted 2 network meta-analyses (Soh et al. 2020 and Hasan et al. 2022) that explored the effectiveness of various digital CBT-I and face-to-face CBT-I and broadly concluded that the clinical effectiveness of these treatments is likely to be similar. The committee noted some limitations with these meta-analyses, for example few of the included studies assessed face-to-face CBT-I. It recognised that the lack of comparative clinical evidence between Sleepio and face-to-face CBT-I was a limitation in the evidence. The committee concluded that people should not be referred for Sleepio if they are eligible for and have access to face-to-face CBT-I.

Drop-out rates

There are high drop-out rates with Sleepio, but these are thought to be consistent with other forms of CBT-I

4.6 The evidence shows a high drop-out rate for people using Sleepio, from 11.2% (Luik et al. 2017) up to 61.6% (Freeman et al. 2017). High drop-out rates were also observed from the rollout of Sleepio in Buckinghamshire. These occurred throughout the programme from session 1 to session 5. The EAC highlighted that the definition of a drop-out varied among these studies. The committee noted that the meta-analysis (Soh et al. 2020) that compared digital CBT-I (including Sleepio) and face-to-face CBT-I reported similar levels of engagement and completion in both arms. Clinical experts explained that in some cases people's insomnia symptoms can resolve after sleep hygiene advice or active CBT-I treatment. The Sleepio programme includes sleep hygiene advice and active CBT-I treatment, and it is possible some people's symptoms may resolve before completing all 6 sessions of the programme. However, the reason for participants dropping out was not recorded, so people may have left the programme because their symptoms did not improve. The committee concluded that the direction of bias as a result of high drop-out rates with Sleepio is unclear, but recognised that high drop-out rates are common with CBT-I in general and not specific to Sleepio.

Other patient benefits or issues

Sleepio may be another option for pregnant women, who currently have fewer options to treat insomnia

- 4.7 The EAC identified 2 studies that assessed digital CBT-I in pregnant women (Felder et al. 2020 and Kalmbach et al. 2020). The studies concluded that Sleepio is more effective than control in treating insomnia symptoms. The clinical experts highlighted how important it is to do a medical assessment in pregnant women before referral to CBT-I, because insomnia can mimic other conditions like restless legs, or it could be a consequence of undiagnosed sleep apnoea. The clinical experts also explained that, although hypnotic medication is avoided in pregnant women, some drugs are given for short courses when symptoms are likely to resolve soon. The committee concluded that Sleepio may be an alternative option for insomnia symptoms in pregnant women who have had a medical assessment to rule out other conditions.

Following the Sleepio programme can be challenging but the Sleepio community provides support

- 4.8 The patient expert described the sleep restriction component and quarter-hour rule as particularly challenging aspects of the Sleepio programme that were difficult to implement, especially in the beginning. These challenges were also reported by people who responded to the patient survey. The patient expert said the support from the Sleepio website community was particularly helpful during this time. The company said that the community is monitored by volunteers with experience of using Sleepio. It also said that Sleepio users can access a weekly question and answer session on the Sleepio forum, facilitated by a clinical psychologist who specialises in insomnia. The committee noted the importance of the Sleepio community and its role in supporting people using Sleepio.

Sleepio may be difficult to use for some people

- 4.9 Sleepio requires access to a computer and the internet, which some

people do not have at home. The patient expert said that it was possible to use Sleepio by accessing the internet occasionally (for example, at a public library) and keeping a paper sleep diary, but that this was more difficult. Some users of Sleepio may find it difficult to use a computer, such as people with a visual or cognitive impairment, limited manual dexterity or hearing impairment. The patient expert said that using Sleepio was relatively straightforward and that people with minimal computer skills could use it. But they agreed that some skill in using a computer is needed. They added that the Sleepio community can help people who need it. Also, Sleepio may be difficult to use for people who have limited English language skills. The company noted that the programme is being restructured so it can be translated into other languages. The committee accepted that Sleepio would be harder to use for some people with access or language restrictions.

Training

Patient selection and the implementation model used for introducing Sleepio might affect patient uptake

- 4.10 The company said that during the roll out of Sleepio they noticed that the different levels of training it provided for referring services (such as GP practices) affected the uptake of Sleepio. It said that training and support varies depending on the implementation model used to introduce it. In the 9 GP practices in Buckinghamshire, which used a comprehensive implementation model, the estimated uptake was 0.94%. Regions that did not have this implementation model had an uptake of 0.54% to 0.55% (Sampson et al. 2021). Clinical experts said patient selection was important to improve the chances of people using Sleepio properly and benefiting from it. They also said it would be helpful to give feedback to referrers, such as GPs, about how many people register to use Sleepio and what impact it has on their insomnia symptoms. This would help to understand outcomes and inform referral and training. The committee agreed that the training and support for referrers has an important effect on patient uptake.

Side effects and adverse events

Adverse events are rare in people using Sleepio

- 4.11 The EAC explained that very few adverse events were reported in the literature, and no serious adverse events were related to using Sleepio. Sleepio has been available in some regions of the NHS since 2013 and unpublished real-world evidence reports that over 100,000 people have used Sleepio in the UK. For full information about adverse events in the studies, see [section 6 of the EAC's assessment report in the supporting documents](#).

Sleepio is unlikely to harm people who have other sleeping disorders

- 4.12 Clinical experts said that some people who present with symptoms of insomnia might have underlying conditions causing their symptoms. They explained that using Sleepio in this population may delay them having more appropriate treatment but is unlikely to cause harm. The company said that it has procedures in place for managing risk and adverse events but that they are uncommon. The committee concluded that Sleepio is unlikely to harm people who have sleeping difficulties because of an underlying condition.

Cost modelling overview

There are uncertainties in the cost modelling because of the limited data available

- 4.13 The resource use captured in the Sampson et al. (2021) study was used to inform the cost modelling. The statistical analysis in this study assumed that all changes in resource use over the study duration were because of the introduction of Sleepio. The committee had concerns about whether the variables included in the generalised linear model adequately captured all the important parameters, such as seasonal affect and comorbidities. The EAC reviewed the statistical analysis

described in the study and confirmed that it was appropriate, and that it gave similar results to its own preferred statistical model. Despite some reassurance on the statistical analysis, the committee understood it was only possible to adjust for known confounders, and the quasi-experimental nature of the study means some uncertainty remains. The EAC also reported that it was not possible to link individual patient data from Sleepio with NHS resource use data. So, from the NHS data it is unclear which patients used Sleepio, if their symptoms improved with use, and what the associated resource impact was. This meant it was not possible to include remission status in the cost modelling. The committee accepted that the data available was limited, particularly around linking user data to NHS system data, and understood that this resulted in uncertainties in the cost modelling.

Potential for cost savings

At the initial proposed prices, the technology was unlikely to be cost saving compared with treatment as usual

4.14 When the population-based price proposed in the company submission was used in the EAC base case, Sleepio was cost incurring compared with treatment as usual after 1 year and 3 years. The main driver of the results was the uptake rate of the technology across the population. The EAC reduced the uptake rate to 0.58% from the company's estimate of 1%, and this increased the cost of Sleepio from £90 to £155.17 per user. The committee agreed with the EAC estimates and noted that any cost savings depended on the uptake rate. The tiered licence-based cost model was proposed after the first committee discussion and the price per user was updated to £66.11. When this cost was applied in the EAC base case, Sleepio was cost incurring by £16.59 per user at the end of year 1 but cost saving by £68.97 per user at 3 years. The committee did not agree that there was enough evidence to extrapolate the data to 3 years and concluded that the cost savings were uncertain.

At the new proposed price, Sleepio is cost saving at 1 year compared with treatment as usual

4.15 At consultation, the company proposed a price of £45 per user. When the EAC applied this new cost in its base case, Sleepio was cost saving compared with treatment as usual after 1 year, and the cost savings increased if benefits were extrapolated beyond 1 year. The committee noted that there were limitations in the economic modelling because of its dependence on the Sampson et al. (2021) study and the lack of remission outcomes. However, the committee decided on balance that at this price the technology was likely to be at least cost neutral and very likely cost saving, and decided to recommend it as an option for people with insomnia and insomnia symptoms who would otherwise receive treatment as usual.

The economic model assumes that Sleepio is clinically equivalent to face-to-face CBT-I but more evidence is needed to evaluate this

4.16 Both the company's and the EAC's cost models assumed Sleepio was clinically equivalent to face-to-face CBT-I. This assumption was based on indirect evidence from several different digital CBT-I interventions. The committee noted that the resource use for these models was based on the Sampson et al. (2021) study, which includes a large population with different severities of insomnia. It noted that it was not possible to identify people who would have been eligible for CBT-I according to the criteria in [NICE's clinical knowledge summary on insomnia](#), to evaluate the clinical effectiveness of Sleepio in that group. Derose et al. (2021) reported reduced resource use for Sleepio users compared with people attending face-to-face CBT-I group sessions in the US. The committee noted however that no clinical outcomes were reported, and it was not clear how generalisable this study is to the NHS in terms of the patient characteristics and type of face-to-face CBT-I used. It concluded that a study on people eligible for CBT-I that includes both resource use data and clinical outcomes is needed to evaluate the resource impact of making Sleepio available to this population.

Further research

A real-world study is suggested to compare the effectiveness of Sleepio with face-to-face CBT-I

- 4.17 The committee concluded that more research is needed on the effectiveness of Sleepio as an alternative to face-to-face CBT-I. It noted that there are some studies comparing Sleepio with face-to-face CBT-I, but the evidence is limited. The committee acknowledged the difficulties of carrying out comparative research, given the accessibility issues with face-to-face CBT-I in the NHS. It understood that a study based on real-world evidence that collects clinical and resource use data in a population eligible for face-to-face CBT-I, may be appropriate. It also considered a link between any Sleepio user data and resource use would help address uncertainties in the economic modelling. The committee also agreed that high-quality, non-UK based direct evidence could be acceptable.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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Accreditation

