NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Sleepio for adults with difficulty sleeping.

1 Technology

1.1 Description of the technology

Sleepio (Big Health) is a self-help sleep improvement programme based on cognitive behavioural therapy for insomnia (CBT-I). It is accessed through a website or an app for iOS mobile devices, and can link to a compatible wearable fitness tracker to monitor sleep (currently Fitbit and any other device that uses Apple's Healthkit). It is available in the NHS apps library.

The programme is structured around a sleep test, weekly interactive CBT-I sessions, and regular sleep diary entries. The sessions are focussed on identifying thoughts, feelings and behaviours that are contributing to the symptoms of insomnia. Cognitive interventions aim to improve the way a person thinks about sleep and behavioural interventions aim to promote a healthy sleep routine. Although the programme can be completed in 6 weeks users can access the programme for 12 months from registration. 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 may be automatically uploaded from a compatible wearable tracking device. The programme does not share the users' data.

Sleepio is accessed via self-referral on the product website or through referral by a health care professional in regions of the NHS where it is commissioned. For patients with mental health conditions managed in routine care, use of Sleepio may benefit from the involvement of a healthcare professional.

1.2 Relevant diseases and conditions

Sleepio is intended for use by people that have difficulty sleeping or have been diagnosed with insomnia. Insomnia is characterised by symptoms of difficulty initiating or maintaining sleep, with subsequent daytime functional impairment (e.g. mood, fatigue, cognitive impairment).

The prevalence of people that have symptoms of insomnia in the population varies widely from 5 to 50% depending on the definition used. Short term insomnia typically lasts less than 3 months; long-term insomnia lasts 3 months or longer.

Around one third of adults in Western countries experience sleep problems at least once a week with 6-10% fulfilling the criteria for insomnia disorder (NICE Insomnia clinical knowledge summary, last updated 2020). Insomnia is diagnosed when symptoms have a negative impact on a person's ability to carry out daily tasks. The International classification of diseases -10 (ICD-10) defines the criteria for insomnia as being difficulty sleeping three times a week or more for at least 1 month. The Diagnostic and Statistical Manual of mental health disorders-5 (DSM-5) defines insomnia disorder as an unhappiness with the quality and quantity of sleep for 3 times a week or more for at least 3 months. Both diagnoses require that the symptoms of insomnia have an impact on a person's ability to carry out daily tasks.

Prevalence of insomnia is higher in people with comorbid conditions and around half of all people with diagnosed insomnia have a comorbid psychiatric disorder such as depression or anxiety (Wilson, 2019)

1.3 Current management

Current management of insomnia is described in guidelines published by the British Association of Psychopharmacology published in 2010 and updated in 2019. Current treatment options for adults with difficulty sleeping is dependent on the duration of the symptoms. People that present with symptoms of insomnia are offered advice about sleep hygiene. If sleep hygiene fails and daytime impairment is severe and causing significant distress, a short course (3-7 days) of a non-benzodiazepine hypnotic medication may be prescribed.

Hypnotic medication should only be considered if symptoms are likely to resolve soon (for example being because of a short-term stressor). If symptoms are unlikely to resolve soon, face-to-face or digital cognitive behavioural therapy for insomnia (CBT-I) should be offered. A short-term course of hypnotic medication can be offered in addition to CBT-I but should not be offered routinely and only for a short period of time. People should be offered regular follow up consultations to review the symptoms. Follow up visits should be between every 2 and 4 weeks.

NICE's Insomnia clinical knowledge summary presents a summary of the latest, evidence-based information on the management of insomnia in primary care. Management is summarised according to short term insomnia (< 3 months) and long term insomnia (> 3 months). For both short term and long term insomnia the advice is to consider the need for referral to a sleep clinic or neurology if symptoms of another sleep disorder are present, and to address any triggers or causal factors for insomnia. In addition, advice is to ensure comorbidities (such as anxiety and depression) are optimally managed. The advice regarding sleep hygiene, use of hypnotic medication and use of CBT-I is in line with the recommendations described above by the British Association of Psychopharmacology guideline.

People with insomnia often present with a comorbid psychiatric condition. NICE's clinical guideline for common mental health problems (CG123) recommends that people are assessed using the improving access to psychological therapies (IAPT) screening tools and validated scales. A person's treatment is dependent on the severity of their symptoms. This approach is referred to as a stepped-care model. Education and monitoring are recommended for people with mild symptoms, computerised and group CBTi are offered to people with moderate symptoms and CBTi and medication are offered to people with severe symptoms.

1.4 Regulatory status

The Sleepio received a CE mark in October 2018 as a class 1 device for adults with difficulty sleeping or insomnia disorder.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Provides effective therapy that directly addresses the behavioural and cognitive underpinnings of insomnia.
- Improves other salient outcomes, particularly to mental health, wellbeing and to quality of life.
- Provides access to CBT for people who otherwise would have been provided with sleep hygiene, non-indicated pharmacotherapy or who would not have received any treatment at all.
- Provides CBT for insomnia in a stigma free environment.
- Eliminates waiting time for CBT for insomnia.
- Reduces hypnotic usage and associated risks i.e. dependency, withdrawal, risk of falls and unresolved insomnia.

The benefits to the healthcare system claimed by the company are:

- Reduces primary care appointments.
- Improves quality of care by enabling primary care to meet clinical guidelines.
- Reduces hypnotic drug prescriptions and associated costs.
- Provision of CBT service where face to face CBT is not available or has long waiting times.
- Improves range of treatment options available to primary care prescribers.
- Reduced downstream costs of untreated insomnia.

2 Decision problem

Population	Adults with difficulty sleeping
Intervention	Sleepio
Comparator(s)	• Sleep hygiene • Hypnotic drugs • Face-to-face CBT for insomnia • Digitally-facilitated CBT for insomnia
Outcomes	The outcome measures to consider include:

	Sleep related outcomes • Sleep quality • Sleep quantity • Sleep-related satisfaction and quality of life • Health related quality of life measures • Symptoms of comorbid health conditions (mental and physical) directly impacted by difficulty sleeping System related outcomes • Access to CBT for insomnia • Waiting time for CBT for insomnia • Number of primary care appointments • Hypnotic drug prescription • Incidence of comorbid health conditions Device related outcomes • Device-related adverse events
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The cost modelling should reflect the business model the company is proposing to use in the NHS, for example if a regional approach is adopted the intervention cost should reflect that rather than the intervention cost when the technology is being purchased per patient. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	• Pregnant women • People who have not had an insomnia diagnosis • People with short term insomnia (symptoms present for less than 3 months) • People with long term insomnia (symptoms present for 3 months or longer) • People with insomnia and a comorbid condition
Special considerations, including those related to equality	Patient-facing digital health technologies such as Sleepio may be unsuitable for people with visual or cognitive impairment, problems with manual dexterity or learning disabilities. Disability is a protected characteristic under the Equality Act. Sleepio is not suitable for those hard of hearing or where English is not well understood.

	Access to internet-enabled devices, access to the internet and user engagement with the technology may be more difficult for the people in deprived communities. Socio-economic status is not a protected characteristic and so is not protected under the Equality Act 2010 but factors affecting access to care delivered using digital devices should be considered. The technology can be used in pregnant women that are contraindicated for hypnotic medication. Pregnancy and maternity are protected characteristics of the equality Act 2010.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable	

3 Related NICE guidance

Published

- Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term management of insomnia (published 2004, last reviewed 2010) NICE technology appraisal guidance 77.

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- British Association of Psychotherapists
- British Neuropsychiatry Association
- British Psychotherapy Foundation
- Faculty of Public Health Medicine
- Institute of Psychiatry

- Royal College of Psychiatrists

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- Anxiety UK
- British Sleep Society
- Mind