## NICE HealthTech Programme

## HTE10068 Digital technologies delivering CBT for insomnia in adults

### Scope consultation - Comments table

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| 1 | Company consultee (Big Health) | 14 | 5 | We welcome the updates to the scope and the increased alignment with MTG70 as highlighted in Figure 1. | Thank you for your comment. |
| 2 | Company consultee (Big Health) | 18 | 10 | *"Are digital technologies delivering CBT for insomnia offering cost-effective use of NHS resources?"*<br><br>We understand the need to assess whether digital technologies offer cost-effective use of NHS resources. Evidence of clinical efficacy and effectiveness are a core part of this. Will NICE determine whether each individual treatment in the MTA is clinically effective, based on product-specific evidence? This is in line with NICE's recommendations where *each* digital treatment technology must independently demonstrate clinical effectiveness under NICE's Evidence Standards Framework (ESF) Tier C standards for Digital Health Technologies (DHT) that treat a condition. Under Standard 14, the framework explicitly requires: "*The studies used to support claimed benefits should be done on the DHT in question*". | Thank you for your comment. Information on the methods and processes the assessment will follow are outlined in the previous version of the NICE HealthTech programme manual (PMG48), and NICE's health technology evaluations manual (PMG36). These manuals were in place when the topic started scoping.<br>Section 2.1.30 of PMG48 noted that "When multiple technologies are considered, each should be assessed independently, unless the committee believes it is appropriate for available data that has been generated using a technology to be used for others. The committee may need to consider any difference between technologies in terms of whether they may solve the specified unmet need and any differences in further evidence needs. Different recommendations can be made for different technologies included in the guidance". Section 3.3 of the external assessment group's protocol notes that "The cost-effectiveness (efficiency) of the different technologies will be considered |

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| | | | | | within a full incremental analysis and supplemented with cost-effectiveness estimates for each technology independently. If evidence does not allow robustly assessing the cost-effectiveness of one or more of the six dCBT-I technologies separately, we will consider the exchangeability of the clinical effectiveness data across technologies and/or class of technologies". |
| 3 | Company consultee (Big Health) | 6 | 3.2.2 | *"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."*<br><br>Prior to this statement, a trained professional delivering face-to-face CBT-I is defined as: "*sleep specialist nurses, psychological wellbeing practitioners and CBT therapists*".<br><br>We require specification of the staffing model for "human oversight" in dCBT-I. This is a required component of the MTA cost-effectiveness analysis and professional oversight must be defined per Standard 6 in NICE's Evidence Standards Framework (ESF). Please clarify the following: Staff grade and credentials (which staff group such as sleep specialist nurse, PWP, or CBT therapist and at what Agenda for Change band, and how this compares to face-to-face CBT-I). Clinical functions that constitute "human oversight" such as asynchronous data review, message response, crisis escalation, initial assessment, and clinical supervision. Time per patient, including approximately how many hours per episode of care. Training requirements including what initial training and ongoing supervision NHS staff would require.<br><br>The NICE Reference Case requires all NHS resource use, including staff time, to be identified, quantified, and costed | Thank you for your comment. This assessment will consider digital technologies that deliver the core components of cognitive behavioural therapy for insomnia (CBT-I), with a substantial portion delivered through the technology. This includes both technologies with a hybrid mode of delivery, and fully-automated technologies. The level of human oversight will depend on the design of the technology. Initial information from companies has highlighted that the level and frequency of human oversight vary and this will be taken into account when each technology is costed in its own right. It is outside of the remit of this NICE assessment to define the staffing model that a technology should have. The external assessment group will consider relevant model inputs in their cost-effectiveness model. This may include clinical inputs, resource use and costs. |

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| | | | | by skill level. These are direct inputs to the ICER and cannot be deferred to local implementation. | |
| 4 | Company consultee (Big Health) | 6 | 3.2.2 | *"A medical assessment may be needed to ensure suitability of CBT-I before it is started. This may be done by a healthcare professional, or appropriate triaging software if a person is using a self-referral platform to access dCBT-I. Factors that may make CBT-I unsuitable for a patient include…"*<br><br>A *"medical assessment"* prior to CBT-I is clinically unnecessary. Technologies should screen for suitability using validated tools for insomnia and should tailor the programme to the needs of individual patients. This is evidenced by NICE MTG70 and by how Sleepio is used in NHS populations in Scotland and in England, in line with that guidance.<br><br>We welcome NICE's recognition that "*appropriate triaging software*" can fulfil the screening function in self-referral pathways. Technologies can and should perform this triaging function as already demonstrated by Sleepio's established practice and MTG70 evidence. The Sleepio triage process is supported by evidence from clinical trials and real-world implementation, including the NICE MTG70 evidence review, which assessed safety and effectiveness across diverse populations accessing via multiple pathways in the NHS.<br><br>1. The scope should remove the requirement for a "Medical Assessment"<br>2. The scope should specify that technologies should screen for suitability factors. | Thank you for your comment. Section 3.1 notes that "diagnosis of insomnia is typically made following an initial assessment", including aspects such as "an assessment of their symptoms and sleep history, review of any current medication, past and current medical history and substance use". Section 3.2.2 outlines access routes for CBT-I: "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". This section then gives examples of factors which may require further signposting, and when a medical assessment is needed: "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" (in line with recommendation 1.2 of HTG624 (previously MTG70)). |
| 5 | Company consultee (Big Health) | 6 | 3.2.2 | "*Acceptability*". *Appropriate as Pre-Treatment Criterion?* **Not appropriate and should be removed.**<br><br>Sleepio has demonstrated high patient acceptability across multiple populations and settings, including primary care, | Thank you for your comment. This section has been amended for clarity. |

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| | | | | employers, and direct-to-patient self-referral pathways. Patient satisfaction and acceptability have been evaluated in clinical trials & cohort studies supporting NICE MTG70. Acceptability is an outcome of treatment experience, not a pre-treatment screening criterion.<br><br>"*Willingness*". *Appropriate as Pre-Treatment Criterion?* **Not appropriate and should be removed.**<br><br>Willingness is demonstrated by access via self-referral itself, i.e., the act of someone seeking treatment. It cannot be reliably assessed beforehand. MTG70 does not exclude the use of Sleepio for patients in the NHS today who have not yet demonstrated '*willingness*'. | |
| 6 | Company consultee (Big Health) | 6 | 3.2.2 | *"Other sleep disorders" Appropriate as Pre-Treatment Criterion?* **Requires clarification.**<br><br>Other sleep disorders may require medical investigation but should not prevent access to digital CBT-I. MTG70 confirms that "*Sleepio is unlikely to harm people who have sleeping difficulties because of an underlying condition*" (Section 4.12). This supports a screening approach rather than exclusion.<br><br>The ACP Clinical Practice Guideline recommends that all adult patients receive CBT-I as the initial treatment for chronic insomnia disorder, including those with comorbid conditions (Qaseem et al., 2016). | Thank you for your comment. This section has been amended for clarity. |
| 7 | Company consultee (Big Health) | 6 | 3.2.2 | *"Drug or alcohol use that would affect their ability to engage" Appropriate as Pre-Treatment Criterion?* **Requires clarification.**<br><br>Severe substance use may impair ability to engage with CBT-I treatment. However, this is detected by screening for severe impairment, not exclusion of all substance users. MTG70 does not exclude the use of Sleepio for | Thank you for your comment. This section has been amended for clarity. |

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| | | | | patients who use alcohol or other substances in the NHS today. | |
| 8 | Company consultee (Big Health) | 6 | 3.2.2 | *"Other medication or methods of self-management". Appropriate as Pre-Treatment Criterion?* **Requires clarification.**<br><br>Current hypnotic medication use should not be an exclusion criterion. CBT-I is effective for medicated patients and supports safe deprescribing (Luik et al., 2020). Over 8 million prescriptions for medicines commonly used to manage insomnia are issued annually in England, with 5 million being for z-drugs (Organista, 2025), and Davies et al., (2017) found that over 297,000 people in England are taking dependency-forming hypnotic medication for far longer than recommended (≥12 months). This population has a significant need for access to CBT-I as an alternative to ongoing pharmacological dependence. Further, other methods of self-management are considered treatment as usual in clinical trials of Sleepio (Espie et al., 2019) assessed in MTG70, and should not constitute an exclusion criterion. This exclusion is not implemented in the way Sleepio is used today in NHS populations in Scotland and in England. | Thank you for your comment. This section has been amended for clarity. |
| 9 | Company consultee (Big Health) | 6 | 3.2.2 | *"Whether a person has significant cognitive impairment or comorbidity". Appropriate as Pre-Treatment Criterion?* **Appropriate - but this is more of a theoretical rather than clinical concern.**<br><br>Severe cognitive impairment may limit engagement, however Sleepio is effective in patients with Mild Cognitive Impairment (Hoyos et al., 2024) and comorbid chronic conditions. Henry et al. (2021; and 2023) and Espie et al., (2019) demonstrate bidirectional improvement when Sleepio addresses insomnia in comorbid populations. Treating insomnia with Sleepio improves comorbid conditions, and addressing comorbidities improves sleep outcomes. | Thank you for your comment. This section has been amended for clarity. |

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| | | | | Therefore, 'impairment' and 'comorbidity' should not be treated as exclusion criteria and should instead be addressed through adaptation, not exclusion. The scope should clarify this distinction. | |
| 10 | Company consultee (Big Health) | 6 | 3.2.2 | *"Patient has severe active psychosis or is currently in crisis". Appropriate as Pre-Treatment Criterion?* **Appropriate - but this is more of a theoretical rather than clinical concern and should be removed.**<br><br>Active psychosis or acute mental health crisis requires immediate clinical intervention, and these patients should be signposted to appropriate services.<br><br>It should be noted that patients in this state are highly unlikely to self-refer to a digital insomnia programme; this criterion has limited practical relevance in a self-referral pathway and was not identified as a concern in MTG70. | Thank you for your comment. This section has been amended for clarity. |
| 11 | Company consultee (St Vincents) | 5 | | The sleep restriction example on p.5 of the Scope document mentions a time in bed window of 4 hours but it is not recommended that one restrict their time in bed to less than 5 hours in standard guidelines, or to potentially the more conservative 5.5 hours in unguided digital CBT. | Thank you for your comment. The description has been updated. |
| 12 | Company consultee (St Vincents) | 5-6 | | Pages 5-6 mention factors that may make CBT-I unsuitable. It may also be worth mentioning that there are some contraindications for sleep restriction including seizure disorders, bipolar disorder, and untreated sleep apnoea, though these are likely mentioned as part of the individual treatment programmes. | Thank you for your comment. This section has been amended to include factors which are contraindicated for aspects of CBT-I. |
| 13 | Company consultee (St Vincents) | 13 | 5.6 | Requested revisions to the section on THIS WAY UP to clarify that St Vincent's owns the program, how the lockout works, and availability of the intervention through the self-guided pathway. Updated wording: | Thank you for your comment. The wording for THIS WAY UP has been updated. |

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| | | | | "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 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 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." | |
| 14 | Consultee 1 | 1 | 1 | Refers to questions from Scoping in Appendix A but not included | Thank you for your comment. This legacy reference has now been removed. |
| 15 | Consultee 1 | 9 | 5 | Given the variance of technologies would it be useful to summarise in table format perhaps in a referenced appendix-this might be easier to read and bring out the differences in a more focussed form and highlight, for example, where a product does not have CE/UKCA marking | Thank you for your comment. A summary table of technologies has been added. |
| 16 | Consultee 1 | General | General | Suggest 'comorbid' needs a fuller definition perhaps as part of a glossary. | Thank you for your comment. A definition has been provided on the first use of this term in section 2: "Riemann et al., 2023 reports |

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| | | | | | comorbidities (simultaneously present conditions) and contributory factors to chronic insomnia". |
| 17 | Consultee 1 | General | General | There is no reference to chemically induced insomnia such as caused by endocrine drugs resulting from chemical menopause symptoms, this may be part of the 'comorbid' reference however there is reference to antidepressants which are often prescribed for side effects so perhaps this needs to be brought out more. dCBT-I may not work for this population. | Thank you for your comment. Section 2 has been updated to include that "Some medications may also have a side effect of sleep problems (e.g. endocrine drugs)". Section 3.1 notes that a review of any current medication should take place during assessment for insomnia. |
| 18 | Consultee 1 | 1 | 1 | References are made to the cost effectiveness of dCBT-I but there is little reference in the document about a framework to assess-although this should not be detailed it should perhaps be outlined | Thank you for your comment. The decision problem for this assessment is outlined in Table 2 of the scope, this outlines the framework for this assessment. Further information on the methods and processes by which the assessment will follow are outlined in the previous version of the NICE HealthTech programme manual (PMG48), and NICE's health technology evaluations manual (PMG36). |
| 19 | Company consultee (Sleepstation) | 1 | 1 | The revised scope was produced after the scoping workshop and there is no Appendix A included. Thus the sentence referencing these should be removed | Thank you for your comment. This legacy reference has now been removed. |
| 20 | Company consultee (Sleepstation) | 2 | 2 | The Morphy 2007 reference gives a figure of 36.8% having insomnia on 'most nights'. However, it is not clear if this is referencing merely to 'sleep problems' or insomnia disorder as the questionnaire they used was not suitably sophisticated. Thus it does not seem to support the statement. | Thank you for your comment. This figure has been updated, reporting "that up to 10% of the adult population in Europe have insomnia (Riemann et al., 2023)". |
| 21 | Company consultee (Sleepstation) | 2<br>16 | 2<br>8.1 | It is unclear where the 6-10% figure quote comes from, the Wilson 2019 paper states that "6–15% are thought to meet the criteria of insomnia in that they report sleep disturbance as well as significant daytime dysfunction" This is significantly different to the 6-10% quoted in the revised scope | Thank you for your comment. This figure has been updated, reporting "that up to 10% of the adult population in Europe have insomnia (Riemann et al., 2023)". |

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| 22 | Company consultee (Sleepstation) | 2<br>16 | 2<br>8.1 | AAMA 2015 merely links to a NICE webpage https://cks.nice.org.uk/topics/insomnia/references/ Assessment to management of adult insomnia. Clinical practice guideline. Alberta Medical Association 2015. However the link on this page does not work and I can find no trace of this document on the Alberta Medical Association website https://www.albertadoctors.org/practice/clinical-resources/clinical-practice-guidelines/ nor anywhere else for that matter. The 2007 https://nperesource.casn.ca/wp-content/uploads/2017/02/insomnia_assessment_guideline07.pdf and 2010 https://albertapt.getclear.ca/df_media/W1siZiIsIjIwMjEvMDIvMDEvMjEvMzgvMDkvNDAyNjc0MmEtZGEzNC00YjljLTg5MzMtMzBmZTYxZTMyYTM3L1RPUCBpbnNvbW5pYV9tYW5hZ2VtZW50X2d1aWRlbGluZS5wZGYiXV0/TOP%20insomnia_management_guideline.pdf?sha=6a4eff807ae6de30 versions are accessible. It is not scientifically appropriate to quote non-peer reviewed publications. | Thank you for your comment. This source has been updated: “insomnia prevalence [is] also estimated to be higher in females than in males (statistically significant odds ratio of 1.58 reported in Zeng et al., 2020).” |
| 23 | Company consultee (Sleepstation) | 2<br>16 | 2<br>8.1 | The Matheson 2017 paper states that “Women are more likely than men to experience insomnia and twice as likely to be diagnosed with insomnia”. “Diagnosis of insomnia” is neither the same as prevalence nor an accurate reflection of prevalence. | Thank you for your comment. This source has been updated: “insomnia prevalence [is] also estimated to be higher in females than in males (statistically significant odds ratio of 1.58 reported in Zeng et al., 2020).” |
| 24 | Company consultee (Sleepstation) | 2<br>16 | 2<br>8.1 | The Ballot 2017 abstract states that “Sleep disturbances become very common during menopause with an estimated 40% to 60% of menopausal women reporting poor sleep quality **and** about 25% meeting criteria for an insomnia disorder.” this is different than the way it is worded in the revised scope which implies that it is 25% of the 40-60% rather than 25% of menopausal woman | Thank you for your comment. The wording here has been updated for clarity: “It has been estimated that 40% to 60% of menopausal women report poor sleep quality and around 25% of menopausal women meeting the criteria for an insomnia disorder (Ballot et al., 2017).” |

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| 25 | Company consultee (Sleepstation) | 2<br>16 | 2<br>8.1 | The Yamamoto 2023 paper references the Baker 2018 reference also given. The other reference given in the Yamamoto paper is Arakane M, Castillo C, Rosero MF, Peñafiel R, Pérez-López FR, Chedraui P. Factors relating to insomnia during the menopausal transition as evaluated by the Insomnia Severity Index. Maturitas. 2011 Jun 1;69(2):157-61. Which quotes a figure of 31.9% having mild, moderate or severe insomnia as measured by ISI, 23.6% having mild insomnia according to the ISI. It is therefore not clear that this data supports the figure in the revised scope of 'more than 25%'. | Thank you for your comment. The statistic on insomnia in perimenopause has been removed for clarity. |
| 26 | Company consultee (Sleepstation) | 3 | 3.1 | Pedantically the European Insomnia Guidelines 2023 does not 'summarise' the DSM-5 diagnostic criteria, with only ICSD-3 is given in table 3 and ICD-11 in table 4. It Merely notes that DSM-5, ICD-11 and ICSD-3 are "broadly similar" | Thank you for your comment. The scope has been updated to note that the "European Insomnia Guideline (2023) notes that the [ICD-11, ICSD-3-TR and DSM-5-TR] are broadly aligned". |
| 27 | Company consultee (Sleepstation) | | | What is the reference for the statement that "People who experience sleep related symptoms in the absence of any daytime impairment are not regarded as having an insomnia disorder. However, these people may be regarded as having insomnia symptoms." | Thank you for your comment. This section has been amended: "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". |
| 28 | Company consultee (Sleepstation) | 3 | 3.1 | Note for future reference that since 2022 it is DSM-5-TR (American Psychiatric Association. (2022). Diagnostic and statistical manual of mental disorders (5th ed., text rev.)) and since 2023 it is ICSD-3-TR (American Academy of sleep Medicine International Classification of Sleep Medicine 3rd ed Text revision (2023)) | Thank you for your comment. This has been updated. |
| 29 | Company consultee (Sleepstation) | 4 | 3.2 | BNSSG ICB 2025, It is not scientifically appropriate to quote non-peer reviewed publications. | Thank you for your comment. This reference has been removed. |

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| 30 | Company consultee (Sleepstation) | 4 | 3.2.1 | Royal Society of Medicine 2019, Expert Consensus on Minimum Standards of Practice in the use of Cognitive Behavioural Therapy for Insomnia (CBT-I) 2019. It is not scientifically appropriate to quote non-peer reviewed publications. | Thank you for your comment. This expert consensus statement was considered to be a useful source of information during scope development. Its reference in section 3.2.1 on reduction of Z drugs has been replaced by a similar statement from NICE's CKS on insomnia. |
| 31 | Company consultee (Sleepstation) | 15 | 7 | Where is the evidence for the statement "For example, some people may prefer to try a dCBT-I intervention before trying z-drugs, perhaps because of concerns about dependency." Would people really go through a 6-8 week course of dCBT-I before getting a short course of 'z' drugs'? | Thank you for your comment. This was included as an example of a preference that may be held by some people, to highlight the importance of patient choice. This example has been removed. |
| 32 | Company consultee (Sleepstation) | 16 | 8.1 | There are legitimate concerns about the use of dCBT-I in pregnancy.<br>Somryst an FDA cleared dCBT-I product state that "Patients with the following conditions or disorders should not use Somryst:- "individuals who are pregnant" (Morin CM. Profile of Somryst prescription digital therapeutic for chronic insomnia: overview of safety and efficacy. Expert review of medical devices. 2020 Dec 1;17(12):1239-48.).<br>The AASM says "Limitations that providers should be familiar with include that nearly all current dCBT-I are in English and exclude: (1) children (except Night Owl and Sleep Easy); (2) patients with moderate to severe depression, bipolar disease, schizophrenia or who are pregnant (except Sleepio); (3) shift workers. https://aasm.org/digital-cognitive-behavioral-therapy-for-insomnia-platforms-and-characteristics/<br>Big Health say "Sleep restriction is not appropriate for everyone. Please consult your doctor prior to initiating Sleepio if you: Are pregnant" https://info.sleepio.com/suitability | Thank you for your comment. Section 3.2.2 has been amended for clarity to note that "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". |

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| 33 | Company consultee (Sleepstation) | 16 | 8.1 | The reference to Mindell 2014 is incorrect. The Journal shows that the relevant paper was made available online on 5th January 2015 and PubMed gives the citation as Mindell JA, Cook RA, Nikolovski J. Sleep patterns and sleep disturbances across pregnancy. Sleep Med. 2015;16(4):483-488. doi:10.1016/j.sleep.2014.12.006 | Thank you for your comment. This reference has been removed. |
| 34 | Consultee 2 | 1 | Title | Maybe I've missed it, but the age applicability of these guidelines doesn't appear to have been clearly defined. Insomnia is something that also affects children and for this CBT-I is also recommended. Does 'for adults' need to be included in the title? | Thank you for your comment. The proposed population is "Adults (aged 18 and over) who have insomnia and for whom CBT-I is suitable". |
| 35 | Consultee 2 | 1 | 2 | You state, 'These symptoms can lead to daytime drowsiness and impact on mood'<br>While diagnostic criteria include sleepiness as a possible symptom of insomnia, it is recognised across the board that clinically, people with insomnia rarely exhibit drowsiness, which implies sleepiness. When people with insomnia complete the Epworth Sleepiness Scale, they consistently score at the low end of the normal range. This is so prominent that daytime sleepiness is used as a differential factor, probably indicating another sleep disorder (e.g. sleep apnoea). This is due to the state of hyperarousal that insomnia induces. Patients with insomnia do however consistently complain of fatigue/exhaustion/tiredness. I feel that the use of the word 'drowsiness' is misleading and reinforces a common misunderstanding about insomnia. I would prefer this were changed to 'fatigue' which is a consistent and accurate feature of insomnia. | Thank you for your comment. This wording has been updated. |

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| 36 | Consultee 2 | 1 | 2 | You state, 'Common causes of sleep problems include….'<br>The word 'causes' implies that sleep problems are secondary and reinforces the myth that if we treat the primary condition, the sleep will resolve. Decades of research shows this is not the case. It also implies that if the associated condition cannot be improved, there is not much that can be done about the sleep.<br><br>We know that while certain underlying conditions may act as predisposing or precipitating factors for insomnia, the perpetuating factors (see Spielman's 3 Ps model) are behavioural and psychological, which lead to conditioned hyperarousal. Essentially the body gets stuck in a rut and repeats the pattern.<br><br>Using the word 'triggers' instead of 'causes' would avoid reinforcing the misleading perspectives outlined in my first paragraph. | Thank you for your comment. This has been updated. |
| 37 | Consultee 2 | 2 | 3.1 | I'm not sure how this can be tackled or reflected in the document but 'formal diagnosis' of insomnia is rarely made or attempted even by HCPs. HCPs commonly accept the patients' self-diagnosis of insomnia. I see this in the referrals we receive which commonly say things like, 'Dear insomnia clinic, please see this lovely lady with a 10 year history of insomnia. She reports loud snoring and daytime sleepiness. Please assess for sleep apnoea'. A diagnosis of 'insomnia' is commonly made on the basis of sleep dissatisfaction without a sleep history or comparison of symptoms to diagnostic manuals. This leads to huge amount of misdiagnosis with people with obvious symptoms of another sleep | Thank you for your comment. This assessment will look at treatment effects of dCBT-I for adults who have insomnia and for whom CBT-I is suitable. Diagnosis of insomnia (whether through clinician diagnosis or established via a triaging step in a self-referral pathway) is therefore assumed in the population using these technologies. Accuracy of diagnosis is an important consideration, but falls outside of the remit of this assessment which will focus on treatment effect. |

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| | | | | disorder e.g. OSA, being fobbed off or being inappropriately prescribed hypnotics.<br><br>Therefore, the details listed under 'current practice' are really what should be happening in practice rather than what is happening! | |
| 38 | Consultee 2 | 3 | 3.1 | While talking about diagnosis, can we speak to the fact that insomnia should not be attributable to another sleep disorder? This is included in diagnostic criteria and while primary care may not be able to carry out respiratory polygraphy, they can ask some basic questions to establish if there are associated sleep apnoea or parasomnia symptoms.<br>It is common but poor practice that insomnia is currently treated as an umbrella term. As highlighted in my above point, this leads to people receiving the wrong treatment and is highly relevant if we want to treat people with insomnia with dCBT-I. | Thank you for your comment. Section 3.1 notes that "A referral to secondary care may be made for an assessment of co-occurring conditions or other sleep disorders which may mask as insomnia (e.g. circadian rhythm disorders, obstructive sleep apnoea or restless legs syndrome), if these are suspected". |
| 39 | Consultee 2 | 4 | 3.2 | Any chance the third sentence could be reordered from:<br>Symptoms will not resolve naturally for people living with undiagnosed insomnia disorder….<br>To:<br>For people living with insomnia disorder, symptoms will not resolve naturally…..<br>This clearly signposts who the statement relates to at the start of the sentence and reduces the cognitive load of realising half way through the sentence that we are talking about a different set of people | Thank you for your comment. This wording has been updated. |
| 40 | Consultee 2 | 5 | 3.2.2 | In terms of the 'elements', can the examples be stated as 'examples' to emphasise that the techniques are not limited to the lists that you have given | Thank you for your comment. This section notes that there are some core components of CBT-I, but "Other components may also be offered as part of CBT-I, for example relapse prevention". |

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| 41 | Consultee 2 | 5 | 3.2.2 | You have stated, 'Stimulus control to reduce the negative associations between the bedroom and anxieties around sleep'.<br>Can we phrase this in a positive way to describe what stimulus control is trying to do rather than trying to avoid e.g. 'Stimulus control to promote a strong association between the bed and sleep' or 'Stimulus control to condition a strong, positive association between the bed and sleep' | Thank you for your comment. This wording has been updated. |
| 42 | Consultee 2 | 5 | 3.2.2 | 'Sleep scheduling'<br>Can we add 'otherwise known as sleep restriction'<br>While behavioural sleep medicine is recognising that the term sleep restriction is unhelpful (especially to patients), if any GP looks in a textbook, they are likely to find the term sleep restriction. | Thank you for your comment. This wording has been updated. |
| 43 | Consultee 2 | 5 | 3.2.2 | 'Sleep scheduling involves a fixed waking time and the person goes to bed at planned times'<br>This doesn't really capture the essence of sleep scheduling.<br>I would suggest something like:<br>'Sleep scheduling 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.' | Thank you for your comment. This wording has been updated. |
| 44 | Consultee 2 | 6 | 3.2.2 | 'Muscle relaxation'<br>The technique you are referring to is called 'Progressive muscle relaxation' | Thank you for your comment. This wording has been updated. |
| 45 | Consultee 2 | 6 | 3.2.2 | 'Breathing control'<br>Would recommend 'breathing exercises' – as soon as someone tries to exert 'control' over breathing (or | Thank you for your comment. This wording has been updated. |

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| | | | | even sleep), it backfires. Most clinicians would therefore avoid the word control in this context. | |
| 46 | Consultee 2 | 6 | 3.2.2 | Under 'Factors that may make CBT-I unsuitable for a patient include:'<br>I'd be tempted to include<br>Unstable shiftwork pattern/complex social issues e.g. no fixed abode/acute suicidality/high medical risk due to eating disorder/acutely symptomatic of severe mental health condition/significant circadian delay<br><br>This is a good article by the way:<br>Smith, M. T., & Perlis, M. L. (2006). Who is a candidate for cognitive-behavioral therapy for insomnia?. *Health psychology*, *25*(1), 15. | Thank you for your comment. Section 3.2.2 has been amended. |
| 47 | Consultee 2 | 7 | 3.2.3 | It would seem more logical to me to mention Daridorexant before Melatonin, given the former is licensed for adults of any age but the latter is a select older population. | Thank you for your comment. This change has been made. |
| 48 | Consultee 2 | 7 | 3.2.4 | In this section you state that 'Primary care services cannot screen for other sleep disorders' but section 3.2.2 states that that suitability for CBT-I should be established before it is started and 'other sleep disorder' may make CBT-I unsuitable.<br>These statements clearly conflict unless we are suggesting that CBT-I is only recommended by secondary care sleep services.<br>I would propose that primary care can and should screen for other sleep disorders. This in reality would require additional training as most HCPs including GPs receive little to no sleep training. Failing this, they can screen using basic questions and validated questionnaires. What they are less able to do is 'assess' or 'diagnose' other sleep disorders which | Thank you for your comment. Section 3.1 has been updated to reflect this. "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. |

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| | | | | require more advanced knowledge and/or diagnostics. | |
| 49 | Consultee 2 | 8 | 4 | In terms of why CBT-I is not always offered, lack of awareness of it as being the gold standard treatment is another major factor. Many HCPs do not know that it exists or falsely assume it is traditional CBT applied to insomnia. | Thank you for your comment. The wording has been updated to “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” |
| 50 | Consultee 2 | 9 | 5 | I wonder if it may be relevant in the summary of dCBTI technology to state whether they support patients who are taking sleeping pills and furthermore whether they help them titrate doses down.<br>Even if this is not considered relevant to the company summaries in section 5, it will be relevant when considering the cost effectiveness of various technologies. | Thank you for your comment. This information may be sought for during the assessment phase. |
| 51 | Consultee 2 | 14 | Figure 1 | I’m just wondering, is ‘face-to-face’ the accepted term for treatment that may occur face to face, virtually or even over the phone?<br>You probably know better than I do if this term is evolving to be more inclusive but to me it means in the same room.<br>Clinician led may be more accurate? | Thank you for your comment. The wording has been updated to “therapist-led CBT-I”. |
| 52 | Consultee 2 | 14 | Figure 1 | Where it states, ‘CBT-I unsuitable or unavailable’ does this include pt refusal. Many patients feel hugely fobbed off when they are offered digital interventions, many want clinician led interventions not digital.<br>While it may not fit here, I’m not sure this sentiment comes through on this document but it is a very real issue! | Thank you for your comment. Section 7 notes “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” |
| 53 | Consultee 2 | 14 | Figure 1 | In the two locations where it says dCBT-I ineffective, does this include disengagement by the pt? This is the biggest challenge with digital interventions, rather than their efficacy. | Thank you for your comment. The care pathway diagram is intended to be illustrative of what may happen in practice and the relative position of the various treatment options. Patient engagement may be a factor in considering |

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| | | | | | whether dCBT-I has been effective. Adherence to treatment is included in the decision problem as an outcome. |
| 54 | Consultee 2 | 14 | Figure 1 | In the box that starts with 'dCBT-I' and then has 'F2F CBT-I from talking therapies or other CBT-I provider' underneath, this is somewhat confusing. At present it looks like dCBT-I is the title and the writing underneath the subtext, but I don't think it is meant to look like this. | Thank you for your comment. The diagram has been updated for clarity. |
| 55 | Consultee 2 | 14 | 6 | In terms of comparators, a common (and confusing) one which is not captured here is general CBT. Many of our patients have been previously referred for CBT after complaining about their sleep, because the GP has assumed that this is the same as CBT-I or that insomnia is a secondary condition. Many patients express frustration at this, "I told the GP I'm not depressed and I only feel miserable after a bad night, but they insisted I be seen by talking therapies". | Thank you for your comment. General CBT has not been included as a comparator for this assessment because it is not a recommended treatment for insomnia. The role of talking therapies is described in the scope. |
| 56 | Consultee 2 | 15 | 7 | I'm not sure if this section captions the biggest challenge to dCBT-I which is getting people to do what they need to do to improve their sleep. Onboarding is not a measure of success. Many people need more than just knowledge or being told what to do (the obesity crisis is a good example of where knowing what to do is not sufficient to create change). Most people find the suggestion of digital treatment upsetting (my problem is not even worthy of seeing a real person), then they are confronted with a machine asking them to make really difficult and scary changes. | Thank you for your comment. Section 7 notes some people may "instead [prefer] to have input from a healthcare professional as part of dCBT-I to motivate and support them in improving their sleep". |
| 57 | Consultee 2 | 15 | 7 | This section may not fully capture the most significant challenge facing dCBT-I. The primary barrier to dCBT-I efficacy may be the challenge of motivating patients to adhere to demanding treatment steps, | Thank you for your comment. Section 7 notes some people may "instead [prefer] to have input from a healthcare professional as part of dCBT-I |

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| | | | | such as sleep restriction. Data shows that adherence to digital therapeutics is low. We encounter a significant clinical challenge where patients express a strong preference for clinician-led therapy, often feeling that an app-based treatment minimizes the severity of their condition. The lack of a strong human therapeutic alliance can make it difficult for patients to navigate the difficult and scary changes required for improvement, as they miss the personalisation and accountability a clinician provides. | to motivate and support them in improving their sleep". |
| 58 | Consultee 2 | 15 | 7 | Final paragraph you've mentioned the importance of 'technical support'. While I agree 'technical' support is important because a bug could deter further attempts to use the app, this in itself is not a stand out method to improve adherence. Surely 'technical' issues with apps are minimal as they can be avoided with adequate design, testing and iteration. What's more important is clinical support. A real person who can help encourage and guide a person or tailor their treatment to make it acceptable and viable for them. | Thank you for your comment. Section 7 notes some people may "instead [prefer] to have input from a healthcare professional as part of dCBT-I to motivate and support them in improving their sleep". |
| 59 | Consultee 2 | 17 | 8.2 | I'm wondering if visually impaired people should be mentioned here.<br>Digital technology is obviously harder for them to access but these people often experience higher rates of insomnia, not least because visual impairments can result in reduced light perception, which disrupts the body's natural circadian rhythm. | Thank you for your comment. Section 8.2 notes that "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." |
| 60 | Consultee 2 | 17 | 8.2 | 'CBT-I provision with access generally limited to larger centres with specialist sleep/insomnia services' This is more of an FYI than anything else, as far as I am aware, there are only three clinician led NHS insomnia services in the UK - QVH, RSCH (my service) and RLHIM. I don't know of any services in Midlands or above! Maybe you know of others. | Thank you for your comment. |

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| 61 | Consultee 2 | 17 | 9 | For consistency and clarity throughout the document, it would be beneficial to standardise the capitalization of 'Cognitive Behavioural Therapy for Insomnia.' The term currently appears in different formats (e.g., 'Cognitive Behavioural Therapy for insomnia' here, versus 'cognitive behavioural therapy for insomnia' in section 3.2.2). I would recommend adopting the title case 'Cognitive Behavioural Therapy for Insomnia' consistently. This aligns logically with the capitalized 'I' in the accepted abbreviation CBT-I. | Thank you for your comment. The abbreviation CBT-I has been written “cognitive behavioural therapy for insomnia” following NICE’s style guide. |
| 62 | Consultee 2 | 19 | 11 | Under sleep related outcomes you have listed ‘sleep quality’. This is an immensely ambiguous term with no single definition nor easy way to define subjectively. I would advocate for removing it. | Thank you for your comment. The external assessment group will search for evidence on this outcome, narratively summarising how this was defined wherever it is reported. The committee will then be able to draw their own conclusions on the available evidence. |
| 63 | Company consultee (Mementor) | 2 | 3.1 | As ICD-10 is the classification currently used in routine care in the UK, it could be mentioned as well. | Thank you for your comment. Section 3.1 notes that “other diagnostic criteria may still be in use in some areas”. |
| 64 | Company consultee (Mementor) | 5 | 3.2.2 | NICE’s Insomnia clinical knowledge summary says: CBT-I should be offered if symptoms have not resolved with treatment provided, or immediately if it is unlikely that they resolve quickly after sleep hygiene measures have failed. This should be added. Example: “NICE’s Insomnia clinical knowledge summary recommends that cognitive behavioural therapy for insomnia (CBT-I) should be offered if symptoms are unlikely to resolve quickly by using hypnotic medication or if symptoms have not resolved with treatment offered so far in short-term insomnia, and as the first-line treatment for chronic insomnia.” | Thank you for your comment. This section has been amended to say “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” |

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| 65 | Company consultee (Mementor) | 6 | 3.2.2 | According to European guideline the sleep restriction therapy is not suitable for specific patient groups. It might be worth mentioning this under the point "Factors that may make CBT-I unsuitable for a patient include": "Contraindications for treatments like stimulus control or sleep restriction that may entail partial sleep deprivation include any kind of epilepsy and conditions that might be aggravated by sleep loss. | Thank you for your comment. Section 3.2.2 has been amended in line with this suggestion. |
| 66 | Company consultee (Mementor) | 11f | 5.4 | The description of somnio was prepared in the absence of the RFI. Please consider the information provided in the RFI. | Thank you for your comment. The description of somnio was checked against the RFI provided. As part of the assessment phase, the information provided in the RFIs of companies with technologies in the final scope will be shared with and considered by the external assessment group in their review. |
| 67 | Company consultee (Mementor) | 14 | 5.7 | The text from the arrow "unlikely to resolve soon" going from the box "short course of z drugs (3-7 days)" to the box "long term insomnia" should be changed to "ineffective" or "symptom persist". The wording "unlikely to resolve soon" should be added to the box "sleep hygiene advice", clarifying that if it is unlikely that adding short course of z drugs is unlikely to resolve the symptoms, dCBT-I should be initiated | Thank you for your comment. This suggested change has been made. |

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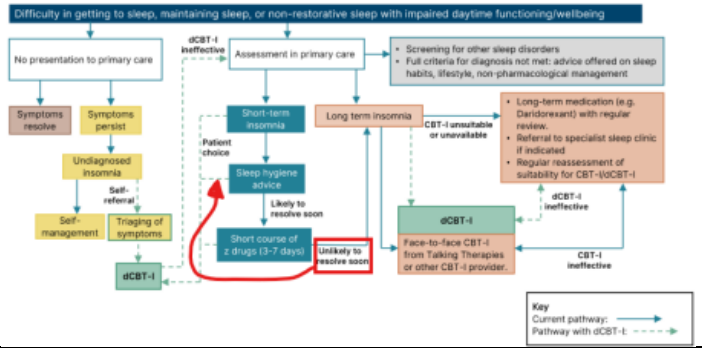
| | | | | (see screenshot).<br>  | |
| 68 | Company consultee (Mementor) | 15 | 7 | Sentence: “Engagement and adherence with digital technologies that do offer an aspect of human interaction may be better for many patients”. It should be noted that adherence and engagement can vary across technologies and therefore should be evaluated individually for each solution. As written, it could imply that guided solutions are inherently superior to unguided / fully automated approaches. To support this point, it would be preferable to include a reference indicating whether guided technologies seem to improve engagement and adherence compared to unguided solutions. | Thank you for your comment. This section was included to highlight patient preferences, and has been updated to say: “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-facilitated CBT-I services in order to find a solution that is most effective for them.” |
| 69 | Company consultee (Mementor) | | | It is currently unclear what the outcome of this assessment will be, e.g., will there be a (positive) list of cost-effective solutions, ... . It would be appreciated if this could be clarified in the scoping document. | Thank you for your comment. Table 2 of the previous version of the NICE HealthTech programme manual gives an overview of the recommendations used in HealthTech programme guidance. Different recommendations can be made for technologies included in the same guidance. |

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| 70 | Consultee 3 | 6 | | Is the list of exclusions supposed to be exhaustive or just examples? Head Injury and history of epilepsy / seizures are not included in the list | Thank you for your comment. It has been noted that contraindications for CBT-I include (but are not limited to) the examples given. |
| 71 | Consultee 3 | 11-13 | | [redacted] | Thank you for your comment. The scope reports information provided by companies and from the public domain. |
| 72 | Consultee 3 | 11-13 | | There is also a big difference between the descriptions for each of the technologies. Is there some standardisation that needs to occur? For example, it is difficult to determine in some cases which are therapist guided and which are not and what components are and are not included from the individual descriptions. | Thank you for your comment. A summary table of the included technologies has been included (Table 1 in the scope). The technologies included were discussed at the scoping workshop, and the group were asked whether all of these technologies offer the core components of CBT-I. The scope reports information provided by companies and from the the public domain. |
| 73 | Consultee 3 | 18 | Table 1 | There is no clear definition of whether the assessment will be made for acute or chronic insomnia or both as it states 'Adults who have insomnia'. [redacted] | Thank you for your comment. Following discussion at the scoping workshop, it was agreed that subgroups of "short-term" and "long-term" insomnia would be removed. This is because these groups are not mutually exclusive, and many people living with insomnia will not seek treatment straight away. The proposed population in the revised scope is "Adults (aged 18 and over) who have insomnia and for whom CBT-I is suitable". The external assessment group will search for and report on evidence in this population as per the protocol. |
| 74 | Consultee 3 | 19 | Table 1 | Is Daridorexant a comparator? – my assumption was that it was not and to be used if an individual was unwilling or unable to do CBT-I | Thank you for your comment. The comparator for this assessment is current NHS practice. This 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:<br>• Therapist-led CBT-I |

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| | | | | | • No CBT-I available<br>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).<br><br>Where therapist-led CBT-I is not available, following recommendations in TA922 a person may be offered Daridorexant. Where therapist-led CBT-I is not available, but digital CBT-I interventions are available, a person could instead be offered a digital intervention before Daridorexant. Daridorexant will therefore be considered part of the "No CBT-I available" comparator. |
| 75 | Consultee 3 | 19 | Table 1 | Outcomes: Will uptake be considered as a separate outcome under acceptability? If we are discussing patient preference this may be an important aspect to consider. Will 'drop out rates' also be included under adherence (presumably adherence will consider adherence to the module content)? | Thank you for your comment. "Uptake, adherence and acceptability of dCBT-I interventions" is included as an outcome. Any evidence on dropout is anticipated to be covered by the "adherence" outcome. |
| 76 | Consultee 3 | 19 | Table 1 | Sleep Related Outcomes: Would no longer meeting criteria for insomnia (remission) be an additional outcome to consider? Also using Insomnia Severity Index outcomes for treatment responder may be helpful? | Thank you for your comment. Insomnia remission has been added as an outcome to the scope. In the decision problem, specific outcome measures have not been named however we expect that the Insomnia Severity Index is one of the measures that will be used by the external assessment group to measure sleep quantity. |
| 77 | Company consultee (Amwell/Silvercloud) | 2 | 2 | Wilson 2019 suggests around half of people with insomnia diagnosed also have a comorbid common mental health problem. If somebody presents with sleep problems alongside depression / anxiety, the scope should include recommendations around when the insomnia should be treated as the primary problem and when it should be secondary to the | Thank you for your comment. The aim of this assessment is to determine whether digital interventions delivering CBT-I for adults who have insomnia and for whom CBT-I is suitable, are a cost-effective use of NHS resources. If evidence is available, subgroups of people with mental or physical comorbidities will be considered. Diagnosis of insomnia is outside the remit of this assessment |

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| | | | | depression / anxiety. (This is also described in Wilson) | |
| 78 | Company consultee (Amwell/Silvercloud) | 4 | 3.2 | Given the contraindications for CBT-I it the consultation should explicitly state that all individuals need an initial assessment that examines the nature of their sleep problems (and any other co-morbid problems) and unsuitability criteria (e.g. risk populations) prior to commencing the CBT-I treatment (however they could be given access to sleep hygiene information prior to this). | Thank you for your comment. Section 3.1 has been updated to reflect possible elements for an assessment for insomnia and some considerations which may need a referral. The revised section 3.2.2 also notes some factors that may require signposting when CBT-I is initiated, or that mean that aspects of CBT-I are contraindicated. |
| 79 | Company consultee (Amwell/Silvercloud) | 5 | 3.2.1 | The digital technologies should be flexible enough to provide treatment in a way that matches the treatment approach – for short-term insomnia, sleep hygiene first with escalation to CBT-I if sleep hygiene is unsuccessful (and no access to CBT-I prior to that point). For chronic insomnia, CBT-I should be available on first use.<br><br>Alternatively, the consultation could recommend different products for different conditions – e.g. a product that has CBT-I available from the start would only be suitable for people diagnosed with chronic insomnia, whereas a sleep hygiene only product would only be suitable for those with short-term insomnia / insomnia symptoms. | Thank you for your comment. This assessment will only consider digital technologies that deliver the core components of CBT-I, with a substantial portion delivered through the technology. Technologies which provide sleep hygiene advice or platforms which support therapist-led CBT-I are not within scope and will not be considered.<br>Section 5.1 notes that "The included technologies will only be assessed within their intended use in terms of target condition and population". Figure 1 illustrates where in the insomnia care pathway dCBT-I could sit. The decision problem in the scope lists the technologies which have been identified as meeting the criteria for this assessment and so will be included in the assessment and final guidance. |
| 80 | Company consultee (Amwell/Silvercloud) | 6 | 3.2.2 | "*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."* | Thank you for your comment. Section 3.1 notes that "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, |

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| | | | | Whilst not all technologies may require human oversight to deliver the content, all individuals using CBT-I should either be overseen by a suitably trained clinician who is able to spot when additional support is required (e.g. for the reasons outlined in section 3.2.4 Referral to secondary care) or the product should evidence that it can effectively identify when the primary care treatment has failed and escalate appropriately. | through which triaging programmes may be used to diagnose insomnia". Section 5 of the scope notes the escalation pathways that should be in place to ensure that issues and risks are identified and managed appropriately. |
| 81 | Company consultee (Amwell/Silvercloud) | 6 | 3.2.2 | *"A medical assessment **may** be needed to ensure suitability of CBT-I before it is started"*<br><br>This statement does not follow from the guidance given previously – given the different severities of insomnia, the contraindications with certain types of work and the co-morbidities with other conditions it would seem like a medical assessment should always be needed to ensure suitability of CBT-I. Products providing access to sleep hygiene (excluding CBT-I) could be provided without an assessment. | Thank you for your comment. Figure 1 illustrates the proposed position of dCBT-I which would only be offered after an assessment to diagnose insomnia. The assessment could be done in primary care or by a self-referral platform which has triaging software.<br>Section 3.1 has been updated to reflect components of the assessment for insomnia. This includes "assessment of their symptoms and sleep history, review of any current medication, past and current medical history and substance use. Where appropriate, screening for depression and anxiety may be done, or a physical examination to help identify comorbid conditions". Section 3.2.2 also notes factors which may be identified during assessment and require further signposting, investigation or mean CBT-I is contraindicated. |
| 82 | Company consultee (Amwell/Silvercloud) | 8 | 4 | "*Digital technologies delivering CBT for insomnia (dCBT-I) may increase treatment access for people living with undiagnosed insomnia, through means of self-referral."*<br><br>Due to the impact CBT-I can have on daily lives, if a product is being accessed via self-referral without a | Thank you for your comment. The population for this assessment is "Adults (aged 18 and over) who have insomnia and for whom CBT-I is suitable". Section 3.2.2 notes that "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 |

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| | | | | clinician explaining the approaches first, the product should be required to clearly inform the user of the potential side effects and contraindications (e.g. work involving heavy machinery, seizures) prior to commencing treatment and to provide advice on how to seek help if CBT-I is contraindicated. | whom CBT-I may be offered". This section also notes factors that may be identified as subsequently requiring signposting, further investigation or mean CBT-I is contraindicated. |
| 83 | Company consultee (Amwell/Silvercloud) | 10 | 5 | "*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"*<br><br>The consultation should consider what is "appropriate" in relation to each product. Products which are assessing the severity of a sleep problem and providing tailored treatment without the involvement of human oversight are likely to require class 2 medical device registration.<br><br>There seems to be some disparity in the class markings of the products that are being considered. | Thank you for your comment. NICE has checked with the MHRA that the technologies are likely to have been appropriately regulated. . The disparity in class is likely because of differences in the regulation requirements for therapeutic software between the European MDR regulations and the UK MDD. |
| 84 | Company consultee (Amwell/Silvercloud) | 14 | 5.7 Figure 1 | Alongside "triaging symptoms", where the full CBT-I intervention is being offered, this self- referral pathway should also include providing informed consent regarding the treatment approach and the impact it may have on patients (as outlined in section 7 of the document) and the considerations regarding co-morbidities (as outlined in section 8.1) | Thank you for your comment. This assessment will assess evidence related to the treatment effect of the included technologies for people with insomnia for whom dCBT-I has been identified as being appropriate (by a clinician or through triage on the self-referral pathway). We will not be making recommendation about the triaging software used to identify people with insomnia on the self-referral platform. |
| 85 | Company consultee (Amwell/Silvercloud) | 18 | 10 | [redacted] | Thank you for your comment. During the evidence assessment the companies will be asked for the cost of their technologies including any commercial arrangements available to the |

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| | | | | [redacted] | NHS. The external assessment group will use the most appropriate cost for each technology in the cost effectiveness calculations. |
| 86 | Company consultee (Amwell/Silvercloud) | 18 | 10 | While cost-effectiveness is essential, the NHS Long Term Plan emphasises digital innovation as a mechanism for increasing system efficiency. The key decision question might benefit from explicitly accounting for the impact of digital CBT-i technologies on improved cost-efficiency (e.g. service productivity, workforce utilisation, and operational efficiency) — not only health outcomes per pound spent. | Thank you for your comment. A further outcome has been added to the decision problem. |
| 87 | Consultee 4 | 5 and 6 | | The behavioural techniques, sleep scheduling and stimulus control (15 min rule) are very likely to be the most efficacious in multicomponent CBT-I. (Steinmetz et al 2024 latest meta analysis but there is previous literature that indicates this.<br>So, I think that these should be at the top of this paragraph of different components and I do not agree with the statement that there is no consensus on the proportion that should be offered as a minimum.. and tink the beavioural techniques should be offered early in any programme of therapy. | Thank you for your comment. The behavioural elements have been moved to the top of the list of examples. The statement regarding consensus of proportions has been removed, with this now reading “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.” |
| 88 | Consultee 4 | 7 | | I have not seen triaging soft ware before, where is this available to view? | Thank you for your comment. The triaging software mentioned in the scope does not refer to a single technology that is in use, and assessment of such a software falls outside of |

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| | | | | You should avoid starting a sentence with “But” in a scientific report.<br><br>I think saying GP’s cannot screen for other sleep disorders is a bit of a strong statement, they certainly can ask about sleep apnoea with the STOP bang questionnaire, Epwort Sleepiness Scale etc and ask about restless legs which they often treat without investigation or referral.<br><br>z drugs are usually abbreviated “Z drugs”.<br><br>Temazepam also still used.<br><br>Important to mention that quetiapine and olanzapine are used in some people for insomnia, off licence and SSRI’s can cause restless legs.<br><br>My clinical impression is that “hybrid”or person led dCBT-I is more user friendly, although the evidence base for this is mixed and unclear. This scope is not including any hybrid? | the scope of this assessment which is intended to assess the effects of dCBT-I as a treatment. Rather, this triaging step is included in the scope to highlight an important step in any self-referral pathway through which dCBT-I may be accessed. This is to ensure that people who self-refer will only be directed to dCBT-I if this has been assessed as being suitable for them.<br><br>Section 3.1 has been updated to: “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 diagnose other sleep conditions, so onward referral may be necessary”<br><br>The scope of the assessment includes technologies of different delivery modes, including both digital technologies that are fully automated and those that have some aspect of human oversight. Therapist-led CBT-I (for example, a face-to-face CBT-I session with a therapist) is included as a comparator for this assessment, as it is understood that (though not widely available) this is how CBT-I is delivered in current practice. |
| 89 | Consultee 4 | 9 | | An important side effect of sleeping pills is Falls on arising due to hangover sedation, particularly important to consider in the elderly | Thank you for your comment. This has been added to section 4. |
| 90 | Consultee 4 | 15 | | Also women looking after young children at home may benefit from dCBT-I due to access problems. | Thank you for your comment. Section 7 acknowledges that people may find it easier (and prefer to) engage with or adhere to CBT-I of a certain delivery mode. |

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| 91 | Company consultee (Sleepstation) | 1 | 1 | The following content has been added:<br><br>"This guidance will **update** NICE's medical technologies guidance on Sleepio to treat insomnia and insomnia symptoms."<br><br>This creates a framing effect that elevates Sleepio as the benchmark and embeds its legacy guidance into the narrative, potentially biasing the assessment.<br><br>How will NICE ensure that Sleepio's prior MTG70 status does not prejudge comparative value or evidence thresholds applied in this new assessment?<br><br>Will all technologies be evaluated on a level playing field, independent of legacy guidance?<br><br>Will NICE MTG be **replaced**? Rather than updated? | Thank you for your comment. NICE PMG49 outlines processes and methods for guidance surveillance.<br><br>"NICE considers the impact of information identified through monitoring and decides whether further action is needed. Further actions could include:<br>• changing the wording of recommendations (for example, to add clarity to or reduce ambiguity of a recommended action).<br>• carrying out a surveillance review, if more information is needed to inform a proposal as to whether to update NICE guidance"<br><br>"A surveillance review can be done in response to information identified through monitoring (reactive surveillance review). Subject to constraints on capacity, NICE carries out reactive surveillance reviews if new information is received through monitoring that is likely to have an impact on guidance recommendations and needs further investigation. This informs a decision on whether to make any changes to guidance".<br><br>PMG49 notes that surveillance review outcomes include<br>• updating or amending the guidance (which could involve collaborating with another organisation)<br>• retiring guidance or guidance recommendations<br><br>Information on other interventions delivering CBT-I has informed the decision of NICE's prioritisation board to select this topic for |

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| | | | | | MultiTech guidance development. The topic has been re-scoped because of this, to ensure that the assessment includes other interventions. In this instance this piece of guidance will update and replace HTG624 (previously MTG70) on publication. |
| 92 | Company consultee (Sleepstation) | 4 and 8 | 3 and 4 | The scope appears to assume that NHS patients can access CBTi only after formal diagnosis. | Thank you for your comment. Section 3 has been amended to include that “People in some areas may also be able to go down a self-referral route, through which triaging |

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| | | | | Sections 3 and 4 state that without a diagnosis people "cannot access recommended treatment options", yet digital CBTi can safely be used with triage.<br><br>Sleepstation screens for comorbidities and risk and escalates appropriately.<br><br>The scope underplays the risk of fully automated products being used without diagnosis or oversight, especially among people with other undiagnosed sleep disorders.<br><br>Questions:<br><br>Will the evaluation differentiate between technologies with validated triage and escalation processes and those without?<br><br>How will NICE evaluate safety risks associated with automated dCBTi in people with OSA, RLS, bipolar disorder or untreated mental health conditions? | programmes may be used to diagnose insomnia", with section 3.2.2 noting that "CBT-I may be accessed […] through a self-referral platform which has a triaging software to identify people with insomnia for whom CBT-I may be offered".<br><br>Section 5 has been added to note the risk management and escalation pathways that should be in place to ensure issues and risks are identified and managed appropriately. This section notes that "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". Information on escalation pathways will be sought for during the assessment and presented to the committee. Should evidence be identified for subgroups of people with other mental or physical conditions, this will be reported in the external assessment report. |
| 93 | Company consultee (Sleepstation) | 5 | 3.2.2 | In the updated scope, a new sentence has been inserted into section 3.2.2:<br><br>"NICE MTG70 recommends a digital CBT-I technology, Sleepio, as an option for people who would be offered sleep hygiene or z-drugs."<br><br>Why has this been added?<br><br>This reference introduces a single commercial product into a section that titled "Cognitive behavioural therapy for insomnia (CBT-I)" which should be independent of specific manufacturers. | Thank you for your comment. HTG624 (previously MTG70) is referenced in the scope as it is an existing piece of relevant NICE guidance, that is also referred to in NICE's Insomnia clinical knowledge summary. It is acknowledged that despite HTG624 recommendations, the intervention has not been widely implemented or used in NHS practice. Section 4 of the scope discusses the unmet need in the area of insomnia treatment, which includes limited access to CBT-I. HTG624 recommendations will be superseded by those made during this MultiTech NICE assessment. Reference to this guidance remains in section 1 |

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| | | | | No other digital CBT-I technologies have ever been assessed by NICE, and this review is intended to evaluate all technologies on a fair and equal basis.<br><br>No other technology is referenced in the current-practice section.<br><br>No equivalent mention is made of:<br>• Sleepstation's NHS-wide availability,<br>• hybrid models,<br>• human-supported CBTi<br>• group CBTi or<br>• any of the other technologies included in the scope.<br><br>The inclusion is therefore selective, unnecessary, and distorting.<br><br>Including Sleepio here:<br>• selectively elevates one product,<br>• reinforces a historic NICE position that this evaluation is specifically intended to review and update, and<br>• risks biasing the committee by implying pre-existing preference or superiority.<br><br>We therefore request that this sentence is removed to ensure a neutral and even-handed scope ahead of the full assessment.<br><br>It should also be noted that despite a positive NICE recommendation – commissioners have not chosen | to acknowledge that this MultiTech assessment of digital technologies delivering CBT for insomnia in adults will update and replace HTG624. |

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| | | | | Sleepio – they have chosen to commission other digital CBTi options instead so NICE MTG70 appears to be redundant as it has not been effective. | |
| 94 | Company consultee (Sleepstation) | 6 | 3.2.2 | Section 3.2.2 states “There is no consensus on the proportion of each core CBTi component required”<br><br>This creates an opportunity for non-CBTi apps to be included without delivering core therapeutic components.<br><br>Questions:<br><br>Will NICE define minimum CBTi components required to qualify as CBTi?<br>How will NICE prevent inclusion of products that dilute CBTi fidelity?<br>Colin Espie has created a ‘Standard CBT-I Protocol for the Treatment of Insomnia Disorder” – has this been considered? | Thank you for your comment. This section has been updated for clarity, noting the core components of CBT-I that were discussed at the scoping workshop, with examples of each component given. It is then noted that “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.”. The technologies included in the assessment, and for which the committee will make recommendations, are those described in section 5 of the scope. That is, technologies that deliver the core components of cognitive behavioural therapy for insomnia (CBT-I), with a substantial portion delivered through the technology. |
| 95 | Company consultee (Sleepstation) | 15 | 7 | How will NICE ensure safety differences between hybrid and automated systems are fairly evaluated?<br>Hybrid versions (e.g. Sleepstation) provide risk assessment, monitoring, and escalation to NHS care.<br>Automated models appear to lack these safeguards.<br>Questions:<br>Will NICE require all products to demonstrate safe handling of risk, comorbidity and deterioration? | This assessment will consider digital technologies that deliver the core components of cognitive behavioural therapy for insomnia (CBT-I), with a substantial portion delivered through the technology. This includes both technologies with a hybrid mode of delivery, and fully-automated technologies. Included technologies must also have appropriate regulatory marking (CE or UKCA mark) where required, or be actively working towards this. Evidence for all included technologies will be considered as per the external assessment group’s assessment protocol. Section 5 has |

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| | | | | | been added to note the risk management and escalation pathways that should be in place to ensure issues and risks are identified and managed appropriately. This section notes that "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". Information on escalation pathways will be sought for during the assessment and presented to the committee. Should evidence be identified for subgroups of people with other mental or physical conditions, this will be reported in the external assessment report. |
| 96 | Company consultee (Sleepstation) | 14 | 5 | The revised diagram now positions digital CBT-I as a frontline option for undiagnosed insomnia and gives equal visual weight to automated and hybrid models. It does not reflect the differences in safety, triage, escalation, or human oversight between technologies. This may mislead readers into assuming all dCBT-I products are interchangeable. We recommend redrafting the figure to distinguish supervised from unsupervised models. | Thank you for your comment. This assessment will consider digital technologies that deliver the core components of cognitive behavioural therapy for insomnia (CBT-I), with a substantial portion delivered through the technology. This includes both technologies with a hybrid mode of delivery, and fully-automated technologies. Figure 1 is not intended to distinguish between individual dCBT-I technologies with different modes of delivery. The diagram is intended to be illustrative of where dCBT-I technologies could sit in the care pathway. The external assessment group note in their protocol that the cost-effectiveness of the dCBT-I technologies will be compared to the relevant comparator(s) (i.e., usual care alternatives at a particular position in the care pathway) in people with insomnia. It is standard practice for each technology to be considered in its own right unless evidence is deemed to be generalisable from one technology to another. |

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| | | | | | The population in the scope is adults (aged 18 and over) who have insomnia and for whom CBT-I is suitable. For people who self-refer, a triage step is assumed to take place to determine whether they have insomnia and should be referred to dCBT-I. This triage step may determine that a person does not have insomnia or that dCBT-I is not suitable. |
| 97 | Company consultee (Sleepstation) | 14 | 6 | The revised scope expands the comparator set to include **"no intervention or self-management (e.g. over-the-counter medication, alcohol)"**. This represents a major shift from the initial scope and introduces options that do *not* reflect realistic NHS clinical decision-making.<br><br>It is **not appropriate** to compare regulated digital CBT-I technologies (including those with human oversight and NHS-integrated pathways) to "no treatment" or to informal consumer behaviours such as alcohol use or over-the-counter sleep aids. These are not accepted NHS treatment pathways for insomnia, nor are they alternatives that commissioners are choosing between when evaluating dCBT-I solutions.<br><br>Using "no intervention" as a comparator risks **distorting cost-effectiveness modelling**, because even minimal clinical benefit delivered by low-intensity, fully automated tools may appear highly cost-effective when compared against doing nothing. This artificially advantages low-touch automated products and disadvantages hybrid or supported pathways that deliver significant value but also incur legitimate delivery costs.<br><br>**Comparators should reflect realistic clinical alternatives, not consumer behaviour.**<br>Appropriate comparators are those actually available to NHS clinicians and commissioners, such as sleep hygiene, | Thank you for your comment. During the scoping workshop, lay experts discussed that many people self-manage their insomnia using OTC medicine, alcohol etc. This information was added into the scope as background information, based on discussion at the scoping workshop. "No intervention" was added as a comparator in the scope, because many people are receiving no NHS treatment for their insomnia. Sections 2.1.15 and 2.1.16 of NICE's PMG48 (published 14 July 2025) note that:<br>• "The scope identifies relevant comparators that are established practice in the NHS or are recommended in existing guidance from NICE or other bodies. This can include 'no activity' if nothing is done in current practice. Comparators may include technologies that do not have regulatory approval for the population defined in the scope if they are considered established clinical practice in the NHS. The comparator will typically not include use of the intervention being assessed, even if it is currently in use in practice to some degree."<br><br>• "The comparators should be defined as precisely as possible. It is important this accurately represents current care. It is also important that any challenges with current |

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| | | | | short-course z-drugs, therapist-delivered CBT-I, daridorexant, or referral to specialist sleep services. These represent the true options within NHS care pathways.<br><br>We therefore recommend:<br><br>1. **Removing "no intervention" and consumer self-management (including alcohol and OTC sleep aids) from the comparator list.**<br>2. Alternatively, **stratifying comparators by severity and pathway**, ensuring technologies are assessed against the evidence-based NHS options that commissioners genuinely choose between.<br><br>This change is needed to ensure a fair, clinically grounded, and methodologically valid assessment across all technologies included in the evaluation. | care which may form part of the value proposition for the intervention are accurately represented (for example, access to care, variation in practice or delays to having treatment or appointments)."<br><br>The comparator for this assessment is current NHS practice. This 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:<br>• Therapist-led CBT-I<br>• No CBT-I available<br>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).<br>The updated revised scope mentions examples self-management techniques (e.g. OTC products, alcohol) as background information, but these are not part of the decision problem (such that self-management techniques would not be economic model inputs). |
| 98 | Company consultee (Sleepstation) | 18-19 | 10 | A new outcome, "time to intervention initiation", has been added. If "intervention" is not properly defined, this may favour automated tools that can be 'accessed' instantly but through which an 'intervention' is not delivered at the point of access. Therefore, it will be important for NICE to define 'intervention' to ensure that CBTi is in fact being delivered.<br><br>Meaningful outcomes should focus on clinical effect, adherence, safety, and long-term maintenance, not perceived operational speed. We request reconsideration or stratification. | Thank you for your comment. Section 4 "unmet need" notes that "waiting lists for CBT-I [are] many months to years in some regions". The outcome "time to intervention initiation" is intended to capture any evidence reporting the time for CBT-I to be started, given digital technologies could enable faster access to CBT-I than waiting for a therapist-led session. The interventions are those technologies included in section 5 of the scope, which were discussed at the scoping workshop. |

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| 99 | Consultee 5 | 1 | 2 | This is the first reference to disorder which is used 27 times in the document. Many people with lived experience dislike the term disorder as it implies that they are fundamentally flawed, and it can also cause/add to self-stigma. As a someone with lived expertise my preference would be to use recovery focused language i.e. replace 'disorder' with 'condition' throughout the document. | Thank you for your comment. The frequency of the term "insomnia disorder" has now been reduced in the document. There are still some instances included in the document, for example where statistics have been quoted from external publications that use this term. For example: "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)". The term has also been used where this makes up part of a company's technology description in section 5. |
| 100 | Consultee 5 | 1 | 2 | Consider including psychosis in the example of mental health conditions as studies show a strong link between poor sleep and psychotic experiences like hallucinations and delusions, with reduced sleep directly followed by increased symptom severity. Severe, prolonged sleep deprivation can cause acute psychotic episodes in anyone. | Thank you for your comment. This has been added to section 2 as an example. |
| 101 | Consultee 5 | 2 | 2 | Consider replacing comorbid with cooccurring particularly in reference to mental health conditions as this word has unhelpful connotations. | Thank you for your comment. The term "comorbid" is defined in the scope as "simultaneously present conditions". This term has been removed from the equalities section, but does remain in other sections of the scope where scientifically appropriate to describe the nature of other conditions that are present alongside insomnia. |
| 102 | Consultee 5 | 3 | 3.1 | 'Concerns about or dissatisfaction with sleep' does not capture the acute anxiety and palpitations, that I and many others like me, experience at the very thought of not sleeping, which then becomes a self-perpetuating cycle. | Thank you for your comment. Section 8.1 notes "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" |
| 103 | Consultee 5 | 3 | 3.1 | If people drink alcohol, it might also be worth keeping a record of their intake and the time they consume it, as this may affect sleep quality and duration. | Thank you for your comment. Section 3.1 notes "NICE's Insomnia clinical knowledge summary (last revised 2025) recommends that |

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| | | | | | 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**" |
| 104 | Consultee 5 | 4 | 3.2.2 | Consider clarifying whether this includes group CBT-I | Thank you for your comment. Section 3.2.2 notes that "CBT-I may be offered in different formats depending on local service capacity and provision:<br><br>• 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.**" |
| 105 | Consultee 5 | 7 | 4 | Daytime drowsiness can be an issue, but for me and many others I know, the worst part is the first hour or so in the morning after which the 'hangover feeling' subsides. Sleepiness during day is then not a problem. Perhaps reword to: 'early morning drowsiness (for me it feels like brain fog) and/or daytime drowsiness'. | Thank you for your comment. This section has been updated to say "periods of fatigue (e.g. early morning)". |
| 106 | Consultee 5 | 8 | 4 | 'Patient groups that are harder to reach' is a term that usually referrers to underserved communities who are often digitally excluded, whereas in this context it is referring to people who are geographically dispersed from treatment centres. Consider rephrasing for clarity. | Thank you for your comment. This has been updated to say "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". |
| 107 | Consultee 5 | 11 | 5.5 | In the green Assessment box in figure 1 consider including migraine, in addition to epilepsy and CF, as this condition | Thank you for your comment. Examples of conditions that could trigger sleep problems are included in section 2: "Common triggers of sleep |

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| | | | | can lead to disturbed sleep e.g. being woken up with auras during the night | 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)." |
| 108 | Consultee 5 | 12 | 7 | Many patients find peer support very helpful. Could group CBT-I be included as an option? Also, potentially more cost effective. | Thank you for your comment. It is understood that group CBT may already be offered in some regions as part of current practice. In this assessment, NICE are looking for digital technologies that deliver CBT-I with a substantial portion delivered through the technology (rather than being platforms to support therapist-led CBT-I). |
| 109 | Consultee 5 | 13 | 8.1 | Presumably grief is a cause of short term and long-term insomnia, perhaps more so in women as men have a higher mortality rate? Women are also more likely to experience violence and domestic abuse leading to PTSD etc. | Thank you for your comment highlighting examples of other groups who may experience higher rates of insomnia. |
| 110 | Consultee 5 | 14 | 8.2 | Cultural considerations and sensitivities may influence whether people wish to access CBT-I, either digitally or in person E.g., if admitting to having a sleep problem is regarded as shameful or a weakness. Also, for digital access lack of privacy for those living with several other family members in a single hotel bedroom might be an issue. | Thank you for your comment. Section 7 notes that "people may benefit from having a choice of dCBT-I technologies or therapist-facilitated 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)." |
| 111 | Consultee 6 | 14 | 6. Comparator | In the initial draft scoping document, we were surprised to see that our product, daridorexant, was included as a comparator. We raised this point at the scoping workshop and are therefore disappointed to see that, in the latest draft of the scoping document, daridorexant is still listed as a comparator to CBTi.<br>NICE's own HTA guidance (TA922), published two years ago, is explicit that daridorexant should only be used where CBTi has failed or is unsuitable. This is aligned with the NICE Clinical Knowledge Summary (CKS), 'Managing | Thank you for your comment. The comparator for this assessment is current NHS practice. This 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:<br>• Therapist-led CBT-I<br>• No CBT-I available<br>Where no CBT-I is available, current practice may include no NHS treatment being received, |

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| | | | | Insomnia' which also makes clear reference to the currently approved dCBTi – Sleepio<br><br>The relevant excerpts from the NICE CKS is set out below:<br>How should I manage someone with long-term insomnia (more than 3 months duration)?<br>• Offer cognitive behavioural therapy for insomnia (CBTi) as the first-line treatment for chronic insomnia in adults of any age.<br>Sleepio is a digital CBTi-based treatment recommended by the National Institute for Health and Care Excellence (NICE).<br>• For adults with chronic insomnia whose daytime functioning is considerably affected, consider offering daridorexant, only if CBTi has been tried but not worked, or is unavailable or unsuitable<br><br>Paragraph 3.2.3 and Figure 1 of the latest version of the draft scope also makes specific reference to this clear positioning. The excerpt from this is as follows:<br>3.2.3 Other pharmacological interventions<br>For people over 55 years of age with persistent insomnia, treatment with a prolonged-release melatonin may be considered. Daridorexant is recommended by NICE for treating long-term insomnia in adults, only if long-term insomnia persists despite CBT-I 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. If treatment is continued, assess whether it is still working 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 | sleep hygiene and pharmacological treatments (see sections 3.2.1 and 3.2.3).<br><br>Recommendation 1.1 of TA922 states that "Daridorexant is recommended for treating insomnia […] only if:<br>• cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or<br>CBTi is not available or is unsuitable.".<br><br>Where therapist-led CBT-I is not available, following recommendations in TA922 a person may be offered daridorexant. Where therapist-led CBT-I is not available, but digital CBT-I interventions are available, a person should be offered digital CBT-I before daridorexant. Daridorexant will not be compared directly with CBT-I in terms of clinical effectiveness, but daridorexant will be considered part of the "No CBT-I available" comparator designed to reflect current NHS practice. The assessment will not change the existing pathway, rather it will expand options for delivering CBT-I. The recommendations in this assessment will not affect the recommendations made in TA922. If a digital CBT-I intervention was to be offered and prove to be ineffective for a person, they may then be offered daridorexant as per the recommendations in TA922 that place daridorexant as a second line treatment.<br><br>Any manufacturer companies of products that are not considered intervention technologies for an assessment are not expected to complete a request for information or request for evidence |

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| | | | | conditions, which unintentionally improve (or in some cases, worsen) insomnia.<br>In section 6 of the revised draft scope, the wording appears to imply that the only reason for daridorexant being a comparator relates to the fact that CBTi is not available in some parts of the country (despite being approved by NICE). This is illogical because, if CBTi is not available, it cannot be a comparator. If it is available, then CBTi should be used first and daridorexant only in the event of failure or unsuitability.<br>We contributed fully to the production of that HTA, at considerable financial and resource cost to our company, and believe that the TA922 guidance remains up-to-date and appropriate. Nothing has changed in the NHS to call that into question.<br>We now appear to be faced with the prospect of having to undergo another assessment of our product with CBTi as a comparator. I am unclear as to exactly what that assessment will involve, or how much ability we will have to contribute fully to it but - in any case - daridorexant should not be part of an assessment relating to dCBTi. The exercise has the feel of a process that started out as a tightly defined review of dCBTi, but has now become a broader HTA-style clinical guideline for the whole of insomnia. This is surely not what NICE had in mind when it commenced the MTA of the dCBTi products?<br>NICE has already approved one dCBTi (Sleepio) for use within the NHS and clearly positioned daridorexant after CBTi. This assessment should therefore focus purely on the cost effectiveness of the different dCBTi applications in their appropriate position within the existing pathway. It should not seek to rewrite the pathway (in the absence of any prior review of the pathway), or to compare products that do not appear in the same position within the existing pathway. | as part of an assessment, but are welcome to remain as stakeholders for the assessment. |

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| 112 | Consultee 7 | 14 | 6 | The availability of CBT-I across the UK is probably variable. There are likely to be limited face to face CBT-I programs. Will the guidance suggest that DCBT-I is available in all locations. Also will this be something that pharmacists will be able to advise patients of and provide at point of contact. | Thank you for your comment. The decision problem that this assessment will aim to answer is “Are digital technologies delivering CBT for insomnia offering cost-effective use of NHS resources?”. This assessment will result in the publication of MultiTech NICE HealthTech guidance. Healthcare providers across the NHS can use this guidance to help inform procurement decisions. |
| 113 | Consultee 7 | 15 | 7 | It is imperative that to meet equality and equity a range of CBT-is available in all health care regions. | Thank you for your comment. Section 4 (“Unmet need”) acknowledges the variation in current practice in the treatment of insomnia. |
| 114 | Consultee 7 | 14 | Fig 1 | Regarding the path for patients who may present within the 3months and be deemed not chronic. Is there room to signpost to dCBT-I but a light version outlining the basics of sleep management? | Thank you for your comment. This assessment will consider only the technologies included in the decision problem outlined in the scope of this assessment. The guidance will only contain recommendations on these technologies. |
| 115 | Consultee 7 | 19 | 10 | dCBT-I should be considered as a cost effective options where the research exists for particular programs and as a option for patients who prefer digital. | Thank you for your comment. |