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STUDY PROTOCOL

A protocol for a mixed-methods analysis of the usability and acceptability of a digital cognitive-behavioural therapy for insomnia (dCBT-I) intervention (*Sleepio*™) in participants with cognitive impairment.

[version 1; peer review: 2 approved]

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Abstract

Background

Sleep disturbance is common among those with cognitive impairment, potentially contributing to negative outcomes. Furthermore, growing evidence suggests that sleep disturbance is associated with the onset and progression of cognitive decline. There is therefore increasing interest in treating sleep disturbance in people with cognitive impairment.

Non-pharmacological treatments for sleep disturbance are unhindered by many of the adverse effects associated with pharmacological treatments, yet evidence supporting their use in clinical practice is often lacking. Cognitive behavioural therapy for insomnia (CBT-I) is the first-line treatment for insomnia and has demonstrated effectiveness in people with cognitive impairment in a small number of trials. Digital CBT-I (dCBT-I) overcomes many of the obstacles associated with accessing CBT-I (such as limited availability of therapists and transportation) whilst presenting others (such as internet access and digital literacy).

Aim

Open Peer Review

Approval Status ✓ ✓

	1	2
version 1 18 Jun 2025	✓ view	✓ view

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Any reports and responses or comments on the article can be found at the end of the article.

To undertake a mixed-methods analysis of the usability and acceptability of a dCBT-I intervention (*Sleepio*) among people with cognitive impairment.

Methods

Participants will be community-dwelling adults aged ≥50 years with cognitive decline and probable insomnia. Study partners (being caregivers, family or friends of participants) will be recruited, if available, to examine how their involvement influences usability and acceptability.

Participants will be given access to *Sleepio*, a fully automated and personalised dCBT-I programme delivered over the course of six weekly sessions. Usability and acceptability will be assessed by a bespoke questionnaire incorporating the System Usability Scale and the Usability Metric for User Experience - Lite (UMUX-Lite). Semi-structured interviews will explore participants' experience of using the intervention.

Conclusion

By examining barriers and facilitators to the usability and acceptability of *Sleepio* among people with cognitive impairment, this study will provide insight into the potential efficacy of the intervention in this population whilst informing the design of a future definitive clinical trial.

Keywords
Sleep, Cognitive Impairment, Dementia, Digital Cognitive Behavioural Therapy for Insomnia, Qualitative, Usability, Acceptability.

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Competing interests: ALH is employed by, receives a salary from, is a shareholder and has equity options in Big Health Ltd (the manufacturer of Sleepio, the dCBT-I intervention used in this study). While ALH has been involved in the design of this study and in the preparation of this protocol, he will not be involved in the conduct of the study or in the interpretation of the results. The remaining authors have no competing interests to declare.

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Introduction

Sleep is essential to maintain good physical and mental health[1–3] and plays a central role in many physiological functions[4]. Nevertheless, insomnia is common with approximately one-third of all adults experiencing insomnia symptoms[5], increasing to 75% in those aged over 65 years[6]. Sleep patterns change as we age[7]. Normal ageing is associated with reductions in total sleep time, sleep efficiency and slow wave sleep[8]. Sleep disturbance is even more common among older adults with cognitive impairment[9]. Compared to healthy aged-matched controls, people with mild cognitive impairment (MCI) experience reduced total sleep time, sleep efficiency and duration of REM, whilst sleep onset latency, wakefulness after sleep onset, and duration of stage one sleep are increased[10,11].

Indeed, there is a well-established association between sleep disturbance and cognitive impairment[12], with evidence suggesting that the relationship may be causal and bi-directional[13]. A meta-analysis of observational studies estimated that 15% of Alzheimer's Disease may be attributable to sleep disturbance[14]. Despite the recent Dementia Prevention, Intervention and Care: 2024 report of the Lancet Commission concluding that further research is needed to clarify the effect of sleep disturbance on cognitive decline[15], therefore, interest is growing in sleep disturbance as a potential modifiable risk factor for cognitive impairment[16]. The European Academy of Neurology Brain Health Strategy, for example, has included sleep as a determinant of brain health[17].

Furthermore, sleep disturbance tends to worsen as cognitive impairment advances[18,19], leading to deteriorating cognitive outcomes[20] and quality of life[21], as well as strained relationships with caregivers who experience considerable physical and emotional distress and burnout as a consequence[22,23]. The increased caregiver burden caused by sleep disturbance in people with dementia has been shown to lead to sub-optimal care[24] and early institutionalisation[25,26]. Sleep is therefore an important treatment target throughout the natural history of dementia, to potentially slow the progression of early-stage disease and to reduce the burden of symptoms in more advanced cases.

Pharmacological treatments for sleep disturbance are associated with a range of adverse effects, including sedation and increased risk of falls, headaches and dizziness[27]. This has led to the American Geriatric Society Beers Criteria recommending against the use of pharmacological agents to treat sleep in older people[28]. Additionally, there is evidence to suggest that pharmacological treatments to improve sleep can worsen cognitive function in older people[13]. There is therefore increasing focus on exploring non-pharmacological approaches to treating sleep disturbance among older people with cognitive impairment[29].

Cognitive behavioural therapy for insomnia (CBT-I) is the first-line treatment recommended for insomnia and is supported by a large evidence base[30–33]. A recent meta-analysis of controlled clinical trials of sleep treatments for people with cognitive impairment included two trials of CBT-I and both demonstrated significant improvements in sleep[34]. One of the trials, involving 28 participants from independent living facilities, achieved significant improvement in both subjective and objective measures of sleep using the Insomnia Severity Index (ISI) and wrist actigraphy respectively[35]. The other trial, involving 35 participants recruited from outpatient clinics, found no improvement in objective sleep measures, with significant improvements only in subjective sleep quality[36]. Participants in the latter trial did not have significant sleep disturbance at baseline, however, and it is perhaps for this reason that meta-analysis of the two trials did not find any significant effect on sleep. Given the promising results in the trial that included participants with sleep disturbances at baseline, there is a need to further investigate the potential application of CBT-I to treat sleep disturbances among people with cognitive impairment.

Unfortunately, however, CBT-I is often difficult to access for many due to the shortage of trained therapists[37]. Digital CBT-I (dCBT-I) provides a possible solution to overcome the barriers associated with accessing the traditional therapist-delivered model of CBT-I. Indeed, evidence demonstrates the effectiveness of dCBT-I[38,39], which has also recently been shown to be feasible and effective in older people[40]. A small mixed-methods study involving 12 participants has demonstrated preliminary acceptability of dCBT-I (SHUTi OASIS) among older people with MCI[41]. More recently, a small open-label randomised controlled feasibility trial demonstrated preliminary efficacy of dCBT-I (*Sleepio*) in improving the ISI of people with MCI[42]. This latter trial was conducted remotely, indicating that the participants likely had relatively mild deficits and were adept at using digital technology. A recent qualitative study, conducted among patients who were recovering from stroke, identified some difficulties accessing and operating the *Sleepio* programme[43]. Nevertheless, nine out of a total of eleven participants successfully completed the programme, although three did require the assistance of their respective caregivers to do so.

It has been suggested that more qualitative research is required to explore barriers and facilitators to the uptake and acceptability of alternative modes of delivery of CBT-I, such as dCBT-I[44]. By its exploratory and inductive nature[45], qualitative research can provide more nuanced and subtle insights into the participants' perspective of how interventions are delivered in practice[46], thus helping to guide the design of future interventions and clinical trials.

Aim

Given the importance of treating co-morbid sleep disturbance at all stages of cognitive decline, we propose to undertake a mixed-methods analysis of the usability and acceptability of dCBT-I (*Sleepio*) among people with varying degrees of cognitive decline, ranging from subjective cognitive decline (SCD) through to MCI and mild-moderate dementia. We will also endeavour to assess whether usability and acceptability can

be improved by the availability of a study partner to assist with operation of the dCBT-I (*Sleepio*) programme. This will help to determine which people with cognitive impairment may be able to use and benefit from dCBT-I (*Sleepio*) to treat co-morbid sleep disturbance.

Methods

Intervention

Sleepio is a fully-automated and personalised dCBT-I intervention designed to treat insomnia using a combination of cognitive, behavioural, sleep hygiene and relaxation techniques. It is delivered through a web-based platform, supporting iOS or Android mobile applications. Underlying algorithms organise the delivery of information, support, and advice in a manner tailored to each individual patient based on their responses to an initial sleep study questionnaire and subsequent daily sleep diary entries throughout the duration of the programme. The programme consists of six sessions, each between five and twenty minutes in duration. *Sleepio* can be completed within a six-week period. However, the average time taken to complete the programme is 9–10 weeks. No time restriction is placed on the user to complete the sessions, and all previously viewed sessions remain available to the user to re-watch throughout the duration of the programme. Participants are offered daily notifications to prompt adherence to the programme.

Participants

Potential participants will be community-dwelling adults aged fifty years and older with probable insomnia attending outpatient memory clinics affiliated with the Mercy University Hospital in Cork, Ireland. Only participants with probable insomnia will be included because, although previous studies have suggested the effectiveness of *Sleepio* in sub-clinical insomnia[47], other studies have demonstrated that participants' motivation to adhere to the *Sleepio* programme was proportional to the severity of their sleep disturbance[43]. Study partners, if available, will also be recruited for dyadic participation and may include caregivers, family members or friends attending memory clinic with the participants. A previous qualitative study of the usability of *Sleepio* amongst patients following stroke found that some had to rely on help from partners to operate the programme and suggested that more people may be able to use dCBT-I if given support from a partner or caregiver[43]. It is anticipated that study partners may play an important role in facilitating successful adherence of participants to the *Sleepio* programme, particularly among participants with more advanced cognitive impairment[48]. While ideal and likely to enrich the study, the availability of a study partner will not be an inclusion/exclusion criterion. We will nevertheless endeavour to include them when available. Other inclusion/exclusion criteria are as follows:

Inclusion criteria:

1. Aged ≥50 years.
2. Sleep Condition Indicator (SCI)[49] Score ≤16/32. The SCI is an 8 item scale validated to assess insomnia based on DSM-5 criteria. Scores range from 0–32, with scores ≤16 indicating probable insomnia.
3. Established SCD, MCI or mild-moderate dementia, diagnosed by a consultant physician specialised in cognitive disorders prior to enrolment in the study. Dementia will be defined using DSM-5 classification and staged according to the Reisberg FAST scale[50] into early/mild/moderate stage. MCI will be defined using Petersen's criteria[51]. Participants must score between 0 – 2 on the Clinical Dementia Rating (CDR) scale[52], a commonly used clinician-rating scale of global symptom severity in dementia.
4. Sufficient physical/sensory (visual/hearing) capacity to use the intervention, as judged by the clinician/investigator.
5. English-speaker (intervention only available in English).
6. Community-dwellers (non-institutionalised).
7. Ability to provide informed written consent.

Exclusion criteria:

1. Known history of an International Classification of Diseases (ICD) defined sleep disorder other than insomnia disorder.
2. Receipt of a sleep-related cognitive behavioural therapy intervention within the past six months.
3. CDR >2
4. Severe depression (defined as depression requiring hospitalization in the past 12-months or visit to psychiatry outpatient clinic in the past three months).
5. Unstable depression/anxiety disorders or panic attacks (unstable will be defined as changes in antidepressant medications within the last three months - i.e. no start, stop or change in dose).
6. Other relevant major neuropsychiatric disorders, including schizophrenia, psychosis, mania, bipolar affective disorder, epilepsy or seizure disorder.
7. Ongoing substance or alcohol abuse.
8. Long-term physical or sensory impairment, pain or other medical condition which, in the opinion of the principal investigator, could impair participation for reasons other than cognitive impairment.
9. Planned surgery or hospitalisation during the study that could interfere with participation.
10. Medical conditions rendering the patient too unwell to continue to participate in the study in the opinion of the principal investigator.
11. A change in the following medication within the three months prior to enrolment:

a. Benzodiazepine and non-benzodiazepine hypnotic or anxiolytics agents

b. Cholinesterase inhibitors or Memantine

c. Antidepressants

d. Antipsychotics

e. Amphetamine derivatives

f. Decongestants

g. Narcotic analgesics

h. β-Blockers

i. Pulmonary medications (Theophylline and Albuterol)

j. Melatonin

Recruitment

All patients attending memory clinics affiliated with the Mercy University Hospital in Cork, Ireland will be screened for eligibility. Consecutive patients who meet eligibility criteria will be invited to participate in the study. It is hoped to recruit 20–30 participants over a four month period. Where possible, study partners including friends or family members of participants, will be recruited to support participants throughout the study.

Consent process

Fully informed written consent will be obtained from each participant prior to enrolment. The capacity of all participants to provide valid informed consent to participate in the study will be determined by a consultant physician in geriatric medicine. Fully informed written consent to participation will also be obtained from study partners (caregivers, friends, and or family members) if available and willing to participate. Participants and their study partners (if applicable) will be provided with a Participant Information Leaflet detailing the purpose of the study and what participation in the study would entail for them. Copies of the Participant Information Leaflet and Consent Forms that will be used in the study are available in the extended data.

Enrolment

Once recruited, participants will be provided with access to the study intervention (*Sleepio*). Given the digital nature of the intervention, each participant's digital literacy will be assessed using the Mobile Device Proficiency Questionnaire[53]. Every participant will be provided with a training/orientation session to teach them how to use the *Sleepio* programme. Additionally, each participant will be provided with clear written instructions on how to access and use the *Sleepio* programme. If a study partner is available, and both the participant and the study partner consent to their participation in the study, the partner will be also included in the training session.

Data collection

Data collection will be carried out in accordance with the European Union's General Data Protection Regulation and local data protection policies. The following data will be recorded in respect of every participant at baseline:

- Demographic data, including: age, sex, marital status, level of education, and employment status.
- Charlson Co-morbidity Index[54]
- Cognitive diagnosis and stage of cognitive impairment
- Medications

Following completion of the *Sleepio* programme, usability and acceptability will be assessed initially by a bespoke questionnaire incorporating the System Usability Scale[55], adapted for cognitive impairment[56], and the Usability Metric for User Experience - Lite (UMUX -Lite)[57]. The System Usability Scale is a validated and commonly employed 10 item Likert-type scale that provides a global assessment of how user-friendly a system or product is perceived to be. The UMUX-Lite is a more condensed two item Likert-type scale that also measures user-satisfaction with a system or product. Finally, participants and their study partners (where applicable) will be interviewed to further assess the usability and acceptability of the programme. The interview will be audio-recorded and conducted in a semi-structured manner using the topic guide included in the supplementary material. Participants and their study partners will be asked to expound on any difficulties they had in complying with the programme and whether they found the programme beneficial. In order to reduce the possibility of social desirability and positivity bias, the participants and their study partners (where applicable) will be informed that the interviewer is not affiliated with *Sleepio* and that the objective of the study is to obtain an accurate understanding of their experience using the programme in order to guide future research.

Data analysis

In respect of the bespoke questionnaire on usability and acceptability, categorical variables will be described in frequencies and percentages, while mean scores will be reported for the incorporated Systems Usability Scale and UMUX-Lite.

The audio-recorded semi-structured interviews will be transcribed verbatim. Transcripts of the interviews will be anonymised and the audio-recordings will be destroyed immediately following transcription. Transcripts will be read and re-read to ensure data immersion. Thematic analysis will be undertaken using open coding to identify patterns and themes in a six-stage process involving: familiarisation, generating initial codes, developing themes, reviewing themes, defining and naming themes, and reporting findings[46]. This process of analysis will be undertaken manually at first and then repeated using a qualitative data management software system to ensure thorough analysis. Emerging patterns and themes will be discussed periodically amongst all the researchers involved in this study (except ALH – see competing interests statement below) to facilitate collaborative reflexive analysis as consensus is reached[58]. The Standards for Reporting Qualitative Research will be adhered to when reporting the findings of the study[59].

Discussion

This mixed-methods study will explore the usability and acceptability of a dCBT-I (*Sleepio*) intervention in people with cognitive impairment. CBT-I is the first-line treatment for insomnia[30–33]. However, the effectiveness of cognitive behavioural therapy may be limited in people with cognitive impairment by their diminished ability to comprehend, learn, remember and apply the skills taught by the therapy programme[48]. This may be more marked for dCBT-I. By including participants with cognitive impairment ranging from SCD to mild-moderate dementia, this study will help identify the categories of people from amongst this cohort who are most likely to benefit from dCBT-I. By examining the barriers and facilitators that influence usability and acceptability of the *Sleepio* programme amongst people with cognitive impairment, this study will investigate how the delivery of dCBT-I may be adapted to enhance usability and acceptability amongst this population. In particular, the effect of digital literacy and the availability of study partners to support adherence to the programme will be analysed. Improved understanding of the influence of these factors will assist in the development of guidance on the use and application of dCBT-I in clinical practice for this cohort and older adults in general, who often rate their own comfort and familiarity with technology as poor or average[60]. By providing insights into the factors that influence usability, acceptability and potential efficacy of dCBT-I amongst people with cognitive impairment, this study will also help inform the design of a future definitive randomised controlled trial that will assess the effectiveness of dCBT-I to treat probable insomnia amongst this population.

Conclusion

This mixed-methods analysis of the usability and acceptability of a dCBT-I (*Sleepio*) intervention in people with cognitive impairment will help inform the design of a future randomised controlled trial that will assess the effectiveness of the intervention in this population.

Ethics & consent statement

This mixed-methods qualitative study will be conducted in accordance with the Declaration of Helsinki. Ethical approval for this study was granted by the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) on the 5th December 2023, under CREC reference number: ECM 4 (gg) 05/12/2023. Results of the study will be published in a peer-reviewed journal and presented at relevant academic conferences. Fully informed written consent will be obtained from each participant prior to enrolment.

Data availability

Underlying data

No data are associated with this article.

Extended data

Open Science Framework: A protocol for a mixed-methods analysis of the usability and acceptability of a digital cognitive-behavioural therapy for insomnia (dCBT-I) intervention (*Sleepio*) in participants with cognitive impairment.

https://doi.org/10.17605/OSF.IO/U8CBY

This article contains the following extended data[61]:

- Interview Topic Guide
- Participant Information Leaflet & Consent Form (Participant)
- Participant Information Leaflet & Consent Form (Study Partner)

Reporting guidelines

Open Science Framework: A protocol for a mixed-methods analysis of the usability and acceptability of a digital cognitive-behavioural therapy for insomnia (dCBT-I) intervention (*Sleepio*) in participants with cognitive impairment.

https://doi.org/10.17605/OSF.IO/U8CBY

This article contains the following reporting guidelines[61]:

- Standards for Reporting Qualitative Research

Data are available under the terms of the Creative Commons Zero "No rights reserved" data waiver (CC0 1.0 universal).

References

1. Kyle SD, Henry AL: **Sleep is a modifiable determinant of health: implications and opportunities for health psychology.** *Br J Health Psychol.* 2017; **22**(4): 661–670.
PubMed Abstract | Publisher Full Text
2. Lim DC, Najafi A, Afifi L, *et al.*: **The need to promote sleep health in public health agendas across the globe.** *Lancet Public Health.* 2023; **8**(10): e820–e826.
PubMed Abstract | Publisher Full Text | Free Full Text
3. Luyster FS, Strollo PJ Jr, Zee PC, *et al.*: **Sleep: a health imperative.** *Sleep.* 2012; **35**(6): 727–34.
PubMed Abstract | Publisher Full Text | Free Full Text
4. Walker M: **Why we sleep.** Harlow, England: Penguin Books, 2018.
Reference Source
5. Krueger PM, Friedman EM: **Sleep duration in the United States: a cross-sectional population-based study.** *Am J Epidemiol.* 2009; **169**(9): 1052–63.
PubMed Abstract | Publisher Full Text | Free Full Text
6. Nguyen V, George T, Brewster GS: **Insomnia in older adults.** *Curr Geriatr Rep.* 2019; **8**(4): 271–290.
7. Bliwise DL: **Sleep in normal aging and dementia.** *Sleep.* 1993; **16**(1): 40–81.
PubMed Abstract | Publisher Full Text
8. Ohayon MM, Carskadon MA, Guilleminault C, *et al.*: **Meta-analysis of quantitative sleep parameters from childhood to old age in healthy individuals: developing normative sleep values across the human lifespan.** *Sleep.* 2004; **27**(7): 1255–73.
PubMed Abstract | Publisher Full Text

9. Guarnieri B, Adorni F, Musicco M, *et al.*: **Prevalence of sleep disturbances in mild cognitive impairment and dementing disorders: a multicenter Italian clinical cross-sectional study on 431 patients.** *Dement Geriatr Cogn Disord.* 2012; **33**(1): 50–8.
PubMed Abstract | Publisher Full Text | Free Full Text

10. D'Rozario AL, Chapman JL, Phillips CL, *et al.*: **Objective measurement of sleep in mild cognitive impairment: a systematic review and meta-analysis.** *Sleep Med Rev.* 2020; **52**: 101308.
PubMed Abstract | Publisher Full Text

11. Wei J, Wang M, Guo Y, *et al.*: **Sleep structure assessed by objective measurement in patients with mild cognitive impairment: a meta-analysis.** *Sleep Med.* 2024; **113**: 397–405.
PubMed Abstract | Publisher Full Text

12. Shi L, Chen SJ, Ma MY, *et al.*: **Sleep disturbances increase the risk of dementia: a systematic review and meta-analysis.** *Sleep Med Rev.* 2018; **40**: 4–16.
PubMed Abstract | Publisher Full Text

13. Mander BA, Winer JR, Jagust WJ, *et al.*: **Sleep: a novel mechanistic pathway, biomarker, and treatment target in the pathology of Alzheimer's disease?** *Trends Neurosci.* 2016; **39**(8): 552–566.
PubMed Abstract | Publisher Full Text | Free Full Text

14. Bubu OM, Brannick M, Mortimer J, *et al.*: **Sleep, cognitive impairment, and Alzheimer's disease: a systematic review and meta-analysis.** *Sleep.* 2017; **40**(1).
PubMed Abstract

15. Livingston G, Huntley J, Liu KY, *et al.*: **Dementia prevention, intervention, and care: 2024 report of the *Lancet* standing Commission.** *Lancet.* 2024; **404**(10452): 572–628.
PubMed Abstract | Publisher Full Text

16. Minakawa EN, Wada K, Nagai Y: **Sleep disturbance as a potential modifiable risk factor for Alzheimer's disease.** *Int J Mol Sci.* 2019; **20**(4): 803.
PubMed Abstract | Publisher Full Text | Free Full Text

17. Bassetti CLA, Endres M, Sander A, *et al.*: **The European Academy of Neurology Brain Health Strategy: one brain, one life, one approach.** *Eur J Neurol.* 2022; **29**(9): 2559–2566.
PubMed Abstract | Publisher Full Text

18. Liguori C, Placidi F, Izzi F, *et al.*: **Sleep dysregulation, memory impairment, and CSF biomarkers during different levels of neurocognitive functioning in Alzheimer's disease course.** *Alzheimers Res Ther.* 2020; **12**(1): 5.
PubMed Abstract | Publisher Full Text | Free Full Text

19. Prinz PN, Vitaliano PP, Vitiello MV, *et al.*: **Sleep, EEG and mental function changes in senile dementia of the Alzheimer's type.** *Neurobiol Aging.* 1982; **3**(4): 361–70.
PubMed Abstract | Publisher Full Text

20. Wennberg AMV, Wu MN, Rosenberg PB, *et al.*: **Sleep disturbance, cognitive decline, and dementia: a review.** *Semin Neurol.* 2017; **37**(4): 395–406.
PubMed Abstract | Publisher Full Text | Free Full Text

21. Vitiello MV, Borson S: **Sleep disturbances in patients with Alzheimer's disease: epidemiology, pathophysiology and treatment.** *CNS Drugs.* 2001; **15**(10): 777–96.
PubMed Abstract | Publisher Full Text

22. Donaldson C, Tarrier N, Burns A: **Determinants of carer stress in Alzheimer's disease.** *Int J Geriatr Psychiatry.* 1998; **13**(4): 248–256.
PubMed Abstract | Publisher Full Text

23. Pudelewicz A, Talarska D, Bączyk G: **Burden of caregivers of patients with Alzheimer's disease.** *Scand J Caring Sci.* 2019; **33**(2): 336–341.
PubMed Abstract | Publisher Full Text

24. McCurry SM, Vitiello MV, Gibbons LE, *et al.*: **Factors associated with caregiver reports of sleep disturbances in persons with dementia.** *Am J Geriatr Psychiatry.* 2006; **14**(2): 112–20.
PubMed Abstract | Publisher Full Text

25. Gaugler JE, Edwards AB, Femia EE, *et al.*: **Predictors of institutionalization of cognitively impaired elders: family help and the timing of placement.** *J Gerontol B Psychol Sci Soc Sci.* 2000; **55**(4): P247–P255.
PubMed Abstract | Publisher Full Text

26. Pollak CP, Perlick D, Linsner LP, *et al.*: **Sleep problems in the community elderly as predictors of death and nursing home placement.** *J Community Health.* 1990; **15**(2): 123–35.
PubMed Abstract | Publisher Full Text

27. Lam S, Macina LO: **Therapy update for Insomnia in the elderly.** *Consult Pharm.* 2017; **32**(10): 610–622.
PubMed Abstract | Publisher Full Text

28. By the 2023 American Geriatrics Society Beers Criteria® Update Expert Panel: **American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults.** *J Am Geriatr Soc.* 2023; **71**(7): 2052–2081.
PubMed Abstract | Publisher Full Text

29. O'Caoimh R, Mannion H, Sezgin D, *et al.*: **Non-pharmacological treatments for sleep disturbance in mild cognitive impairment and dementia: a systematic review and meta-analysis.** *Maturitas.* 2019; **127**: 82–94.
PubMed Abstract | Publisher Full Text

30. Edinger JD, Arnedt JT, Bertisch SM, *et al.*: **Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline.** *J Clin Sleep Med.* 2021; **17**(2): 255–262.
PubMed Abstract | Publisher Full Text | Free Full Text

31. Qaseem A, Kansagara D, Forciea MA, *et al.*: **Management of chronic insomnia disorder in adults: a clinical practice guideline from the American College of Physicians.** *Ann Intern Med.* 2016; **165**(2): 125–33.
PubMed Abstract | Publisher Full Text

32. Riemann D, Espie CA, Altena E, *et al.*: **The European Insomnia guideline: an update on the diagnosis and treatment of insomnia 2023.** *J Sleep Res.* 2023; **32**(6): e14035.
PubMed Abstract | Publisher Full Text

33. Wilson S, Anderson K, Baldwin D, *et al.*: **British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders: an update.** *J Psychopharmacol.* 2019; **33**(8): 923–947.
PubMed Abstract | Publisher Full Text

34. Crowley P, Flanagan E, O'Caoimh R: **A protocol for the systematic review and meta-analysis of clinical trials of interventions to improve sleep in people with mild cognitive impairment or dementia. [version 1; peer review: 1 approved with reservations].** *HRB Open Res.* 2024; **7**: 63.
Publisher Full Text

35. Cassidy-Eagle E, Siebern A, Unti L, *et al.*: **Neuropsychological functioning in older adults with mild cognitive impairment and Insomnia randomized to CBT-I or control group.** *Clin Gerontol.* 2018; **41**(2): 136–144.
PubMed Abstract | Publisher Full Text

36. Naismith SL, Pye J, Terpening Z, *et al.*: **"Sleep Well, Think Well" group program for mild cognitive impairment: a randomized controlled pilot study.** *Behav Sleep Med.* 2019; **17**(6): 778–789.
PubMed Abstract | Publisher Full Text

37. Koffel E, Kuhn E, Petsoulis N, *et al.*: **A randomized controlled pilot study of CBT-I Coach: Feasibility, acceptability, and potential impact of a mobile phone application for patients in cognitive behavioral therapy for insomnia.** *Health Informatics J.* 2018; **24**(1): 3–13.
PubMed Abstract | Publisher Full Text

38. Soh HL, Ho RC, Ho CS, *et al.*: **Efficacy of digital cognitive behavioural therapy for insomnia: a meta-analysis of randomised controlled trials.** *Sleep Med.* 2020; **75**: 315–325.
PubMed Abstract | Publisher Full Text

39. Zachariae R, Lyby MS, Ritterband LM, *et al.*: **Efficacy of internet-delivered cognitive-behavioral therapy for insomnia – a systematic review and meta-analysis of randomized controlled trials.** *Sleep Med Rev.* 2016; **30**: 1–10.
PubMed Abstract | Publisher Full Text

40. Lee Y, Kim I, Lee S, *et al.*: **Information and communication technology-based application for cognitive behavioral therapy among community-dwelling older adults with Insomnia: development and validation study.** *Healthcare (Basel).* 2024; **12**(1): 106.
PubMed Abstract | Publisher Full Text | Free Full Text

41. Mattos MK, Manning CA, Quigg M, *et al.*: **Feasibility and preliminary efficacy of an Internet-delivered intervention for insomnia in individuals with Mild Cognitive Impairment.** *J Alzheimers Dis.* 2021; **84**(4): 1539–1550.
PubMed Abstract | Publisher Full Text | Free Full Text

42. Hoyos C, Espinosa N, Marshall N, *et al.*: **0441 sleep disturbance in MCI: a pilot study of a Cognitive Behavioural Therapy digital intervention (SUCCEED).** *Sleep.* 2024; **47**(Suppl 1): A189.
Publisher Full Text

43. Smejka T, Henry AL, Wheatley C, *et al.*: **A qualitative examination of the usability of a digital Cognitive Behavioral Therapy for Insomnia program after stroke.** *Brain Inj.* 2022; **36**(2): 271–278.
PubMed Abstract | Publisher Full Text | Free Full Text

44. Koffel E, Bramoweth AD, Ulmer CS: **Increasing access to and utilization of Cognitive Behavioral Therapy for Insomnia (CBT-I): a narrative review.** *J Gen Intern Med.* 2018; **33**(6): 955–962.
PubMed Abstract | Publisher Full Text | Free Full Text

45. Savin-Baden M, Major CH: **Qualitative research: the essential guide to theory and practice.** Routledge, 2023.
Publisher Full Text

46. Braun V, Clarke V: **Using thematic analysis in psychology.** *Qual Res Psychol.* 2006; **3**(2): 77–101.
Publisher Full Text

47. Denis D, Eley TC, Rijsdijk F, *et al.*: **Is digital Cognitive Behavioural Therapy for Insomnia effective in treating sub-threshold insomnia: a pilot RCT.** *Sleep Med.* 2020; **66**: 174–183.
PubMed Abstract | Publisher Full Text

48. Kraus CA, Seignourel P, Balasubramanyam V, *et al.*: **Cognitive-Behavioral Treatment for anxiety in patients with dementia: two case studies.** *J Psychiatr Pract.* 2008; **14**(3): 186–92.
PubMed Abstract | Publisher Full Text | Free Full Text

49. Espie CA, Kyle SD, Hames P, *et al.*: **The Sleep Condition Indicator: a clinical screening tool to evaluate insomnia disorder.** *BMJ Open.* 2014; **4**(3): e004183.
PubMed Abstract | Publisher Full Text | Free Full Text

50. Reisberg B: **Functional Assessment Staging (FAST).** *Psychopharmacol Bull.*

1988; **24**(4): 653–659.
PubMed Abstract

51. Petersen RC, Smith GE, Waring SC, *et al.*: **Mild cognitive impairment: clinical characterization and outcome.** *Arch Neurol.* 1999; **56**(3): 303–8.
PubMed Abstract | **Publisher Full Text**

52. Morris JC: **The Clinical Dementia Rating (CDR): current version and scoring rules.** *Neurology.* 1993; **43**(11): 2412–4.
PubMed Abstract | **Publisher Full Text**

53. Roque NA, Boot WR: **A new tool for assessing mobile device proficiency in older adults: the Mobile Device Proficiency Questionnaire.** *J Appl Gerontol.* 2018; **37**(2): 131–156.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

54. Charlson ME, Pompei P, Ales KL, *et al.*: **A new method of classifying prognostic comorbidity in longitudinal studies: development and validation.** *J Chronic Dis.* 1987; **40**(5): 373–83.
PubMed Abstract | **Publisher Full Text**

55. Lewis JR: **The System Usability Scale: past, present, and future.** *Int J Hum Comput Interact.* 2018; **34**(7): 577–590.
Publisher Full Text

56. Holden RJ: **A simplified System Usability Scale (SUS) for cognitively impaired and older adults.** *Proc Int Symp Hum Factors Ergon Healthc.* 2020; **9**(1): 180–182.
Publisher Full Text

57. Lewis JR, Utesch BS, Maher DE: **UMUX-LITE: when there's no time for the SUS.** In: *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems.* Association for Computing Machinery: Paris, France, 2013; 2099–2102.
Publisher Full Text

58. Olmos-Vega FM, Stalmeijer RE, Varpio L, *et al.*: **A practical guide to reflexivity in qualitative research: AMEE guide no. 149.** *Med Teach.* 2023; **45**(3): 241–251.
PubMed Abstract | **Publisher Full Text**

59. O'Brien BC, Harris IB, Beckman TJ, *et al.*: **Standards for Reporting Qualitative Research: a synthesis of recommendations.** *Acad Med.* 2014; **89**(9): 1245–1251.
PubMed Abstract | **Publisher Full Text**

60. Scanlon L, O'Shea E, O'Caoimh R, *et al.*: **Technology use and frequency and self-rated skills: a survey of community-dwelling older adults.** *J Am Geriatr Soc.* 2015; **63**(7): 1483–4.
PubMed Abstract | **Publisher Full Text**

61. Crowley P, Flanagan E, O'Caoimh R: **A protocol for a mixed-methods analysis of the usability and acceptability of a digital Cognitive-Behavioural Therapy for Insomnia (dCBT-I) intervention (Sleepio) in participants with cognitive impairment**.
http://www.doi.org/10.17605/OSF.IO/U8CBY

Open Peer Review

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✔ **Inga Antonsdottir**

Johns Hopkins Medicine, Baltimore, Maryland, USA

Review for: A protocol for a mixed-methods analysis of the usability and acceptability of a digital cognitive-behavioural therapy for insomnia (dCBT-I) intervention (*Sleepio*™) in participants with cognitive impairment.
General comment: Thank you for the opportunity to review this well-written and relevant manuscript. The manuscript outlines a protocol for the important topic of understanding the usability and acceptance of a digital cognitive behavioral therapy for insomnia intervention for people with cognitive impairment.

Abstract: Clear and well-written.
Keywords: appropriate.
Introduction:

- This sentence in the second paragraph, *"Despite the recent Dementia Prevention, Intervention and Care: 2024 report of the Lancet Commission concluding that further research is needed to clarify the effect of sleep disturbance on cognitive decline15, therefore, interest is growing in sleep disturbance as a potential modifiable risk factor for cognitive impairment16."* Is a little long-winded and difficult to follow. Please consider breaking it up.

Methods:

- There is no time restriction placed on the user to complete the sessions, it may be beneficial to place a generous time restriction to allow participants some sort of guideline to follow, such as 12 or 15 weeks? Or does time restriction refer to the number of hours it takes for participants to finish a session? Please clarify – thanks!
- Anxiety and depression disorders are listed, are there any neuropsychiatric symptoms that could impact the intervention that you may want to exclude? Such as nighttime agitation, sundowning, wandering? Potentially add to exclusion number 6, "other relevant major NEUROPSYCHIATRIC SYMPTOMS or major neuropsychiatric disorders…"?
- In the recruitment section, consider adding how many patients are seen in the clinic during a month.

Discussion & Conclusion: well written, no comments.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: dementia, caregiving, sleep, cbti

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 18 August 2025

https://doi.org/10.21956/hrbopenres.15590.r48112

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Alexandra Hinterberger
Salzburg University, Salzburg, Austria

The authors propose a mixed-methods protocol to investigate the usability and acceptability of a dCBT-I program (Sleepio) in participants with cognitive impairment. 20-30 adults aged 50+ with MCI and likely insomnia will use Sleepio over (a minimum of) six weeks. Questionnaires and interviews will evaluate the program's usability and user experience. Study partners (caregivers or relatives) will also be included to assess their influence.
Overall, the authors present a well thought-through study design suitable for addressing the main question of interest and include various adequate measures.

Including only patients with probable insomnia is obvious to investigate the usability of a dCBT-I program in an affected population.

I particularly endorse the use of not only questionnaires, but also semi-structured interviews for the assessment of participants' program experience to get a more realistic and profound perspective. It is however, to be accounted for answers biased by social desirability (even when explicitly mentioning that the interviewer is not affiliated with Sleepio). Furthermore, I appreciate the assessment of participants' digital literacy to account for potential difficulties due to the digital nature of the CBT-I program.

The interview questions provided seem to cover the most relevant aspects while leaving room for open answers and conversation.

While the protocol covers the most important points, some questions/points require further consideration:

1) How will the authors ensure, that participants with cognitive impairment will fully understand the questionnaire items to assess usability? Will the questionnaires be read and explained to participants if needed?

2) How will the progress of the dCBT-I program be tracked (completion of exercises, duration of time spent in the program, etc)? And how does this align with data protection regulations?

3) Did the authors plan on including any forms of objective sleep measurement (PSG, actigraphy, HRV-based measurements)? Or will the effects of the dCBT-I program on sleep be solely assessed using the subjective experience?

4) Is there a specific reason as to why the Insomnia Severity Index (ISI) was not included in this protocol? Including it would foster comparability with other, similar study protocols as described by the authors in the introduction.

5) The dCBT-I program is being tailored to the individual. To what extend does the content of the program vary (e.g., are all patients still presented with all core elements of CBT-I, like bed time restriction)? And if the content delivered differs significantly between patients, how do the authors ensure comparability of the usability and acceptability?

6) Speaking of bed time restriction: How will the adherence to more challenging elements of dCBT-I be ensured/monitored? Or are participants free to choose what exercises they follow through?

7) Please provide a short overview regarding the questions participants will have to answer (daily?) in the sleep diary.

8) The authors say that no time restriction will be placed regarding the completion of the program, Does this mean that study participants will have up to 4 months (duration of the study) to complete the 6 sessions? If so, is the progress between participants and therefore potential stress and beneficial effects still comparable?

9) The authors state "Receipt of sleep-related cognitive behavioral therapy intervention within the past six months" as an exclusion criterion. I am wondering whether six months might be too little time to show (potential) effects of the dCBT-I program. The authors might benefit from either excluding patients who have already completed CBT-I, or increasing the time that should have passed between the interventions.

10) In the Participant Information Document, please add that the interview will be recorded for full transparency.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: psychology, sleep research, insomnia, CBT-I

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.