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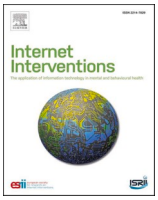

The Sleep Course: An inclusive trial examining the feasibility, acceptability, and preliminary efficacy of a digital sleep intervention for adults with self-reported sleep difficulties

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ABSTRACT

Cognitive Behavioural Therapy for Insomnia (CBTi) is a well-established first-line treatment for insomnia and sleep difficulties, yet numerous barriers hinder its widespread adoption. One potential criticism of the existing evidence base for CBTi is that many trials exclude participants that would commonly be seen in in primary care, such as those aged over 65, with comorbid health conditions, or prescribed sleep medication. The current pilot study therefore aimed to assess the acceptability and efficacy of a brief, digitally delivered sleep intervention, the Sleep Course, using a broad range of participants. Participants ($n = 74$) completed the 6-week, 4-lesson intervention alongside measures of sleep disturbance, sleep-related impairment, depression, anxiety and sleep-wake patterns (via sleep diary). Generalized estimating equations analysis modelled change in participants' outcomes from pre- to post-treatment and 3-month follow-up, and subgroup analyses explored the role of possible moderators (e.g., age over 65, co-morbidities, and concurrent prescription medication use). The intervention was associated with good rates of satisfaction (79 %) and lesson completion (70 %). Results showed significant and large reductions in insomnia, sleep disturbance and associated symptoms (e.g., $d = 1.06$–1.37 change in insomnia symptoms). Evidence of high acceptability and clinical improvement was found irrespective of age, physical comorbidity, and sleep medication use. However, there was evidence of less improvement among those taking medications or having tried psychological treatment in the past. These results provide strong preliminary evidence for the intervention as an acceptable, efficacious and scalable treatment for a broad range of participants with sleep difficulties. Larger randomised controlled trials are needed.

1. Introduction

Sleep difficulties are common in the community, with approximately 30 % of adults reporting difficulty falling and/or staying asleep each night (Morin and Jarrin, 2022). Insomnia disorder refers to the persistence of such difficulties and associated daytime impairment or distress, and affects between 5 and 15 % of the population (American Psychiatric Association and Association, 2013; Morin and Jarrin, 2022). Insomnia and subthreshold symptoms carry significant adverse consequences for physical and psychological health (Morin and Jarrin, 2022). For example, insomnia is associated with impaired cognitive function (Wardle-Pinkston et al., 2019), significantly increased risk of cardiovascular disease (Laugsand et al., 2011) and increased prevalence of psychiatric disorders (Hertenstein et al., 2019). Given their high frequency and consequences, there is a significant public health interest in the effective prevention and treatment of insomnia.

Fortunately, Cognitive Behavioural Therapy for Insomnia (CBTi) has amassed a significant evidence base as an effective treatment for people with insomnia (Van Straten et al., 2018) and subthreshold symptoms (Denis et al., 2020). Given its strong evidence, it is recommended as the first-line treatment for these concerns (Morin et al., 2023). Digital CBTi is also a well-established alternative to face-to-face treatment (Soh et al., 2020; Hedman-Lagerlöf et al., 2023). The content of these digital CBTi interventions is the same as traditional face-to-face treatments, though some approaches use fully automated and tailored guidance based on algorithms (Ritterband et al., 2009; Espie et al., 2019). Digital CBTi may help to overcome many of the well-known barriers to accessing evidence-based care (e.g., cost, geographical isolation) as well as the unique undersupply of health professionals trained in behavioural sleep medicine and CBTi (Koffel et al., 2018).

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One notable limitation of both face-to-face and digital CBTi research is the tendency of clinical trials to exclude individuals who are commonly seen in routine practice. These include people with co-morbid sleep disorders or chronic disease, older age (e.g., over 65), taking medications for sleep, and people who have engaged with past or concurrent psychological treatment (Soh et al., 2020). These practices are important and necessary when evaluating the initial efficacy of treatments, because they control for possible factors that might affect symptom change that is unrelated to the intervention. However, such criteria mean that trial participants do not always reflect the characteristics of patients seeking care. This has been documented in depression; a study applied the inclusion and exclusion criteria of 158 antidepressant RCTs to a large sample (n = 1271) patients seeking outpatient care (Zimmerman et al., 2019). They found that between 44.4 and 99.8 % of outpatients would have been excluded from individual RCTs, with a mean of 86 %. The lack of generalisable samples in clinical trials is thought to explain why treatments perform more poorly in routine care (Kennedy-Martin et al., 2015). Unfortunately, patient characteristics that would lead them to be excluded from CBTi (e.g., co-morbidities, concurrent use of prescription medication, age over 65) are highly common. For example, the prevalence of insomnia is almost double in people with sleep apnoea than the general population (Sweetman et al., 2021), and studies have found that over 50 % of people with chronic pain are above the clinical threshold for insomnia (Tang et al., 2007). Similarly, insomnia prevalence and severity increases with advancing age, reaching a prevalence of 26 % in the elderly (compared to 8–9 % in younger adults from the same sample) (Sivertsen et al., 2009). Finally, between 40 % and 60 % of people with insomnia report using concurrent hypnotic medication such as zolpidem and trazodone (Grandner et al., 2022; Dawson et al., 2023). While there is good evidence that CBTi is efficacious in specific populations (e.g., co-morbid insomnia and sleep apnoea (Sweetman et al., 2019), insomnia in older adults (Lovato et al., 2014)), large and pragmatic studies are still needed to confirm the broad efficacy of CBTi.

In this context, the current pilot study sought to evaluate the feasibility, acceptability and efficacy of brief, digital CBTi for individuals with insomnia symptoms and sleep difficulties. We imposed minimal exclusion criteria, recognising the high likelihood of subclinical symptoms, co-morbidities, older age, and concurrent or past psychological treatment within this population. Our second aim was to understand whether the presence of these participant characteristics would be associated different treatment acceptability, engagement, and response.

2. Methods

2.1. Design

The current study was a single group pre-post design. The trial was prospectively registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12623000331639) and the ethical aspects were approved by the Macquarie University Human Research Ethics Committee. Participants read about the study and completed a screening assessment to take part via the eCentreClinic website (www.ecentreclinic.org). The eCentreClinic is a specialist research clinic providing access to treatment via participation in clinical trials. The intervention was promoted on the eCentreClinic website as well as via social media. Participants were also informed about the study and treatment via word of mouth and health professional referrals. After providing informed consent, participants completed an online screening assessment, which involved questionnaires assessing the degree of sleep disturbance, treatment history, and depression symptom severity. Following online screening, eligible participants were contacted via telephone by study clinicians (AJS or TH) to further assess their sleep disturbance and co-morbidities, to provide further information and answer questions about the intervention, and to confirm eligibility.

2.2. Participants

Eligible participants were (1) aged 18 years or older, (2) living in Australia, and (3) had a self-reported difficulty with sleep (either falling asleep, staying asleep, or waking early) which caused daytime distress or impairment. No minimum symptom duration was imposed. Participants were excluded if they; (1) had a current severe medical or psychiatric disorder that required immediate treatment (e.g., severe depression and unable to keep themselves sage), (2) were taking part in another treatment at the clinic or (3) reported a co-morbid sleep or health condition that was the primary cause of their sleep complaint, and that did not appear to be properly managed (e.g., obstructive sleep apnoea with self-reported insufficient adherence to continuous positive airway pressure therapy, and a main complaint of excessive daytime sleepiness).

2.3. Intervention

The internet-delivered intervention, the Sleep Course, is based on the core components of cognitive behavioural therapy for insomnia. It is designed to teach core information and skills to help participants manage unhelpful thoughts and behaviours known to perpetuate insomnia, such as extended time in bed, excessive sleep-related worry, and conditioned arousal (Harvey, 2002). The structure and delivery of the intervention is similar to existing protocols and includes four lessons, which provide psychoeducation, sleep restriction, stimulus control, cognitive restructuring and behavioural activation (see Table 1). Each lesson is presented in the form of a slide show, comprising 30 to 40 slides, and taking approximately 20 to 30 min to read. The lessons are delivered over 6 weeks and each lesson is accompanied by homework exercises and other printable materials (e.g., sleep diary) to facilitate skills practice. The intervention also contained additional resources based on common areas of interest or concern for participants (e.g., relaxation resources, managing shift work, relapse prevention). All intervention lessons and associated resources are available on a web browser, which is compatible with both computer and mobile devices. See Table 1 for an overview of the course content and its timing. Each lesson also incorporated case examples of participants sharing their experiences and how they applied the skills.

Support by a clinical psychologist (AJS or TH) was made available to participants throughout the duration of the course. This support was

Table 1
Course overview.

Course week	Lesson content	Additional resources
1	Psychoeducation about sleep difficulties and the psychological, biological and social influences of sleep. Overview of the two-process model of sleep (i.e., introduction to circadian rhythms and sleep pressure system)	Sleep myth-busting Keeping a sleep diary
2	Introduction to sleep restriction[a] and stimulus control therapy.	Sleep and shift work Diet, medication and exercise
3	No material released. Participants given time to continue with sleep restriction therapy or stimulus control.	
4	Overview of the role of unhelpful thoughts in sleep. Introduction to cognitive challenging and scheduled worry time.	Relaxation strategies Nightmares
5	Overview of the role of unhelpful behaviours that maintain sleep problems (e.g., under-activity). Introduction to activity scheduling. Introduction to wind-up and wind-down routines.	Relapse prevention
6	No material released. Participants encouraged to share feedback about the course and collaborate with course clinician in the final treatment week.	

[a] For sleep restriction therapy, a goal of 85 % sleep efficiency was recommended before increasing minimum TIB.

provided via telephone and a secure messaging system based on participant preference. Participants were welcomed into the course by their appointed clinician in the first week and asked to indicate their preferences for contact (i.e., whether they wished to work through with support or on their own, and whether they would prefer to speak on the phone or via secure messaging). Both clinicians have extensive CBT training and experience, with further specialist training in the management of sleep disorders. Their role was to support participants to work through the materials and help participants with skills, particularly sleep restriction and/or stimulus control. Alongside clinical contact, participants were sent emails throughout the course, which provided updates about new lessons being released, and promoted engagement with course materials.

2.4. Measures

2.4.1. Primary outcomes

The Patient-Reported Outcomes Measurement Information System (PROMIS-8) Sleep Disturbance (SD) scale is an 8-item measure designed to evaluate the quality and disturbances of sleep experienced over the preceding week. The PROMIS-SD was selected as a transdiagnostic measure that was developed to assess the severity of sleep-wake problems on a continuum and applicable across a range of conditions (Yu et al., 2012). Participants rate each item on a 5-point Likert scale, ranging from 0 (not at all) to 4 (very much). Higher scores indicate greater sleep disturbance. In order to understand the severity of participants' sleep disturbance, raw scores were compared to an associated T-score (i.e., a standardised metric with a mean of 50 and standard deviation of 10). Participants' scores subsequently fell into 4 categories; none or slight problems with sleep, mild, moderate and severe (see Table 2 for further details).

In addition to severity of sleep disturbance, the feasibility and acceptability of the intervention was examined in various ways. The number of lessons completed by participants was recorded within the eCentreClinic clinical software platform. In addition, participants satisfaction with the treatment was measured at post-treatment. Participants were also asked to provide free-text comments about what they liked and disliked about the course, and whether they had any suggestions for its improvement.

2.4.2. Secondary outcomes

The Insomnia Severity Index (ISI; (Bastien et al., 2001)) is a brief questionnaire used to assess the severity of insomnia symptoms over the past 2 weeks. It comprises 7 items, each rated on a 5-point Likert scale. Total scores range from 0 to 28, with higher scores indicating more severe insomnia. Established clinical cut-offs are applied to categorize participants into different severity bands: 0–7 = absence of insomnia, 8–14 = subthreshold insomnia, 15–21 = moderate insomnia, and 22–28 = severe insomnia, based on their total scores.

The PROMIS Sleep Related Impairment (SRI-8a) scale assesses the impact of sleep disturbances on daytime functioning (Yu et al., 2012). It consists of eight items related to cognitive, emotional, and social

Table 2
Baseline characteristics ($n = 74$).

Demographic		Clinical characteristics and treatment history		Co-morbidity details	
Sex		PROMIS-SD, M (SD)	19.4 (4.1)	Diagnosed with chronic disease?	47 (63.5)
Female	63 (85.1)	None/slight (T-score 55 or less)	26 (35.1)	Chronic pain	25 (33.8)
Male	11 (14.9)	Mild (T-score 55–59)	29 (39.2)	Fibromyalgia	6 (8.1)
Age (M (SD))	52.1 (14.4)	Moderate (T score 60–69)	19 (25.7)	Migraine	9 (12.2)
<29 (N, %)	7 (9.5)	Severe (T score ≥ 70)	0	Cancer remission	6 (8.1)
30–39	5 (6.5)	Insomnia Severity Index (ISI), M (SD)	16.5 (4.3)	Cardiovascular disease	6 (8.1)
40–49	21 (28.4)	None	1 (1.4)	Hypothyroidism	4 (5.4)
50–59	17 (23.0)	Subthreshold	24 (32.4)	FGIDs	4 (5.4)
60–65	7 (9.5)	Clinical – moderate	39 (52.7)	Asthma	3 (4.1)
>65	17 (23.0)	Clinical – severe	10 (13.5)	Other	22 (29.7)
Employment		PROMIS-SRI	13.2 (5.1)	Depression symptoms (PHQ-9)	8.4 (3.9)
Full-time work	25 (33.8)	None/slight (T-score 55 or less)	27 (36.5)	Minimal	13 (17.6)
Part-time/casual work	17 (23.0)	Mild (T-score 55–59)	29 (32.4)	Mild	32 (43.2)
Student	4 (5.4)	Moderate (T score 60–69)	18 (24.3)	Moderate	24 (32.4)
Unemployed	4 (2.7)	Severe (T score ≥ 70)	0	Moderately severe	5 (6.8)
Registered disability	10 (13/5)	DBAS	88.8 (17.7)	Severe	0
Retired	12 (23)	Sleep diary		Depression symptoms without sleep items (PHQ-9)	6.3 (3.7)
Stay at home parent	2 (2.7)	TIB (min)	560 (89.6)	Minimal	24
Relationship status		SOL (min)	48.3 (43.6)	Mild	36
	14 (18.9)	TST (min)	365 (85.9)	Moderate	12
Married/de facto	51 (69.0)	WASO (min)	52.7 (41.7)	Moderately severe	2
Widowed/separated	9 (12.2)	SE (%)	65.8 (15.3)	Severe	0
Education		Sleep problem duration (years, M (SD))	9.4 (10.7)	Anxiety symptoms (GAD-7)	5.9 (3.7)
Year 12 or less	6 (8.1)	Seen health professional for sleep problem?	53 (71.6)	Minimal	29 (39.2)
Undergraduate/diploma	11 (14.9)	General practitioner	46 (62.2)	Mild	33 (44.6)
Trade certificate	7 (9.5)	Psychiatrist	5 (6.8)	Moderate	10 (13.5)
Bachelor's degree	34 (45.9)	Psychologist or counsellor	16 (21.6)	Severe	2 (2.7)
Masters or doctoral degree	12 (21.6)	Sleep specialist	18 (24.3)	Diagnosed with sleep disorder?	9 (12.1)
		specialist	3 (4.1)	Sleep apnoea	7 (9.5)
		Ear, nose and throat specialist	2 (2.7)	Restless legs syndrome	2 (2.7)
		Naturopath	8 (8.1)		
		Other	1 (1.4)		
		Treatments tried			
		Non-prescription medication (e.g. vitamins)	59 (79.7)		
		Prescription medication	48 (64.9)		
		Complementary/alternative medicine	15 (20.3)		
		Counselling or psychotherapy	21 (28.4)		
		Other	13 (17.6)		

PROMIS-SD, patient reported outcomes measurement information system, sleep disturbance scale; PHQ-9, patient health questionnaire; GAD-7, generalized anxiety disorder 7-item scale; DBAS, dysfunctional beliefs and attitudes about sleep; TIB, time in bed, TST; total sleep time; SOL, sleep onset latency; WASO, wake after sleep onset; SE, sleep efficiency; FGIDs, functional gastrointestinal disorders.

functioning, with responses rated on a 5-point Likert scale ranging from 0 (not at all) to 4 (very much).

The Patient Health Questionnaire-9 (PHQ-9; (Kroenke et al., 2001)) is widely used to evaluate the severity of depression symptoms. It consists of 9 items rated on a scale from 0 to 3, with higher scores indicating more severe depression. Total scores range from 0 to 27, with a score of ≥10 indicating clinically significant depression. Additionally, the PHQ-9 provides severity bands: 0–4 = minimal depression, 5–9 = mild, 10–14 = moderate, 15–19 = moderately severe, and ≥20 = severe symptoms, based on total scores. Item 3 of the PHQ-9 measures sleep disturbance ('trouble falling or staying asleep, or sleeping too much'.) Because of its potential to be confounded with sleep difficulties, and consistent with past research (Van der Zweerde et al., 2019), results on the PHQ-9 were reported with and without this item.

The Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS-16; (Morin et al., 2007)) assesses dysfunctional beliefs and attitudes about sleep, common in individuals with sleep difficulties such as insomnia. It comprises 16 items, each rated on a 10-point Likert scale. Total scores range from 16 to 160, with higher scores indicating greater dysfunctional beliefs about sleep.

The Generalized Anxiety Disorder-7 (GAD-7; (Spitzer et al., 2006)) questionnaire evaluates the severity of generalized anxiety disorder symptoms over the past 2 weeks. It consists of 7 items rated on a scale from 0 to 3. Total scores range from 0 to 21, with higher scores indicating more severe anxiety. A score of ≥10 suggests clinically significant anxiety.

2.4.3. Sleep diary

Participants were instructed to complete the Consensus Sleep Diary (CSD; (Carney et al., 2012)) for seven consecutive nights prior to starting the course, as well as immediately post-treatment. The CSD is a widely used instrument for subjective assessment of various sleep parameters. Each night, participants recorded the time they went to bed, the time attempted to initiate sleep, the time they woke up in the morning (final wake time), the number and duration of awakenings during the night, and the time they got out of bed in the morning (rise time). From these data, several key sleep parameters were calculated. Total sleep time (TST) was defined as the total duration of sleep from sleep onset to final wake time, excluding periods of wakefulness after sleep onset. Time in bed (TIB) represented the total duration spent in bed from bedtime to rise time, regardless of sleep or wakefulness. Sleep onset latency (SOL) was calculated as the time elapsed from bedtime to sleep onset. Wake after sleep onset (WASO) was the total duration of wakefulness during the sleep period, excluding the initial SOL. Finally, sleep efficiency (SE) was computed as the percentage of time spent asleep relative to the total time spent in bed (TST/TIB x 100).

2.5. Statistical analysis

2.5.1. Sample size calculation

At least 25 participants were required to detect at least a moderate within-groups effect of $d = 0.70$ (with a power of 0.90 and alpha of 0.05). However, we also sought to determine the potential moderating effect of sample subgroups (see subgroup analyses below). As such, we aimed for twice this original sample ($n = 50$), and aimed to recruit 75 participants to safeguard against attrition during the trial (estimated conservatively at 30 %).

2.5.2. Main analyses

Statistical analyses were conducted in SPSS v.29 using an intent-to-treat approach, where all participants who provided pre-treatment data were included in the analyses. Baseline demographic and clinical information was calculated using descriptive analyses, and means and frequencies were reported. Multiple Imputation was applied to impute missing values, taking into account participants' baseline symptom severity (on the PROMIS-SD and ISI) as well as their lesson completion. These were included because of the known association between baseline severity, treatment adherence, and missing data (Karin et al., 2018a). We utilized Generalized Estimation Equation (GEE) models to assess changes in symptoms over time within the treatment group. To address skewness within the dependent variables, we specified a gamma distribution with a log link function (Karin et al., 2018b). Additionally, an unstructured working correlation matrix was employed to accommodate varying rates of change over time. Our analysis focused on evaluating changes from pre-treatment to post-treatment, as well as from post-treatment to the 3-month follow-up. Estimated marginal means and their standard errors were derived from the analyses, and pairwise comparisons were used to determine the statistical significance of scores between time-points. Estimated marginal means and standard errors were also used to determine the percentage change in participants' scores and associated 95 % CIs, as well as Cohen's d effect sizes. Finally, to enable comparison with existing published research and in line with recognized benchmarks regarding response and remission (Morin et al., 2011), we reported participants achieving symptom response and remission on the ISI. Symptom response was defined as an improvement of ≥8 points, and remission as a score < 8, both reported at post-treatment and at the 3-month follow-up.

2.5.3. Subgroup analysis

Subgroup analyses were conducted to determine whether symptom change differed depending upon participants' co-morbidities and treatment history. Specifically, the PROMIS-SD and ISI were compared between participants who did and did not report: (1) age over 65 years; (2) concurrent prescription medication use for sleep (including hypnotic medication but excluding melatonin); (3) a concurrent sleep disorder; (4) a concurrent chronic disease; (5) a concurrent chronic pain condition; and (5) whether participants reported receiving past psychological treatment for insomnia. We added these characteristics into separate GEE models which tested for main effects (i.e., time, moderator) and importantly the interaction (time by moderator). This allowed us to examine whether improvement from pre- to post-treatment differed depending upon these important characteristics, treatment history or co-morbidities. We also examined whether these moderators were associated with different treatment engagement and satisfaction associated with the treatment. Generalized linear models were used to compare satisfaction rates depending upon subgroup, and chi-square analyses were used to compare the percentage of participants' lesson completion, and compared the percentage of participants' indicating they were satisfied or very satisfied with the course according to the above moderators.

2.5.4. Qualitative feedback

Participant responses to open-ended questions were also reviewed and analysed using a qualitative content analysis approach (Hsieh and Shannon, 2005). Participants were asked what they liked about the course, what they found most helpful in the course, and what they would suggest for improvement. Each response was reviewed and coded according to its content. Any feedback element that was mentioned twice or more was labelled and reported.

3. Results

See Fig. 1 for participant flow through the intervention. Over the recruitment period, 116 participants applied to participate in the course. Of these, 81 enrolled into treatment. Of the 34 who were not enrolled, the most common reason for being excluded was inability to be contacted for the telephone assessment interview. Four participants withdrew prior to the pre-treatment time-point, citing it was no longer a good time to participate. Three participants did not complete adequate sleep diary entries for inclusion in the study. Most participants were female ($n = 63$, 85.1 %), married ($n = 51$, 69 %) and aged over 40 (n = 63, 83.8 %). According to the PROMIS-SD, most participants reported

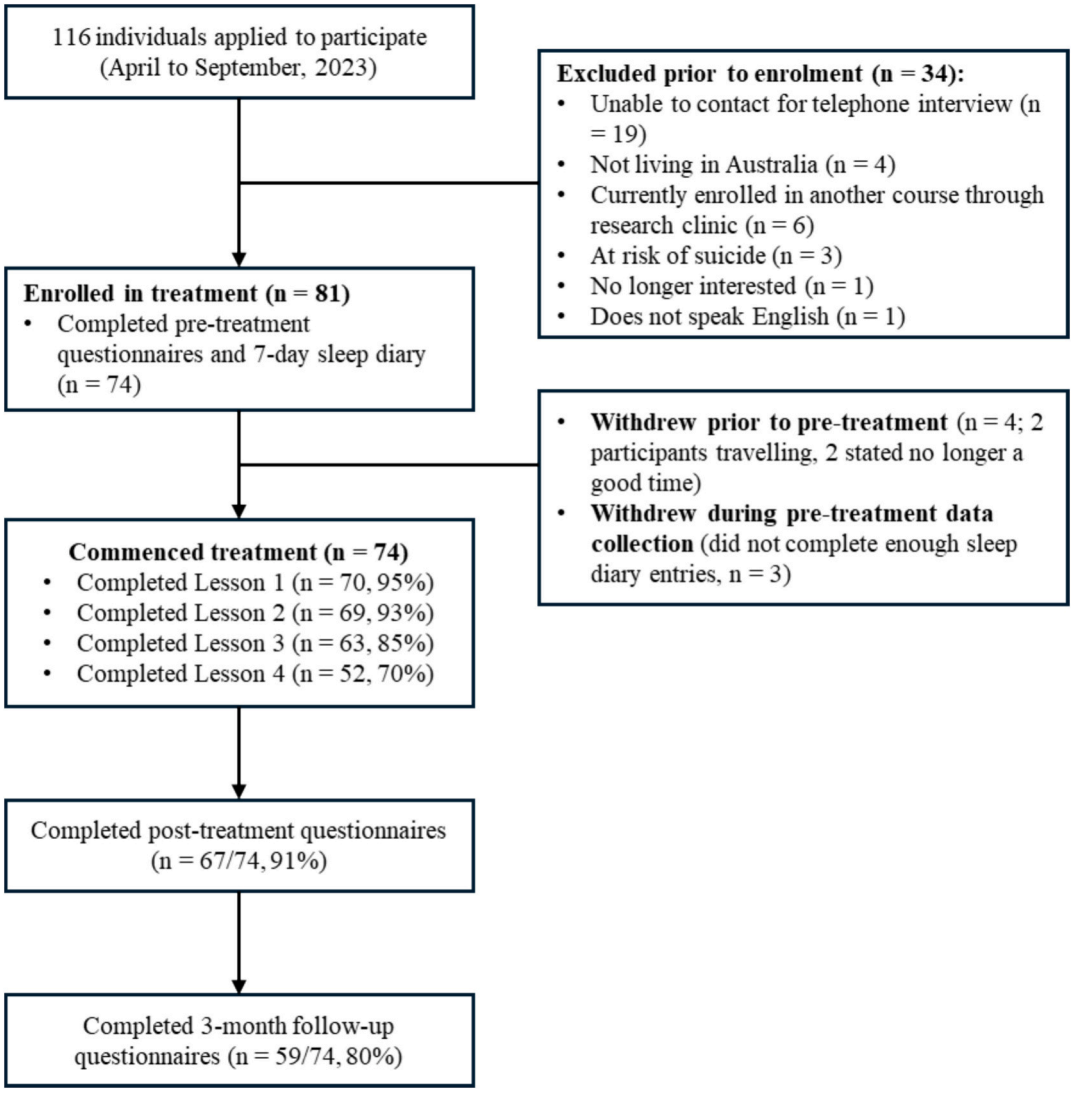

Fig. 1. CONSORT flow diagram.

slight or mild sleep problems (i.e., a t-score of 59 or less; $n = 55$, 74 %). This was somewhat at odds with the ISI, with most people reporting insomnia symptom severity in the moderate or severe range ($n = 49$, 66 %).

Table 3
Estimated marginal means, percent change, and Cohen's d effect sizes across all primary and secondary variables.

	Estimated marginal means (standard error) and *p*-values					Percent change		Cohen's d	
	Pre (SE)	Post (SE)	$P_{between}$	3MFU (SE)	$p_{post\ to\ 3MFU}$	Post	3MFU	Post-treatment	3MFU
Sleep Disturbance (PROMIS-D)	19.42 (0.5)	14.4 (0.6)	<0.001	14.0 (0.7)	0.565	26 (20,32)	28 (21, 35)	1.06	1.04
Insomnia severity (ISI)	16.5 (0.5)	10.0 (0.6)	<0.001	9.5 (0.7)	0.433	39 (32, 47)	43 (35, 50)	1.37	1.34
Daytime impairment (PROMIS-SRI)	13.2 (0.6)	9.2 (0.5)	<0.001	10.9 (0.9)	0.028	30 (22, 38)	17 (4, 31)	0.84	0.35
Depression (PHQ-9)	8.4 (0.5)	5.5 (0.4)	<0.001	5.9 (0.6)	0.141	35 (24, 45)	29 (14, 45)	0.74	0.53
Depression without sleep items (PHQ-9)	6.26 (0.4)	3.93 (0.4)	<0.001	3.80 (0.4)	0.77	37 (26, 49)	39 (27, 52)	0.68	0.71
Anxiety (GAD-7)	5.9 (0.4)	4.5 (0.5)	0.002	4.6 (0.5)	0.652	23 (8, 39)	23 (5, 40)	0.36	0.33
Dysfunctional beliefs attitudes (DBAS-16)	88.8 (2.0)	64.5 (3.1)	<0.001	–	–	27 (20, 34)	–	1.08	–
Sleep Diary Data									
TIB	560.3 (8.3)	548.5 (13.8)	0.337	–	–	2 (−3, 7)	–	0.12	–
TST	365.3 (9.9)	395.1 (17.2)	0.042	–	–	8 (2, 18)	–	0.25	–
SOL	48.3 (5.0)	38.2 (4.4)	0.088	–	–	21 (3, 39)	–	0.33	–
WASO	52.6 (4.8)	42.6 (4.8)	0.054	–	–	19 (1, 37)	–	0.24	–
SE (%)	65 % (0.1)	73 % (0.2)	0.003	–	–	12 (4, 18)	–	0.42	–

The percentage change from baseline statistics are estimates of relative change derived from the GEE models conducted separately for each outcome.
3MFU, 3-month follow-up; PROMIS-SD, patient reported outcomes measurement information system, sleep disturbance scale; ISI, insomnia severity index; PHQ-9, patient health questionnaire; GAD-7, generalized anxiety disorder 7-item scale; DBAS, dysfunctional beliefs and attitudes about sleep; TIB, time in bed, TST; total sleep time; SOL, sleep onset latency; WASO, wake after sleep onset; SE, sleep efficiency.

3.1. Treatment completion and acceptability

See Fig. 1 for lesson completion within the sample. Of the 74 participants who completed pre-treatment questionnaires and sleep diaries, 70 (95 %) completed lesson 1. Four participants withdrew prior to completing lesson 1, citing travel and inconvenience as reasons for not continuing with the course. Fifty-two participants (70 %) completed all the intervention lessons within 6 weeks. Of the 67 (91 %) participants who completed post-treatment questionnaires, 61/67 (91 %) said they would feel confident recommending the course to others, while 59/67 (88 %) said the course was worth their time. Regarding global satisfaction, 53/67 (79 %) reported being 'satisfied' or 'very satisfied' with the course, while 11 participants reported being 'neutral.' No participants reported being dissatisfied and one participant reported being very dissatisfied with the course.

3.2. Primary outcome

See Table 3 for within-group analyses, estimated marginal means, Cohen's *d* effect sizes and percentage change for the primary and secondary outcomes. For the primary sleep disturbance outcome, there was a significant within-group effect from pre- to post-treatment ($p < .001$). Participants reported a 26 % (95 % CI, 20,32) reduction in symptoms, which reflected a within-groups effect size of $d = 1.06$. This improvement was maintained at 3-month follow-up ($p = .57$).

3.2.1. Secondary outcomes

We also observed significant improvements on other indicators of sleep and insomnia symptoms. A significant improvement on the ISI was observed (39 % improvement, 95 % CI 32, 47, $p < .001$), reflecting a Cohen's *d* of 1.37. Participants daytime sleep-related impairment also improved by 30 % (95 % CI 22, 38, $p < .001$). At 3-month follow-up, there was evidence that improvements on sleep-related impairment were not maintained. Specifically, participants reported a significant increase in SRI from post-treatment to baseline, however this still reflected a 17 % improvement from baseline scores (17 % [95 % CI 4, 31] improvement from baseline, $p = .03$). We also observed significant improvements in dysfunctional beliefs and attitudes about sleep from pre- to post-treatment (27 % improvement, 95 % CI 20, 24, $d = 1.08$, $p < .001$). Regarding the sleep diary, statistically significant improvements were observed in TST and SE ($p = .04$, .003, respectively). While participants reported, on average 10-minute reductions in both sleep onset latency and wake after sleep onset (reflecting 21 % and 19 % improvements respectively), these were non-significant ($p = .08$ and .05 respectively).

Significant improvements were also observed on measures of psychological distress. Participants' self-reported depression and anxiety symptoms improved by 35 % (95 % CI 24, 45, $p < .001$) and 23 %, (95 % CI 5, 40 %, $p = .002$) respectively. These reflected effect sizes of $d = 0.74$ for depression and $d = 0.36$ for anxiety.

3.2.2. Response and remission

Regarding ISI response (symptom improvement ≥ 8 on the ISI), 40 % of participants (95 % CI 36, 45) reported a response at post, and 45 % at 3-month follow-up (95 % CI 40, 50). Regarding ISI remission (score below 8 on the ISI), this was reported by 47 % of participants at post-treatment (95 % CIs 42, 51) and 57 % of participants at 3-month follow-up (95 % CIs 51, 62).

3.3. Subgroup analyses

See Table 4 for the results of subgroup analyses regarding symptom change, treatment satisfaction and treatment completion rates. There were no significant group by time interactions found across any outcomes for participants depending on the presence of a sleep co-morbidity, chronic health condition, chronic pain, and being aged over 65.

3.3.1. Concurrent prescription medication

Participants who reported currently taking prescription medication for sleep reported more modest benefits regarding sleep disturbance and insomnia symptom severity (see Table 4). While both groups reported significant improvement over time, the magnitude was smaller than participants who were not currently taking prescription medication. For example, participants taking current prescription medications reported a −3.89 (SE = 1.4) mean improvement in insomnia symptoms, compared to −7.30 (0.64) among those who were not taking concurrent prescription medication. There were non-significant differences regarding treatment completing and satisfaction between subgroups.

Table 4
Symptom change, satisfaction and engagement according to subgroups.

	Sleep Disturbance (PROMIS-SD)		Insomnia Severity (ISI)		Treatment Satisfaction		Treatment completion	
	Pre-post change	Wald chi (p-value)	Pre-post change	Wald chi (p-value)	(% satisfied, 95 % CI)	Wald chi (p-value)	(% completed, 95 % CI)	Chi-square (p-value)
Sleep co-morbidity								
Yes (n = 14)	−5.11 (1.30)	0.04 (0.85)	−5.62 (1.32)	1.01 (0.35)	80 (67, 92)	0.19 (0.71)	72 (60, 83)	0.29 (0.59)
No (*n* = 60)	−4.80 (0.76)		−6.44 (1.72)		81 (59, 100)		64 (39, 89)	
Chronic health condition								
Yes (*n* = 47)	−5.39 (0.78)	1.03 (0.34)	−6.28 (0.74)	0.11 (0.80)	81 (78, 94)	0.10 (0.76)	72 (60, 85)	0.26 (0.61)
No (*n* = 27)	−3.92 (1.2)		−6.31 (1.17)		79 (62, 75)		67 (49, 84)	
Chronic pain								
Yes (*n* = 25)	−5.86 (1.15)	1.44 (0.25)	−7.22 (0.10)	0.69 (0.47)	81 (60, 100)	0.26 (0.69)	64 (45, 83)	0.71 (0.40)
No (n = 49)	−4.34 (0.79)		−5.81 (0.83)		80 (68, 91)		73 (61, 86)	
Current prescription medication								
Yes (*n* = 22)	**−2.65 (1.17)**	**8.82 (0.005)**	**−3.89 (1.4)**	**12.11 (0.001)**	66 (43, 89)	3.7 (0.10)	68 (49, 88)	0.07 (0.80)
No (*n* = 52)	**−5.79 (0.76)**		**−7.30 (0.64)**		86 (74, 97)		71 (59, 83)	
Aged over 65								
Yes (*n* = 17)	−4.45 (1.16)	0.69 (0.43)	−4.86 (1.21)	2.14 (0.16)	78 (57, 98)	0.20 (0.71)	82 (64, 100)	1.5 (0.22)
No (*n* = 57)	−4.98 (0.79)		−6.71 (0.74)		81 (68, 94)		67 (54, 79)	
Previous psychological treatment								
Yes (*n* = 16)	−3.01 (1.40)	1.88 (0.19)	**−4.15 (1.07)**	**5.14 (0.03)**	79 (57, 100)	0.06 (0.88)	56 (32, 81)	1.9 (0.17)
No (*n* = 58)	−5.36 (0.73)		**−6.88 (0.75)**		80 (69, 92)		74 (63, 85)	

Bold text denotes statistically significant group difference ($p < .05$).

3.3.2. Previous psychological treatment

Participants who reported previous psychological treatment also showed more modest improvements regarding their insomnia symptoms, compared to those who had not seen a psychologist in the past (see Table 4). Specifically, those receiving past psychological treatment reported a −4.15 (SE = 1.07) improvement in symptoms, compared to −6.88 (0.75) among those who had not seen a psychologist in the past. There was a non-significant difference between these subgroups regarding the primary sleep disturbance outcome. There was also no significant difference in treatment completion and satisfaction between these subgroups.

3.4. Qualitative feedback

See Table 5 for results of qualitative analysis of course feedback. Regarding the question "what did you find most helpful?", eight different course components emerged (i.e., were mentioned twice or more). Participants reported that strategies to improve sleep efficiency (either via stimulus control or sleep restriction) was the most helpful component, followed by psycho-education about the two-process model of sleep (and associated behavioural changes). See Table 5 for additional components and relevant participant quotes. When asked "what did you like about the course?", participants responded with a variety of features relating to the course structure, content, and approach. Participants most commonly mentioned liking the skills and knowledge they obtained, either specifically or in general ($n = 29$), followed by the general pace and structure of the course ($n = 23$). Fourteen participants mentioned having access to clinical support if needed.

Participants were also asked "what did you not like about the course?" with the most common response being a mention of 'nothing' or the response field being left blank ($n = 40$). Some participants ($n = 14$) reported the pace of the course (some mentioned it was too slow, while others mentioned it was too fast), or external life events and demands, being a disliked factor (e.g., "*I found it hard to have my normal life commitments while doing the course…*"). However, 23 participants also mentioned that the course pace was a feature they liked about the course (e.g., "*The structure meant I had adequate time to read the materials, complete the activities, and make changes before the next lesson.*"). A small number of participants also reported challenges with accessing the materials ($n = 9$), or issues adapting the course to their unique circumstance ($n = 6$). Three participants with long term insomnia mentioned the information was not new, with two mentioning they have covered these concepts in previous treatment. For example, "*unfortunately after 19 years of not sleeping these topics are all ones I have done significant research and work in.*"

3.5. Clinician time

The average total clinician time per participant was 26.6 min (SD = 35.6 min, range 1 to 224 min) over the 6-week treatment period. Thirty-one (42 %) of participants elected to have one or more phone calls. These participants had an average of 1.8 calls (SD 1.1) for an average of 34.8 min (SD 42.5). Clinicians also spent an average of 12.1 (SD 14.3) minutes reading and responding to secure messages.

4. Discussion

The aim of the current study was to determine the feasibility and preliminary efficacy of an internet-delivered CBTi intervention with a broad range of adults reporting sleep difficulties. Recruitment into the study took an inclusive approach to reflect what may be seen among people seeking treatment in routine care. Between pre- and post-treatment, significant improvements in self-reported sleep disturbance (d = 1.06, 26%), insomnia severity (d = 1.37, 39%) and functional impairment (d = 1.08, 27%) were observed. We also observed small to moderate improvements in depression and anxiety (d = 0.74, and d =

Table 5
Qualitative analysis feedback.

Component	Further information	N	Indicative quote/s
"What did you find most helpful?"			
Guidance on improving sleep efficiency	Specific implementation of sleep restriction therapy, stimulus control or being mindful of sleep efficiency.	28	"*I used both the stimulus control and sleep restriction methods simultaneously and they seem to have completely cured my sleep issues.*" "*I think the getting up when I am not sleeping in the middle of the night is the biggest change for me. Really takes the pressure off.*"
Understanding how sleep works from the 2-process model.	Learning about how the circadian rhythm and sleep pressure system work together to govern our sleep. Understanding the problematic role of irregular sleep-wake times, naps, etc.	17	"*Learning about body clocks and sleep pressure gave me a simple and helpful way of thinking through the things I do that help or hinder sleep.*"
Changed sleep perceptions and reduced anxiety about being a poor sleeper.	Learning corrective information about sleep (e.g., that it is normal to wake up during the night, that bad nights of sleep are common).	12	"*I found the myths about sleep really enlightening. Reading them changed my feelings about my sleep. I realised that it wasn't as abnormal as I had thought.*"
Winding down and/or screen time limits	Reducing screen time before bed and implementing a wind-down routine	12	"*Taking time before I go to bed to relax without screens…*"
Remaining active during the day and reducing unhelpful compensatory behaviours	Understanding that sleep is a 24-hour process, and compensating the next day can perpetuate suffering and sleep difficulties.	12	"*Understanding the reactivity cycle that often occurs with bad sleep was so valuable, it's the kind of thing that you get trapped in because you don't know any better. Since learning this, I have pushed myself to do something challenging and something enjoyable each day*"
Reducing hyperarousal during the night with worry time or cognitive strategies	Using cognitive strategies and/or implementing worry time during the day.	10	"*Worry time has been helpful*"
Case stories	Learning or resonating with the case examples	3	"*What Julian went through and the measures he took resonated with me a lot.*"
Relaxation	Doing guided relaxation	2	"*Relaxation skills*"
"What did you like about the course?"			
The skills and knowledge gained	Reference to finding the course information helpful or mentioning of specific information.	29	"*I found all the information helpful and informative*" […] "*understanding of normal sleep cycles*" […] "*it challenges some of the narratives I have around sleep*"
Course pace and structure	Mentioned the pace and arrangement of course materials	23	"*It was user friendly, broken down into brief short chunks of information, which gave a chance to better absorb the information taught*" […] "*gradual introduction to the concepts*" […] "*The*

(continued on next page)

Table 5 (*continued*)

Component	Further information	N	Indicative quote/s
			structure meant I had adequate time to read the materials, complete the activities, and make changes before the next lesson."
Contact with psychologist	Liked having access to clinical support if needed	14	"*The ability to have contact with a psychologist either* via *email or phone was very helpful*" […] "*great intake support and course support from the clinicians by phone and email*"
Course approach	Described the general approach of the course	9	"*The gentle encouraging non judging approach*" […] "*I felt we were all working together and not just being given a set of tasks to complete*"
Case studies	Liked reading the example case studies	8	"*The sample cases were very practical and relatable*"
"What did you not like about the course?"			
Nothing/blank	Participants left the field blank, or stated that there was nothing they did not like.	40	"*Nothing. It was good*" […] "*there was nothing I did not like*"
Timing and external circumstances	Mentioning the pace of the course and/or life interruptions being problematic	14	"*I found it hard to have my normal life commitments while doing the course as those commitments affected my sleep pattern*"
Accessing materials	Issues with the format and accessibility of materials	9	"*I have some difficulties with reading, so I found the entirely text-based delivery of the course somewhat challenging, but it was worthwhile working through it.*" […] "*hard to read the PDF*"
Unique circumstances	Participants mentioning unique situations or health conditions that meant the course was hard to apply	6	"*I found a lot of the content irrelevant to my particular sleep issues*" […] "*I just had to be a bit careful with some of the advice/information which could've been potentially unhelpful in my case due to medical reasons however I received good feedback when I wasn't sure about what exceptions I should make in those circumstances*"
Sleep diary	Specifically mentioning the sleep diary was an aspect they did not like	4	"*Entering times into the electronic Sleep Diary was difficult*"
Information not new	Participants mentioned knowing the materials already and not benefiting from them	3	"*The course information was similar to what I've learnt in the past.*"

0.36 respectively). These effects were maintained at a three-month follow-up time-point, except for sleep-related impairment, where improvements lessened between post-treatment and follow-up (resulting a 17 % improvement from pre- to 3-month follow-up). There was also evidence of improvement in sleep-wake parameters as assessed by sleep diary, including sleep efficiency and total sleep time. Overall, there were high levels of acceptability and engagement with the course, evidenced by treatment completion rates (70 %) and encouraging feedback and satisfaction. Subgroup analyses identified a few moderators which attenuated change over time, including prior psychological sleep intervention and concurrent medication use. However, these participants still benefited from the treatment, and demonstrated similar engagement and satisfaction. Overall, the findings of the current study appear to support the acceptability and potential efficacy of internet-delivered CBTi interventions, including for the people often excluded from trials but frequently seen in routine care contexts.

It was encouraging to observe large and maintained within-group effect sizes regarding insomnia and sleep disturbance symptoms. Although strong conclusions about efficacy cannot be drawn without a control group, these within-group effects from pre- to post-treatment are consistent with interventions that demonstrate efficacy compared to a control group (Blom et al., 2015; Seyffert et al., 2016). Given these outcomes were achieved in the context of an inclusive and ecologically valid sample, these results are promising and would appear to highlight the potential of this kind of sleep intervention for a broad range of people.

We also observed meaningful improvements in depression and anxiety symptoms. Specifically, participants reported a 35 % reduction in depression and a 23 % reduction in anxiety symptoms. This is consistent with past research showing moderate improvements in depression and anxiety following digital CBTi (Lee et al., 2023). Previous studies have demonstrated that while insomnia treatments tend to improve both mental health and sleep, treatments specifically targeting mental health issues do not consistently lead to improvements in sleep quality (Freeman et al., 2020; Blom et al., 2015). Therefore, increasing the availability of sleep interventions, especially when provided to a diverse group of participants, could play a significant role in reducing mental health difficulties across different populations. Remotely delivered treatments might be particularly valuable as they are accessible to a wide audience and require minimal therapist involvement, with an average of 27 min of therapist time needed in the current study.

As mentioned above, we examined whether co-morbidities and concurrent treatments affected rates of improvement and treatment satisfaction. While participants taking prescription medication showed significant symptom improvement, these improvements were smaller than those who did not take prescription medication. These participants also reported similar baseline symptoms to those not taking prescription medication. It is important to note that participants were not advised to cease or taper medication during treatment, and almost all participants who reported concurrent prescription medication use did so on an as-needed basis. Cognitive models suggest people with insomnia tend to engage in safety behaviours (e.g., medication use) that prevent them from disconfirming their sleep-related fears (e.g., that they will never fall asleep; (Harvey, 2002)). It may be that sleep medication served as a safety behaviour in this sample and reduced their ability to benefit. Another possibility is that as-needed use of medications created rebound insomnia symptoms and/or daytime functional impairment (Hintze and Edinger, 2018). Importantly, the current intervention did not provide specific information and skills for reducing prescription medication use. Additionally, data ongoing use or discontinuation of prescription medication was not collected. However, this highlights two potentially important directions for future research in the literature, as most clinical trials exclude participants taking medication or who are not on a stable medication regime. First, future research ought to more closely examine medication use in treatment, and examine how and why (e.g., physiological and psychological mechanisms) 'as-needed' use of sleep medication may hinder the efficacy of treatment. Second, there is potential for future work to explore collaborative models of treatment delivery where, for example, sleep interventions like the current study are provided alongside medically-supported deprescribing (Glare et al., 2020; Bramoweth et al., 2023).

There was also evidence that participants who had previously sought psychological treatment for their sleep difficulty benefited less than

those who had not. This finding aligns with previous studies on CBTi, where treatment-naïve participants tend to show greater improvements (Reins et al., 2019). Recent research also suggests that people who have received CBTi in the past still report lower satisfaction and poorer sleep health compared to healthy sleepers (Lau et al., 2024). In the case of the current study, it may be that people with more chronic insomnia require more specialised treatment to achieve more meaningful symptom improvement. Phenotyping in CBTi research has revealed that individual differences in insomnia presentation and comorbid conditions can significantly influence treatment outcomes. For example, Blanken et al. (2019) identified five distinct and temporally stable subtypes of insomnia, differentiated by features like their degree of distress and reactivity to life events, with implications for targeted interventions that address the unique profiles of each subtype. Future research should examine how to tailor treatments to different phenotypes of insomnia to enhance efficacy and ensure that interventions meet the specific needs of diverse patient populations.

The evidence base supporting CBTi, both in face-to-face and digital delivery, is now very strong (Van Straten et al., 2018; Soh et al., 2020). As such, a critical future direction for research is to examine its efficacy in pragmatic trials such as the current study, and to further understand the utility of lower-intensity treatments within a stepped care framework. Few studies to date have directly compared clinician-guided versus self-guided treatments, particularly in inclusive samples like the current study. Given the availability and efficacy of fully automated approaches (e.g., SHUTi (Ritterband et al., 2009), Sleepio (Espie et al., 2019)), it will be important to understand whether the involvement of a trained clinician is necessary to achieve meaningful insomnia improvements associated with digital CBTi in similar samples. In addition, there is growing evidence supporting the efficacy of nurse-led CBTi, including in digital treatments (Van der Zweerde et al., 2020). Understanding the differential efficacy of these delivery methods may help to inform the optimal allocation of resources and ensure that people receive the most appropriate level of care for their needs. Low-intensity treatments may also serve an important role in preventing chronic and severe insomnia. The current study imposed no criteria around minimum symptom severity or duration, and a meaningful proportion (35 %) of participants reported mild or subthreshold symptoms at baseline. It is possible that the intervention served a preventative role for these participants, which is a question for future research. Overall, this approach underscores the potential for tailored treatment pathways that can maximise accessibility and efficiency in managing insomnia across diverse populations.

Some limitations of the current study should be highlighted. Firstly, as emphasised, we cannot draw strong conclusions about the efficacy due to the lack of a control group. While the degree of symptom improvement in the current study appears meaningfully greater than would be observed over the passage of time, it is not clear whether a less intensive or specialised version of the intervention would achieve similar outcomes. Given many of the sample had subthreshold symptoms, it would be most meaningful to compare the current study to a sleep hygiene education intervention in case such participants benefit from less specialised advice (e.g., simple regularisation of time in bed). In addition, while moderator results provide preliminary support for the wide applicability of the treatment, replication with a larger sample is needed before firm conclusions are drawn. Finally, the current study only utilized self-report measures of participants' sleep-wake parameters. Although objective measures (such as actigraphy or polysomnography) have utility in research and specialist care settings, widespread use of these measures in routine CBTi care would further likely impede access and engagement in care. Finally, it is also important to highlight that subgroup analyses were based off a small sample and often with imbalanced sample sizes for comparison (e.g., 14 people with a sleep co-morbidity compared to 60 people without). These imbalances as well as a lack of statistical power may have meant we were underpowered to detect smaller effects. While the numerical results suggest that treatment-related improvement in these subgroups was similar, the results of this pilot study require replication with larger samples, perhaps also with purposeful recruitment of some participants.

In conclusion, the current study highlights the promise of remotely-delivered CBTi to address sleep disturbance and insomnia symptoms in a broad range of adults with self-reported sleep difficulties. Our results provide preliminary support for the broad acceptability and effectiveness of this treatment approach, including for people who are often excluded from randomised controlled trials. However, future research using sophisticated control groups, larger samples, and more naturalistic recruitment settings is need before strong conclusions can be drawn.

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Declaration of competing interest

The authors have no conflicts of interest to declare.

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