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ORIGINAL ARTICLE

Digital cognitive behavioural therapy for insomnia versus digital sleep education control in an Australian community-based sample: a randomised controlled trial

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Key words
CBT-i, eHealth, difficulties initiating and maintaining sleep, non-pharmacological, online.

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Abstract

Background: Insomnia is a prevalent condition in Australia that increases the risk of depression and anxiety symptoms. Cognitive behaviour therapy for insomnia (CBT-i) is the recommended 'first line' treatment but is accessed by a minority of people with insomnia.

Aims: To improve CBT-i access in Australia, we aimed to develop and test a self-guided interactive digital CBT-i program.

Methods: An online randomised controlled trial was conducted from August 2022 to August 2023 to investigate the effect of digital CBT-i, versus digital sleep education control, on symptoms of insomnia (ISI), depression (PHQ-9), anxiety (GAD-7), fatigue, sleepiness and maladaptive beliefs about sleep at 8-week follow-up. The control group accessed the intervention after the 8-week follow-up. Questionnaires were additionally administered at 16 and 24 weeks. Intent-to-treat mixed models and complete-case chi-squared analyses were used.

Results: Participants included 62 adults with insomnia symptoms (age M (SD) = 52.5 (16.3), 82% female, ISI = 18.6 (2.9)). There were no between-group differences in baseline characteristics or missing 8-week data (14.5%). After adjusting for baseline scores, CBT-i was associated with lower insomnia ($Diff_{adj}$ (95% CI) = 7.32 (5.0–9.6), $P < 0.001$, $d = 1.64$), depression (3.36 (1.3–5.4), $p = 0.002$, $d = 0.84$), fatigue (5.2 (2.5–7.9), $P < 0.001$, $d = 1.00$) and maladaptive beliefs about sleep (11.0 (4.1–18.0), $P = 0.002$, $d = 0.82$), but not anxiety symptoms at 8 weeks (1.84 (−0.1 to 3.8), $p = 0.060$, $d = 0.50$). Compared to control, CBT-i was associated with greater rates of insomnia remission (ISI <8; 0.0%, vs 40.0%, $P < 0.001$) and response at 8 weeks (ISI reduction ≥6; 7.1% vs 72.0%, $P < 0.001$). Improvements in insomnia and depression were maintained at 24 weeks in the CBT-i group.

Conclusions: This interactive digital CBT-i program resulted in large and sustained improvements in symptoms of insomnia, depression, fatigue and maladaptive beliefs about sleep in Australian adults with insomnia symptoms. Implementation programs are required to increase digital CBT-i access and uptake.

Abbreviations: CBT-i, cognitive behavioural therapy for insomnia; DBAS, Dysfunctional Beliefs and Attitudes about Sleep; ESS, Epworth Sleepiness Scale; FFS, Flinders Fatigue Scale; GAD-7, Generalised Anxiety Disorder questionnaire; ISI, Insomnia Severity Index; PHQ-8, Patient Health Questionnaire (re-scaled 8-item version without sleep item); PHQ-9, Patient Health Questionnaire

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Introduction

Chronic insomnia is a debilitating sleep disorder that impacts approximately 10–15% of Australian adults.[1–3] Untreated insomnia is associated with an increased risk of depression, anxiety and reduced physical health and causes substantial economic and societal costs through reduced productivity and quality of life and increased use of health resources.[4–6]

Evidence-based guidelines recommend cognitive behaviour therapy for insomnia (CBT-i) as the 'first line' treatment for insomnia.[7–12] CBT-i is a multicomponent therapy that identifies and treats the underlying psycho-behavioural factors that initiate and maintain insomnia. The treatment is traditionally delivered by clinicians during 4–8 weekly sessions. CBT-i is a cost-effective treatment[13] that results in sustained improvements in insomnia[14] and is effective in the presence of other mental,[15] physical[16] and sleep disorders.[17] Only 1–3% of Australian adults with insomnia access CBT-i,[18,19] partially because of a shortage of appropriately trained clinicians. Most patients are managed with potentially addictive sedative-hypnotic medicines (e.g. benzodiazepines)[19] or provided simple yet ineffective 'sleep hygiene' information.[20,21]

Therapist-delivered CBT-i programs have been translated into self-guided digital CBT-i programs[22,23] that have promising potential to rapidly increase CBT-i access.[22,24,25] Evidence-based static (one-size-fits-all) digital CBT-i programs exist in Australia. However, no self-guided digital program that provides *tailored* and *interactive* education, assessment and cognitive and behavioural treatment recommendations is widely available in Australia. Theoretically, a tailored program may be desirable because of improvements in adherence (e.g. if individuals are more motivated to enact recommendations that are tailored to their unique presentation), safety (e.g. tailored risk monitoring and mitigation) and effectiveness (e.g. if recommendations are more personalised to each individual's sleep and wake parameters).

To increase access to CBT-i in Australia, we aimed to develop and test a self-guided interactive digital CBT-i program tailored for the Australian healthcare system. It was hypothesised that compared to digital sleep education (control), digital CBT-i would result in lower symptoms of insomnia, depression and anxiety at 8-week follow-up in participants with insomnia symptoms. It was additionally hypothesised that improvements in insomnia, depression and anxiety symptoms in the CBT-i group would be maintained by 24-week follow-up.

Methods

Study design

An open-label online randomised controlled trial (RCT) was conducted from August 2022 to August 2023 to evaluate an interactive five-session digital CBT-i program (Bedtime Window), versus 5 weeks of digital sleep education control, on symptoms of insomnia, depression, anxiety, sleepiness, fatigue and maladaptive beliefs about sleep in people with clinically significant insomnia symptoms. Participants completed online information, consent and screening forms, and a baseline questionnaire battery. Participants were randomised 1:1 using a simple computer-generated randomisation sequence. Study coordinators contacted participants through email to assign them to digital CBT-i or control. Participants completed another online questionnaire battery at 8-week post-randomisation. Following the 8-week follow-up, the control group were provided access to the digital CBT-i program. Questionnaire batteries were re-administered to both groups at 16-week and 24-week post-randomisation. This trial was prospectively registered on the ANZCTR (ACTRN12621001395820) and was approved by the Southern Adelaide Human Research Ethics Committee (2021/HRE00287).

Screening and recruitment

Participants were recruited online through advertisements in Australian television, radio and print media, sleep advocacy organisations (Sleep Health Foundation, Sleep Disorders Australia), word of mouth and clinician referral.

Inclusion criteria were selected for feasibility, safety and suitability for self-guided digital CBT-i. Inclusion criteria were age ≥18 years; reliable access to an internet-compatible device; basic English language comprehension; an Insomnia Severity Index (ISI) score of ≥15; an Epworth Sleepiness Scale (ESS) score <16; no diagnosis of bipolar or schizophrenia disorder; no risk of self-harm or suicide (PHQ-9; item 9 score of ≥1); no epilepsy; not currently pregnant; no commercial drivers or people who operate heavy machinery for work; no shift workers; no doctor-diagnosed cognitive impairment or comorbid sleep disorder (sleep apnoea, narcolepsy, circadian rhythm disorder, REM behaviour disorder, restless legs syndrome/PLMS); no past experience of a sleepiness-related motor vehicle accident.

Measures

Intake questionnaire

Prior to randomisation, participants responded to an online screening and intake questionnaire to assess eligibility criteria and indicate their age, height, weight, diagnosed chronic conditions (mental health, cardiometabolic, airway and musculoskeletal), access to other treatments for insomnia in the past 12 months and use of sleeping pills in the past 2 weeks (including medication name, dose, frequency and duration of use).

Outcome questionnaire battery

Participants completed an online questionnaire battery at baseline, 8 weeks, 16 weeks and 24 weeks, which included the ISI,[26] the Patient Health Questionnaire-9 (PHQ-9),[27] the Generalised Anxiety Disorder-7 (GAD-7),[28] the ESS,[29] the Flinders Fatigue Scale (FFS)[30] and the Dysfunctional Beliefs and Attitudes about Sleep-16 (DBAS-16)[31] (see Supporting Information for questionnaire descriptions). As the PHQ-9 includes one item about sleep, a PHQ-8 score was computed in which this 'sleep' item was removed, and scores were re-scaled to match the existing upper and lower limits of the questionnaire (PHQ-8 range: 0–27).

Interventions

Participants allocated to the intervention group were provided immediate access to a self-guided five-session interactive digital CBT-i program (Bedtime Window, Fig. 1). Each weekly session lasts for approximately 20–30 min and includes short videos, text information and images. Underlying algorithms tailor assessment and treatment recommendations according to each user's sleep, wake and lifestyle information at the beginning of the program and as symptoms change during each session. Several billion unique treatment pathways are available. An initial assessment module provides personalised feedback (e.g. on insomnia severity, subtypes and potential comorbidities). Daily sleep–wake diaries are completed online throughout the program to assess sleep–wake data and to inform personalised treatment suggestions at each subsequent session. Tailored bedtime restriction therapy recommendations are designed to balance therapeutic benefits and mitigate sleepiness-related risks (e.g. associated with sleep restriction therapy[32,33]). Immediately following each session, users receive an email with an overview of session content and personalised treatment recommendations. Active treatment components include psychoeducation, stimulus control therapy, sleep restriction therapy, relaxation therapy, cognitive re-focusing and relapse prevention. Sessions become available in a linear sequence at weekly intervals.

The program was developed for the Australian health system. For example, users who are identified as not appropriate for the program are provided recommendations for Australian 'sleep' psychologists in their geographical location. If symptoms of specific mental health comorbidities or sleep conditions are identified, the program provides information about resources available through reputable Australian consumer/education/support organisations (e.g. Lifeline and Beyond Blue). Screening and triaging criteria used to identify suitable candidates for the program reflect the endorsed criteria

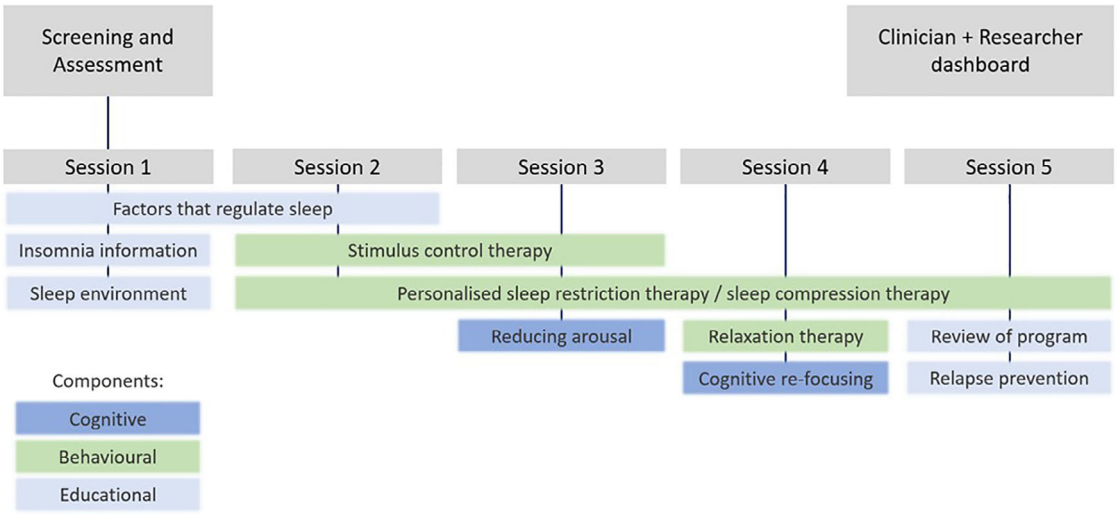

Figure 1 Schematic of five-session interactive digital CBT-i program. CBT-i, cognitive behavioural therapy for insomnia.

of the Australasian Sleep Association and Royal Australian College of General Practitioners.[12] The program includes functions to re-assess insomnia after treatment, provide location-specific further management recommendations, and generate reports for referring clinicians.

To control for access to an online platform and information about sleep health, sleep hygiene and insomnia for 5 weeks, participants in the education control group received five sessions of digital sleep education content. Session content included (i) sleep hygiene and sleep information; (ii) information about caffeine and sleep and changes in sleep across the lifespan; (iii) dispelling common myths, misconceptions and maladaptive sleep beliefs and behaviours; (iv) information about sleep, depression and the body clock; and (v) information about insomnia and the prevention of chronic insomnia (Fig. S1). Rates of access to each digital session were recorded as an indicator of adherence in the CBT-i and control groups.

Statistical analyses

Data were analysed according to a predefined statistical analysis plan with SPSS Version 27 (IBM Corporation, Armonk, NY, USA). A sample size requirement of 60 participants was based on a predicted 4.5-point between-group difference in the ISI (SD = 5), accounting for 50% attrition (this level of attrition is common in digital CBT-i clinical trials). Independent sample *t* tests and chi-squared tests were used to investigate between-group differences in mean (standard deviation) and proportion data at baseline. Intent-to-treat linear mixed models, with baseline values entered as a covariate, were used to investigate between-group changes in insomnia, depression and anxiety symptoms over time. Estimated marginal means and 95% confidence intervals are reported, and *P* values of <0.05 were considered statistically significant. Overall interaction effects were inspected before interpreting pairwise comparisons or the main effects of time. A Bonferroni correction was applied to all pairwise comparisons. Between-group differences at 8-week follow-up, controlling for baseline data, are reported as the main effect size measure. Long-term changes in sleep, mental health and functioning at the 16-week and 24-week follow-up were also explored within each group. Sensitivity analyses were performed to investigate between-group ISI differences in the following groups: (i) participants who completed at least three CBT-i/control sessions, (ii) participants who completed the full CBT-i/control program, and (iii) participants with complete-case data at baseline and 8-week follow-up. Chi-squared tests (and Fisher's exact tests) were used to investigate between-group differences in the proportion of participants reporting minimum clinically important differences (MCIDs) in insomnia (ISI reduction ≥6 points[34]), normalised insomnia scores (ISI <8) and rates of clinically significant insomnia (ISI ≥15) at 8 weeks. Linear mixed models were also used to examine changes in secondary outcomes, including daytime sleepiness, fatigue and dysfunctional beliefs about sleep.

Results

Participant screening, retention and missing data

Figure 2 displays participants' screening, retention and intervention/control session completion numbers. Of 117 screened participants, 62 were recruited to the present study, 22 had an ISI <15 and were directed to a RCT of digital CBT-i in primary care, and eight participants were directed to a RCT to test the program in patients with comorbid insomnia and sleep apnoea. Hence, of the 117 participants who were screened for eligibility, 92 (79%) were identified as appropriate for one of the three digital CBT-i trials, while 25 participants (21%) were directed to a local or telehealth clinical insomnia service. No adverse events were reported in either group. Recruitment stopped after the intended sample size was recruited.

Baseline characteristics

Between-group baseline data are presented in Table 1. Participants were predominantly female (82.2%), were middle-aged, had moderate insomnia, had a history of sleeping pill use and reported a previous diagnosis of a chronic mental health, cardio/metabolic, musculoskeletal and/or airway condition (79%). In total, 61 of the 62 participants reported that symptoms of insomnia had persisted for ≥3 months, consistent with the duration criterion for chronic insomnia disorder.[1]

Insomnia symptoms

A significant group-by-time interaction effect was observed for the ISI (Table 2; Fig. 3). After adjusting for baseline ISI scores, the intervention group reported significantly lower ISI scores at the 8-week follow-up, compared to the control group ($Diff_{adj}$ (95% CI) = 7.32 (5.00–9.63), $P < 0.001$, $d = 1.64$). For the intervention group, ISI scores significantly decreased from baseline to the 8-week follow-up ($Diff_{adj}$ = 9.21 (6.71–11.71), $P < 0.001$, $d = 2.10$). There was no significant within-group change in ISI scores from the 8-week

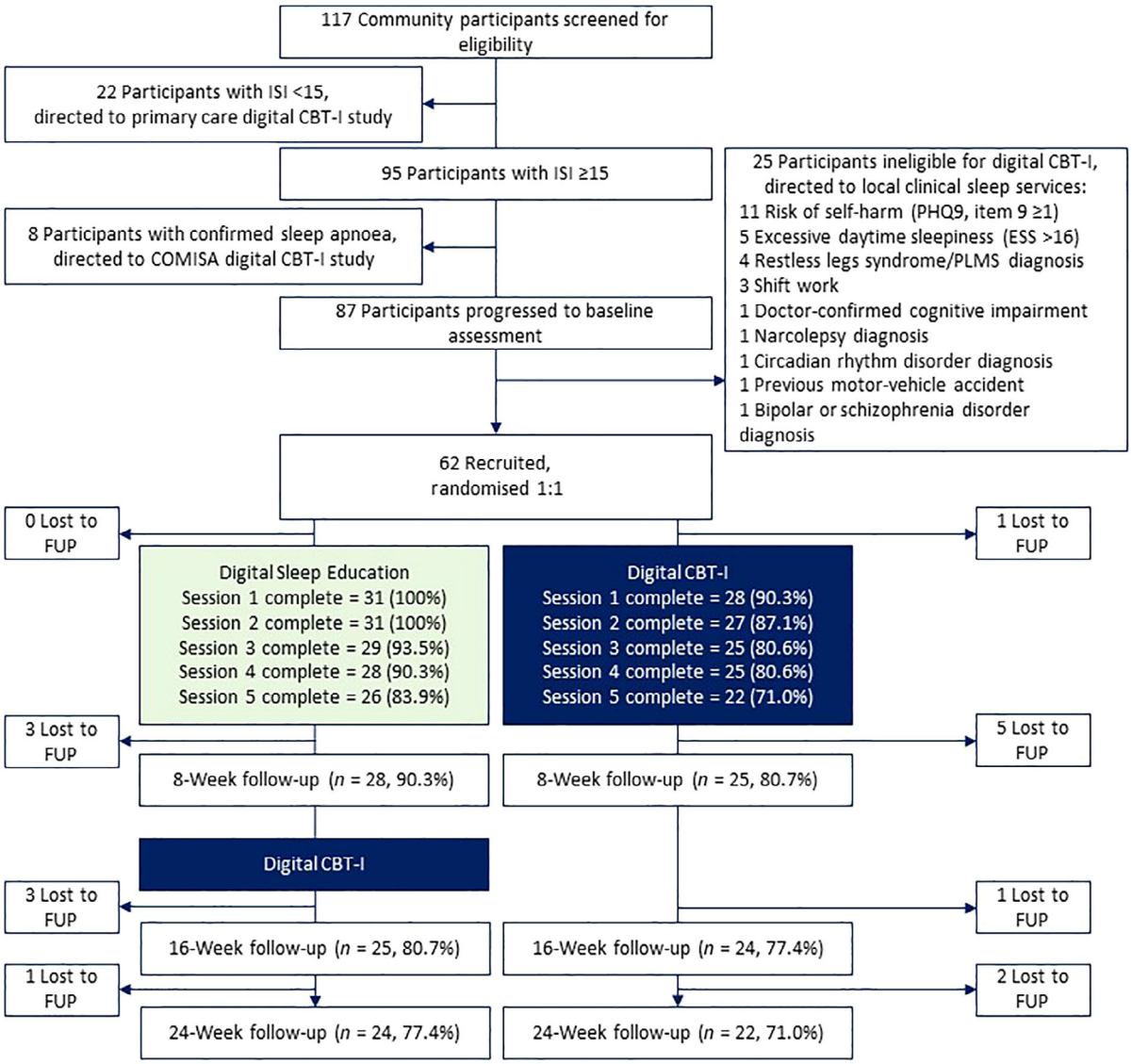

Figure 2 Screening and flow diagram. CBT-i, cognitive behavioural therapy for insomnia; ESS, Epworth Sleepiness Scale; FUP; follow-up; ISI, Insomnia Severity Index; PHQ-9, Patient Health Questionnaire; PLMS, Periodic Leg Movements; RCT, randomised controlled trial. Some participants were excluded because of multiple exclusion criteria. In total, nine of the 62 (14.5%) participants did not complete the 8-week follow-up questionnaire battery. There were no differences in rates of missing questionnaire data at the 8-week follow-up between the intervention group (n missing = 6; 19.4%) and the control group (n missing = 3; 9.7%; Fisher's exact $P = 0.473$). The 16-week questionnaire was completed by 24 (77.4%) and 25 (80.7%) participants in the intervention and control groups respectively. The 24-week questionnaire was completed by 22 (70.1%) and 24 (77.4%) participants in the intervention and control groups, respectively. Participants with an ISI score <15 were directed to a separate primary-care RCT to test the digital CBT-i program in the general practice setting. Participants with comorbid sleep apnoea were directed to a separate RCT to test the effect of the digital CBT-i program in individuals with comorbid insomnia and sleep apnoea. All other ineligible participants were directed to local or telehealth services to access CBT-i from experienced clinicians.

follow-up to the 16-week follow-up ($\text{Diff}_{\text{adj}} = -0.47$ (-3.08 to 2.14), $P = 1.00$, $d = 0.10$), nor between the 8-week follow-up and the 24-week follow-up ($\text{Diff}_{\text{adj}} = -1.97$ (-5.08 to 1.15), $P = 0.564$, $d = 0.42$), suggesting improvements were maintained.

For the control group, there was no significant change in ISI scores from baseline to the 8-week follow-up ($\text{Diff}_{\text{adj}} = 1.58$ (-0.82 to 3.99), $P = 0.482$, $d = 0.37$). However, ISI scores decreased from the 8-week to the 16-week follow-up ($\text{Diff}_{\text{adj}} = 4.94$ (2.40–7.48),

Table 1 Between-group baseline information

	Total	Control	Intervention	Between-group *P*
N	62	31	31	
Female, *n* (%)	51 (82.2%)	28 (90.3%)	23 (74.2%)	0.096
Age, M (SD)	52.46 (16.26)	52.11 (16.41)	52.82 (16.37)	0.866
BMI, M (SD)	25.18 (4.26)	24.65 (4.24)	25.71 (4.29)	0.334
Insomnia (ISI), M (SD)	18.60 (2.89)	18.19 (2.73)	19.00 (3.01)	0.276
Nocturnal subscore, M (SD)	7.15 (1.59)	7.06 (1.41)	7.23 (1.76)	0.840
Daytime subscore, M (SD)	11.45 (2.33)	11.13 (2.09)	11.77 (2.54)	0.279
Depression (PHQ-9), M (SD)	9.97 (4.74)	9.77 (4.61)	10.16 (4.93)	0.751
Anxiety (GAD-7), M (SD)	7.26 (5.12)	7.39 (5.26)	7.13 (5.06)	0.845
Sleepiness (ESS), M (SD)	5.31 (3.84)	5.16 (4.02)	5.45 (3.71)	0.769
Fatigue (FFS), M (SD)	18.29 (6.12)	17.97 (6.70)	18.61 (5.58)	0.682
DBAS, M (SD)	58.84 (13.33)	59.45 (13.41)	58.22 (13.44)	0.721
Overall health (good, very good), *n* (%)	34 (54.8%)	15 (48.8%)	19 (61.3%)	0.307
Current sleeping pill use, *n* (%)	30 (48.4%)	13 (41.9%)	17 (54.8%)	0.309
Access to other treatment/care for insomnia in the past 12 months				
Sleeping pills, *n* (%)	46 (74.2%)	22 (71.0%)	24 (77.4%)	0.337
Psychologist, *n* (%)	6 (9.7%)	4 (12.9%)	2 (6.5%)	0.671†
General practitioner, *n* (%)	23 (37.1%)	12 (38.7%)	11 (35.5%)	0.793
Sleep specialist, *n* (%)	6 (9.7%)	5 (16.1%)	1 (3.2%)	0.195†
Other health professional, *n* (%)	6 (9.7%)	2 (6.5%)	4 (12.9%)	0.671†
Self-guided reading materials (e.g. a self-help booklet), *n* (%)	25 (40.3%)	15 (48.4%)	10 (32.3%)	0.196
Digital sleep-improvement program (e.g. app and online), *n* (%)	13 (21.0%)	6 (19.4%)	7 (22.6%)	1.000†
Another device for sleep-improvement, *n* (%)	9 (14.5%)	4 (12.9%)	5 (16.1%)	1.000†

†Fisher's exact rest statistic used because of low cell count data.

BMI, body mass index (weight (kg)/height $(cm)^2$); DBAS, Dysfunctional Beliefs and Attitudes about Sleep scale; ESS, Epworth Sleepiness Scale, FFS, Flinders Fatigue Scale; GAD-7, Generalised Anxiety Disorder-7; ISI, Insomnia Severity Index; PHQ-9, Patient Health Questionnaire-9.

$P < 0.001$, $d = 1.10$) and from the 8-week to the 24-week follow-up ($Diff_{adj} = 7.33$ (4.37–10.30), $P < 0.001$, $d = 1.62$). There were no significant between-group differences at the 16-week ($Diff_{adj} = 1.90$ (−0.50 to 4.32), $P = 0.120$, $d = 0.40$) or the 24-week follow-up ($Diff_{adj} = 1.98$ (−4.47 to 0.51), $P = 0.118$, $d = 0.41$), suggesting the waitlist control group had similar improvements in insomnia after they accessed the digital CBT-i program.

A consistent pattern of results was observed when examining the ISI nocturnal and ISI daytime subscores (Table 2; Supporting Information) and for sensitivity analyses of between-group differences in the ISI among participants who completed at least three sessions of intervention/control and five sessions of intervention/control (Supporting Information).

Depression symptoms

A significant group-by-time interaction effect was observed for PHQ-9 scores (Table 2). After adjusting for baseline PHQ-9 scores, the intervention group reported significantly lower PHQ-9 scores at the 8-week follow-up, compared to the control group ($Diff_{adj}$ (95% CI) = 3.36 (1.28–5.44), $P = 0.002$, $d = 0.84$). For the intervention group, PHQ-9 scores decreased from baseline to the 8-week follow-up ($Diff_{adj} = 4.42$ (2.22–6.62), $P < 0.001$, $d = 1.12$). There was no significant within-group change in PHQ-9 scores from the 8-week to the 16-week follow-up ($Diff_{adj} = -0.17$ (−2.45 to 2.11), $P = 1.00$, $d = 0.04$) or between 8-week and 24-week follow-up ($Diff_{adj} = -1.44$ (−4.20 to 1.33), $P = 1.00$, $d = 0.34$), suggesting improvements were maintained.

For the control group, there was no significant change in PHQ-9 scores from baseline to the 8-week follow-up ($Diff_{adj} = 0.94$ (−1.17 to 3.05), $P = 1.00$, $d = 0.24$). PHQ-9 scores did not significantly decrease from the 8-week to the 16-week follow-up ($Diff_{adj} = 1.65$ (−0.58 to 3.87), $P = 0.295$, $d = 0.41$) but did significantly decrease from the 8-week to the 24-week follow-up ($Diff_{adj} = 3.31$ (0.68–5.95), $P = 0.006$, $d = 0.81$). There were no significant between-group PHQ-9 differences at the 16-week ($Diff_{adj} = 1.54$ (−0.63 to 3.71), $P = 162$) or the 24-week follow-up ($Diff_{adj} = -1.39$ (−3.63 to 0.86), $P = 0.224$). In sum, improvement in depression symptoms for the control group (once they were given access to the digital CBT-i program) were smaller in magnitude and more gradual to emerge, relative to the intervention group. However, the lack of between-group differences at the 16-week and 24-week follow-up suggest levels of

Table 2 Between-group differences in estimated marginal means ±95% confidence interval (CI) for symptoms of insomnia, mental health, daytime function and dysfunctional sleep-related beliefs during treatment

	Digital CBT-i				Sleep education control group				Overall interaction	Between-group effect at 8 weeks†	
	Baseline	8 weeks	16 weeks	24 weeks	Baseline	8 weeks	16 weeks	24 weeks	*P*	*d*	*P*
Insomnia (ISI)	18.66 ± 1.5	9.45 ± 1.7	9.92 ± 1.7	11.42 ± 1.8	18.35 ± 1.5	16.77 ± 1.6	11.83 ± 1.7	9.43 ± 1.7	<0.001	1.64	<0.001
Noctumal subscore	7.15 ± 0.65	4.01 ± 0.72	4.45 ± 0.74	4.88 ± 0.77	7.11 ± −0.65	6.47 ± 0.68	4.65 ± 0.72	4.03 ± 0.74	<0.001	1.29	<0.001
Daytime subscore	11.52 ± 1.00	5.43 ± 1.09	5.42 ± 1.12	6.49 ± 1.12	11.24 ± 0.99	10.31 ± 1.04	7.20 ± 1.10	5.43 ± 1.12	<0.001	1.68	<0.001
Depression (PHQ-9)	9.68 ± 1.38	5.26 ± 1.51	5.43 ± 1.55	6.70 ± 1.62	9.56 ± 1.38	8.62 ± 1.44	6.97 ± 1.52	5.31 ± 1.56	0.002	0.84	0.002
PHQ-8	8.01 ± 1.38	4.49 ± 1.51	4.46 ± 1.55	5.77 ± 1.61	7.89 ± 1.38	7.04 ± 1.44	6.03 ± 1.52	4.48 ± 1.56	0.017	0.63	0.017
Anxiety (GAD-7)	6.92 ± 1.27	4.37 ± 1.38	3.98 ± 1.42	4.80 ± 1.48	7.01 ± 1.27	6.21 ± 1.32	5.09 ± 1.39	5.15 ± 1.43	0.371	0.50	0.060
Sleepiness (ESS)	5.31 ± 1.10	4.53 ± 1.20	3.66 ± 1.23	4.86 ± 1.28	5.22 ± 1.10	6.20 ± 1.15	4.86 ± 1.21	4.69 ± 1.24	0.119	0.59	0.042
Fatigue (FFS)	18.19 ± 1.78	12.49 ± 1.96	10.86 ± 2.01	12.78 ± 2.10	17.97 ± 1.78	17.68 ± 1.86	14.36 ± 1.97	13.28 ± 2.02	0.005	1.00	<0.001
Dysfunctional beliefs about sleep	58.15 ± 4.63	44.93 ± 5.00	44.33 ± 5.14	45.28 ± 5.26	58.30 ± 4.64	55.94 ± 4.81	48.62 ± 5.06	46.92 ± 5.20	0.009	0.82	0.002

†Between-group effect at 8 weeks adjusted for baseline scores.
ESS, Epworth Sleepiness Scale; FFS, Flinders Fatigue Scale; GAD-7, Generalised Anxiety Disorder-7; ISI, Insomnia Severity Index; PHQ-8, PHQ-9 rescaled after removal of 'sleep' item; PHQ-9, Patient Health Questionnaire-9.
d = Cohen's *d* (95% CI).

depression were similar for both groups at these time points.

The same pattern of results was observed after removing the 'sleep' item from the PHQ-9 and re-scaling the remaining items (Table 2; Supporting Information).

Anxiety symptoms

The group-by-time interaction effect for GAD-7 scores was non-significant (Table 2). After adjusting for baseline GAD-7 scores, there was no between-group difference in GAD-7 scores at 8 weeks ($Diff_{adj}$ (95% CI) = 1.84 (−0.08 to 3.75), $P = 0.060$, $d = 0.50$). A significant main effect of time (F (3147) = 5.69, $P = 0.001$) indicated a decrease in anxiety from baseline to 8 weeks ($Diff_{adj} = 1.67$ (0.28–3.07), $P = 0.010$, $d = 0.66$), but not from 8 to 16 weeks ($Diff_{adj} = 0.76$ (−0.70 to 2.21), $P = 0.994$, $d = 0.29$), or 16 to 24 weeks ($Diff_{adj} = -0.45$ (−1.97 to 1.08), $P = 1.000$, $d = 0.16$).

Responder analyses

Complete-case responder analyses indicated significantly greater rates of insomnia *remission* (ISI <8), *clinically significant insomnia criteria* (ISI < 15) and *MCID* from baseline (ISI reduction ≥6) by 8 weeks in the intervention group (Table 3). Rates of insomnia remission, response and MCID from baseline (ISI reduction ≥6) are also reported at 16-week and 24-week follow-up (Table 3).

Secondary outcomes

Significant group-by-time interaction effects were observed for the FFS and DBAS scale (both $P \leq 0.009$; Table S1), indicating greater improvements in the intervention than the control group at 8 weeks (Fatigue: $Diff_{adj} = 5.20$, 95% CI = 2.49–7.90, $P < 0.001$, $d = 1.00$; Dysfunctional beliefs about sleep: $Diff_{adj} = 11.02$, 95% CI = 4.08–17.95, $P = 0.002$, $d = 0.82$). These improvements were sustained at 24 weeks (Table S1). There was no significant group-by-time interaction effect on the ESS (Table S1).

Discussion

The main findings of this study are that this digital CBT-i program resulted in large and sustained improvements in insomnia, depression, fatigue and dysfunctional beliefs about sleep in a community-based sample of Australian adults with insomnia symptoms. By 8-week follow-up, 72% of participants in the intervention group experienced clinically meaningful improvement in insomnia symptoms, and 40% experienced insomnia remission. With appropriate screening for safety and suitability,

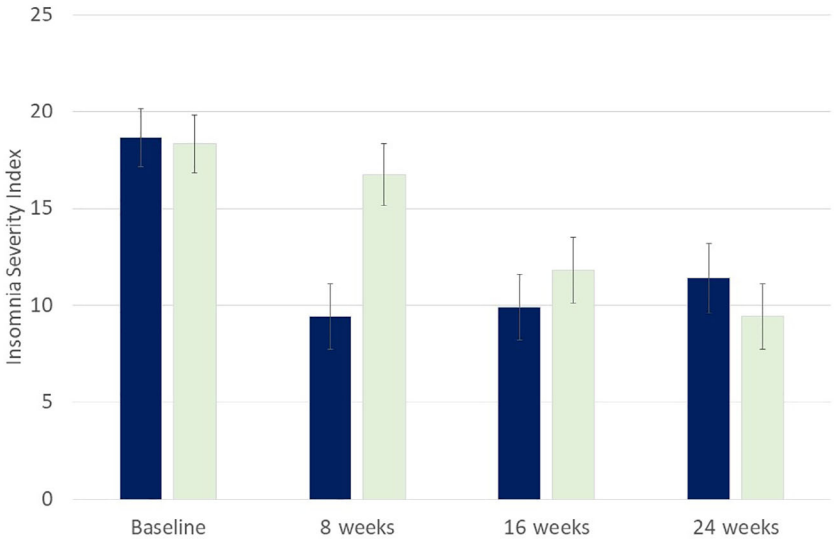

Figure 3 Intention–totreat analysis of between-group changes in estimated marginal mean (±95% confidence intervals) Insomnia Severity Index scores. The intervention group accessed the CBT-i program after the baseline assessment. The control group accessed the CBT-i program after the 8-week assessment. CBT-i, cognitive behavioural therapy for insomnia. (■) Intervention group; (□) Education control group.

interactive digital CBT-i appears to be an effective treatment for insomnia that could be scaled throughout Australia.

The study sample included people throughout Australia, ranging from 22 to 82 years of age. Most participants were female, and 98% of participants indicated chronic insomnia (≥3 months duration), with two-thirds reporting that their symptoms had persisted for at least 5 years and 79% of participants reporting a previous diagnosis of a comorbid chronic condition. Approximately 50% of participants were actively using sleeping pills at baseline, 75% had used sleeping pills in the past 12 months, one-fifth of study participants had used other digital/online programs for insomnia in the past 12 months, and 37% had received insomnia advice/care from a general practitioner. Given the moderate-to-severe levels of insomnia at baseline, it can be summarised that many participants were experiencing a pattern of insomnia that was resistant to other current/recent treatment approaches. Consequently, this digital CBT-i program appears to be effective among people with moderate/severe chronic insomnia that is not responsive to other treatment approaches.

Study inclusion criteria were developed for three reasons: (i) to ensure that the intervention was accessible to study participants (i.e. English language and internet access), (ii) to ensure safety and suitability of self-guided CBT-i (i.e. excluding participants reporting excessive daytime sleepiness, or a history of sleepiness-related motor vehicle accidents), and (iii) to develop a set of triaging criteria for future stepped-care models of insomnia, to identify patients who are suitable for direct access to digital CBT-i versus referral to specialist clinicians. As shown in Figure 2, 21% of participants were identified as appropriate for clinician management and were directed to local/telehealth clinical services. The remaining 79% of participants were identified as appropriate for one of three digital CBT-i RCTs. Given the relatively small number of participants screened for this study, these screening and triaging numbers are currently being studied by a larger sample of Australian adults with insomnia symptoms. However, as a theoretical exercise, directing approximately 80% of people with insomnia to an evidence-based self-guided digital program would be expected to expedite rapid treatment access for these people, facilitate treatment access outside of routine work/clinic hours and reduce the burden on valuable clinician resources to manage the remaining ~20% of people that do require specialist care.[12] Future research programs are required to integrate digital CBT-i into models of insomnia management in Australia, including community settings, primary care and specialist care. It is also very important to develop culturally tailored clinician and self-guided CBT-i programs for First Nations people.[35]

We observed a 46% improvement in depression in the digital CBT-i group, compared to a 10% improvement in the control group by 8 weeks. This finding supports previous studies reporting improvement in depression symptoms following CBT-i.[5] Conversely, there was no group-by-time interaction on anxiety symptoms. At baseline, average anxiety scores were in the mild range, which may have created a floor effect and prevented a significant group-by-time interaction. It is also possible that digital CBT-i may be less effective at reducing anxiety among people with insomnia compared to CBT-i delivered by a trained clinician who can provide more personalised cognitive therapies to identify, test and

Table 3 Between-group rates of insomnia remission, response and minimum clinically important difference (MCID) by 8-week follow-up

	Intervention	Control	*P*
8 weeks			
ISI <8 (remission), *n* (%)	10 (40.0%)	0 (0%)	<0.001
ISI <15 (response), *n* (%)	21 (84.0%)	11 (39.3%)	0.001
ISI reduction ≥6 from baseline (MCID), *n* (%)	18 (72.0%)	2 (7.1%)	<0.001
16 weeks			
ISI <8 (remission), *n* (%)	7 (29.2%)	6 (24.0%)	-
ISI <15 (response), *n* (%)	18 (75%)	17 (68.0%)	-
ISI reduction ≥6 from baseline (MCID), *n* (%)	16 (66.7%)	13 (52%)	-
24 weeks			
ISI <8 (remission), *n* (%)	9 (40.1%)	10 (41.7%)	-
ISI <15 (response), *n* (%)	14 (63.6%)	20 (83.3%)	-
ISI reduction ≥6 from baseline (MCID), *n* (%)	12 (54.6%)	20 (83.3%)	-

Fisher's exact *P* used because of low cell count criteria.
Between-group *P* values are not presented at 16 or 24 weeks, as both groups had received intervention.
ISI, Insomnia Severity Index.

overcome specific anxiety-provoking beliefs about sleep.[36]

Limitations

Despite several strengths, including standardised measures, a sample of people from throughout Australia, a comparator group that controlled for digital access to sleep education material, and a low rate of attrition for a trial conducted entirely online, several important limitations should be considered.

First, 82% of the participants were female, which may reduce the generalisability of the findings to other sexes. This may have resulted from more males being identified and excluded because of comorbid sleep apnoea, a higher prevalence of insomnia in females,[37] different symptom profiles or a higher rate of treatment-seeking behaviour in females.[38] Although there are no established effects of sex on response to CBT-i,[39] future studies are needed to confirm the effectiveness of digital CBT-i in males, females and individuals who identify as non-binary.

Second, we did not control for placebo or demand effects in this study. It is possible that participants in the CBT-i group were aware that they were receiving active treatment and had a greater expectation of improvement or perceived demand to report improvement, compared to those in the education control group. However, the online nature of the study and the minimal contact between study coordinators and participants likely reduced any risk of perceived demand effects. Furthermore, placebo effects would not be expected to produce the maintenance of improvements in sleep, fatigue, specific dysfunctional beliefs or mental health by 24 weeks.

Third, 12.6% of the potential participants were excluded because of evidence of self-harm or suicide risk. Because this was the first trial of the present digital CBT-i program, we felt that it was appropriate to initially test the safety and effectiveness of the program in those without any reported risk of self-harm or severe psychiatric conditions (i.e. bipolar or schizophrenia disorder). Consequently, the results of this study may not generalise to people with self-harm/suicide risk in the community. However, other studies have reported that CBT-i is associated with reduced suicidal ideation among people with comorbid insomnia and suicidal ideation.[40,41]

Fourth, results of between-group responder analyses should be interpreted with caution, as they are based only on participants with observed 8-week data. It is possible that participants who derived less benefit from treatment (and control) were less likely to complete follow-up measures, which may bias the remaining observed data. However, the relatively small rate of missing data for a trial conducted entirely online, and the absence of any between-group difference in missing data at 8 weeks provides confidence in the generalisability of post-treatment responder-analysis data.

Conclusion

This digital CBT-i program led to large and sustained improvements in insomnia, depression, fatigue and dysfunctional beliefs about sleep in an Australian community-recruited sample. This program was deemed appropriate for approximately 80% of participants who were screened, about half of whom were using sedative-hypnotic medicines at baseline and most of whom reported non-response to other treatments/care for insomnia in the past year. Given the great need to

improve access to CBT-i in Australia, these data highlight the potential to use evidence-based interactive digital CBT-i to improve access to CBT-i, while saving limited clinician resources for the minority of people who require specialist care. Implementation trials are required to scale and integrate digital CBT-i throughout Australia.

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Ethics statement

This study was approved by the Southern Adelaide Human Research Ethics Committee (2021/HRE00287).

Data availability statement

Data are not available for sharing according to ethics approvals.

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Supporting Information

Additional supporting information may be found in the online version of this article at the publisher's web-site:

Data S1. Supporting Information.