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Effectiveness of digital cognitive-behavioural therapy for insomnia in cancer survivors: the OncoSleep randomised controlled trial

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Introduction

☁Nearly half of all cancer survivors experience insomnia (difficulty falling or staying asleep). If not properly treated, insomnia can have serious consequences and hinder cancer recovery.[1]
☁Cognitive-behavioural therapy for insomnia (CBT-I), a psychological treatment, is unequivocally recommended as the standard of care for treating insomnia in cancer survivors, but is very seldom available.[2-4] Digital CBT-I widens access and may provide an optimal treatment option for cancer survivors.[1]

We tested the **effectiveness of a digital CBT-I programme with clinician support, OncoSleep, in cancer survivors** through a superiority, parallel-group randomised controlled trial.
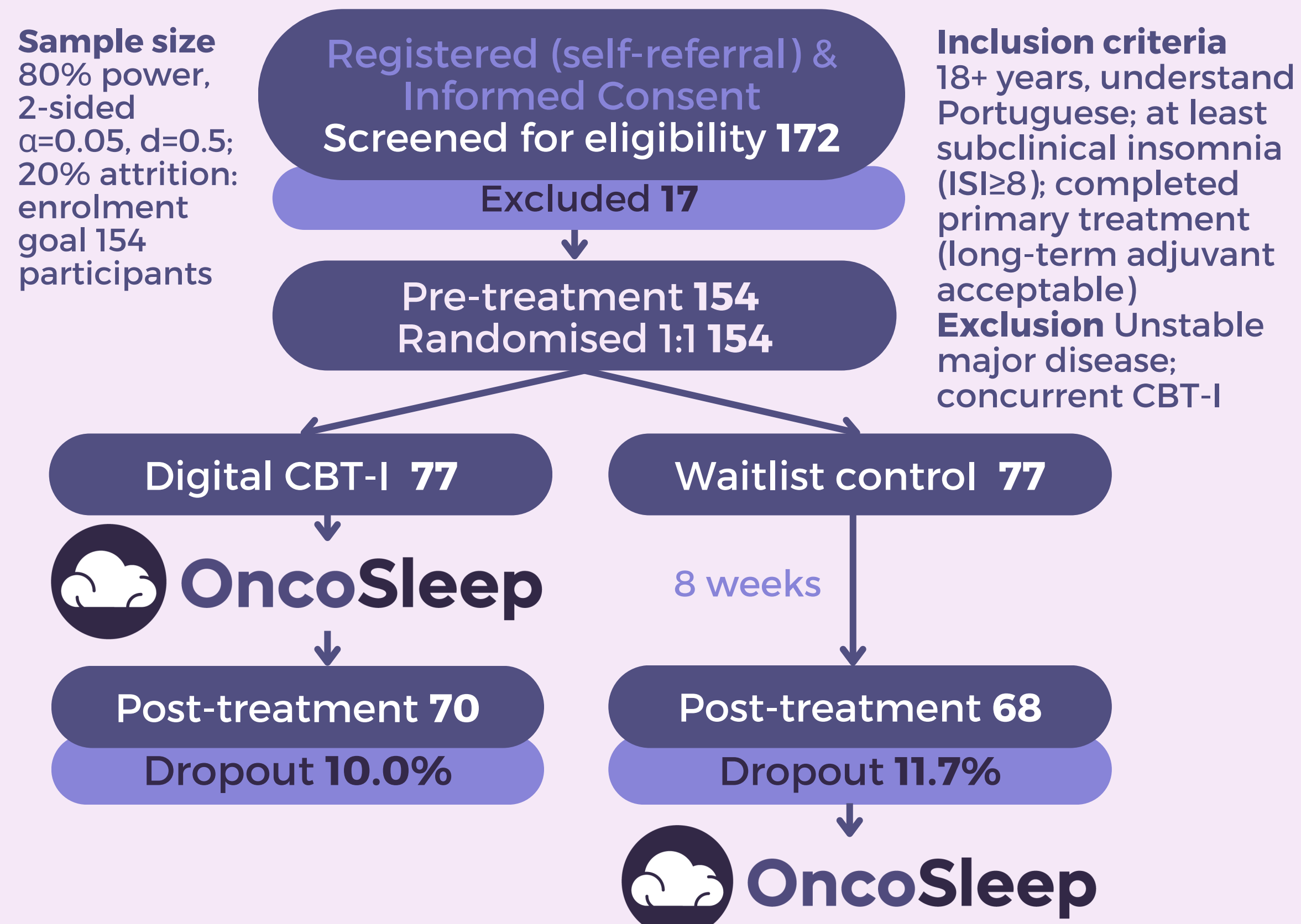
Methods

Aims, patient-reported outcomes and measures (Portuguese versions)
1: Changes in insomnia severity Insomnia Severity Index (ISI)[5]
ISI≥8: insomnia symptoms; ≥15: clinical insomnia
2: Changes in daytime and sleep outcomes
Anxiety, depression Hospital Anxiety and Depression Scale[6], Functioning EORTC Quality of Life Questionnaire[7], Quality of life WHO Quality of Life-brief[8], Fatigue Multidimensional Fatigue Symptom Inventory-Short Form[9]; Total sleep time, sleep onset latency Sleep diary[10]
Exploratory: insomnia changes mediate digital CBT-I effects on daytime outcomes?

Intervention OncoSleep: self-guided modules of web-based automated CBT-I, adapted to survivors + clinician support via email

Module 1 psychoeducation, goal-setting
Module 2 relaxation, sleep hygiene
Module 3 sleep consolidation, stimulus control
Module 4 & 5 cognitive techniques, behavioural activation
Module 6 relapse prevention

Figure 1.
Agenda for OncoSleep weekly modules.

Results

Sample size
80% power, 2-sided α=0.05, d=0.5; 20% attrition: enrolment goal 154 participants

Inclusion criteria
18+ years, understand Portuguese; at least subclinical insomnia (ISI≥8); completed primary treatment (long-term adjuvant acceptable)
Exclusion Unstable major disease; concurrent CBT-I

Registered (self-referral) & Informed Consent
Screened for eligibility 172
Excluded 17
Pre-treatment 154
Randomised 1:1 154
Digital CBT-I 77 — Waitlist control 77
OncoSleep
8 weeks
Post-treatment 70 — Post-treatment 68
Dropout 10.0% — Dropout 11.7%
OncoSleep

Figure 2.
Study flow diagram of the OncoSleep trial NCT04898855.

Participants 94.8% women, mean (M) age=47 years (25-75)
Time since cancer diagnosis M=4.3 years
digital format likely more appealing to younger survivors

Working 54%
Higher education 70%
Completed treatment 37% for M=4.5 years
Breast cancer 72%
Medication use 40% ≥2 nights/week

87% for ≥ 3 months, 61% ≥ 1 year, 21% ≥ 6 years
despite guidelines for short-term use [2-4], side-effects, and safety risks (e.g., drug interactions)

Figure 3.
Demographic and clinical characteristics.
Groups did not differ significantly in background or outcome variables at baseline.

	PRE-TREATMENT		POST-TREATMENT			
	digital CBT-I 77	waitlist 77	digital CBT-I 70	waitlist 68	Cohen's d	**Linear mixed models (intention-to-treat) Group x time**
insomnia severity	17.1	17.0	6.1	15.6	2.56	
anxiety	9.3	9.1	6.7	9.6	0.78	
depression	6.6	6.6	4.7	7.1	0.73	
pain	33.3	35.1	25.6	34.3	0.77	
cognitive functioning	57.8	58.4	76.8	58.3	0.95	*11.0-point reduction in insomnia severity in the treatment group, exceeding the 8-point threshold for clinically significant change [11]*
physical quality of life	54.5	53.7	72.6	53.5	1.24	
psychological quality of life	56.2	54.1	66.1	53.9	0.80	
fatigue	32.0	33.3	10.9	35.2	1.35	
total sleep time [h:mm]	6:13	6:23	7:23	6:22	0.80	
sleep onset latency [h:mm]	0:48	1:00	0:17	1:02	1.10	

p<0.001 (Group x time)

Table 1. Outcomes at pre- and post-treatment.
*All statistically significant effects remained significant after controlling the family-wise error rate for multiple outcomes with Holm's procedure. Cohen's d: between-group differences post-treatment. Higher scores = more severe insomnia, anxiety and depression symptoms, worse pain; better cognitive functioning, better physical and psychological quality of life, and more severe fatigue.
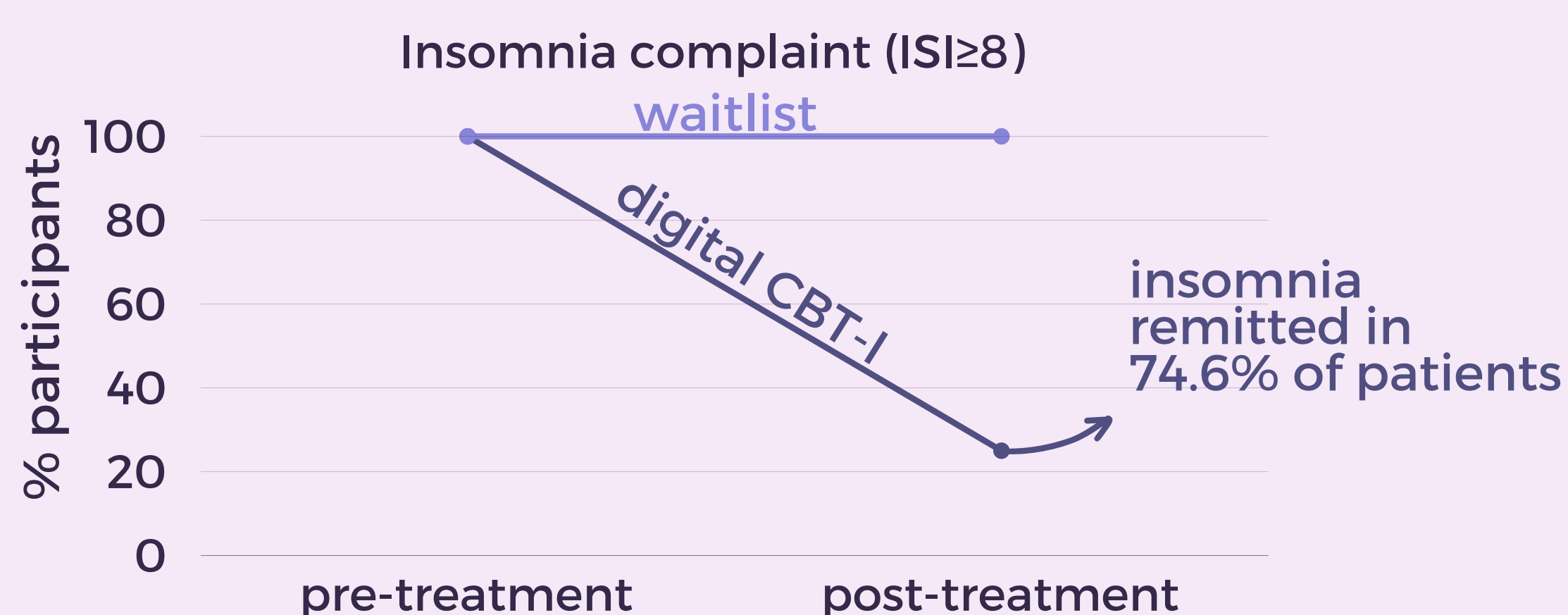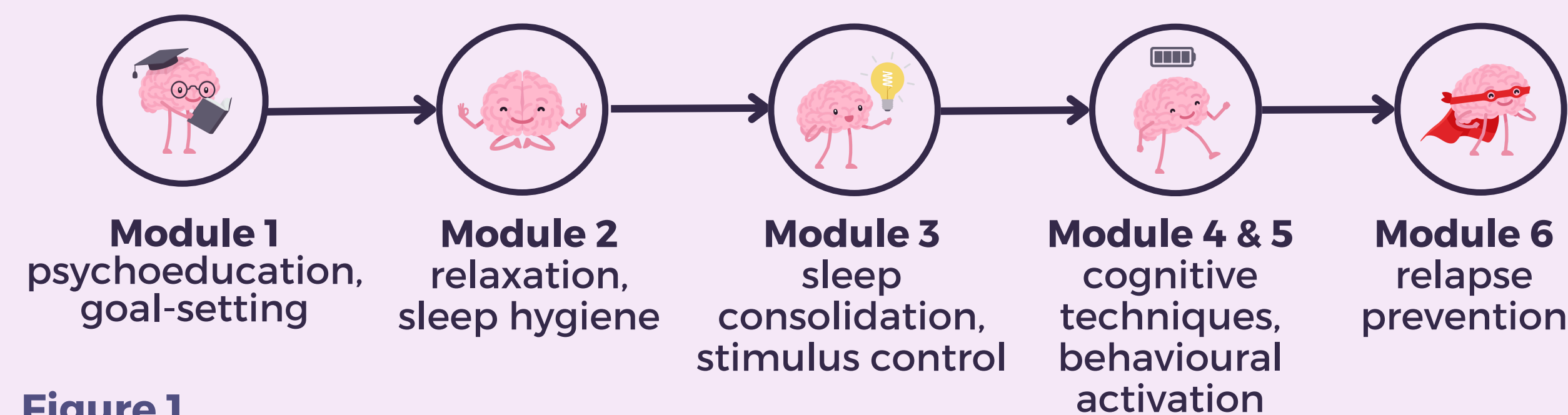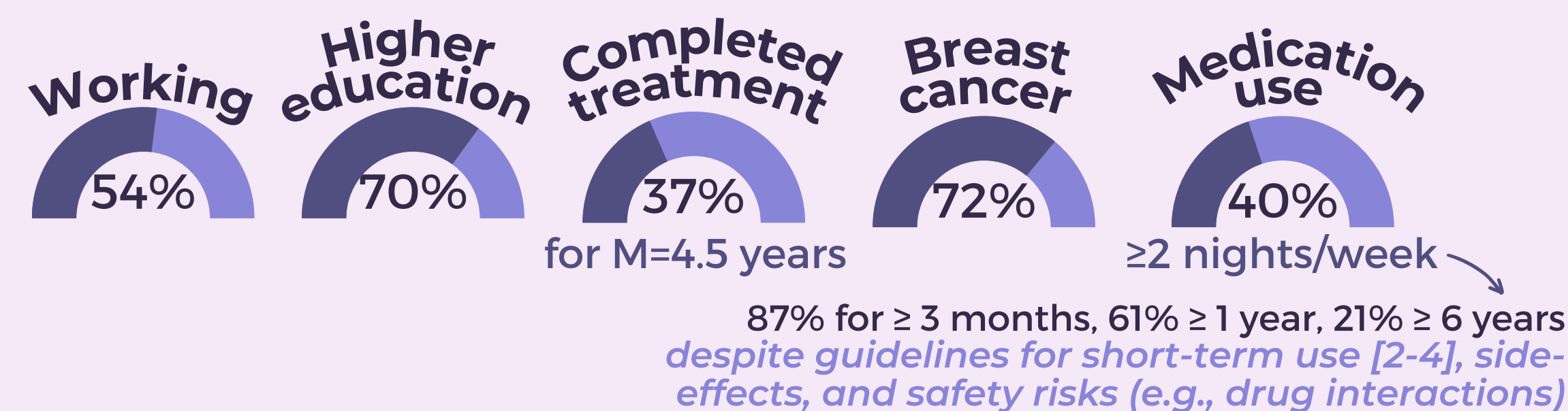

Insomnia complaint (ISI≥8)
waitlist
digital CBT-I
insomnia remitted in 74.6% of patients
% participants (0–100)
pre-treatment — post-treatment

Figure 4. Proportion of participants reporting at least subthreshold insomnia severity (ISI≥8).
Proportion of remitted participants higher in the treatment than control group [0.0%, χ2=82.03, p<0.001].

Changes in anxiety, depression, functioning, and quality of life were fully mediated by decreased insomnia severity, while changes in fatigue were partially mediated by it. CBT-I as a potential treatment for co-ocurring symptoms
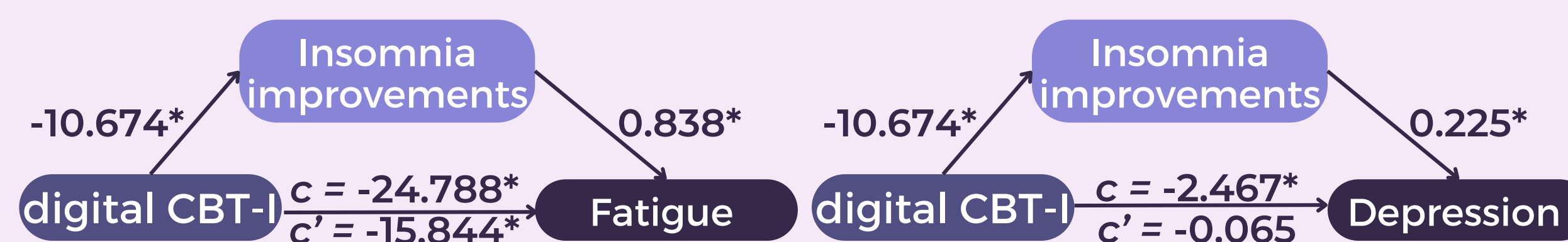

digital CBT-I → Insomnia improvements -10.674* ; Insomnia improvements → Fatigue 0.838* ; c = -24.788* ; c' = -15.844*

digital CBT-I → Insomnia improvements -10.674* ; Insomnia improvements → Depression 0.225* ; c = -2.467* ; c' = -0.065

Figure 5. Mediating role of insomnia severity reduction in the effect of digital CBT-I on daytime outcomes.
*Represents significance, p remained significant after adjusting for multiple comparisons using Benjamini-Hochberg procedure.

Conclusions

☁Digital CBT-I with clinician support appears to be effective in treating insomnia in cancer survivors, with generalized benefits in comorbid symptoms, functioning, and quality of life.
☁Accessible digital CBT-I could be integrated in cancer survivorship plans to reduce the burden of cancer-related insomnia.

References

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