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Digital cognitive behavioural therapy for insomnia in women with cancer: The Sleepio After Cancer (SAC) randomised controlled trial

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Background

Insomnia is common in women with cancer and impairs quality of life. Pharmacotherapy remains the most common treatment despite limited long-term efficacy evidence. The Sleepio After Cancer (SAC) trial evaluated digital cognitive behavioural therapy for insomnia (dCBT-I), delivered via Sleepio, versus sleep hygiene education (SHE) in women with cancer and significant insomnia.

Methods

SAC was a two-arm, open-label randomised trial. 308 women with a current or prior cancer diagnosis and insomnia (Sleep Condition Indicator [SCI] score ≤16) were randomised 1:1 to dCBT-I or SHE, plus treatment as usual. Co-primary endpoints at Week 24 were change in SCI score and the proportion achieving SCI score >16 (remission). Mixed models incorporated all available data under a missing-at-random assumption. Pre-specified subgroup analyses tested treatment-by-subgroup interaction for cancer type and anti-endocrine therapy.

Results

308 participants were randomised (156 dCBT-I, 152 SHE), with a median age of 52 (IQR 46-57). Median BMI was 25.7 (IQR 22.6-28.8). 85% of participants were post-menopausal. Participants had breast (61%), gynaecological (29%), or other cancers (10%). 15% were receiving active cancer treatment and 30% had stage III/IV disease. Among dCBT-I participants, 126/156 (81%) commenced the programme and 61/156 (40%) completed six sessions. Week 24 completion was 69 (44%) and 52 (34%). SCI scores improved significantly more with dCBT-I (mean difference, 6.36 points; 95% CI, 4.96–7.76; P<0.001; Cohen's d=0.99). Remission was achieved by 27% versus 12% (ITT, NNT=7) and 62% versus 19% of completers (NNT=3); robust to tipping-point sensitivity analysis. Treatment benefit was consistent across cancer subgroups (interaction P=0.922) and anti-endocrine therapy status (interaction P=0.313). Secondary outcomes (fatigue, depression, anxiety, hot flash interference) improved significantly more with dCBT-I (effect sizes 0.48–0.77).

Conclusions

In this adequately powered trial of a broad population of women with cancer, dCBT-I produced clinically meaningful, sustained improvements in insomnia and associated symptoms, supporting wider integration of digital CBT-I into routine survivorship care.

Clinical trial identification

NCT05816460.

Legal entity responsible for the study

University College Dublin.

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Disclosure

A. Henry: Financial Interests, Personal and Institutional, Full or part-time Employment: Bighealth. All other authors have declared no conflicts of interest.

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