Background: Insomnia is highly prevalent among cancer survivors. Meta-analyses examining the effects of cognitive-behavioral therapy for insomnia (CBT-I) among cancer survivors have focused on within-group (pre-to-post-intervention) changes, with calls to better evaluate treatment effects.

Objective: To conduct a systemic-review and meta-analysis and evaluate the effects of cognitive-behavioral therapy for insomnia (CBT-I) among cancer survivors, compared with controls, on insomnia.

Methods: We followed recommendations from the Cochrane Handbook and PRISMA guidelines. We comprehensively searched 8 databases (CINAHL/ClinicalTrials.gov/Cochrane Central/Embase/MEDLINE/PEDro/PsychInfo/Web of Science) and included randomized controlled trials (RCTs) in which adult cancer survivors with clinically-significant insomnia were randomized to CBT-I or control conditions that included usual care, waitlist, attention, or sleep hygiene education only. We designated the primary outcome as end-of-intervention Insomnia Severity Index (ISI) and secondary outcomes included sleep diary parameters, fatigue, and health-related quality of life (HRQL). We analyzed between-group mean differences (MD's), standardized-mean-differences (SMD's), and interpreted results using guideline-endorsed, minimal clinically important difference (MCID) or SMD thresholds. We rated evidence certainty facilitated by GRADEpro GDT.

Results: We included 19 RCTs involving 1,803 participants. Participant mean age was 55 and time-since-diagnosis was 2.5 years; 95% were women, mostly survivors of breast cancer. At end-of-intervention, compared with controls, CBT-I improved ISI [MD (95% CI): -4.4 (-5.3, -3.5) points; assessed in 13 trials] that did not reach the MCID threshold (i.e., ≥6 points), but is higher than half of the minimal-important-change (i.e., 3-<6 points, including 95% CI), suggesting that an appreciable number but not many patients derived clinically-important benefit. Subjective

sleep diary (assessed in 12 trials) sleep latency, wake after sleep onset, sleep efficiency, fatigue (11 trials), and HRQL (10 trials) were also improved; however, on average, none of the improvements reached their respective MCID or SMD thresholds to suggest that many patients derived clinically-important benefits. In pre-specified subgroup analyses, no intervention or cancer-related characteristics meaningfully changed results. Evidence certainty was low-to-very-low, primarily due to heterogeneity, performance, publication, and/or reporting bias.

Conclusion: Compared with controls, CBT-I improved insomnia among an appreciable number but not many cancer survivors. Strategies are needed to improve insomnia for many cancer survivors, particularly among non-responders to first-line CBT-I.