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Telehealth group Cognitive Behavioral Therapy for Insomnia (CBT-I) in primary brain tumor: Primary outcomes from a single-arm Phase 2 feasibility and proof-of-concept trial

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Abstract

Background: Cognitive Behavioral Therapy for Insomnia (CBT-I), the front-line treatment for insomnia, has yet to be evaluated among patients with primary brain tumors (PwPBT) despite high prevalence of sleep disturbance in this population. This study aimed to be the first to evaluate feasibility, safety, and acceptability of implementing telehealth group CBT-I as well as assessing preliminary changes in subjective sleep metrics in PwPBT from baseline to follow-up.

Methods: Adult PwPBT were recruited to participate in six 90-minute telehealth group CBT-I sessions. Feasibility was assessed by rates of screening, eligibility, enrollment, and data completion. Safety was measured by participant-reported adverse events. Acceptability was assessed by retention, session attendance, satisfaction, recommendation of program to others, and qualitative feedback. Participant subjective insomnia severity, sleep quality, and fatigue were assessed at baseline, post-intervention, and 3-month follow up.

Results: Telehealth group CBT-I was deemed safe. Following the 76% screening rate, 85% of interested individuals met study eligibility and 98% enrolled (N=44). Ninety-one percent of enrolled participants completed measures at baseline, 79% at post-intervention, and 73% at 3-month follow up. Overall, there was an 80% retention rate of the six-session telehealth group CBT-I intervention. All participants endorsed moderate-to-strong treatment adherence and 97% reported improved sleep. Preliminary pre-post intervention effects demonstrated improvements in subjective insomnia severity, sleep quality, and fatigue with large effect sizes. These effects were maintained at follow-up.

Conclusion: Results of this proof-of-concept trial indicate that telehealth group CBT-I is safe, feasible, and acceptable among PwPBT, providing support for future randomized controlled pilot trials.

Keywords: Cognitive Behavioral Therapy for Insomnia (CBT-I); Insomnia; Primary Brain Tumor; Sleep Disturbance.

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