Effects of a Brief Cognitive Behavioral Treatment vs Attention Control for Body Image-Related Distress Among Head and Neck Cancer Survivors: A Multi-Site Randomized Clinical Trial

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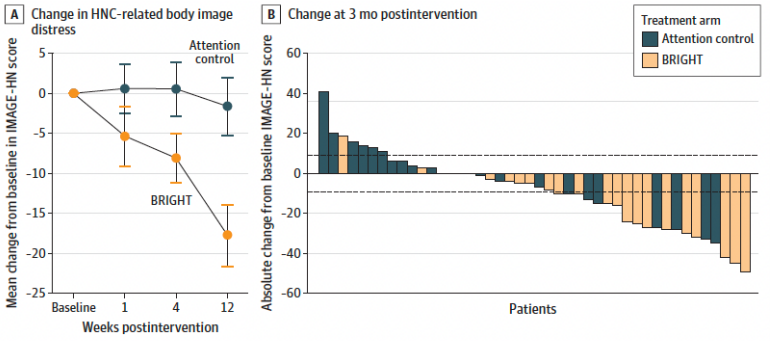
Clinically significant body image distress (BID) affects nearly 1 in 4 survivors of head and neck cancer (HNC) and is a psychosocial morbidity that leads to depression, social isolation, stigma, and adversely affects quality of life (QOL). Although clinically significant HNC-related BID does not improve over time without treatment, evidence-based management strategies to manage BID in this population are lacking. Our team developed BRIGHT (Building a Renewed ImaGe after Head and neck cancer Treatment) as a brief tailored cognitive behavioral therapy (CBT) that targets maladaptive body image coping strategies among HNC survivors. Our previous single-arm trial demonstrated that BRIGHT was feasible, acceptable, and improved BID and HNC-related QOL. In a pilot randomized clinical trial (RCT), BRIGHT decreased HNC-related BID (**Fig**), depression, shame and stigma, and social isolation at 1- and 3-months post-intervention relative to dose and delivery-matched attention control (AC).



A, Line graph demonstrating the mean change from baseline in IMAGE-HN (Inventory to Measure and Assess imaGe disturbancE-Head and Neck) scores over time by intervention allocation. Error bars represent 1 SE above and below the mean. B, Waterfall plot showing response to BRIGHT (Building a Renewed ImaGe after Head and neck cancer Treatment) and attention control, as measured by absolute change from baseline in IMAGE-HN scores at 3 months postintervention. The IMAGE-HN score ranges from 0 to 84, with higher scores indicating worse HNC-related body image distress (and negative bars thus indicating improvement in HNC-related body image distress). The dashed horizontal line at ±9 indicates a clinically meaningful change in IMAGE-HN score.

This R37 proposal seeks to evaluate the efficacy of BRIGHT as a novel treatment for BID among HNC survivors, examine BRIGHT's underlying mechanisms, and characterize factors affecting its future adoption into clinical care. In this parallel-group RCT, we will recruit N=180 adult HNC survivors with BID from 3 diverse cancer centers (MUSC Hollings Cancer Center, Washington University in St. Louis Siteman Cancer Center, Henry Ford Cancer Institute) during routine survivorship encounters. Patients will be randomized to BRIGHT, which consists of 6 weekly psychologist-led video tele–CBT sessions, or AC, which consists of dose- and delivery-matched survivorship education. HNC survivors will complete IMAGE-HN (a valid measure of HNC-related BID; primary endpoint), measures of psychological and social well-being and QOL, and measures of theory-derived mechanisms of change underlying BRIGHT (mediators). We will conduct semi-structured interviews with patients, providers, and administrators and in-depth site visits to develop an implementation toolkit to enhance the adoption of BRIGHT into clinical care.

Findings may help develop new standards of clinical care, improve psychosocial morbidity and QOL for HNC survivors, optimize the effectiveness of CBT for BID, and enhance the implementation of psychosocial interventions for cancer survivors in diverse care settings.