JAMA Otolaryngology–Head & Neck Surgery | Original Investigation | FROM THE AMERICAN HEAD AND NECK SOCIETY

Efficacy of a Brief Tele–Cognitive Behavioral Treatment vs Attention Control for Head and Neck Cancer Survivors With Body Image Distress

A Pilot Randomized Clinical Trial

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IMPORTANCE Although 1 in 4 head and neck cancer (HNC) survivors experience clinically significant body image distress (BID), a psychosocial morbidity that adversely affects quality of life, effective interventions for these patients are lacking.

OBJECTIVE To evaluate the acceptability and preliminary efficacy of BRIGHT (Building a Renewed ImaGe after Head and neck cancer Treatment), a brief tele–cognitive behavioral therapy, at reducing BID among HNC survivors.

DESIGN, SETTING, AND PARTICIPANTS This parallel-group pilot randomized clinical trial recruited adult HNC survivors with BID between August 13, 2020, and December 9, 2021, from the Medical University of South Carolina HNC clinic during a routine survivorship encounter. Data were analyzed from May 3 to June 16, 2022.

INTERVENTIONS BRIGHT consisted of 5 weekly psychologist-led video tele–cognitive behavioral therapy sessions. Attention control (AC) consisted of dose- and delivery-matched survivorship education.

MAIN OUTCOMES AND MEASURES Change in HNC-related BID was assessed using IMAGE-HN (Inventory to Measure and Assess imaGe disturbancE–Head and Neck), a validated patient-reported outcome (score range, 0-84, with higher scores indicating greater HNC-related BID). Clinical response rate was measured as the proportion of patients with a clinically meaningful change in IMAGE-HN scores.

RESULTS Of the 44 HNC survivors with BID allocated to BRIGHT (n = 20) or AC (n = 24), the median (range) age was 63 (41-80) years, and 27 patients (61%) were female. Patients rated BRIGHT's acceptability highly (all metrics had a mean rating of ≥4.5/5), and 19 of 20 patients (95%) receiving BRIGHT were likely or highly likely to recommend it to other HNC survivors with BID. BRIGHT decreased HNC-related BID from baseline to 1 month postintervention relative to AC (mean model-based difference in change in IMAGE-HN score, −7.9 points; 90% CI, −15.9 to 0.0 points) and from baseline to 3 months postintervention relative to AC (mean model-based difference in change in IMAGE-HN score, −17.1 points; 90% CI, −25.6 to −8.6 points). At 3 months postintervention, the clinical response rate of BRIGHT was 6.6-fold higher than AC (model-based odds ratio, 6.6; 90% CI, 2.0-21.8). The improvement in HNC-related BID for BRIGHT vs AC at 3 months was clinically significant, and the effect size was large (Cohen *d*, −0.9; 90% CI, −1.4 to −0.4).

CONCLUSIONS AND RELEVANCE In this pilot randomized clinical trial, BRIGHT was acceptable, may result in a clinically meaningful improvement in HNC-related BID, and showed a high clinical response rate. These promising preliminary data support conducting a large efficacy trial to establish BRIGHT as the first evidence-based treatment for HNC survivors with BID.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT03831100

JAMA Otolaryngol Head Neck Surg. doi:10.1001/jamaoto.2022.3700
Published online December 1, 2022.

Visual Abstract

Supplemental content

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Head and neck cancer (HNC) and its treatment result in substantial life-altering changes related to facial disfigurement, difficulty swallowing, impaired smiling, and challenges speaking.[1] Because these changes are highly visible and affect daily social function, 75% of HNC survivors express body image concerns,[2] and up to 28% have clinically significant body image distress (BID).[3,4] Body image distress is a source of devastating psychosocial morbidity and functional impairment for HNC survivors, contributing to a 6-fold increase in moderate-severe depressive symptoms, an 8-fold increase in moderate-severe anxiety symptoms, as well as social isolation and feelings of stigmatization.[3,5-10]

Although clinically significant HNC-related BID does not improve over time without treatment,[11] evidence-based management strategies to manage BID in this population are lacking.[12] Trials evaluating interventions to conceal disfigurement[13,14] and improve self-compassion[15] have shown that they do not improve BID among HNC survivors. Due in part to the lack of effective treatments, a recent national survey found that management of BID was the single most commonly omitted component of HNC survivorship care.[16]

To address the lack of effective treatment options for HNC survivors with BID, we developed BRIGHT (Building a Renewed ImaGe after Head and neck cancer Treatment)[17] as a brief tele-cognitive behavioral therapy (CBT). Our previous single-arm trial demonstrated that BRIGHT was feasible, acceptable, and resulted in a reduction in BID at 1- and 3-month follow-up.[17] Based on these single-arm data, we designed a single-site pilot randomized clinical trial (RCT) to further evaluate the acceptability of BRIGHT and its preliminary efficacy at reducing BID among HNC survivors relative to an attention control (AC) condition, as well as refine the trial infrastructure in preparation for a multisite RCT.

Key Points

Question Is BRIGHT (Building a Renewed ImaGe after Head and neck cancer Treatment), a brief video tele–cognitive behavioral therapy, an acceptable and potentially effective treatment for head and neck cancer (HNC) survivors with body image distress (BID)?

Findings In this pilot randomized clinical trial of 44 survivors of HNC, BRIGHT was acceptable, resulted in a clinically meaningful improvement in HNC-related BID, and showed a high clinical response rate relative to dose- and delivery-matched attention control.

Meaning These promising preliminary data support conducting a large efficacy trial to establish BRIGHT as the first evidence-based treatment for HNC survivors with BID.

Methods

Study Approval and Guidelines

The study and protocol (Supplement 1) was approved by the institutional review board at the Medical University of South Carolina. Patients provided written informed consent before randomization. Trial and intervention information are presented according to the Consolidated Standards of Reporting Trials Extension (CONSORT Extension) reporting guidelines for randomized pilot[18] and psychological intervention trials,[19] as well as the TIDIeR checklist for intervention reporting.[20]

Participants

Patients were recruited from August 13, 2020, to December 9, 2021, from the Medical University of South Carolina HNC clinic during a routine survivorship encounter. Eligible patients were 18 years or older, had a history of HNC treated with surgery, completed treatment between 6 weeks and 12 months prior to enrollment, were cancer free, and had a Body Image Scale score of 10 or higher (indicating clinically significant cancer-related BID[21,22]). Patients were excluded if they could not speak or read English, were undergoing psychotherapy for any indication, or had a serious mental illness preventing trial participation.

Study Procedures

Following written informed consent and completion of baseline assessments, patients were randomized 1:1 to BRIGHT or AC using a permuted block randomization design with randomly selected block sizes of 4 or 6. The random allocation sequence was generated by the study biostatistician (H.L.) using a computer-generated algorithm and implemented in REDCap (Vanderbilt University). The study team was not blinded to treatment allocation, but patients were blinded as to which arm was the investigational one. Patients received $125 for their time. To enhance equity and minimize a digital divide, patients received a study-issued, cellular-enabled iPad if needed.

Interventions

BRIGHT is a manualized, theory-based[23-26] CBT consisting of 5 weekly 60-minute sessions delivered one-on-one by a licensed clinical psychologist via video telemedicine platform, as previously described.[17] BRIGHT session topics include (1) psychoeducation about the cognitive model of body image; (2) self-monitoring about thoughts, feelings, and body image behaviors; (3) cognitive restructuring to identify and challenge unhelpful automatic HNC-related body image thoughts; (4) positive body image coping strategies; and (5) maintenance and relapse prevention. Patients receive a BRIGHT workbook with objectives, educational materials, in-session exercises, and weekly homework.

Following best practices for choosing control groups within behavior change RCTs,[27,28] we designed AC to match BRIGHT's dose (5 weekly sessions) and delivery method (video-based telemedicine) while not providing the behavior change mechanism in BRIGHT. Attention control is a tele-supportive care intervention consisting of educational videos that address non-body image aspects of HNC survivorship in 5 modules: (1) introduction to survivorship, (2) physical treatment toxic effects, (3) psychosocial effects of HNC, (4) health maintenance, and (5) financial toxicity. Attention control was pretested with HNC survivors and refined to optimize its feasibility, credibility, and relevance.

Study Measures

Demographic data were collected via self-report; clinical characteristics were extracted from electronic health records. Fidelity of BRIGHT delivery was measured using a standardized checklist completed by the interventionist. Patient adherence to study interventions was measured by session attendance, session length, and, for patients allocated to BRIGHT, homework completion and therapist-rated engagement. Acceptability of BRIGHT was assessed at 1 week postintervention using a quantitative program evaluation supplemented with open-ended questions.

Severity of cancer-related BID was measured with the Body Image Scale.[29] The Body Image Scale score ranges from 0 to 30, with higher scores representing worse cancer-related BID. A score of 10 or higher indicates clinically significant cancer-related BID,[21,22] and a change of 3 points or more is clinically meaningful.[15] Severity of HNC-related BID was assessed with IMAGE-HN (Inventory to Measure and Assess imaGe disturbancE–Head and Neck).[30] The IMAGE-HN score ranges from 0 to 84, with higher scores representing worse HNC-related BID.[30] A change in the IMAGE-HN score of 9 points or more is clinically meaningful.[31] We included both the Body Image Scale and IMAGE-HN as outcome measures for the following reasons. At the time of trial design, the Body Image Scale was the most widely used measure of BID among HNC survivors,[12] and had a known cutoff score indicating clinically significant BID,[21] but was developed and validated in a mixed population of patients with cancer (predominantly breast cancer) and lacked content validity for HNC survivors.[12] In contrast, IMAGE-HN had better content validity for BID among HNC survivors but had only recently been validated[30] and did not have a known threshold indicating clinically significant HNC-related BID. Emerging data since this trial was designed have determined that an IMAGE-HN score of 22 or higher indicates clinically relevant HNC-related BID and confirmed that IMAGE-HN is a more sensitive and accurate measure of BID among HNC survivors than the Body Image Scale.[3]

Sample Size Calculation

Sample size calculations in PASS 2008, version 08.0.13 (NCSS), revealed that 44 patients were required to detect a standardized effect of 0.78 for the primary end point of change from baseline to 1 month postintervention in the Body Image Scale scores based on the 2-sample *t* test with 2-sided $\alpha = 0.1$. The targeted effect size (0.78) is large, especially when compared with an active control condition, but was selected due to the pilot design. The selection of $\alpha = 0.1$ and $1 - \beta = 0.8$ was based on the desire to emphasize power over type I error in this pilot RCT to allow for identification of an efficacy signal that could be further evaluated in a fully powered trial targeting a clinically meaningful reduction in BID.

Statistical Analysis

The efficacy analytic population consisted of all eligible, randomized, evaluable patients. Patients who developed a recurrent or new primary cancer went off study per protocol and were not evaluable. Statistical analyses were performed from May 3 to June 16, 2022, using SAS, version 9.4 (SAS Institute). Statistical testing was 2-sided, with $P < .10$ considered statistically significant; 90% CIs were reported for point estimates. The proportion of missing data was small (unit nonresponse for 2 patients, both in AC, at 1 week postintervention and no instances of item nonresponse) and unlikely to alter study results. Therefore, we elected to omit missing data instead of imputing it.

Descriptive statistics were used to characterize the cohort and intervention acceptability, fidelity, and adherence. Body Image Scale and IMAGE-HN scores at 1 and 3 months postintervention were compared between arms using linear regression models to account for partial clustering (ie, patients in BRIGHT were clustered within psychologists; patients in AC were not).[32] This modeling included cluster as a fixed effect because there was no effect on the fixed effect estimates, standard errors, or type I error. Linear and generalized linear mixed models were not fit owing to the limited number of clusters (2) and small sample size. Cohen *d* was calculated as the mean difference between study arms divided by the pooled standard deviation of the 2 groups,[33] and effect sizes categorized as small (0.2), medium (0.5), and large (0.8).[34]

Clinical response rate, the proportion of patients with clinically meaningful improvement in IMAGE-HN score (≥9 points)[21] or Body Image Scale score (≥3 points)[15] from baseline, was compared between groups at 3 months postintervention using a logistic regression model considering the partial clustering structure.[32] Waterfall plots were constructed to show change in IMAGE-HN and Body Image Scale scores for each patient from baseline to 3 months postintervention.

Results

Patient Population

Of the 252 patients screened, 62 (25%) met eligibility criteria, of whom 54 (87%) were accrued to the trial (**Figure 1**). Three randomized patients (6%) dropped out and 7 (13%) went off study per protocol after developing a recurrent or new primary cancer. The remaining patients (n = 44) completed BRIGHT or AC as allocated; all patients completed study assessments at 1 and 3 months postintervention.

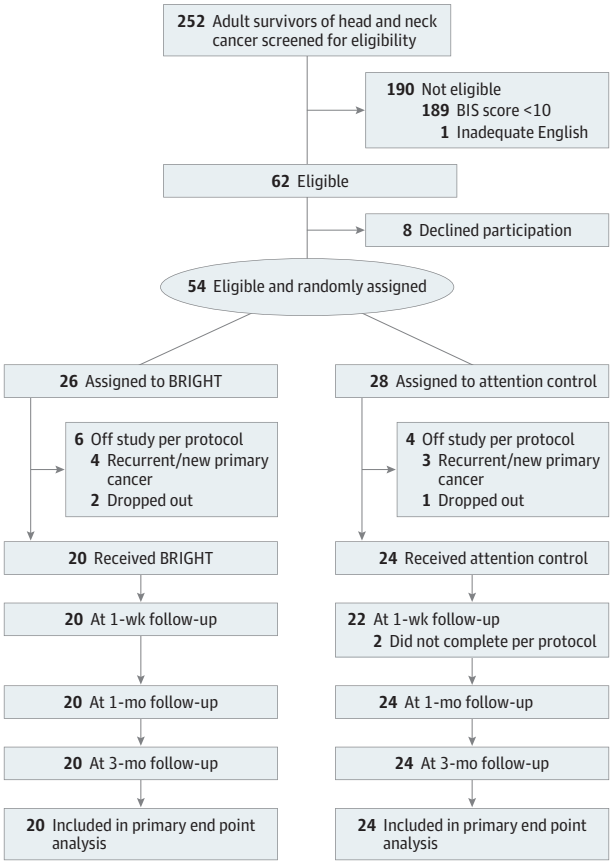
Baseline characteristics are summarized in **Table 1**. Patients had a median (range) age of 63 (41-80) years, and 27 patients (61%) identified as female. The most common head and neck subsite was the oral cavity (n = 44 [50%]); 27 patients (61%) had stage III/IV HNC, and 27 patients (61%) received adjuvant (chemo)radiation.

eTable 1 in Supplement 2 summarizes the fidelity and adherence data. Overall, patients attended 100% of the BRIGHT or AC sessions, and patients in BRIGHT completed 92% (73/80) of homework assignments.

Acceptability

Patients allocated to BRIGHT rated intervention timing (relative to HNC treatment), delivery method, content, workbook, homework, and relevance of the material highly (all mean ratings of ≥4.5/5). Overall, 95% of patients (19/20) reported that they were likely or highly likely to recommend BRIGHT

Figure 1. CONSORT Diagram



BIS indicates Body Image Scale; BRIGHT, Building a Renewed ImaGe after Head and neck cancer Treatment.

to other HNC survivors with BID. Patient responses to open-ended questions confirmed BRIGHT's high acceptability (**Table 2**).

Cancer-Related BID

At 1 month postintervention, the mean change from baseline in Body Image Scale scores was not statistically significantly different for patients in BRIGHT relative to patients in AC (mean model-based difference, −2.1 points; 90% CI, -5.0 to 0.9 points; P = .25). At 3 months postintervention, the mean difference in change from baseline in Body Image Scale scores was improved for patients in BRIGHT compared with patients in AC (mean model-based difference, -5.8 points; 90% CI, -9.1 to -2.5 points; P = .006). At 3 months postintervention, the improvement from baseline in Body Image Scale scores for BRIGHT relative to AC was clinically significant and corresponded to a large effect size (Cohen d, -0.9; 90% CI, -1.4 to -0.4). The longitudinal change in cancer-related BID for patients in BRIGHT and AC, as measured by change in mean Body Image Scale scores from baseline, is shown in **Figure 2**A and eTable 2 in Supplement 2.

The waterfall plot demonstrating each patient's clinical response to BRIGHT or AC, as measured by change in Body Image Scale scores from baseline to 3 months postintervention is shown in Figure 2B. At 3 months postintervention, the clinical response rate for cancer-related BID (proportion of patients with a clinically meaningful decrease in Body Image Scale scores of ≥3 points) was not statistically significantly different between BRIGHT and AC (model-based odds ratio, 2.1; 90% CI, 0.7-6.1; P = .26; eTable 3 in Supplement 2).

HNC-Related BID

At 1 month postintervention, the mean change from baseline in the IMAGE-HN score was improved for patients in BRIGHT compared with patients in AC (mean model-based difference, -7.9 points; 90% CI, -15.9 to 0.0 points; P = .10). At 3 months postintervention, BRIGHT improved IMAGE-HN scores from baseline relative to AC (mean model-based difference, -17.1 points; 90% CI, -25.6 to -8.6 points; P = .002). At 3 months postintervention, the improvement from baseline in IMAGE-HN scores for patients in BRIGHT relative to patients in AC was clinically significant and corresponded to a large effect size (Cohen d, -0.9; 90% CI, -1.4 to -0.4). The longitudinal change in HNC-related BID, as measured by change in IMAGE-HN scores from baseline, for patients allocated to BRIGHT and AC is shown in **Figure 3**A and eTable 2 in Supplement 2.

The waterfall plot demonstrating each patient's clinical response to BRIGHT or AC, as measured by change in IMAGE-HN scores from baseline to 3 months postintervention, is shown in Figure 3B. At 3 months postintervention, patients in BRIGHT had a 6.6-fold increase in the odds of clinical response (proportion of patients with a clinically meaningful decrease in IMAGE-HN scores of ≥9 points) relative to patients in AC (model-based odds ratio, 6.6; 90% CI, 2.0-21.8; P = .09; eTable 3 in Supplement 2).

Discussion

In this pilot RCT, we showed the feasibility of accruing and retaining HNC survivors with BID to an RCT, established high fidelity for the delivery of BRIGHT and AC, and confirmed the acceptability of BRIGHT to HNC survivors with BID. The preliminary data demonstrate that BRIGHT may result in statistically and clinically significant improvements in HNC- and cancer-related BID relative to AC. In addition, the beneficial effects of BRIGHT for HNC-related BID are realized by most patients, as evidenced by the nearly 7-fold higher response rate (odds of a patient experiencing a clinically meaningful improvement) for patients in BRIGHT compared with patients in AC.

Three published trials have evaluated different strategies to manage HNC-related BID. In a quasi-experimental study, Huang et al showed that a cosmetic rehabilitation intervention did not improve BID among HNC survivors relative to control.[13] An RCT by Chen et al evaluating a skin camouflage program among HNC survivors found no benefit relative to usual care.[14] Finally, a single-arm pre-post study showed that MyChangedBody (MyCB), a web-based self-compassion expressive writing activity, failed to improve BID among HNC

Table 1. Baseline Demographic and Clinical Characteristics

Characteristic	No. (%)		
	BRIGHT (n = 20)	Attention control (n = 24)	Overall (n = 44)
Age, median (range), y	63 (48-80)	63 (41-76)	63 (41-80)
Gender			
Female	12 (60)	15 (62)	27 (61)
Male	8 (40)	9 (38)	17 (39)
Race			
Black	1 (5)	6 (25)	7 (16)
White	19 (95)	18 (75)	37 (84)
Relationship status			
Married/current partner	14 (70)	13 (54)	27 (61)
Single/separated/divorced/widowed	6 (30)	11 (56)	17 (39)
Insurance			
Private	8 (40)	9 (38)	17 (39)
Medicare	10 (50)	12 (50)	22 (50)
Medicaid/uninsured	2 (10)	3 (13)	5 (11)
BMI, median (range)	27 (17-40)	25 (19-39)	27 (17-40)
Head and neck subsite			
Oral cavity	7 (35)	15 (63)	22 (50)
Oropharynx	3 (15)	2 (8)	5 (11)
Larynx/hypopharynx	0	4 (17)	4 (9)
Facial cutaneous/major salivary	10 (50)	3 (13)	13 (30)
Ablative surgery[a]			
Mandibulectomy	4 (20)	4 (17)	8 (18)
Glossectomy	6 (30)	11 (45)	17 (39)
Maxillectomy	1 (5)	2 (8)	3 (7)
Pharyngectomy	3 (15)	2 (8)	5 (11)
Total laryngectomy	0	3 (13)	3 (7)
External neck/facial skin	5 (25)	5 (21)	10 (23)
Parotidectomy	5 (25)	2 (8)	7 (16)
Neck dissection	20 (100)	23 (96)	43 (98)
Reconstructive surgery			
Primary closure, local flap, or nonvascularized graft	4 (20)	2 (8)	6 (14)
Soft tissue free flap	13 (65)	18 (75)	31 (71)
Osseous free flap	3 (15)	4 (17)	7 (16)
AJCC, 8th edition, pathologic T category			
0-2	8 (40)	11 (46)	19 (43)
3-4	12 (60)	13 (54)	25 (57)
AJCC, 8th edition, pathologic N category			
0	13 (65)	20 (83)	33 (75)
1-3	7 (35)	4 (17)	11 (25)
AJCC, 8th edition, overall pathologic stage			
I-II	5 (25)	12 (50)	17 (39)
III-IV	15 (75)	12 (50)	27 (61)
Adjuvant therapy			
None	5 (25)	12 (50)	17 (39)
Radiation therapy	12 (60)	11 (46)	23 (52)
Chemoradiation therapy	3 (15)	1 (4)	4 (9)
Months since completion of treatment, median (IQR)	4 (2-8)	3 (2-5)	3 (2-6)
Psychosocial characteristics, mean (SD)			
BIS score[b]	18 (6)	15 (5)	17 (6)
IMAGE-HN score[c]	45 (18)	41 (18)	43 (18)

Abbreviations: AJCC, American Joint Commission on Cancer; BIS, Body Image Scale; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BRIGHT, Building a Renewed ImaGe after Head and neck cancer Treatment; IMAGE-HN, Inventory to Measure and Assess imaGe disturbancE–Head and Neck.

[a] Percentages for ablative surgery may add up to more than 100 because patients may undergo more than 1 type of ablative surgery concurrently.

[b] Scores range from 0 to 30, with higher scores indicating greater cancer-related body image distress.

[c] Scores range from 0 to 84, with higher scores indicating greater head and neck cancer–related body image distress.

Table 2. BRIGHT Acceptability

Measure	Rating, mean (SD)[a]	Illustrative quotations from open-ended questions
The timing of the program worked well for me	4.5 (0.8)	"It was exactly the right time…I feel that after undergoing cancer treatment I could finally relate to the body image problem. If done before I would not have been able to relate." (Patient 10)
The method of program delivery (telemedicine) worked well for me	4.5 (0.9)	"The convenience of it made the treatment accessible for me." (Patient 4) "I live a few hours away from MUSC, so having someone to speak with online worked well." (Patient 39)
The content of each session was helpful to me	4.7 (0.6)	"The topics covered [in BRIGHT] touch everyone with head and neck cancer. I think everyone should experience this." (Patient 2) "BRIGHT made me think more clearly about my situation and how to cope with things every day." (Patient 43)
The BRIGHT workbook was useful to me	4.5 (0.7)	"Having the workbook kept me on track doing the homework assignments. The workbook was great—I even kept it! The part I liked best about it was the reminders…when my brain starts going down a rabbit hole and spiraling (omg omg) and I enter this circle of depressing thoughts, the book helps me remind myself that these are not helpful thoughts and then I talk myself out of it." (Patient 4) "Through working with the workbook, I discovered feelings and fears I never realized." (Patient 21)
The BRIGHT homework assignments were useful to me	4.5 (0.6)	"The homework was not too much time or effort. It takes about 30 minutes to complete each week. I usually write things down for the homework as they come to me." (Patient 2) "The homework made me look inside of me to find exactly how I feel about all the changes." (Patient 20)
The in-session activities with the therapist were useful for me	4.8 (0.4)	"I have never worked with a therapist before, but as I said it was good to talk through my concerns and self-image." (Patient 34) "I felt I could talk about things that I could not with anyone else." (Patient 52)
The material was relevant to the concerns that I was experiencing	4.7 (0.9)	"Recognizing unhelpful thoughts and reminding myself that they are just that and reminding me of coping techniques that have worked for me." (Patient 4) "The study hit on the topics that have been bothersome to me since my treatment." (Patient 20)
Overall, I was satisfied with the BRIGHT program	4.7 (0.5)	"Overall BRIGHT was wonderful. It helped me so much. I have been on cancer sites with thousands of people talking about head and neck cancer, and they say crazy things. This really helped me cope with my issues." (Patient 2) "The program was very helpful to me and how to cope with the few things that were negatively affecting me." (Patient 20)
I am likely to recommend BRIGHT to a different head and neck cancer survivor	4.7 (0.6)	"BRIGHT helped me think about my life and what I have been through…it is really helpful. I really enjoyed it." (Patient 5) "Yes! I think the BRIGHT program helped me accomplish things that I could not do before. For example, I recently had the first COVID vaccine shot—I had to stand in line with lots of people—I was NOT bothered by it!!! I knew that I would probably see someone I knew while standing in line and I did, but I did not try to hide (I would have before the sessions)…BRIGHT helped me accomplish my goals of not avoiding others by helping with coping skills and learning to have positive thoughts instead of negative thoughts." (Patient 10) "This program helped me more than I can explain." (Patient 31)

Abbreviations: BRIGHT, Building a Renewed ImaGe after Head and neck cancer Treatment; MUSC, Medical University of South Carolina.

[a] Ratings range from 0 to 5, with higher values representing greater satisfaction or stronger agreement.

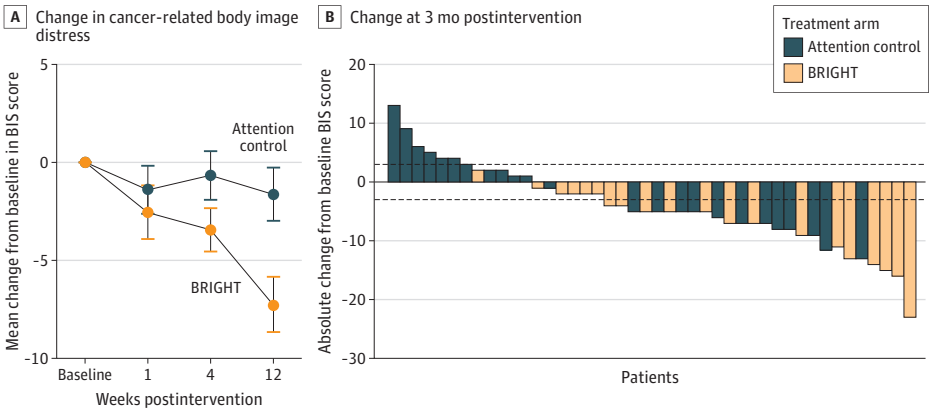
survivors.[15] The lack of efficacy of MyCB among HNC survivors with BID is important because MyCB improved BID among breast cancer survivors in a large RCT (n = 304) relative to control.[22] Collectively, these trials confirm the need for novel strategies to improve BID among HNC survivors and suggest that a fundamentally different approach may be necessary.

Although multiple meta-analyses have demonstrated that CBT produces durable reductions in BID in patients without visible disfigurement (eg, body dysmorphic disorder),[35-38] the evidence supporting CBT for BID in patients with visible disfigurement is weaker.[24,39,40] To our knowledge, the findings from this pilot RCT showing statistically and clinically significant improvement in HNC-related BID following treatment with BRIGHT are the first randomized trial data showing efficacy of an intervention in this population. These data build on the promising findings from the single-arm trial of BRIGHT[17] and provide valuable evidence supporting the potential of brief video tele-CBT as a novel strategy to improve BID among HNC survivors.

The strong recruitment, retention, adherence, and acceptability data from this current trial build on prior findings[17] and support BRIGHT's implementation and scalability. Although BRIGHT is delivered using a telemedicine-based platform to enhance access to care in a patient population that is challenging to reach for mental health services, further research is necessary to identify and address implementation barriers to ensure that BRIGHT will reach its target population outside of a trial.

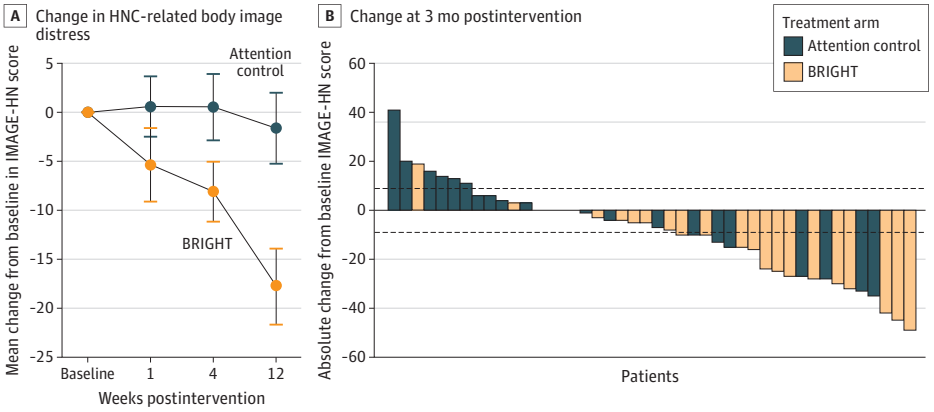
To our knowledge, this trial is the first among HNC survivors with BID to use a validated patient-reported outcome (PRO) of HNC-related BID as an end point. By using IMAGE-HN, we were able to measure more precisely the effectiveness of BRIGHT on BID in this patient population and demonstrate the positive effects of BRIGHT on cancer-specific and HNC-specific BID. Future trials evaluating strategies to manage BID among HNC survivors should consider using exclusively IMAGE-HN or other recently developed PROs of HNC-related BID (eg, the McGill body image concerns scale for use in head and neck oncology[41]) as the primary end point.

Figure 2. Mean Change From Baseline and Response of Cancer-Related Body Image Distress for Patients in BRIGHT and Attention Control



A, Line graph demonstrating the mean change from baseline in Body Image Scale (BIS) 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 BIS scores at 3 months postintervention. The BIS score ranges from 0 to 30, with higher scores indicating worse cancer-related body image distress (and negative bars thus indicating improvement in cancer-related body image distress). The dashed horizontal line at ±3 indicates a clinically meaningful change in BIS score.

Figure 3. Mean Change From Baseline and Response of Head and Neck Cancer (HNC)-Related Body Image Distress for Patients in BRIGHT and Attention Control



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.

Limitations

Although this trial contains a number of strengths, including its rigorous randomized design, manualized intervention, comparison to dose- and delivery-matched AC, use of validated PROs, and focus on clinically relevant end points, a number of limitations exist. Consistent with its pilot nature, the study had a small sample size and short follow-up (3 months after completion of the intervention). We are therefore cautious to overinterpret these encouraging but preliminary findings. Further evaluation of BRIGHT in a multicenter, fully powered efficacy trial featuring a sample of HNC survivors diverse by age, gender, and race and ethnicity with longer-term follow-up to assess the durability of the response to BRIGHT is thus necessary to confirm the efficacy signal and enhance the external validity of these preliminary findings. Although AC was dose- and delivery-matched to BRIGHT, it did not specifically control for professional attention or common factors (eg, empathy, credibility, expectations), which could explain the differences in outcomes between treatment arms.[42] The current trial is also limited through its comparison of BRIGHT vs AC without inclusion of a standard of care/no intervention third arm, as such a design would have helped elucidate the true potential benefit of BRIGHT beyond current standard of care. There is also a possibility that conducting the trial during the COVID-19 pandemic could bias study findings. Although the effect of masking and social avoidance measures on HNC

survivors with BID is unknown, we believe that conducting the trial during the pandemic actually resulted in an underestimate of the effect of BRIGHT on BID because patients in BRIGHT did not have the opportunity to use their new cognitive reappraisal and body image coping skills as they would have outside of the pandemic. Finally, because of the partial clustering design, it is important to account for within-therapist dependence on outcomes to ensure appropriate power.[43] Future trials with a larger number of clusters could address clustering of patients within therapists in the trial design and adapt multilevel models for partially clustered data to assess treatment effects in the analysis.

Conclusions

In this pilot RCT, preliminary data suggest that BRIGHT may result in a clinically meaningful improvement in BID among HNC survivors. BRIGHT appears to be a highly effective intervention for the majority of HNC survivors with BID, as evidenced by the large proportion of HNC survivors who experienced a clinically meaningful improvement in their HNC-related BID. Collectively, these promising preliminary data support conducting a large multisite efficacy trial to establish BRIGHT as the first evidence-based treatment for HNC survivors with BID.

ARTICLE INFORMATION

Accepted for Publication: October 1, 2022.

Published Online: December 1, 2022. doi:10.1001/jamaoto.2022.3700

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Author Contributions: Drs Graboyes and Li had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
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Critical revision of the manuscript for important intellectual content: Graboyes, Maurer, Balliet, Li, Williams, Osazuwa-Peters, Yan, Padgett, Ruggiero, Sterba.
Statistical analysis: Li.
Obtained funding: Graboyes, Balliet.
Administrative, technical, or material support: Maurer, Balliet, Williams, Padgett, Rush, Ruggiero.

Conflict of Interest Disclosures: Dr Graboyes reported grants from the National Cancer Institute during the conduct of the study, as well as grants from the National Cancer Institute, the Doris Duke Charitable Foundation, and the Triological Society/American College of Surgeons, and personal fees from the National Cancer Institute and Castle Biosciences outside the submitted work. Dr Osazuwa-Peters reported grants from the National Institute of Dental and Craniofacial Research and personal fees from Navigating Cancer outside the submitted work. Dr Ruggiero reported grants from the National Institutes of Health, the US Department of Homeland Security/Federal Emergency Management Agency, the Substance Abuse and Mental Health Services Administration, and US Department of Justice during the conduct of the study. Dr Sterba reported grants from the National Cancer Institute and the Health Resources and Services Administration outside of the submitted work. No other disclosures were reported.

Funding/Support: This work was supported by the National Cancer Institute at the National Institutes of Health (R21CA245941 to Dr Graboyes) and the National Center for Advancing Translational Sciences (UL1TR000062).

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: Dr Graboyes serves on the Editorial Board and Dr Osazuwa-Peters is Deputy Editor, Diversity, Equity, and Inclusion of *JAMA Otolaryngology–Head & Neck Surgery*, but they were not involved in any of the decisions regarding review of the manuscript or its acceptance.

Data Sharing Statement: See Supplement 3.

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