Original Article

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A cognitive behavioral therapy–based intervention to address body image in patients with facial cancers: Results from a randomized controlled trial

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Abstract

Objectives. Body image adjustment is a crucial issue for patients with facial cancer, but body image–specific interventions are scarce. We report results of a novel psychotherapeutic intervention to address body image concerns during acute postoperative recovery following facial reconstructive surgery. Our primary aims were to evaluate the intervention's feasibility, acceptability, and efficacy on body image concerns, psychological distress, and quality of life (QOL).

Methods. Adults with facial cancers who endorsed body image concerns were recruited to participate in a randomized controlled trial. The intervention group participated in 4 in-person counseling sessions. The control group received an educational booklet and a brief phone call. Participants completed measures of body image, distress, and QOL at baseline and at the 4-week follow-up to assess the impact of the intervention. Intervention outcomes were assessed with 2 sample *t*-tests or Mann–Whitney *U* tests as appropriate.

Results. Twenty-nine participants completed both the baseline and follow-up assessments. The intervention demonstrated good feasibility with a high retention rate (79%), visit completion rate (81%), and high satisfaction scores (75% reported mean satisfaction score of >3). Intervention did not result in an observed statistically significant difference in reduction in body image dissatisfaction and disturbance, psychological distress, or improvement in QOL compared with the control group. However, intervention resulted in statistically significant difference in perceived social impact (−1 vs. −8.3, $p = 0.033$) compared to control group.

Significance of results. Our study highlights the potential clinical benefits of a novel psychotherapeutic intervention that targets body image concerns and suggests the need for further evaluation.

Introduction

Body image is crucial for patients with facial cancer because of possibility of disfigurement and dysfunction from either the disease or effects of treatment. Due to visible nature and involvement of socially significant part of the body, distress about changes can lead to social isolation, intimacy problems, and depression or anxiety (Katz et al. 2003; Krouse et al. 1989). Psychosocial issues are pronounced among patients who undergo facial reconstructive surgery; they are at elevated risk for experiencing disfigurement and functional impairment due to the extent and severity of disease. Because of the significant degree of psychological distress experienced, patients may benefit from a psychotherapeutic intervention aimed at body image disturbance.

In oncology, although body image–specific interventions are limited, various approaches, such as psychotherapeutic, psychoeducational, physical activity based, or cosmesis-enhancing, have been considered (Fingeret et al. 2014; Lewis-Smith et al. 2018b). Most studies have been done in patients with breast cancer, and either cognitive behavioral therapy (CBT) or components of CBT are utilized (Fadaei et al. 2011; Lewis-Smith et al. 2018a; Rahmani and Talepasand 2015). Among facial cancer patients, only 2 studies addressing body image have been reported.

While one study assessed the impact of a telemedicine-based CBT intervention (Graboyes et al. 2020b), another study assessed a skin camouflage program to alleviate body image concerns in patients with head/neck cancer (Chen et al. 2017; Nicoletti et al. 2014).

Body image–specific interventions that are theory based provide an opportunity to understand how various components of the intervention help patients with body image concerns. Specific to oncology, White's (2000) model explains that individuals who value appearance or body integrity are prone to triggering of body image schema in certain situations, which may result in negative distortions and compensatory behaviors. For facial cancers, social situations may trigger body image concerns; hence, interventions that address social adaptation are crucial for body image adjustment. Closer examination of body image dissatisfaction during the facial cancer treatment trajectory at our institution revealed the acute postoperative phase, that is between the pre-surgery visit and the 1-month follow-up, to be the most difficult for body image adjustment, indicating that a psychotherapeutic intervention targeting body image issues during this period may be most beneficial (Henry et al. 2022; Trahan et al. 2015). Although telemedicine-based, facilitator-led body image intervention has been assessed (Graboyes et al. 2020b), a program using in-person facilitation has not been done. This may prove to be significant, as in-person therapy affords the facilitator the opportunity to provide nonverbal support to the patient, which may not be easily conveyed through the telemedicine. Here, we report results of a novel psychotherapeutic intervention, delivered in-person by a psychologist, for patients with facial cancer during the acute postoperative phase after facial reconstructive surgery. The aims of our study were to evaluate the feasibility and acceptability of a 4-session psychotherapeutic intervention and its efficacy in terms of body image concerns, psychological distress, and quality of life (QOL). We also evaluated potential changes over time in constructs theorized to drive body image concerns, that is, appearance investment, body image coping strategies, and perceived social impact (PSI).

Methods

Study participants and setting

After Institutional Review Board approval, we screened and recruited adults with facial cancers (skin cancers that involve the facial area and cancers that affect the mouth, oral cavity, nose, nasal cavity, ears, and eyes) from the Center for Reconstructive Surgery at our institution from 16 December 2013 to 27 August 2015. Eligibility criteria were as follows: (1) at least 18 years old, (2) within 6 weeks of facial reconstructive surgery, (3) expresses body image concerns (score ≥ 6 on the body image scale (BIS) or ≥ 1.6 on the Body Image Disturbance Questionnaire (BIDQ), and (4) English speaking. Body image concerns at baseline were identified when either cutoff criteria was met. Patients with pre-existing facial disfigurement from trauma or a congenital defect or those with serious mental illness or undergoing current body image therapy were excluded.

Study design and procedures

Potential participants were identified by chart review and then approached with a phone call. Those who met the age, surgery time, and language eligibility criteria were asked if they had body image concerns, if they responded affirmatively, and if they would be interested in participating in the study. Those who expressed interest met with a psychologist at the time of their follow-up visit with their reconstructive surgeon. Once informed consent was obtained, the participant was screened for body image concerns with the BIS and BIDQ. Two tools were used to comprehensively capture body image concerns. BIS measures body image dissatisfaction, that is, the degree to which one is satisfied or dissatisfied with his or her appearance or body shape (Thompson et al. 1999). BIDQ assesses body image disturbance, which encompasses many aspects of negative body image, including body image dissatisfaction, distress (or dysphoria), and dysfunction (or impairment) (Cash and Grasso 2005). If the score on either measure was above the cutoff score, the participant continued in the study.

For sample size, we assumed the difference in reduction is 0.9 between the 2 arms. With 20 patients per arm, the power to detect the significant difference between the arms is 80%, using a 2-sample *t*-test at an alpha level of 0.05.

Participants completed a baseline evaluation consisting of the standardized measures described below and were randomized using a minimization technique into intervention and control groups. Minimization, a form of adaptive randomization, results in better study arm balance with respect to participant characteristics when compared with traditional randomization. Participants were assigned to each condition while balancing study arms on the following characteristics: age, gender, disease site (periphery vs. midface), and disease stage.

Study participation lasted 4 weeks. Intervention group participants received 4 counseling sessions (1 per week, 60 minutes each) with a psychologist. Three psychologists conducted the sessions. Their team consisted of a supervisor and 2 postdoctoral trainees who met regularly to discuss the study, delivery of the intervention, and adherence to the protocol. A structured manual was created and adhered to throughout the study so that there was no observers' rate intervention fidelity. Control group participants received psychoeducational materials entitled *When Cancer Affects the Way You Look* (a publication from the organization Changing Faces), along with a follow-up phone call providing brief psychosocial support (lasting about 15 minutes) approximately 2 weeks after study enrollment. Both groups completed a follow-up assessment 4 weeks after the baseline assessment. This assessment consisted of the same measures, plus a questionnaire evaluating satisfaction with the program. Participants were compensated with an incentive valued at $25 following the baseline assessment and an additional $25 following the follow-up assessment.

Feasibility was determined based on retention rate (retaining 75% of enrolled participants at the end of the study) and completion of study visits within the intervention group (participants completing 75% of their scheduled counseling visits). Intervention acceptability was determined with satisfaction score on a scale that ranged from "not at all" (0) to "very much" (4); an average score of more than 3 was considered acceptable.

Intervention content is summarized in Table 1, and theoretical model, which the intervention was based on, is described in Figure 1. The model suggests that our intervention will ultimately influence body image concerns through reductions in appearance investment (importance placed on appearance), improved body image coping strategies (reduced avoidance and appearance fixing and improved positive rational acceptance), and reductions in PSI of appearance changes. This model is supported by research in oncology (White 2000) and in the general population (Cash 2012).

Table 1. Intervention content

Session	Content
1: Introduction to body image and facial cancer	Psychoeducation
	Setting realistic expectations for body image outcomes
	Mindfulness and relaxation exercises
2: Dealing with functional changes and appearance assumptions	Psychoeducation
	Identifying appearance beliefs and body image thought patterns
	Increasing body image acceptance
3: Improving your relationship with your body	Identifying and challenging body image assumptions
	Cognitive restructuring of problematic body image thoughts
	Positive body esteem activities
4: Dealing with the outside world and looking toward the future	Behavioral activation and resuming activities
	Managing the reactions of others
	Social skills and communication skills training

Measures

Primary outcomes

Body image dissatisfaction in cancer patients was measured with the BIS, a 10-item self-report measure with summed scores ranging from 0 to 30; higher scores indicate higher body image concerns. It has demonstrated high reliability (alpha = 0.93) and strong discriminant validity between breast cancer patients undergoing mastectomy vs. breast-conserving surgery (Hopwood et al. 2001). Body image disturbance was measured with the BIDQ, a 7-item, 5-point Likert response quantifying the extent of body image impairment as a combination of dissatisfaction, distress, and dysfunction. BIDQ evaluates negative body image, with higher scores indicating higher distress. Total BIDQ score is the average of all items, with a score range from 1 to 5. Originally validated in a college sample, the BIDQ has been validated in various patient populations (Auerbach et al. 2014; Bowe et al. 2011). Previous research suggests that a score equal to or greater than 1.6 indicates higher body image disturbance (Cash et al. 2004b).

Secondary outcomes

General psychological distress was measured with the *Brief Symptom Inventory-18*, a widely-used 18-item scale for patients with medical illness, with internal consistency ranging from 0.74 to 0.89; higher scores of global severity index (GSI) indicate higher distress. Calculation of raw score and conversion to T scores were done as per the scoring and procedures manual (Derogatis 1993).

QOL was measured with the *Functional Assessment of Chronic Illness Therapy–Head and Neck Cancer (FACT-HN)*, a 39-item questionnaire measuring 4 general domains of well-being (physical, social, functional, and emotional) and a fifth disease-specific domain. The 4 general domains of well-being consist of 27 questions: 7 questions each for physical, social, and functional well-being (score range 0–28) and 6 questions for emotional well-being (score range 0–24). The disease-specific domain consists of 12 questions, of which 10 are scored (score range 0–40). Summing

the scores of all 5 domains results in a total score that ranges from 0 to 148 (Cella et al. 1993). Higher scores indicate higher QOL. The scores were calculated using scoring guidelines on the testing website, https://www.facit.org/measures/FACT-HN. For our study, we reported total QOL and head/neck-specific QOL scores. The FACT has good internal consistency (alpha = 0.92) and reliability (r = 0.81) and has demonstrated good convergent, divergent, and criterion validity (List et al. 1996).

Theoretical mechanisms for body image dysfunction

Psychological investment in physical appearance was measured with the *Appearance Schemas Inventory–Revised (ASI-R)*, a 20-item Likert scale instrument that measures the salience of basing self-worth on appearance and motivation to engage in one's own appearance. Scores range from 1 to 5, and the average of all items is the composite ASI-R score, with higher scores indicating higher investment (Cash et al. 2004a). It has good internal consistency, ranging from 0.88 to 0.91, and it has strong concurrent validity with constructs of body image dysphoria and perfectionism (Cash et al. 2004a).

Body image coping strategies were measured with the *Body Image Coping Strategy Inventory* (BICSI), a 29-item scale that measures the extent to which people engage in 3 strategies for coping with body image threats or challenges: avoidance (8 items), appearance fixing (10 items), and positive rational acceptance (11 items). The mean of items in each subscale yields a score (range 0–3) for that subscale. Higher scores on the avoidance and appearance-fixing subscales indicate higher distress, whereas the converse is true for the positive rational acceptance subscale (Cash et al. 2005). The BICSI has adequate reliability, ranging from 0.73 to 0.86 (Cash et al. 2005).

PSI was assessed as part of the *Adapted Satisfaction with Appearance Scale (ASWAP)*, a 15-item self-report scale with high reliability (alpha = 0.88). The PSI subscale (7 items) with a score range 0–42 was used. Higher scores reflect negative cognitions and discomfort in social situations (Heinberg et al. 2007).

Statistical methods

Satisfaction with the intervention, age, BMI, and coping and psychosocial scores were summarized with descriptive statistics; frequencies and percentages were used for categorical variables. Demographic variables were compared between the intervention and control groups using chi-square or Fisher exact test. Changes in outcomes and theorized mechanisms for body image were assessed by comparing the appearance investment, body image coping, and PSI scores between the intervention and control groups, using the 2-sample *t*-test or Mann–Whitney *U* tests. The normality of distribution of the scores was assessed using Q–Q plots and Shapiro–Wilk test. Data analyses were performed for patients with eligible data. To mitigate bias due to missing data, sensitivity analysis was performed on imputed data. Missing values were imputed using single imputation method. All tests were 2-sided. A *p*-value of <0.05 was considered significant. The analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC) and R (The R Foundation for Statistical Computing) software.

Results

Patient characteristics

Patients were recruited from clinics of 14 different plastic surgeons. Details of patient enrollment are outlined in Figure 2;
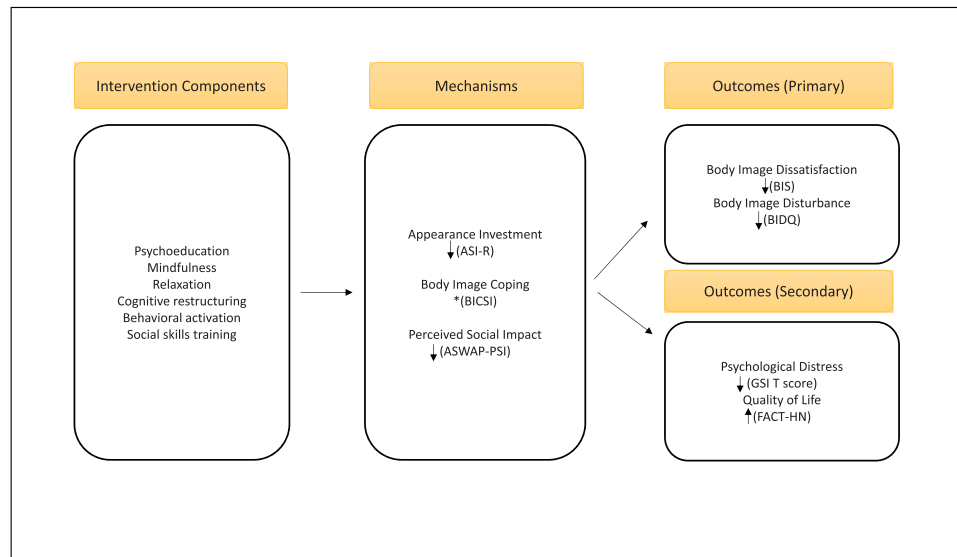
Fig. 1. Theory-based model for intervention components, mechanisms related to body image, and outcomes of interest. The measures and expected direction of score changes after the intervention are shown (up arrow, improvement; down arrow, reduction).
ASI-R, Appearance Schemas Inventory–Revised; BICSI, Body Image Coping Strategy Inventory; ASWAP-PSI, Adapted Satisfaction with Appearance Scale–Perceived Social Impact; BIS, Body Image Scale; BIDQ, Body Image Disturbance Questionnaire; GSI T score, psychological distress; and FACT-HN, Functional Assessment of Cancer Therapy–Head & Neck.*BICSI has 3 components: AF (appearance fixing), avoidance (AV), and positive rational acceptance (PA). AF and AV are negative coping strategies expected to be reduced after the intervention; PA is a positive coping strategy expected to improve.
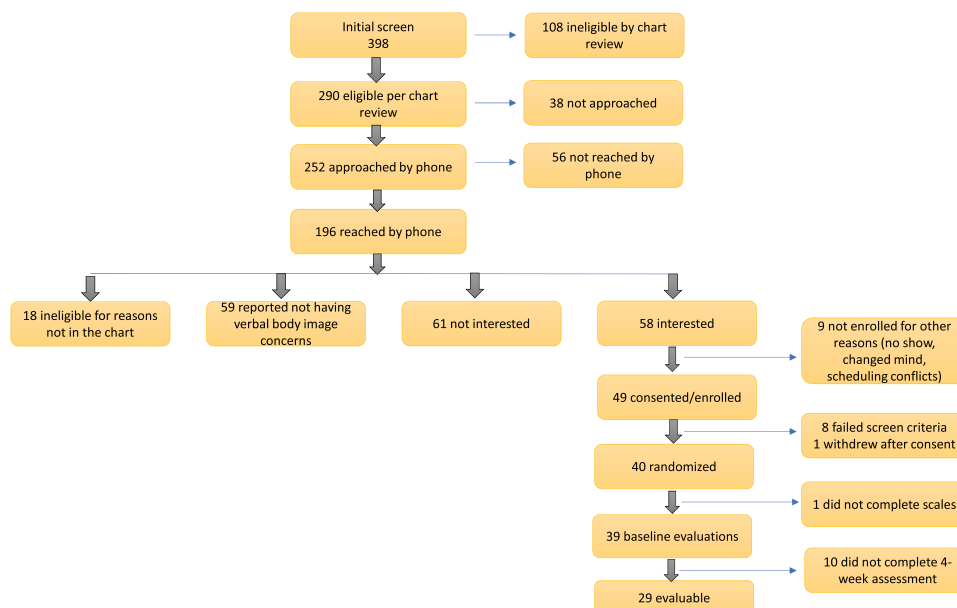
Fig. 2. Recruitment flowchart.

39 patients participated in the trial. The intervention group ($N = 20$) and control group ($N = 19$) did not differ significantly in many demographic variables except for education (Table 2). The average age was 57.5 years; the patients were predominantly men (56%) and not working (56%); 46% were nonsmokers; 46% had education levels of high school or associate degree; and half the patients had not had previous facial surgery. The 2 groups did not differ significantly in baseline body image concerns or psychological distress or QOL scores (Table 3).

Intervention feasibility and acceptability

Of the 39 participants who completed the baseline assessments, 31 also completed either counseling sessions (intervention arm) or follow-up phone call (control arm), resulting in an overall retention rate of 79%. Within the intervention group, 81% of participants attended at least 3 of the 4 face-to-face sessions.

The average satisfaction score for the intervention group was 3.73 (SD 0.65), indicating a very high level of satisfaction. This score was 30% higher than the satisfaction score for the control group (mean 2.85, SD 1.34), but the difference was not statistically

Table 2. Summary of patients' characteristics

Variable	All patients, N (%)	Control group, N (%)	Intervention group, N (%)	p-Value
Number of patients	39	19	20	
Age, y (mean ± SD)	57.5 ± 11.7	56.5 ± 14.7	58.6 ± 8.2	0.768
Sex				0.855
Female	17 (44)	8 (42)	9 (45)	
Male	22 (56)	11 (58)	11 (55)	
Employment				0.805
Not working[a]	22 (56)	11 (58)	11 (55)	
Employed	11 (28)	5 (26)	6 (30)	
Unknown	6 (15)	3 (16)	3 (15)	
Smoking status				0.615
Nonsmoker	18 (46)	8 (42)	10 (50)	
Smoker	17 (44)	9 (47)	8 (40)	
Unknown	4 (10)	2 (11)	2 (10)	
Previous surgery				0.845
No	20 (51)	10 (53)	10 (50)	
Yes	15 (39)	7 (37)	8 (40)	
Unknown	4 (10)	2 (11)	2 (10)	
Education				0.028
High school/associate degree	18 (46)	12 (63)	6 (30)	
Bachelor's degree/master's degree/PhD	17 (44)	5 (26)	12 (60)	
Unknown	4 (10)	2 (11)	2 (10)	
Facial region involved with cancer				–
Cheek (cheek, cheek and eyelid, and cheek and parotid gland)	3 (8)	2 (11)	1 (5)	
Ear	1 (3)	0 (0)	1 (5)	
Eyelid and eye	2 (5)	1 (5)	1 (5)	
Lip	1 (3)	1 (5)	0 (0)	
Mandible	7 (18)	4 (21)	3 (15)	
Mandible and maxilla	1 (3)	1 (5)	0 (0)	
Maxilla (maxilla, maxilla and nose, and maxilla and cheek)	4 (10)	2 (11)	2 (10)	
Parotid gland	7 (18)	3 (16)	4 (20)	
Tongue	6 (15)	2 (11)	4 (20)	
Tongue and mandible	2 (5)	1 (5)	1 (5)	

[a]Not working includes the following: keeping house/raising children full time (2), retired (12), and unable to work (8).

Table 3. Outcomes for all patients and by intervention groups

Variable	Number of patients	All patients (mean ± SD)	Control group (mean ± SD)	Intervention group (mean ± SD)	p-Value
BIS (score range 0–30)					
Pre	39	13.6 ± 6.4	13.4 ± 7	13.8 ± 6	0.768
Post	29	11.2 ± 6.1	11.8 ± 6.1	10.4 ± 6.3	0.538
Diff	29	−1.8 ± 4.6	−1.3 ± 5.1	−2.5 ± 3.9	0.582
BIDQ (score range 1–5)					
Pre	39	2.8 ± 0.9	2.7 ± 1	2.8 ± 0.9	0.632
Post	29	2.4 ± 0.8	2.5 ± 0.9	2.2 ± 0.6	0.455
Diff	29	−0.5 ± 0.8	−0.2 ± 0.6	−0.7 ± 1	0.356
GSI T scores (score range 33–81)					
Pre	34	57.9 ± 9.8	57.1 ± 9.5	58.7 ± 10.3	0.448
Post	25	52.5 ± 8.6	52.4 ± 9.4	52.7 ± 8.1	0.913
Diff	24	−4.3 ± 9.8	−4.4 ± 8.5	−4.1 ± 11.6	0.839
FACT-HN disease–specific subscale (score range 0–40)					
Pre	35	21 ± 9.3	21.5 ± 10.8	20.6 ± 7.9	0.817
Post	29	21.9 ± 9.8	21.6 ± 9.6	22.3 ± 10.4	1.000
Diff	28	−0.2 ± 7.6	−0.9 ± 6.4	0.7 ± 9.1	0.300
FACT-HN total (score range 0–148)					
Pre	34	90 ± 26	90 ± 29.5	90 ± 22.9	0.863
Post	29	103 ± 22.3	101.7 ± 21.8	104.6 ± 23.8	0.878
Diff	27	10.6 ± 17.6	8.9 ± 17.5	12.8 ± 18.3	0.479

BIS, Body Image Scale; BIDQ, Body Image Disturbance Questionnaire; GSI T, measure of psychological distress; and FACT-HN, Functional Assessment of Cancer Therapy–Head & Neck (measure of QOL).

significant ($p = 0.79$, Wilcoxon rank-sum test). Since the satisfaction score of the intervention group was more than 3, the intervention was considered acceptable.

Intervention's effect on body image concerns

Measures were compared between groups at the 4-week time point compared to baseline. Both body image measures (BIS and BIDQ) had larger reductions in body image concerns/disturbance in the intervention group (BIS: −2.5 and BISQ: −0.7) compared to the controls (BIS: −1.3 and BISQ: −0.2); however, these differences were not statistically significant for either measure (Table 3). Evaluation of participants who answered both pre and post body image measures also revealed similar results, that is, more reduction in body image concerns/disturbance in the intervention group (BIS: −2.5 and BIDQ: −0.7) compared to controls (BIS: −1.3 and BIDQ: −0.2); however, these differences were not statistically significant (Table 4). Sensitivity analysis also did not reveal differences between the groups (Supplementary Table S1).

Intervention's effect on theorized mechanisms for body image concerns

Intervention group had statistically significant reduction on PSI compared to control group, indicating that participants became

Table 4. Outcomes for patients who answered both pre and post body image measures and by intervention groups

Variable	Number of patients	All patients (mean ± SD)	Control group (mean ± SD)	Intervention group (mean ± SD)	*p*-Value
BIS (score range 0–30)					
Pre	29	13.0 ± 6.0	13.4 ± 7	13.8 ± 6	0.768
Post	29	11.2 ± 6.1	11.8 ± 6.1	10.4 ± 6.3	0.538
Diff	29	−1.8 ± 4.6	−1.3 ± 5.1	−2.5 ± 3.9	0.582
BIDQ (score range 1–5)					
Pre	29	2.8 ± 0.9	2.7 ± 1	2.8 ± 0.9	0.632
Post	29	2.4 ± 0.8	2.5 ± 0.9	2.2 ± 0.6	0.455
Diff	29	−0.5 ± 0.8	−0.2 ± 0.6	−0.7 ± 1	0.356
GSI T scores (score range 33–81)					
Pre	24	57.4 ± 10.8	57.1 ± 9.5	58.7 ± 10.3	0.448
Post	24	53.1 ± 8.3	52.4 ± 9.4	52.7 ± 8.1	0.913
Diff	24	−4.3 ± 9.8	−4.4 ± 8.5	−4.1 ± 11.6	0.839
FACT-HN disease–specific subscale (score range 0–40)					
Pre	28	22.3 ± 9.4	21.5 ± 10.8	20.6 ± 7.9	0.817
Post	28	22.1 ± 9.9	21.6 ± 9.6	22.3 ± 10.4	1.000
Diff	28	−0.2 ± 7.6	−0.9 ± 6.4	0.7 ± 9.1	0.300
FACT-HN total (score range 0–148)					
Pre	27	93.8 ± 25.6	90 ± 29.5	90 ± 22.9	0.863
Post	27	104.4 ± 22.5	101.7 ± 21.8	104.6 ± 23.8	0.878
Diff	27	10.6 ± 17.6	8.9 ± 17.5	12.8 ± 18.3	0.479

BIS, Body Image Scale; BIDQ, Body Image Disturbance Questionnaire; GSI T, measure of psychological distress; and FACT-HN, Functional Assessment of Cancer Therapy–Head & Neck (measure of QOL).

Table 5. Theorized mechanisms for all patients and by intervention groups

Variable	Number of patients	All patient	Control	Intervention	*p*-Value
ASI-R (score range 1–5)					
Pre	35	3.1 ± 0.5	3 ± 0.5	3.2 ± 0.4	0.049
Post	28	3.2 ± 0.5	3.1 ± 0.5	3.3 ± 0.6	0.416
Diff	27	0.1 ± 0.5	0.1 ± 0.5	0.1 ± 0.4	0.788
AF (score range 0–3)					
Pre	35	1.5 ± 0.6	1.6 ± 0.7	1.4 ± 0.5	0.298
Post	29	1.1 ± 0.6	1.4 ± 0.5	0.8 ± 0.6	0.023
Diff	28	−0.3 ± 0.7	−0.2 ± 0.7	−0.5 ± 0.6	0.368
AV (score range 0–3)					
Pre	35	1.2 ± 0.6	1 ± 0.6	1.3 ± 0.5	0.116
Post	29	1 ± 0.4	1 ± 0.3	1 ± 0.6	0.826
Diff	28	−0.1 ± 0.6	0.1 ± 0.6	−0.3 ± 0.6	0.139
PA (score range 0–3)					
Pre	35	1.6 ± 0.4	1.7 ± 0.4	1.5 ± 0.4	0.043
Post	29	1.6 ± 0.5	1.7 ± 0.3	1.4 ± 0.6	0.086
Diff	28	0 ± 0.4	0 ± 0.4	−0.1 ± 0.4	0.835
ASWAP-PSI subscale (score range 0–42)					
Pre	35	20.6 ± 9.7	20.8 ± 8.8	20.3 ± 10.8	0.882
Post	28	15.7 ± 9.8	19 ± 10.6	11.3 ± 6.7	0.029
Diff	27	−4.2 ± 9.2	−1 ± 8.7	−8.3 ± 8.4	0.033

ASI-R, appearance investment; AF, appearance fixing (subscale of body image coping); AV, avoidance (subscale of body image coping); PA, positive rational acceptance (subscale of body image coping); and ASWAP-PSI, perceived social impact (subscale of Adapted Satisfaction with Appearance scale).

more comfortable with their appearance in the presence of family, friends, and/or strangers (Table 5). The other theorized mechanisms of coping strategies and appearance investment did not yield statistically significant different scores between groups (Table 5).

Intervention's effect on secondary outcomes

Overall QOL improved more in the intervention group than in the control group, and head/neck-specific QOL improved only in the intervention group, but the differences were not statistically significant (Table 3). Reduction in psychological distress in both groups was not statistically significant (Table 3).

Results from qualitative questionnaire

Revealed high percentage of intervention group patients preferred face-to-face interaction rather than interaction by phone (67%), felt 4 sessions was "just right" (73%), and many would recommend the program to peers (87%) (Supplementary Table S2).

Discussion

We evaluated the feasibility, acceptability, and efficacy of a brief, theory-based, psychologist-led body image intervention for patients with facial cancer expressing body image concerns and

found that the intervention had good feasibility and acceptability. The group receiving the 4-session, in-person program was compared with a control group who received an educational booklet and brief phone call providing psychosocial support. After the study period, the intervention group, but not the control group, had reductions in body image concerns, body image disturbance, PSI, and one of the negative coping scores, as well as improved overall QOL, compared to baseline. However, when we compared the amount of change in the intervention group with the amount in the control group, the difference between groups was not statistically significant for any measure except PSI. Thus, determining whether the 4-session intervention is clearly beneficial requires further investigation.

Our report provides information about patients' response to in-person delivery of a novel psychotherapeutic intervention targeting body image delivered soon after facial reconstructive surgery. The high retention rate and completion of visits in the intervention group attest to patients' level of interest and commitment to the psychotherapeutic program. This was further supported by results from qualitative questionnaire, which indicate that intervention content offers meaningful targets to consider when addressing body image concerns in patients with facial cancers. Within this patient group, there is a wide array of body image issues ranging from physical changes in appearance to functional changes affecting speaking, eating, and swallowing. As such, these patients

can have difficulties with their own personal reactions to body image changes but can also be sensitive to others' reactions to them. Hence, in-person interaction with a mental health specialist in body image concerns may help to not only identify their body image concerns but also process these concerns in a therapeutic environment.

Although the intervention group did not achieve statistically significant differences compared with the control group in either body image dissatisfaction or disturbance, we believe that clinically meaningful changes in scores were potentially observed. The reduction in body image dissatisfaction (BIS score) was almost twice in the intervention group than that of the control group. Researchers from a single institution note a BIS score change of 5 points or more to be clinically helpful; however, the level of change that is clinically meaningful has not been established (Graboyes et al. 2020a). The level of change in our intervention group was 2.5, which was 50% more than the control group. Similarly, for the intervention group, reduction in BIDQ score, a second measure of body image outcome in our study, was more than twice that of the control group. BIDQ evaluates not only the appearance but also associated functional concerns; thus, reduction in BIDQ scale is a more comprehensive measure of impact. We selected 2 different body image measures due to the complex and multidimensional nature of body image. However, it is important to note that these measures were not developed specifically for head and neck cancer patients, and therefore have limitations. Due to broad array of physical appearance and functional bodily changes that often result from head and neck cancers, use of disease-specific body image instrument may be warranted and show greater utility.

Body image adjustment is an important aspect of QOL in facial cancer. In our study, head/neck-specific QOL improved in the intervention group but was not statistically different from the control group. Null findings could be due to inherent heterogeneity of patients with head/neck cancer. Some patients may have more visible changes while others may have more concerns related to dysfunction, and some may have both disfigurement and dysfunction concerns but present in varying degrees. To address disease-related heterogeneity, a larger sample size may be needed. Thus, combination of improvement in QOL and reduction in initial body image symptoms may indicate the clinical usefulness of a psychotherapeutic intervention in this patient population.

Examination of theorized mechanisms of body image concerns revealed significant reductions in PSI in the intervention group compared to the control group. Aspects of the intervention that may be responsible for the change could be that 1 session was devoted to social skills training and the presence of a facilitator who may have helped with challenging aspects of social adjustments that patients may be tempted to avoid otherwise. Another theoretical factor, negative body image coping, was reduced more in the intervention group than in the control group, especially in patients without prior facial surgery, but the difference did not achieve statistical significance. Targeting negative coping is important to prevent further progression of body image concerns and may be achieved with a psychotherapeutic intervention. In contrast, the theorized factor of appearance investment did not change in either group. Research suggests that appearance investment is a trait-level variable, and therefore more than 4 intervention sessions may be needed to achieve a significant change (Moreira and Canavarro 2010). In the future, an additional follow-up time point to assess the sustained impact of the intervention may be considered.

In comparison to Graboyes et al.'s telemedicine-based 5-weekly, single-arm, body image–specific CBT intervention that included

10 survivors (Graboyes et al. 2020b), our study addressed body image concerns via an in-person facilitator at a specific time point, that is, within first 6 weeks after facial reconstructive surgery (Graboyes et al. 2020b). Our sample size was slightly larger with more men, and evaluation of theorized mechanisms was done with validated instruments. In our study, the reduction in BIS score was not statistically significant and was not assessed at a second follow-up time point. However, improvement in head/neck-specific QOL, although not significant in our intervention group, was noted in both studies. Overall in-person facilitator may be equally valuable for addressing body image–specific concerns in patients who may not be able to utilize telemedicine.

Another study that utilized skin camouflage techniques in 24 patients with facial cancer noted significant reduction in body image as assessed by QOL measure (Chen et al. 2017). Chen et al. did not prescreen for body image concerns, focused on female survivors in Taiwan, and the program was led by a research nurse (Chen et al. 2017). Our study sample was predominantly men, consistent with the clinical profile of patients with head/neck cancer in America and was led by a psychologist. Because our intervention was based on CBT, presence of a mental health professional trained in CBT would more meaningfully address cognitive distortions and problematic behavioral patterns. Comparison of body image concerns was difficult because of use of different measure.

The strengths of our study were use of a theory-based approach with a tailored body image program for patients with facial cancer, delivered during postoperative recovery from facial reconstruction in a randomized controlled trial with validated scales. Further strengths were as follows: clinical impact was evaluated at a specific time point in the cancer treatment trajectory, body image concerns were assessed with 2 different tools, and patients were recruited from clinics of multiple plastic surgeons.

Limitations

Due to the pilot nature of the study, the sample size was small. Although we observed differences between the intervention and control groups, these differences did not reach a statistically significant level. The data from this novel study will provide practical information for estimating effect sizes for future larger studies. While consistent with the clinical profile of head/neck cancer patients, the study was limited to a single institution, which may limit generalizability. The study predated the SARS-Cov-2 pandemic. Lastly, reason(s) for dropout were not tracked but may be considered in future studies, especially to understand its relation to study findings or to compare different modes of intervention delivery.

Significance of results

Given the dearth of evidence related to body image–specific interventions in oncology, our study adds to the literature and highlights effects on such concerns in the acute postoperative phase for patients with facial cancers. Our novel psychotherapeutic intervention was valued by patients and helped reduce PSI of physical changes with cancer treatment. Extending the study to a larger sample, possibly with similar cancer site and comparing different methods of delivery will help understand the impact of body image–specific intervention in detail. Additional intervention content related to addressing intimacy concerns or enhanced content involving communication strategies and acceptance-based approaches could be explored. Similarly, if specific body image

concerns are identified early on, then intervention could either target cognitive (problematic thoughts/actions) or behavioral (social situation and self-viewing) issues. Our current intervention was time limited with in-person delivery, which was well received. If telemedicine becomes a more sustained part of routine clinical care, then more sessions to incorporate above themes could be considered in future studies.

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