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Impact of a telehealth intervention on quality of life and symptom distress in patients with head and neck cancer

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Abstract

Background—Patients undergoing treatment for head and neck cancer commonly experience significant changes in quality of life (QoL) and levels of symptom distress. It is not known if a telehealth intervention would mitigate these changes.

Objective—To evaluate the impact of a telehealth intervention on QoL and symptom burden in patients undergoing initial treatment for head and neck cancers.

Methods—A randomized clinical trial comparing the impact on QoL and symptom distress of telehealth intervention and standard care was conducted with 80 patients (45 treatment, 35 control) who had been diagnosed with head or neck cancer and were receiving 1 or more treatment modalities. Treatment group participants responded daily to symptom management algorithms using a simple telehealth messaging device, QoL was evaluated by the Functional Assessment of Cancer Therapy-Head&Neck Scale (FACT-HN) and symptom burden by the Memorial Symptom Assessment Scale (MSAS). Control group participants completed assessments while they received routine care.

Results—In the posttreatment phase, the telehealth participants had significantly better scores than the controls for physical well-being (20.6 vs 17.0, $P = .02$) and trial outcome index (59.9 vs. 50.2, $P = .04$) on the FACT-HN, and total scores on the MSAS (0.9 vs. 1.2, $P = .04$).

Limitations—The moderate sample size of 80 patients limits the power to measure more subtle impacts of the intervention.

Conclusions—Using telehealth to provide support to patients with head and neck cancer during the acute phase of treatment improved some aspects of posttreatment QoL and symptom burden.

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Recent technological advancements have allowed for innovative telehealth interventions of various levels of sophistication. In cancer care, telephone-based computer systems,[1–3] handheld computers,[4] and mobile phone technology[5] have been used to monitor patients during chemotherapy treatment. Touchscreen computers have been successfully used by patients to report pain,[6,7] symptoms, and QoL[9] during clinic and office visits. Similar interventions have been used in head and neck cancer. In the Netherlands, touchscreen computers were used to gather data on QoL and distress for use by clinicians in assessing patients during treatment visits,[10] and laptop computers were used to report symptoms and issues, communicate with physicians and other patients, and access information.[11,12] The latter study found that patients who received the intervention had significantly improved QoL in 5 of the 22 studied parameters at the end of the intervention, but only 1 of those parameters remained significantly different at 12 weeks.

QoL considerations play a prominent role in head and neck cancer care. Previous QoL research in this population has consistently demonstrated a deterioration in QoL during the first 3 months after start of treatment followed by a slow recovery.[14] Most recently, QoL scores have been found to predict survival in head and neck cancer patients,[13,14] which further demonstrated the importance of addressing QoL in this population. However, there have been few hypothesis-driven studies of interventions designed to have an impact on QoL in these patients.[15,16] A systematic review found emerging support for psycho-education interventions in head and neck cancer populations,[16] but many of the studies had notable limitations, which precluded firm conclusions regarding about benefit. These studies included small samples or used pilot study methodologies that did not incorporate the random assignment or control group comparisons[16,17] necessary to evaluate efficacy.

Knowing that treatment for head and neck cancer has a significant and adverse impact on QoL[18–21] as well as physical[22–24] and psychological[25–29] symptom distress, we developed a multidisciplinary telehealth intervention to monitor, support, educate, and empower patients to become actively engaged in their care during active treatment. We hypothesized this intervention would have a positive impact on QoL and reduce the symptom burden in contrast to a standard-of-care/assessment-only condition.

Methods

Design

After receiving institutional review board approval, including an informed consent process, we conducted a parallel two-group randomized clinical trial comparing the telehealth intervention to standard-of-care/assessment-only in patients who had been recently diagnosed with head and neck cancer.

Site

Study participants were recruited over a two-year period from patients receiving care from the multidisciplinary head and neck cancer team in a metropolitan university teaching clinic. This team was composed of head and neck surgeons, medical oncologists, radiologists, nurses, speech therapists, registered dieticians, psychologists, and social workers. The team

developed a comprehensive assessment and treatment plan during the patient's initial visit to the cancer clinic.

Sample

Eligible patients met the following inclusion criteria: initial diagnosis of head or neck cancer, including cancers of the oral cavity, salivary glands, paranasal sinuses, nasal cavity, pharynx, and larynx; involvement in a treatment plan including 1 or more modalities (surgery, chemotherapy, radiation, or any combination); capacity to give independent informed consent; and ability to speak, read, and comprehend English on a 6th grade level or above. Patients were excluded from participation if they had a known active substance abuse problem, no access to a telephone landline, a thought disorder, compromised cognitive functioning, or were incarcerated.

After securing informed consent, the study coordinator consulted a randomization grid which considered treatment modalities to ascertain if the participant would be assigned to treatment or control. Baseline data was also collected at the time of initial consent.

A power analysis considering the instruments to be used and using a conservative within group correlation of 0.50 for the measurements across time, had previously determined that with 40 participants per group, there would be at least 80% power.

Measures

The selected instruments were self-administered or completed by phone or in a face-to-face interview. The participants were instructed to respond independently (as opposed to allowing surrogate respondents). The Functional Assessment of Cancer Therapy-Head & Neck Scale (FACT-HN) and the Memorial Symptom Assessment Scale (MSAS) were used to assess primary outcomes of QoL and symptom burden.

FACT-HN.

The FACT-G (General) is a multidimensional QoL instrument designed for use with cancer patients. The instrument has 28 items divided into 4 subscales: Functional Well-Being, Physical Well-Being, Social Well-Being, Emotional Well-Being. The generic core questionnaire, validated over 2 decades, meets or exceeds requirements for use in oncology on the basis of ease of administration, brevity, reliability, validity, and responsiveness to clinical change.[30] Added to the core questionnaire is the head and neck cancer-specific subscale consisting of 11 items specific to this cancer site. Together these questionnaires constitute the totality of the FACT-HN. The Trial Outcome Index (TOI), considered to be a measure of overall physical impact of the cancer, is obtained by adding together scores on the physical, functional, and cancer-specific subscales.

List and colleagues[31] found the FACT-HN to be reliable and sensitive to differences in functioning for patients with head and neck cancers (Cronbach alpha for total FACT-G, 0.89; for head and neck subscale, 0.63). The patients found the FACT-HN was relevant to their problems, easy to understand, and preferable to other validated head and neck cancer QoL questionnaires.[32] The FACT-HN was chosen for this study because it is nonspecific related

to a treatment modality or subsite in head and neck cancers; allows comparison across cancer diagnoses while still probing issues specific to head and neck cancer; is short and can be completed quickly; includes the psychosocial domains of social/family and emotion subscales as well as physical and functional areas; and is self-administered.

MSAS.

This multidimensional scale measures the prevalence, severity, and distress of the most common symptoms experienced by cancer patients. Physical and emotional subscale scores as well as a Global Distress Index (GDI) are generated from patient responses. The MSAS has demonstrated validity and reliability in inpatient and outpatient cancer populations.[33–35] Initial analysis used factor analysis to define 2 subscales: psychological and physical symptoms, with Cronbach coefficients of 0.88 and 0.83, respectively; convergent validity was also established.[34] It was chosen for this study because of its proven ability to measure both the presence and the intensity of symptoms.[33,35–37]

All of the participants completed these 2 measures at baseline (pretreatment), at the midpoint of treatment (at least 3 weeks into treatment), and posttreatment (3 weeks after completion of treatment). In addition, basic demographic information, medical history, specific treatments, and planned timing of the treatments were documented.

Description of the intervention

Participants who had been randomly assigned to the treatment group had the telehealth device connected to a telephone landline in their home. Research study staff delivered, set up, and demonstrated equipment operation. The participants were instructed on how to reply to algorithm questions that appeared on the monitor screen by using 4 large keys below the possible answers (Figure 1). They began responding on the first day cf treatment and continued responding daily (unless hospitalized) throughout the study period. Daily response time took 5–10 minutes.

Symptom-control algorithms that had been developed with the use of participatory action research and evidence-based practice[38] were programmed into the telehealth messaging system. Patients were asked questions related to the symptoms anticipated during their treatment scenario. Depending on their responses, they would receive specific information related to self-management of symptoms, including recommendations as to when to contact clinicians. Algorithms were constructed to encourage self-efficacy and independent action on the part of the participant when possible.

Responses to the previous day’s cuestions were automatically uploaded overnight and questions with related information for the next day were downloaded. Programming precluded interruption of phone service, completing the downloading and uploading of information during the middle of the night and could be repeated without data loss if service was somehow disrupted. After new algorithms had been transferred, a green light on the device would begin flashing to alert the participant that new questions were available for response.

Participant responses were stored in a secure server. Patient responses were risk-stratified according to the level of risk associated with the self-reported symptom or behavior and accessed electronically daily by study coordinators. Unrelieved symptoms or those targeted as requiring immediate intervention (eg, serious consideration of suicide) would result in the coordinator contacting the patient directly by phone and/or contacting clinicians to assure effective and immediate intervention. Direct intervention by study staff was infrequent because most of the symptoms were addressed independently by the participant in accordance with the study focus on self-management and self-efficacy. If a participant.did not respond for 3 consecutive days, then the coordinator would contact the patient to ascertain the reason for nonadherence.

Statistical methods

Data were analyzed using SPSS software.[39] Scores on the MSAS, FACT-HN subscales, FACT-HN TOI, and total FACT-HN were calculated for each patient at 3 time points (pretreatment, during treatment, posttreatment). Differences in scores on these scales were tested between the 2 groups over time. A priori power calculations suggested power of 81% to find a moderate-to-small effect size (Cohen's $d = 0.25$).

Descriptive statistics for the 2 groups were calculated. To test for differences in continuous variables t-tests were used, and chi-squared techniques were used to test for differences in categorical variables. Subsequently, to test for differences in trends in outcomes over time, between the 2 groups, generalized linear mixed effects modeling techniques were developed. Group (treatment or control) was incorporated as a fixed effect, and time since randomization was incorporated as a repeated measures effect. Because it was hypothesized that a group effect could be observed simply because 1 group (eg, control group) was associated with decreasing values and the other group (eg, treatment group) was associated with unchanged values, a secondary analysis was performed to explore whether a significant change over time existed within each group.

Results

Of the 191 patients who were assessed for eligibility, 86 met the study criteria and were randomized to the treatment (n = 48) or control (n = 38) groups. Figure 2 depicts the CONSORT flow diagram of the screening and randomization process. In all, 80 patients completed the study protocol (45 treatment, 35 control).

There were no significant differences in demographic characteristics between the treatment and control groups at baseline (Table 1). In addition, there were no differences in any outcome measures between the 2 groups pretreatment. These results suggest the randomization scheme was successful. Although there were no significant differences in outcomes during treatment, differences were observed at follow-up. Because 69 of the 80 patients were men, we were not able to evaluate for gender-based outcome differences.

As shown in Table 2, the generalized linear mixed effects model suggests that the telehealth approach was associated with better total scores over time for the MSAS ($P = .013$), MSAS-PSYCH ($P = .009$), Physical Well-Being ($P = .001$), and TOI ($P < .001$). No differences

were observed globally over time, although post hoc comparisons at each time point are described hereinafter and in Table 3. In addition, no interaction effects existed.

Although differences in outcomes were observed during treatment, none reached statistical significance. At posttreatment, however, the telehealth participants had significantly better scores than the controls for Physical Well-Being (20.6 [SD, 12.1] vs 17.0 [11.7], respectively; $P = .021$), TOI (59.9 [26.3] vs 50.2 [28.4]; $P = .042$) and total MSAS (0.9 [0.5] vs 1.2 [0.6]; $P = .0440$). That is, although improvements in outcomes were observed during treatment, significant differences were not observed until after treatment. The telehealth approach, however, did not significantly improve the scores for Emotional Well-Being (18.04 control vs 18.75 treatment, $P = .250$) or Social Well-Being (21.91 control vs 23.21 treatment, $P = .477$). QoL measured by Total FACT-HN scores, which include the Social and Emotional Well-Being subcomponents, where also not significantly different between the 2 groups. Because these were post hoc comparisons at each time point, and each was viewed as important in isolation, no alpha-splicing for multiple testing (eg, Bonferroni) was performed.

Discussion

In this randomized, controlled trial, data analyses revealed that patients who were treated for head and neck cancer and were exposed to a simple telehealth intervention reported significantly better QoL and a lower symptom burden posttreatment compared with patients who received routine cancer care. As far as we know, this is the first published clinical trial in the United States to use a telehealth device for symptom management during head and neck cancer treatment. The devices were well accepted by patients and clinicians, had few technical issues, and none were lost or damaged.[40]

Physical symptoms, represented by the FACT-HN QoL subscale scores and the MSAS symptom burden measures, demonstrated the greatest improvement with the intervention. Patients' social and emotional well-being were not improved, possibly because they were stable traits of individual patients during the treatment period. QoL and symptom burden were improved by the intervention in the weeks after treatment but not during the treatment phase. We hypothesize that the physical burdens during active multimodality cancer treatment produced strong symptoms that were resistant to an intervention. During the immediate recovery phase however, the telehealth intervention did return quality life and symptom burden to near pretreatment levels, findings from previous studies have shown a more gradual return to baseline QoL,[41] whereas our findings demonstrated a more rapid improvement. Thus, telehealth interventions may shorten the recovery time and enhance survivorship in patients undergoing treatment for head and neck cancer.

Head and neck cancer patients may have unique features that make telehealth interventions more effective. The patient's ability to communicate is often impaired, disfigurement can lead to social isolation, and initial surgical treatment can have a long recovery period. In addition, surgeons, medical oncologists, radiation oncologists, and allied therapists are all typically involved, and telehealth devices may provide some continuity among multiple disciplines' treatment plans. Daily messaging related to self-management of symptoms may

establish belief in one's self-efficacy, which may extend into the recovery period and result in improved disease management and return to baseline functioning.

We purposefully chose to use a simple device for this trial, one using a landline and a simple four-button keypad, with daily prompting from a green flashing light. Previous studies of telehealth modalities in cancer patients have shown mixed use of websites and smart phone technologies[1–5] that may not be as feasible in this specific patient population. Our methodology prompted the patient to respond, as opposed to patient-initiated interaction with specific websites or applications. This immediacy and prompting may have improved patient engagement, which was strong, and confirms the feasibility and acceptance of this study's particular approach.[40]

Our study has several limitations that should be considered when interpreting these results. First, the sample size of 80 patients is moderate and limits the power to measure more subtle influences of the telehealth intervention. This could be particularly true of several favorably trending, but statistically nonsignificant findings. In addition, our study was conducted at a single institution and before there was more widespread use of surgical robotics in head and neck cancer care. Our patients differed demographically from national norms in head and neck cancer by gender (86% men in our study vs 73% men nationally[42]). Finally, our trial was in one type of cancer and cannot be extrapolated to other types of cancer patients.

Future studies are needed to replicate our findings in other settings and other types of cancers. Our focus was on the initial treatment phase; the value of telehealth support in other phases of the clinical cancer trajectory is unknown. Finally, new technologies are constantly emerging that will also require evaluation.

Head and neck cancer is a common and devastating condition that commonly induces a high level of physical and psychosocial symptom burden. Based on these results, basic telehealth technology offers hope and support for patients to improve QoL and reduce symptom burden. Modalities for such interventions are becoming more affordable and accessible to the general population. If focused on self-management and patient education, interventions have the potential to reduce the costs related to professional oversight, clinic visits, emergency calls and inpatient stays. While more evidence is needed to justify routine use of telehealth in cancer care, a growing body of evidence supports the efficacy of such approaches.

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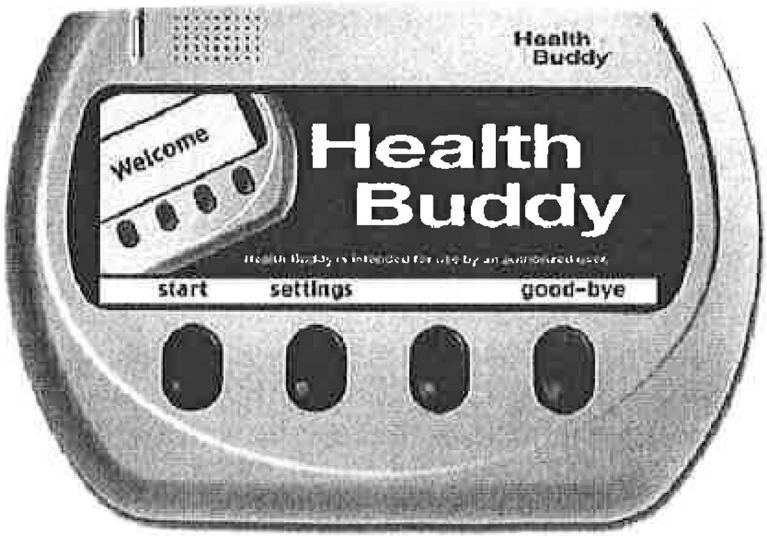

FIGURE 1.
Health Buddy© appliance used in the intervention

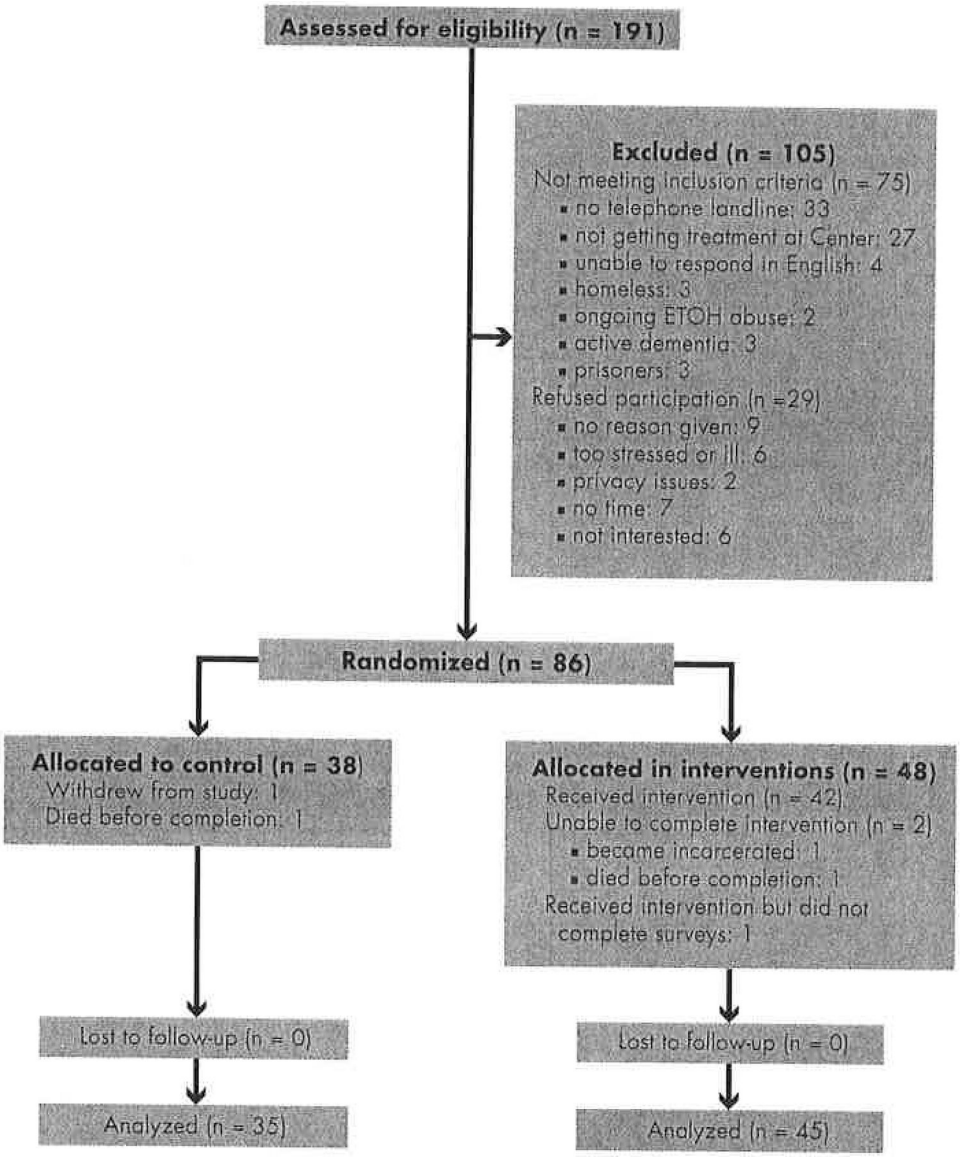

FIGURE 2.
CONSORT patient flow diagram

TABLE 1

Demographics stratified by control and treatment group

	Group, n (%)		
Variable	**Control (n = 35)**	**Treatment (n = 45)**	***P***
	Categorical		
Male	30 (85.1)	39 (87.1)	.48
White	31 (88.6)	40 (87.9)	.20
Urban setting	27 (76.5)	36 (79.1)	.10
Tumor stage			.33
I	5 (14.2)	7 (16.3)	
II	12 (34.2)	15 (33.8)	
III	9 (26.9)	13 (29.0)	
IV	3 (9.5)	4 (9.6)	
In situ	1 (2.1)	1 (1.2)	
Unknown	5 (14.2)	5 (10.1)	
Radiation	31 (85.7)	41 (91.1)	.79
Chemotherapy	20 (57)	33 (73.3)	.13
Surgery	4 (11.4)	4 (8.9)	.69
Site			.15
Oral cavity	6 (17.1)	8 (16,7)	
Pharynx	10 (29.5)	14 (31.1)	
Larynx	11 (30.1)	13 (29.0)	
Salivary glands	3 (9.5)	4 (9.6)	
Paranasal sinuses	1 (2.1)	1 (1.2)	
Angiosarcoma	1 (2.1)	1 (1.2)	
Unknown	1 (2.1)	5 (10.1)	
	Continuous		
Mean age, y (SD)	59.67 (11.8)	60.73 (10.2)	.20
Mean BMI, kg/m^2 (SD)	28.1 (8.4)	26.9 (7.6)	.82

TABLE 2

Repeated measures ANOVA of outcomes over time stratified by group

Outcome	Predictor	*P*
PWB	Group	.001*
	Time	.510
	Group × Time	.470
SWB	Group	.478
	Time	.316
	Group × Time	.171
EWB	Group	.781
	Time	.436
	Group × Time	.912
FWB	Group	.542
	Time	.508
	Group × Time	.705
H&NCS	Group	.647
	Time	.521
	Group × time	.733
TOI	Group	< .001*
	Time	.249
	Group × Time	.676
FACT-G	Group	.499
	Time	.501
	Group × Time	.997
FACT-HN	Group	.129
	Time	.871
	Group × Time	.148
Total MSAS	Group	.013*
	Time	.058
	Group × Time	.182
MSAS-PHYS	Group	.090
	Time	,061
	Group × Time	.338
MSAS-PSYCH	Group	.009*
	Time	.141
	Group × Time	.602
MSAS-GDI	Group	.341
	Time	.077
	Group × Time	.697

EWB, Emotional Well-Being; FACT-G, Functional Assessment of Cancer Therapy-General: FACT-HN, Functional Assessment of Cancer Therapy-Head & Neck; FWB, Functional Welt-Being; H&NCS, Heed & Neck Cor1cer Specific; MSAS-GDI. Memorial Symptom Assessment Scale-Global Distress Index; MSAS-PHYS, Memorial Symptom Assessment Scale-Physical Symptom Distress; MSAS-PSYCH, Memorial Symptom

Assessment Scale-Psychological Symptom Distress; PWB, Physical Well-Being; SWB, Social/Family Well-Being; TOI, Total Outcome Index; Totol MSAS, Total Memorial Symptom Assessment Scale

*Significant at .05.

TABLE 3

Scores over time stratified by treatment or control

Variable	T1	*P*	T2	*P*	T3	*P*
PWB		.983		.312		.021*
Treatment	20.84		18.15		20.61	
Control	22.63		15.54		17.04	
SWB		.953		.432		.477
Treatment	20.47		22.22		23.21	
Control	21.13		21.38		21.91	
EWB		.892		.534		.250
Treatment	18.71		18.21		18.75	
Control	18.33		16.79		18.04	
FWB		.795		.925		.191
Treatment	16.92		13.67		18.13	
Control	15.75		13.21		16.21	
H&NCS		.142		.560		.052
Treatment	19.45		17.64		20.30	
Control	16.37		16.41		17.83	
TOI		.914		.782		.042*
Treatment	61.83		48.02		59.94	
Control	58.00		44.92		50.16	
FACT-G		.825		.667		.180
Treatment	74.06		67.55		78.29	
Control	78.04		67.71		73.84	
FACT-HN		.803		.865		.103
Treatment	100.25		85.63		101.53	
Control	98.81		84.60		89.86	
Total MSAS		.902		.140	0.87	.044*
Treatment	0.84		1.23		1.22	
Control	0.85		1.47			
MSAS-PHYS		.373		.294		.460
Treatment	0.70		1.46		1.13	
Control	0.79		1.66		1.30	
MSAS-PSYCH		.531		.595		.095
Treatment	1.09		1.25		0.85	
Control	0.95		1.39		1.37	
MSAS-GDI		.833		.943		.113
Treatment	1.14		1.77		1.27	
Control	1.10		1.78		1.69	

EWB, Emotional Well-Being; FACT-G, functional Assessment of Cancer Therapy-General; FACT-HN, Functional Assessment of Cancer Therapy-Head & Neck; FWB, Functional Well-Being; H&NCS, Head & Neck cancer Specific; MSAS-GDI, Memorial Symptom Assessment Scale-Global Distress Index; MSAS-PHYS, Memorial Symptom Assessment Scale-Physical Symptom Distress; MSAS-PSYCH, Memorial Symptom Assessment Scale-Psychological Symptom Distress; PWB Physical Well-Being; SWB, Social/Family Well-Being; T1, Time 1; T2, Time 2; T3, Time 3; TOI, Total Outcome Index; Total MSAS, Memorial Symptom Assessment Scale

[a]Significant at 0.05.