Underserved head-and-neck and lung cancer patient characteristics are associated with caregiver participation in a clinical trial

Gillian R. Ulrich [a],[*], Krista W. Ranby [a], Evelinn Borrayo [b]

[a] *Department of Psychology, University of Colorado Denver, Denver, CO, USA*
[b] *Department of Community & Behavioral Health, University of Colorado School of Public Health, Aurora, CO, USA*

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ABSTRACT

Background: Patient-caregiver relationships affect cancer outcomes, yet factors related to joint enrollment in cancer research trials are unclear. This work examined associations between cancer patients' sociodemographic and health factors and their caregivers' trial participation.

Methods: Baseline data were drawn from a parent trial testing psychosocial interventions delivered to medically underserved head-and-neck cancer (HNC) and lung cancer (LC) patients (N = 274) and caregivers (N = 210). Logistic regression evaluated whether patient characteristics were associated with participating alone versus with a caregiver(s) and type of caregiver.

Results: Many patients (65.0%) had a caregiver in the study, which was more common for married (OR = 2.05, p < .01) and retired patients (OR = 1.95, p < .05). Patients who indicated Hispanic (OR = 2.31, p < .05), Medicaid insurance (OR = 4.12, p < .001), monthly income <\$4000 (OR = 3.04, p < .01), and smoked (OR = 2.87, p < .01) were more likely to enroll with a non-spouse/partner caregiver versus a spouse/partner. Participation was unrelated to distress.

Conclusions: Patient characteristics highlight caregiver relationships, informing trial design and recruitment for medically underserved cancer populations. Psychosocial interventions targeting underserved patients and their informal caregivers, those most in need of intervention support, should consider the inclusion of non-spousal cancer caregivers. Understanding how patient factors may be associated with caregiver involvement informs recruitment strategies and increases the utility of psychosocial interventions.

1. Introduction

Head-and-neck cancer (HNC) and lung cancer (LC) are cancers of the aerodigestive tract, and patients with HNC have a high risk of developing LC [1]. HNC and LC are described as two of the most distressing types of cancer [2] to experience for patients and their loved ones due to their intensive treatment regimens, heavy symptom burden, and high risk for treatment failure and mortality [3–5]. Patients tend to experience higher levels of psychological distress [6] and stigma [7] than survivors of other cancer types, in part due to cancer-risk behaviors such as cigarette smoking [8], and they endorse persistent psychological distress post-treatment [9]. Within the realm of cancer, health inequities contribute to greater rates of cancer risk behaviors, pre-existing conditions, and cancer incidences and to lower rates of preventative cancer screenings; thus, cancers among underserved patients are often diagnosed at later stages with worse prognoses [10]. Underserved HNC and

LC patients, including those of minoritized ethnic backgrounds, are significantly more likely to experience greater psychological distress and lower quality of life [11] and are less likely to access palliative or supportive cancer care than cancer patients from dominant societal groups [12]. Thus, it is especially important to consider demographic characteristics, social determinants, and health inequities when understanding physical and mental health outcomes among underserved patients.

Cancer-related events are interpersonal, affecting patients and those in their proximal social networks. The relationship between patients and their informal caregivers (e.g., spouses, partners, children, siblings) is more than just the sum of individuals; rather, relationships have their own specific norms, cultures, and behaviors, which may promote or impede each individual's health [13,14]. Many informal cancer caregivers are spouses, and a high quality marriage is positively associated with improved cancer prognoses and survival outcomes for various cancer types [15] including HNC and LC [16,17]. Mechanisms by which

patient-caregiver dyads may influence each person's health include concordance (likeness), interdependence [18], dyadic coping [19], communal coping [20], social support, and social control. Given this mutual influence, researchers have begun to conceptualize patients and caregivers as emotional systems rather than purely distinct individuals.

Coping with threat of cancer often strains relationships [21], highlighting the need for relationship-focused psychosocial interventions. Caregiving burden and psychological distress among HNC and LC family caregivers is prevalent and interdependent with patients' distress at various timepoints [22–25]. Yet, caregivers are less likely than patients to receive professional help for their psychological distress [26]. Thus, psychosocial dyadic intervention designs may have greater utility and efficacy over interventions targeting only the cancer patient or only the caregiver as they account for both individual and interpersonal health mechanisms. Preliminary randomized control trials testing dyadic psychosocial interventions in HNC and LC have shown effectiveness [27–29]. However, it is important to consider how social factors (e.g., patient demographics, the type of patient-caregiver relationship) may be associated with trial enrollment.

Despite the strong theoretical foundation and emerging evidence for couples- and family-based psychosocial interventions in cancer, recruiting both cancer patients and their caregivers poses many methodological challenges, especially when working with underserved groups who are coping with distressing cancer side-effects. Researchers must consider recruitment language (i.e., spouses may not identify with term "caregiver"), eligibility for each partner, feelings of coercion around consent, confidentiality of data collection, managing attrition at a dyadic level and dyadic analytical strategies. Additionally, recruiting underserved HNC and LC samples adds further considerations and challenges. Families who are uninsured or under-insured or lack access to healthcare may be difficult to recruit in clinical settings, and it may be difficult to rely on technology-assisted efforts as low-income families may lack or share devices. Underserved patients are often diagnosed with more advanced disease stages and experience greater levels of mortality, psychological distress, and poorer quality of life than other cancer patients [11,12]; thus, they may feel too burdened and overwhelmed to participate in research, and if they consent, their attrition may be due to mortality or health complications. When working with couples and families, researchers need to consider how to treat bereft caregivers from ethical, humanitarian, and statistical perspectives. Therefore, family-focused intervention designs should be sensitive to the unique burdens faced by medically underserved families facing cancer.

Factors related to individual versus joint participation in psychosocial cancer research are unclear. A more advanced understanding of patient-caregiver samples, especially within medically underserved cancer populations, may increase feasibility, inform inclusive and effective recruitment and intervention methodologies, enhance external validity, and bolster clinical relevancy. This study addresses current knowledge gaps by describing enrollment in a randomized control trial for medically underserved HNC and LC patients and caregivers. In this secondary exploratory analysis, sociodemographic and physical and mental health factors of patients were explored and used to evaluate group differences in participation form (e.g., alone, with one caregiver, with multiple caregivers) and relationship type (e.g., spouses/partners, parent-child). Finally, participation form and relationship type were examined as correlates of both patients' and caregivers' psychological distress.

2. Methods

2.1. Study sample

Data were drawn from the randomized control trial, "*A stepped care intervention to reduce disparities in mental health services among cancer patients and caregivers*" [30]. The trial was a longitudinal, multi-site study that explored the efficacy of a stepped-care intervention for

reducing distress and improving coping skills as compared to enhanced usual care in medically underserved (i.e., low-income, uninsured, underinsured) HNC and LC patients and their caregivers. The current study utilized data collected from baseline, which occurred before randomization to trial arms. Eligibility for the parent trial is published [30]. Participants were recruited from five hospitals in Colorado. Site coordinators pre-screened patients to identify recently diagnosed HNC and LC patients, recruited patients at scheduled medical visits, typically their first treatment encounter, and obtained the patients' permission to invite their caregiver(s) to the study. The trial was delivered to patients and their caregivers separately, and patients and caregivers individually completed all study questionnaires. Thus, caregiver participation was not required for patients' enrollment. Caregivers were only included in analyses if the patient they cared for completed baseline measures. Some patients had multiple caregivers participate.

2.2. Measures

Participation Form and Relationship: Participation Form denotes patients who participated alone, with one caregiver, or with multiple caregivers. Caregivers self-reported their relationship to the patient. Caregivers also indicated (yes/no) whether they were the primary caregiver to the patient; the primary caregiver variable was only used to form dyads when a patient had more than one caregiver.

Sociodemographic Factors: Patients and caregivers reported their age, gender, ethnicity, race, preferred language (i.e., English and/or Spanish), highest level of education, employment status, marital status, health insurance status and type, and monthly income.

Health Factors: Patients indicated their primary cancer site, treatment plan (i.e., surgery, chemotherapy, radiation therapy, biological therapy), and whether they started treatment (yes/no). Both patients and caregivers provided their mental health history including their history of anxiety and depression, use of prescription medication or counseling for mental health purposes, and use of social support services related to cancer. Patients and caregivers also reported recent cancer risk behaviors by indicating (yes/no) to whether they smoked cigarettes, drank six or more alcoholic beverages on at least one occasion, or used marijuana in the past month.

Psychological Distress: Both patients and caregivers completed the Hospital Anxiety and Depression Scale (HADS) [31]. Participants rated each of the 14 items on a 4-point scale ranging from 0 (absence) to 3 (significant presence). Five items were reverse scored. Scores were summed for a total possible score of 42. Clinically significant distress was defined as a total HADS score of 15 or above, which is the recommended cutoff score for cancer patients treated in an outpatient department [32]. Both the English and Spanish versions of the HADS have demonstrated high internal consistency, sensitivity, specificity, and predictive validity in cancer patients and caregivers [33–35].

Psychological distress was also measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) [36]. Cancer patients completed the cancer version for depression (30 items) and anxiety (23 items), and caregivers completed the PROMIS adult version for depression (8 items) and anxiety (8 items). On all PROMIS scales, participants were asked to rate their depression or anxiety in the past seven days on a 5-point scale from 1 (Never) to 5 (Always). All items were summed to create a raw score. These measures have demonstrated good psychometric properties in ethnically diverse groups including both English and Spanish speakers [37,38].

2.3. Data analysis plan

The frequency of participation forms (e.g., alone, with one caregiver, with multiple caregivers) and patient-caregiver relationship types (e.g., spouses/partners, parent-child) were assessed. Additionally, descriptive statistics including frequencies, means, and standard deviations were calculated for sociodemographic and mental and behavioral health

factors for both patients and caregivers. Rates of missingness were very low with fewer than 2% of values missing, except for retired status (7% missing) and income (5% missing). Pairwise deletion was used for all analyses.

To evaluate whether patients' sociodemographic and health factors predicted participation form, we dichotomized patients who participated alone (n = 96) compared to those who had at least one caregiver participate (n = 178). Among participants who had at least one caregiver participate, we explored relationship type with patients' primary caregiver by comparing patients with spouse/partner (n = 112) versus non-spouse/partner caregivers (n = 66) and patients with spouse/partner (n = 112) versus child (n = 40) caregivers. Correlations (point biserial and phi coefficients) and logistic regression were used to evaluate whether patients' sociodemographic and health factors were associated with participation form and relationship type. Additionally, participation form and relationship type were explored as correlates of emotional distress in both patients and caregivers. Analyses done with all caregivers included caregivers from the same family, so were run in MPlus 8 [39] to adjust standard errors for non-independence to produce unbiased statistical tests.

3. Results

3.1. Sample characteristics

A total of 274 patients with HNC (n = 95, 34.7%) or LC (n = 179, 65.3%) completed the baseline survey. More than half of patients (HNC 64.2%, LC 56.7%) started treatment (e.g., surgery, chemotherapy, radiation) prior to completing baseline. It is important to note that some patients' treatment plans were pending when they completed the baseline survey.

Roughly one third of all patients (n = 96, 35.0%) did not have a caregiver participate in the parallel caregiver intervention, with rates appearing similar across cancer types (Table 1). A total of 149 patients (HNC n = 57, 60.0%; LC n = 92, 51.4%) had one caregiver who participated in the caregiver intervention and 29 patients (HNC n = 6, 6.3%; LC n = 23, 12.8%) had two or more caregivers participate. Our total sample of caregivers included 210 participants. For analyses involving patient-caregiver dyads, we included patients who had at least one caregiver complete the baseline measures (n = 178 dyads). Of all patient-caregiver dyads, the most common relationship type consisted of spouses/partners (all dyads n = 112 dyads, 62.9%) followed by parent-child relationships (all dyads n = 46, 25.8%). The vast majority of parent-child dyads involved the patient and their child, and this was more common in LC dyads (LC n = 33, 28.7%; HNC n = 7, 11.1%). Refer to Table 1 for additional details on participation form and dyad composition by cancer type.

Patients' and caregivers' sociodemographic factors and health history are presented for the full sample as well as by cancer type in Table 2. On average, patients (M = 66.3 years) were older than caregivers (M = 57.0 years), and the mean age of patients and caregivers was similar across cancer types. The majority of all patients were male (60.8%), and the majority of all caregivers were female (80.9%). Marital status was only asked of patients, and 60.3% of patients were married/partnered. Roughly a quarter of the sample was Hispanic (patients 20.1%, caregivers 24.4%), the vast majority of the sample was White (patients 85.4%, caregivers 82.4%), and most participants only spoke English (patients 84.8%, caregivers 81.7%). For 48.4% of patients and 39.0% of caregivers, high school or less was the highest level of education. Ethnicity, race, language spoken, and education were similar across HNC and LC patients and caregivers. More caregivers (40.0%) than patients (18.3%) were employed, and more patients (65.5%) than caregivers (47.3%) were retired; however, rates differed by cancer type. Regarding health insurance, Medicare was most common among LC patients (LC patients 70.9%, HNC patients 45.3%, all caregivers 43.8%). Rates of Medicaid were similar among patients (24.1%) and caregivers (22.4%) across cancer types. Finally, the majority of all patients' and caregivers' (66.1%–70.3%) monthly income was less than $4000 after taxes.

Regarding patients' and caregivers' mental health history, 11.3% of patients and 14.8% of caregivers were diagnosed with a depressive disorder, and 6.9% of patients and 14.8% of caregivers were diagnosed with an anxiety disorder. Roughly a quarter of LC patients, 10% of HNC patients, and 20% of all caregivers used medication for a mental condition in the past month. In the past month, very few of all patients (5.9%) and caregivers (6.7%) used counseling for behavioral reasons; though more patients (HNC 25.3%, LC 14.4%) sought social support services or resources related to cancer. Regarding patients' and caregivers' cancer risk behaviors in the past month, 22.8% of HNC patients and 20.5% of LC patients smoked cigarettes. About 16.3% of caregivers smoked in the past month. Roughly 19% of HNC patients and 11% of LC patients and 10% of all caregivers had six or more alcoholic drinks on at least one occasion. Lastly, marijuana use was generally more common among patients (20.1%) than caregivers (12.0%). Additional details on patients' and caregivers' health history by cancer type are provided in Table 2.

3.2. Participation group differences by sociodemographic and health factors

All sociodemographic and health factors described in Table 2 were explored as possible correlates of participation form and relationship type. Age, Medicare insurance, VA insurance, history of anxiety or depression, use of medication or counseling for a mental health condition, use of support services or resources for cancer, and alcohol and marijuana use were not significantly correlated with participation form or relationship type. All pairwise correlations for patient characteristics and participation were run. All patient characteristics that were significantly correlated with participation are reported in Table 3. All patient characteristics were considered as predictors in logistic regression models, but only significant predictors are reported in Table 4 to provide odds ratios of these associations.

Logistic regression results are outlined in Table 4. All analyses were run with coding of the outcome in a way that produced odds ratios greater than 1. In this way, the table is organized to show predictors that increased the likelihood of being in caregiver participation group. Regarding participation form, for patients who were married/partnered or retired, the odds were about two times greater that they participated with a caregiver than alone (married partnered OR = 2.05, Wald z = 7.63, p < .01; retired OR = 1.95, Wald z = 6.00, p < .05). However, for patients who spoke only English, were employed, or had private insurance, the odds were greater that they participated alone, respectively (English OR = 3.03, Wald z = 6.45, p < .05; employed OR = 2.62, Wald

Table 1
Participation by cancer type.

	Cancer Type		
Participation Form	All (n = 274 patients)	HNC (n = 95 patients)	LC (n = 179 patients)
Alone	n = 96, 35.0%	n = 32, 33.7%	n = 64, 35.8%
With One Caregiver	n = 149, 54.4%	n = 57, 60.0%	n = 92, 51.4%
With More than One Caregiver	n = 29, 10.6%	n = 6, 6.3%	n = 23, 12.8%
Relationship Type	All (n = 178 dyads)	HNC (n = 63 dyads)	LC (n = 115 dyads)
Spouses/Partners	n = 112, 62.9%	n = 42, 66.7%	n = 70, 60.9%
Parent-Child Relationship	n = 46, 25.8%	n = 11, 17.5%	n = 35, 30.4%
Child of Patient	n = 40, 22.5%	n = 7, 11.1%	n = 33, 28.7%
Parent of Patient	n = 6, 3.4%	n = 4, 6.3%	n = 2, 1.7%
Siblings	n = 8, 4.5%	n = 6, 9.5%	n = 2, 1.7%
Other-Relative	n = 4, 2.2%	n = 1, 1.6%	n = 3, 2.6%
Non-Relative	n = 8, 4.5%	n = 3, 4.8%	n = 5, 4.3%

Table 2
Sociodemographic factors and health history.

	Patients			Caregivers		
	All (n = 274)	HNC (n = 95)	LC (n = 179)	All (n = 210)	HNC (n = 69)	LC (n = 141)
Sociodemographic Factors						
Age *(M, SD)*	66.3, 10.9	61.6, 12.3	68.9, 9.1	57.0, 15.1	56.7, 13.2	57.2, 16.0
Gender (Male)	60.8%	76.8%	52.2%	19.1%	8.7%	24.3%
Married/Partnered	60.3%	53.7%	63.8%	–	–	–
Ethnicity (Hispanic)	20.1%	19.1%	20.7%	24.4%	23.9%	24.6%
Race (White)	85.4%	85.3%	85.5%	82.4%	87.0%	80.1%
Language						
Only Spanish	4.4%	5.3%	4.0%	4.3%	4.4%	4.3%
Both Spanish and English	10.8%	8.7%	11.8%	14.0%	8.8%	16.4%
Only English	84.8%	86%	84.2%	81.7%	86.8%	79.3%
Highest Level of Education						
High School or Less	48.4%	49.5%	47.8%	39.0%	44.9%	36.2%
College	39.1%	36.8%	40.4%	50.5%	46.4%	52.5%
Post-Graduate	12.5%	13.7%	11.8%	10.5%	8.7%	11.3%
Employment[a]						
Currently Employed	18.3%	26.3%	14.0%	40.0%	39.1%	40.4%
Retired	65.5%	48.3%	74.4%	47.3%	43.3%	49.3%
Health Insurance (all that apply)						
Medicare	62.0%	45.3%	70.9%	43.8%	37.7%	46.8%
Medicaid	24.1%	27.4%	22.3%	22.4%	21.7%	22.7%
VA Coverage	12.8%	10.5%	14.0%	4.8%	5.8%	4.3%
Private Insurance	40.9%	41.1%	40.8%	50.1%	44.9%	53.9%
Monthly Income (After Taxes) Less than $4000	66.9%	70.3%	65.1%	66.3%	66.1%	66.4%
Health History						
Mental Health Diagnoses						
Depressive Disorder	11.3%	7.4%	13.4%	14.8%	13.0%	15.6%
Anxiety Disorder	6.9%	6.3%	7.3%	12.4%	8.7%	14.2%
Used medication for a mental condition in the past month (Yes)	19.4%	10.6%	24.0%	20.6%	18.8%	21.4%
Used counseling for behavioral reasons in past month (Yes)	5.9%	5.3%	6.2%	6.7%	7.2%	6.5%
Sought social support services or resources related to cancer in the past month (Yes)	18.2%	25.3%	14.4%	–	–	–
Health Behaviors (past month)						
Smoked Cigarettes	21.3%	22.8%	20.5%	16.3%	11.8%	18.6%
Had ≥6 drinks on 1 or more occasion(s)	14.1%	19.1%	11.4%	10.4%	9.0%	11.1%
Used Marijuana	20.1%	26.1%	17.0%	12.0%	7.2%	14.3%

– Items were only asked of patients.

[a] Current employment and retirement status were asked as separate questions.

z = 9.14, p < .01; private insurance OR = 1.90, Wald z = 6.25, p < .05). Regarding relationship type (spouse/partner vs. non-spouse/partner caregiver), married/partnered patients had much greater odds of participating with a spouse/partner caregiver (OR = 18.84, Wald z = 53.56, p < .001). Additionally, the odds that patients participated with a spouse/partner caregiver over a non-spouse/partner caregiver were roughly five times greater for male or White patients (male OR = 5.09, Wald z = 23.31, p < .001; White OR = 4.88, Wald z = 11.89, p < .01), three times greater for patients with private insurance (OR = 3.29, Wald z = 10.74, p < .01), and two times greater for retired patients (OR =

Table 3
Correlations between patient characteristics and participation form/type.

Patient Characteristic (all coded 1)	Participation Form Alone (coded 0) vs. At Least 1 Caregiver (coded 1)	Relationship Type Non-Spouse/Partner Caregiver (coded 0) vs. Spouse/Partner Caregiver (coded 1)	Child Caregiver (coded 0) vs. Spouse/Partner Caregiver (coded 1)
Cancer Type (HNC)	0.02	0.06	0.19*
Male Gender	0.06	0.37**	0.43**
Married/Partnered	0.17**	0.61**	0.56**
Hispanic	−0.09	−0.18*	−0.25**
White Race	0.00	0.28**	0.24**
Language (English Only)	−0.16**	0.04	0.08
Education	−0.16**	0.23**	0.22**
Employed	−0.19**	0.09	0.10
Retired	0.15*	0.16*	0.09
Medicaid Insurance	0.04	−0.30**	−0.27**
Private Insurance	−0.15*	0.25**	0.22**
Monthly Income Less Than $4000	0.02	−0.23**	−0.20*
Smoked Cigarettes in the Past Month	0.04	−0.22**	−0.22**

**Correlation is significant at the 0.01 level, * Correlation is significant at the 0.05 level. All correlations were between two binary constructs (φ), except education, which was continuous (r_pb). Age, Medicare insurance, VA insurance, history of anxiety or depression, use of medication or counseling for a mental health condition, use of support services or resources for cancer, and alcohol and marijuana use in the past month were not significantly correlated with participation form or relationship type.

Table 4
Patient characteristics predict participation form and relationship type.

Participation Form: At Least One Caregiver (n = 178) vs. Alone (n = 96)				
Increased likelihood of Participating with Caregiver	B	OR	Wald z	p
Married/Partnered[a]	0.72	2.05	7.63	.006
Retired	0.67	1.95	6.00	.014
Increased likelihood of Participating Alone				
Language (English Only)[a]	1.11	3.03	6.45	.011
Employed	0.96	2.62	9.14	.003
Private Insurance[a]	0.64	1.90	6.25	.012
Education	0.10	1.11	6.51	.011
Relationship Type: Spouse/Partner Caregiver (n = 112) vs. Non- Spouse/Partner Caregiver (n = 66)				
Increased likelihood of Spouse/Partner Caregiver	B	OR	Wald z	p
Married/Partnered[b]	2.94	18.84	53.56	.000
Male Gender[b]	1.63	5.09	23.31	.000
White Race[b]	1.58	4.88	11.89	.001
Private Insurance	1.19	3.29	10.74	.001
Retired	0.73	2.07	4.28	.039
Education	0.14	1.15	8.53	.003
Increased likelihood of Non-Spouse/Partner Caregiver				
Medicaid Insurance	1.42	4.12	15.25	.000
Monthly Income Less Than $4000	1.11	3.04	8.23	.004
Smoked Cigarettes in the Past Month	1.05	2.87	7.98	.005
Hispanic	0.84	2.31	5.24	.022
Relationship Type: Spouse/Partner Caregiver (n = 112) vs. Child Caregiver (n = 40)				
Increased likelihood of Spouse/Partner Caregiver	B	OR	Wald z	p
Married/Partnered[c]	2.76	15.82	37.93	.000
Male Gender[c]	2.04	7.72	24.69	.000
White Race	1.47	4.33	8.02	.005
Private Insurance	1.17	3.23	7.13	.008
Education	0.14	1.15	6.55	.011
Increased likelihood of Child Caregiver				
Medicaid Insurance	1.32	3.73	9.97	.002
Hispanic	1.21	3.37	8.70	.003
Smoked Cigarettes in the Past Month	1.12	3.06	6.93	.009
Monthly Income Less Than $4000	1.07	2.93	5.35	.021
Cancer Type (LC)	1.04	2.83	5.12	.024

Note: All predictors listed under the group that was associated with a greater likelihood. [a] indicates significant (p < .05) predictor in a multivariate model with 6 predictors of participation form [b] indicates significant (p < .05) predictor in a multivariate model with 10 predictors of spouse/partner vs. non spouse/partner caregiver [c] indicates significant (p < .05) predictor in a multivariate model with 10 predictors of spouse/partner vs. child caregiver.

2.07, Wald z = 4.28, p < .05). In contrast, for patients with Medicaid insurance, a monthly income less than $4,000, who smoked in the past month, or who identified as Hispanic, the odds were greater that they participated with a non-spouse/partner caregiver over a spouse/partner caregiver, respectively (Medicaid OR = 4.12, Wald z = 15.25, p < .001; income <$4000 OR = 3.04, Wald z = 8.23, p < .01; smoked OR = 2.87, Wald z = 7.98, p < .01; Hispanic OR = 2.31, Wald z = 5.24, p < .05). Similar patterns emerged when comparing patients who participated with a spouse/partner caregiver versus child caregiver, except cancer type became a significant predictor. LC patients had more than twice the odds of participating with a child caregiver (LC OR = 2.83, Wald z = 5.12, p < .05). Please refer to Table 4 for information on additional predictors.

3.3. Participation and psychological distress

Approximately 28.6% of patients (M = 10.50, SD = 7.07) and 29.6% of caregivers (M = 11.26, SD = 7.17) had a HADS score of 15 or above, indicating clinically significant distress. On average, patients (Depression M = 49.05, SD = 19.85; Anxiety M = 39.31, SD = 16.30) and caregivers (Depression M = 12.45, SD = 5.57; Anxiety M = 14.89, SD = 6.94) reported fairly low emotional distress on PROMIS scales. Participation with at least one caregiver, caregiver type, cancer type, and whether patients started cancer treatment were not significantly related to distress measures in patients or caregivers (all ps > .05).

4. Discussion

There is a strong theoretical foundation for couples- and family-based psychosocial interventions in cancer; however, recruiting both cancer patients and their caregivers poses methodological challenges, especially when working with underserved groups who are coping with distressing cancers. Little to no research has aimed to explore who participates in patient-caregiver cancer research. This trial's flexible design, which allowed single or joint participation of patients and their caregivers, provided the unique opportunity to examine patient characteristics associated with caregiver trial enrollment.

We found that the majority of all patients (65.0%) had at least one caregiver enroll and complete baseline measures, and rates were consistent across cancer types (HNC 66.3%, LC 64.2%). This finding suggests that couples- and family-focused designs are not only feasible in this population, but attractive to patients and their informal caregivers. Further, there may be opportunities to utilize family focused interventions in LC as 12.8% of LC patients had more than one caregiver participate.

Whether patients had at least one caregiver enroll in the trial and complete baseline measures was associated with several patient characteristics, possibly reflecting unique social patterns among medically underserved families. Namely, patients who were married/partnered or retired were significantly more likely to have at least one caregiver enroll in the trial compared to patients who spoke English only, were employed, had private insurance, or higher education. Thus, availability (i.e., having a partner and time) may motivate familial involvement, and patients working during treatment may have less access to caregiver support or may experience greater stress in their relationships. Previous work has indicated that adults with higher socioeconomic status have higher quality and quantities of social relationships [14], yet in this medically underserved sample, we did not find this pattern regarding caregiver enrollment. Future work should assess if additional patient characteristics, such as living arrangement (e.g., multigenerational households) and cultural orientation (e.g., individualism versus collectivism), may be associated with differences in caregiver enrollment.

Beyond examining patient characteristics associated with caregiver participation, our analyses examined the type of relationship that existed between patients and caregivers. Consistent with the cancer literature, the majority of patient-caregiver dyads consisted of spouses/partners. Further, our proportion of spouse/partner pairs (62.9%) was similar to the reported rates of married/partnered dyads in HNC and LC studies of patients and family caregivers [24,27,40,41]. Our findings regarding the type of patient-caregiver relationship is consistent with previous work describing sociodemographic variation in social ties [14], highlighting the potential association between societal privilege and caregiver type. We found that participants of historically privileged race or gender (e.g., White, male) with resources (e.g., higher levels of education, private insurance, retired) more commonly had spouse/partner caregivers while patients comprising historically underserved groups (e. g., monthly income less than $4000, Medicaid insurance, Hispanic) or who engaged in health-risk behaviors (e.g., smoked cigarettes) typically had non-spouse/partner caregivers participate in the clinical trial. These findings have important methodological implications for dyadic work. It's possible that research designed for spouses/partners may attract more samples of higher socioeconomic gradients. Additionally, individuals with less education have greater rates of divorce [42], indicating that patients with lower socioeconomic status may only have access to non-spousal caregivers. Thus, research targeting more

heterogeneous samples may need to enroll both spousal and non-spousal dyads, especially among racially diverse samples [43].

Although a variety of correlates of psychological distress have been examined in HNC and LC patients and caregivers, little work has explored whether joint participation or relationship type in randomized control trials is associated with psychological distress. Participation with at least one caregiver was not significantly correlated with any patient distress measures. Further, caregiver type (e.g., spouse/partner caregiver, child caregiver) did not significantly correlate with any distress measures for patients or caregivers. Previous work has found that spousal caregivers of HNC and LC tend to report more depressive symptoms than non-spousal caregivers [44] but that finding was not replicated in this study. Lastly, patients' and caregivers' relatively low psychological distress may be explained by the measurement timepoint as 64.2% of HNC and 56.7% of LC patients had started treatment. Integrating our work with existing findings suggests that distress may be similar across caregiver types before or early in treatment but may come to more negatively affect spousal caregivers over the course of cancer treatment. Future research should aim to further understand the trajectory of distress in HNC and LC caregivers, and adaptive (e.g., stepped-care) designs may be utilized to tailor intervention strategies based not only on distress but also caregivers' relationship to patients.

4.1. Strengths and limitations

Primary strengths of this work are the public health and healthcare implications it offers to clinical researchers and health care providers. This research focused on underserved groups most at risk for poor physical and psychosocial cancer outcomes [45], and it is established that health disparities pattern social relationships [14]. Additionally, few randomized control trials in HNC and LC have been designed for both patients and family caregivers rather than couples. By recruiting family caregivers and allowing multiple caregivers to enroll, this novel work highlights that patient factors were associated with caregiver participation and caregiver type. Further, a large number of patient sociodemographic and health factors were explored as correlates of both participation and distress. Future research should further examine these finding by exploring participant characteristics using a multivariate approach (e.g., latent class analysis) rather than individually assessing each participant factor.

There are limitations of this study. This work utilized a correlational study design; thus, only observed relationships may be concluded rather than directionality or causal mechanisms. Additionally, the parent trial was delivered to patients and their caregivers separately and this study focused on trial enrollment by utilizing only baseline data. It is possible that the extent of individual versus joint intervention activities may impact patients and their caregivers willingness to complete an intervention together. Additionally, most patients had begun treatment, though some had not started treatment. Future research may build upon this study by replicating this work in dyadic trials and by examining attrition over time in relation to shared intervention demands, treatment plans, symptom burden, and health outcomes. Another limitation is that we were unable to conclude whether patients who participated alone did so by choice, whether they lacked a caregiver, or whether their caregiver declined participation. Future work that aims to better understand the nature of patients' and caregivers' relationships beyond relationship type, such as social support, relationship satisfaction, and investment in each other's health, may enhance our understanding of how social and relationship factors impact trials' enrollment and success. Because the study was not designed or powered to test any specific association of patient characteristic with caregiver participation, it is possible that characteristics that were not significant predictors in the current study due to restricted range or sample size. Lastly, our medically underserved sample was recruited in Colorado and measures were only offered in English and Spanish. Continued work with larger populations of medically underserved samples across the U.S. that also represent additional races, ethnicities, and socioeconomic gradients may further validate or dispute study findings.

5. Conclusion

Our findings offer important implications for intervention designs. First, our results show that recruiting both patients and caregivers for psychosocial interventions is feasible in this population. Second, our work highlights that research designed for spouses/partners may inadvertently attract more middle-to upper-class and White samples. Thus, psychosocial research targeting underserved samples most in need of interventions should consider broad eligibility criteria that allows for non-spouse/partner caregivers as well as multiple caregiver participation. Finally, participation at baseline was not associated with patients' or caregivers' emotional distress, indicating that sociodemographic and physical health factors may be more greatly associated with enrollment. Stakeholders may build upon these findings and develop inclusive interventions that meet the needs and reflect the lived experiences of historically underserved and marginalized patients and their loved ones.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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