Effect of a Community Health Worker–Led Intervention Among Low-Income and Minoritized Patients With Cancer: A Randomized Clinical Trial

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ABSTRACT

PURPOSE To determine whether a community health worker (CHW)–led intervention could improve health-related quality of life (HRQoL; primary outcome) more than usual care among low-income and racial and ethnic minoritized populations newly diagnosed with cancer.

METHODS This randomized clinical trial was conducted from November 1, 2018, until August 31, 2021, in outpatient cancer clinics in Atlantic City, NJ, and Chicago, IL. Hourly low-wage worker members of an employer union health fund age 18 years or older with newly diagnosed solid tumor and hematologic malignancies were randomly assigned 1:1 to usual care (control group) or usual care augmented with a trained CHW for 12 months (intervention group). The CHW assisted participants with advance care planning (ACP), proactively screened symptoms, and referred participants to community-based resources for identified health-related social needs. Usual care comprised nurse case management and benefits redesign (waived copayments and free transportation for any cancer care received at preferred oncology clinics in each city). The primary outcome was HRQoL. Secondary outcomes included patient activation, satisfaction with decision, ACP documentation, health care use, total health care costs, and overall survival.

RESULTS A total of 160 participants were enrolled. Intervention group participants had a greater increase in mean HRQoL scores at 4-month and 12-month follow-up as compared with baseline than control group participants (expected mean difference, 11.25 [95% CI, 7.28 to 15.22]; 11.29 [95% CI, 6.96 to 15.62], respectively).

CONCLUSION In this randomized trial, a CHW-led intervention significantly improved HRQoL for low-income and racial and ethnic minoritized patients with cancer more than usual care alone.

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Protocol

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INTRODUCTION

Approximately 50% of people with cancer receive advance care planning (ACP) and cancer symptom management—evidence-based services that can improve health-related quality of life (HRQoL) and reduce acute care use and total costs of care.[1-4] Yet, only 20% of low-income and racial and ethnic minoritized populations receive such care.[3,5] Limited clinician time, lack of adequate reimbursement, and systemic racism and implicit biases that promote unaddressed health-related social needs (HRSNs) perpetuate inequitable care delivery among these populations.[6-8] Yet, few interventions address such disparate care.[9]

Previously, we used community-based participatory research and health care redesign to develop a multilevel, multicomponent community health worker (CHW)–led ACP and symptom management intervention.[10] CHWs, supervised by nurses, engage in structured, telephone-based discussions with patients diagnosed with solid tumor cancers and hematologic malignancies to proactively screen symptoms and deliver ACP education. With oncology clinicians, we integrated the intervention into clinical workflows and with payer organizations, redesigned health insurance benefits and reimbursement models to improve uptake and adoption. Such benefits included prior authorization elimination for specialty palliative care and behavioral health,

CONTEXT

Key Objective

Can a multilevel, multicomponent community health worker (CHW)–led advance care planning, cancer symptom management, and health-related social needs intervention improve health-related quality of life (HRQoL) more than usual cancer care for low-income and racial and ethnic minoritized hourly low-wage workers?

Knowledge Generated

Among 160 participants in this multisite, randomized trial, the CHW-led intervention increased HRQoL more at 4 and 12 months postenrollment compared with enrollment than usual care alone. The intervention also increased patient activation, reduced acute care use, improved hospice use, and reduced total health care costs more than usual care alone.

Relevance *(S.B. Wheeler)*

This CHW-led intervention was able to improve quality of life, patient activation, and advanced care planning documentation, as well as reduce acute care use and in total costs of care in a highly diverse population of low-income and racial and ethnic minority patients with cancer. If it can be scaled up, this kind of wrap-around, community-focused intervention has extraordinary potential for addressing social determinants of disparate cancer outcomes.*

*Relevance section written by *JCO* Associate Editor Stephanie B. Wheeler, PhD, MPH.

reimbursement for oncology clinicians and practices, and financial support for CHW and nurse effort. Across four studies in California, comprising mostly White, older adults with advanced stages of solid tumors and hematologic malignancies, specifically Veterans,[1] privately insured patients,[2] and Medicare advantage beneficiaries,[11,12] ACP documentation tripled, acute care use decreased by 60%, and total costs decreased by 20%.

In this study, we collaborated with Unite Here Health (UHH), an employer-union health fund serving 200,000 low-income and racial and ethnic minoritized hourly, low-wage workers and their families.[13] We developed a Community Advisory Board (CAB) and adapted the intervention given the poor HRQoL and unwanted acute care use among UHH members with cancer.[13,14] The adapted intervention, Lay Health Workers Educate, Engage, and Activate Patients to Share (LEAPS), includes an added component to assist patients with identified HRSNs. In a single-arm pilot, we demonstrated the feasibility of LEAPS.[15] The objective of this multisite, randomized controlled trial was to determine whether LEAPS could improve HRQoL more than usual care.

METHODS

Trial Design

This trial was conducted in collaboration with UHH in Atlantic City and Chicago. Before study start, we adapted the trial design for local context with the CAB.[13,14] Eligible participants were UHH members newly diagnosed with all solid tumor and hematologic malignancies or recurrent disease who lived in Atlantic City or New Jersey. Exclusion criteria included members without capacity or ineligible for UHH benefits.

Participants were identified through UHH claims data with newly diagnosed cancer or with three or more cancer-related claims within the prior month indicating recurrent disease. The claims data system also contains information from daily inpatient reports and referrals from hospital staff, primary care physicians, specialists, UHH staff, and union staff and members. Consented participants were randomly assigned within 1 week of their first oncology clinic for a new cancer diagnosis or recurrence to receive either usual care (control group) or LEAPS (intervention group). The statistician randomly assigned participants through a 1:1 simple strategy with a computer-generated, ordered list of randomized numbers within each city. The principal investigator (M.I.P.), statistician (K.K.), data abstractor (D.S.), research assistants (R.As), and coinvestigators (T.C., A.R., I.K.) were blinded to random assignments. The first participant was enrolled on November 1, 2018, and the last on August 31, 2021. Data were analyzed from May 1, 2022, until December 15, 2022. The trial was funded by the National Institute of Minority Health and Health Disparities.

Interventions

Usual Care (control group)

All participants received usual care which included outpatient care delivered from oncology clinics in Atlantic City and Chicago that accepted UHH benefits, including academic health systems and community oncology clinics. Usual care also included case management by a UHH-registered nurse to address financial concerns and care coordination. As part of benefits redesign, the principal investigator (M.P.) collaborated with UHH to identify one preferred oncology clinic in each city. The preferred oncology clinic was a multispecialty

large-volume cancer clinic affiliated with a major academic cancer center. In collaboration with Principal Investigator (M.I.P.), UHH redesigned health benefits which included waived copayments and free transportation to members who chose to receive their cancer care at the preferred clinic.

LEAPS (intervention group)

CHWs, bilingual in Spanish, Hindi, Vietnamese, and Chinese, among other languages, contacted participants randomly assigned to the intervention group weekly, by telephone, for 4 months and monthly thereafter up to 12 months or death, whichever was first. In 30-minute sessions, CHWs delivered ACP education in participants' preferred language. CHWs also proactively screened cancer symptoms by telephone, weekly for the first 4 months and monthly thereafter for 12 months or until death, using the Edmonton Symptom Assessment System,[16] documented scores in the electronic health record (EHR), and triaged scores 4 or above or that changed two points from previous assessments to a UHH nurse to conduct interventions. CHWs also screened for and referred participants to community-based resources for HRSNs (eg, food and housing insecurity, transportation, and financial concerns).

Trial End Points

Trial end points were predetermined by the CAB. The primary end point was effect on change in HRQoL measured from enrollment (baseline) to 4 months. Prespecified, secondary outcomes (defined below) included patient activation, satisfaction with decision, emergency department (ED) and hospital use, ACP documentation, overall survival (OS), and total costs.

Patient-Reported Outcome Measures

Patient-reported outcomes (PROs) were assessed at random assignment (baseline) and 4 and 12 months after random assignment. HRQoL was assessed using the validated 27-item Functional Assessment of Cancer Therapy-General,[17,18] with scores ranging from 0 to 108 with higher scores indicating better HRQoL and a minimal clinically meaningful difference of 4 points.[19] Patient activation was assessed using the validated 13-item Patient Activation Measure-13 with scores ranging from 0 to 100 with higher scores indicating greater activation and a minimal clinically meaningful difference of four points.[20] Satisfaction with decision was assessed using the validated six-item Satisfaction with Decision scale with responses of strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree.[21] Trained RAs administered assessments telephonically in patients' preferred language.

ACP, Health Care Use, Survival, and Cost Measures

We defined ACP as advance directive (AD), goals of care (GOC) and physician orders for life-sustaining treatment (POLST) documentation in the EHR and abstracted documentation at baseline and 4 and 12 months. From UHH claims, we collected the use and dates of specialty palliative care and hospice within 4 and 12 months and ED visits and hospitalizations from baseline to 4 and 12 months or death, whichever was first. For ED visits and hospitalizations, we measured any use and frequency of use. We obtained date of death from the member registry and total costs from claims data. Health care use and total costs 30 days before death were also assessed for the subset who died within 12 months.

Demographic and Clinical Characteristics

Self-reported data included age, sex, ethnicity, race, annual household income, and education. Cancer diagnosis and stage were collected from the EHR.

Intervention Fidelity

CHWs completed self-assessments for each assigned participant including dates, duration, and details of each participant encounter. A supervising UHH nurse conducted monthly in-person observations and weekly chart review of CHW-led intervention activities.

Ethics and Consent

All participants verbally consented to participate. The Protocol (online only) was approved by the Stanford University Institutional Review Board and UHH before study start.

Statistical Analysis

The sample size calculation was based on intention-to-treat analyses. A total of 160 participants (80 in control and 80 in intervention) was calculated to provide >90% power to detect a minimal meaningful difference in change in HRQoL between groups over time (delta change = 4)[19] assuming a within-subject correlation of 0.8 and a standard deviation of the change in score equal to 9.5 on the basis of previous data in this population.[15]

All statistical tests were two-sided, conducted using Stata version 16 (StataCorp LLC, College Station, TX), and adjusted for all collected demographic and clinical characteristics given the association with prespecified outcomes,[22-24] with a $P < .05$ considered statistically significant. No secondary analyses were adjusted for multiplicity, as these were exploratory. The primary analysis was conducted in accordance with our statistical analysis plan and intention-to-treat. Expected mean differences in HRQoL between groups were estimated by generalized estimating equation (GEE) models with outcomes modeled as a function of treatment group, categorical time (baseline, 4 months, 12 months), and an interaction term between treatment group and time with an exchangeable correlation clustered within person. Significance was assessed using a type III F-test on the interaction term. No missingness was observed in demographic or clinical characteristics. Missing PRO data was observed only among participants who died. Observed PROs were included in

primary analyses for the time points that participants contributed to the study as per previous studies.[25] In sensitivity analyses, per previous studies,[26,27] the worst possible HRQoL score (0) was imputed for participants who died before the assessment.

Change in patient activation was estimated using GEE models with Gaussian distribution and identity link as a function of treatment group, categorical time (baseline, 4 months, 12 months), and an interaction term between treatment group and time with an exchangeable correlation clustered within person. Change in patient satisfaction with decision was reported as ratios of odds ratios (ORs) on the basis of GEE models using binomial distribution, logit link function, and as a function of treatment group, categorical time (baseline, 4 months, 12 months), and an interaction term between treatment group and time with an exchangeable correlation clustered within person. ORs for ACP documentation and health care use were calculated using logistic generalized linear regression models. Incidence rate ratios (IRRs) to compare total ED and hospitalizations were calculated with Poisson generalized linear regression models with an offset term for log of follow-up time at each time point (within 4 months and 12 months). Total costs were compared using generalized linear models with gamma distribution and log link function with an offset term for log of follow-up time. OS was assessed visually using Kaplan-Meier models. Subgroup analysis of participants who died used similar models (Fig 1).

RESULTS

Among 160 participants, there were no withdrawals (CONSORT diagram). The median age was 58 years, and 83 (51.8%) were female, 47 (29.4%) Hispanic, 44 (27.5%) African American or Black, 2 (1.3%) American Indian or Alaska Native, 31 (19.3%) Asian, 1 (0.6%) Native Hawaiian, and 82 (51.3%) White. The majority (n = 127; 79.4%) reported annual household incomes <$35,000 US dollars (USD) and less than a high school degree (n = 129; 80.6%). Thirty-seven (23.1%) participants had breast cancer, and 64 (40.0%) had stage IV disease. The groups did not appear to meaningfully differ in demographic or clinical characteristics (Table 1).

Primary Outcome

The control and intervention groups had similar HRQoL scores at baseline (74.1 ± 16.5 *v* 73.5 ± 15.8, respectively). Compared with baseline, at 4 months, the control group declined by 3 points (70.3 ± 16.8) while the intervention group increased by 7 points (80.7 ± 16.4). Compared with baseline, at 12 months, the control group declined 1 point (73.3 ± 15.6) while the intervention group increased by 11 points (84.4 ± 16.5). Compared with the control group, the intervention group had a greater increase in mean HRQoL scores with an expected mean difference between groups of 11.25 (95% CI, 7.28 to 15.22) from baseline to 4 months and 11.29 (95% CI, 6.96 to 15.62) from baseline to 12 months. In sensitivity analyses, compared with primary analyses, mean scores were lower, but results remained statistically significant (Fig 2A; Appendix Tables A1 and A2, online only).

Secondary Outcomes

Patient Activation

The control and intervention groups had similar patient activation scores at baseline (53.5 ± 10.3 *v* 53.4 ± 9.80,

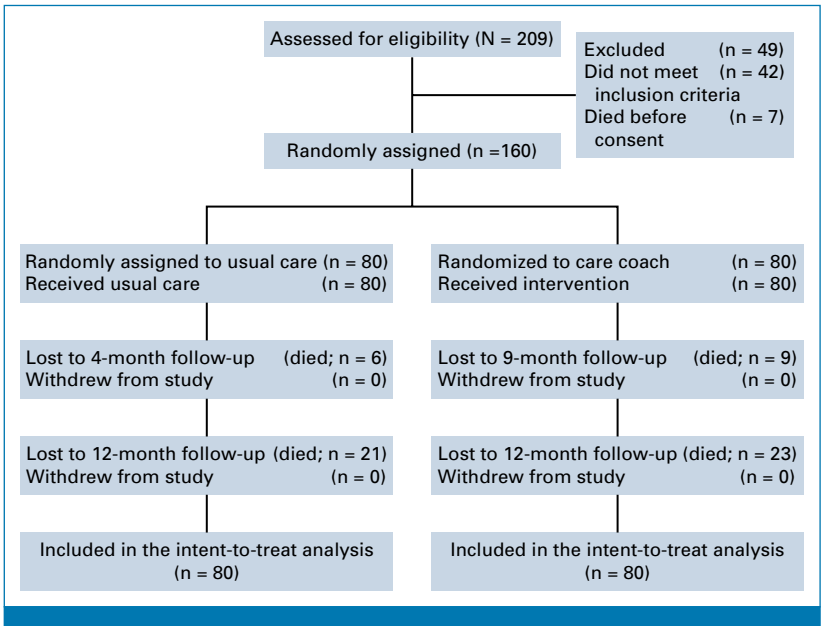

FIG 1. CONSORT diagram. Enrollment and random assignment of participants.

TABLE 1. Baseline Characteristics of Study Participants

Variable	Total (N = 160)	Control Group (n = 80)	Intervention Group (n = 80)
Age, years, median (range)	58 (21-89)	58 (31-89)	58 (21-80)
Gender identity, No. (%)			
Male	75 (46.9)	37 (46.3)	38 (47.5)
Female	83 (51.8)	42 (52.5)	41 (51.3)
Nonbinary	2 (1.3)	1 (1.2)	1 (1.2)
Ethnicity, No. (%)			
Hispanic	47 (29.4)	21 (26.3)	26 (32.5)
Non-Hispanic	113 (70.6)	59 (73.7)	54 (67.5)
Race, No. (%)			
African American or Black	44 (27.5)	23 (28.8)	21 (26.2)
American Indian or Alaska Native	2 (1.3)	0 (0)	2 (2.5)
Asian	31 (19.3)	18 (22.6)	13 (16.3)
Southeast Asian	12 (7.5)	7 (8.8)	5 (6.3)
Vietnamese	10 (6.2)	6 (7.5)	4 (5.0)
Chinese	9 (5.6)	5 (6.3)	4 (5.0)
Native Hawaiian	1 (0.6)	1 (1.3)	0 (0.0)
White	82 (51.3)	38 (47.5)	44 (55.0)
City, No. (%)			
Atlantic City	108 (67.5)	53 (66.3)	55 (68.8)
Chicago	52 (32.5)	27 (33.7)	25 (31.2)
Annual household income, USD, No. (%)[a]			
<$25,000	24 (15.0)	10 (12.5)	14 (17.5)
$25,000-$34,999	103 (64.4)	50 (62.5)	53 (66.3)
$35,000-$49,999	33 (20.6)	20 (25.0)	13 (16.2)
Education level, No. (%)[b]			
Less than high school	129 (80.6)	61 (76.3)	68 (85.0)
High school	25 (15.6)	15 (18.8)	10 (12.5)
2-year college or bachelor degree	6 (3.8)	4 (5.0)	2 (2.5)
Anatomic site of cancer diagnosis, No. (%)			
Breast	37 (23.1)	22 (27.5)	15 (18.8)
Gastrointestinal	30 (18.8)	16 (20.0)	14 (17.5)
Genitourinary	19 (11.9)	10 (12.5)	9 (11.3)
Lung	21 (13.1)	10 (12.5)	11 (13.8)
Ovarian	13 (8.1)	5 (6.3)	8 (10.0)
Malignant hematologic	18 (11.3)	7 (8.7)	11 (13.8)
Head and neck	7 (4.3)	2 (2.5)	5 (6.3)
Others (skin, soft tissue, brain)	15 (9.4)	8 (10.0)	7 (8.7)
Cancer stage at diagnosis, No. (%)			
I	30 (18.7)	19 (23.7)	11 (13.7)
II	23 (14.4)	14 (17.5)	9 (11.3)
III	25 (15.6)	11 (13.7)	14 (17.5)
IV	64 (40.0)	27 (33.8)	37 (46.2)
Not applicable (ie, gliobastoma, hematologic malignancies)	18 (11.3)	9 (11.3)	9 (11.3)

NOTE. No missingness was observed in any of the characteristics. Age, gender identity, ethnicity, race, income, and education were self-reported by participant.

Abbreviation: USD, US dollars.

[a]No participants reported annual household income of ≥$50,000. The average household size reported by participants was 4.0.

[b]No participants reported educational attainment of >2-year college or a bachelor degree.

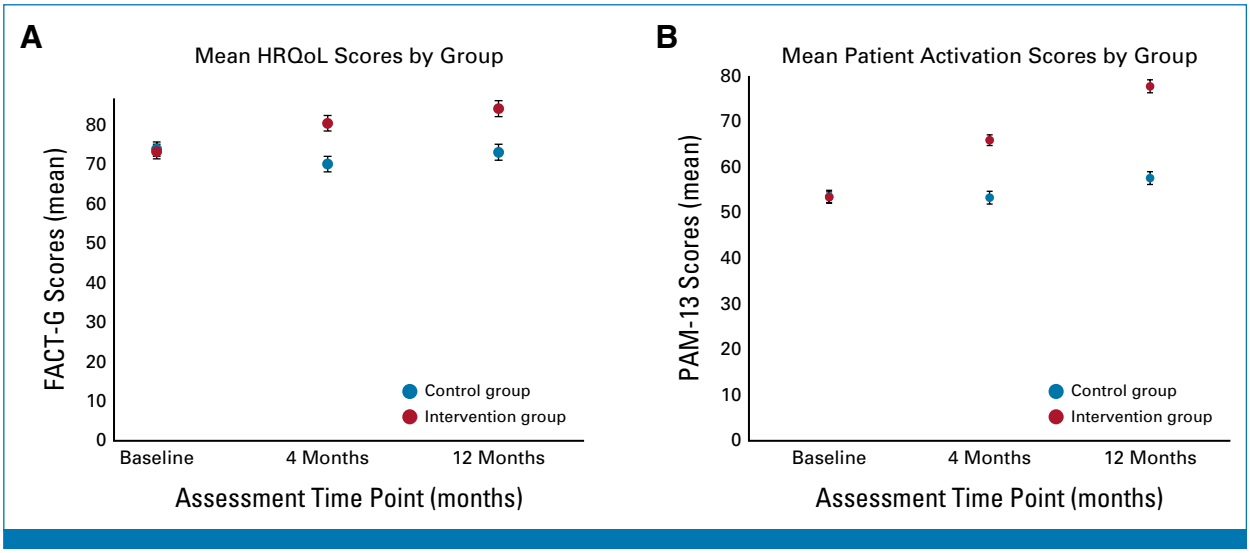

FIG 2. (A) Mean HRQoL by group. A total of 74 participants (92.5%) in the control group and 71 (88.8%) in the intervention group completed this survey question at 4 months after study enrollment. Missingness was only observed because of death among 6 (7.5%) participants in the control group and 9 (11.3%) participants in the intervention group who had died before this 4-month assessment. A total of 59 participants (73.8%) in the control group and 57 (71.3%) in the intervention group completed this survey question at 12 months after study enrollment. Missingness was only observed because of death among 21 (26.3%) participants in the control group and 23 (28.8%) participants in the intervention group who had died before this 12-month assessment. Effect estimates were expected mean differences in HRQoL scores between groups from baseline. *P* values were estimated using a type III F-test to determine significance of the interaction effect between time point and group. Compared with the control group, the intervention group had a greater increase in mean HRQoL scores with an expected mean difference between groups of 11.25 (95% CI, 7.28 to 15.22; $P < .001$) from baseline to 4 months and 11.29 (95% CI, 6.96 to 15.62; $P < .001$) from baseline to 12 months. In sensitivity analyses (Protocol), the results remained statistically significant. (B) Mean patient activation by group. A total of 79 participants (98.8%) in the control group and 80 participants (100%) in the intervention group completed this survey at baseline. A total of 74 participants (92.5%) in the control group and 71 participants (88.8%) in the intervention group completed this survey at 4 months after study enrollment. Missingness was only observed because of death among 6 (7.5%) participants in the control group and 9 (11.3%) participants in the intervention group who had died before the 4-month assessment. A total of 58 participants (72.5%) in the control group and 57 participants (71.3%) in the intervention group completed this survey at 12 months after study enrollment. Missingness was only observed because of death among 21 (26.3%) participants in the control group and 23 (28.8%) participants in the intervention group who had died before this 12-month assessment. Effect estimates were expected mean differences in Patient Activation Measure scores between groups from baseline. Compared with the control group, the intervention group had a greater increase in mean scores between groups from baseline to 4 months (12.77 [95% CI, 9.07 to 16.46; $P < .001$]) and 12 months (19.63 [95% CI, 15.59 to 23.67; $P < .001$]). FACT-G, Functional Assessment of Cancer Therapy-General; HRQoL, health-related quality of life; PAM-13, patient activation measure-13.

respectively). Compared with baseline, at 4 months, the control group was unchanged (53.3 ± 10.1) while the intervention group increased by 12 points (65.9 ± 14.7). Compared with baseline, at 12 months, the control group increased by 4 points (57.6 ± 10.8) and the intervention group increased by 24 points (77.7 ± 11.2). Compared with the control group, the intervention group had a greater increase in mean scores between groups from baseline to 4 months (12.77 [95% CI, 9.07 to 16.46; $P < .001$]) and 12 months (19.63 [95% CI, 15.59 to 23.67; $P < .001$]; Fig 2B; Appendix Table A3).

Satisfaction With Decision

Compared with the control group, the intervention group was more likely to strongly agree with satisfaction with decision across all six items from baseline to 4 and 12 months. Compared with the control group, at 4 months compared with baseline, the intervention group had greater odds of strongly agreeing they felt adequately informed (OR, 3.04 [95% CI, 1.93 to 4.21]), their decisions were the best possible (OR, 2.89 [95% CI, 1.72 to 4.17]), their decisions were consistent with personal values (OR, 3.93 [95% CI, 2.51 to 5.23]), they expected to carry out their decisions (OR, 3.21 [95% CI, 2.03 to 4.23]), their decisions were theirs to make (OR, 2.97 [95% CI, 1.89 to 4.17]), and satisfaction with their decisions overall (OR, 3.42 [95% CI, 2.24 to 4.62]; $P < .001$). Similar patterns were observed at 12 months (Table 2).

ACP Documentation

At 4 months, 10 (12.5%) control group and 44 (55.0%) intervention group participants had GOC documentation. At 12 months, 23 (28.8%) control group and 71 (88.8%)

TABLE 2. Effect on Satisfaction With Decision Between Groups at Baseline and 4 and 12 Months

Variable	Control Group Baseline, No. (%)	Control Group 4 Months, No. (%)	Control Group 12 Months, No. (%)	Intervention Group Baseline, No. (%)	Intervention Group 4 Months, No. (%)	Intervention Group 12 Months, No. (%)	Effect Estimate[a] Baseline-4 Months (95% CI)	Effect Estimate[a] Baseline-12 Months (95% CI)
I am satisfied that I am adequately informed about the issues important to my decision	39/79 (49.4)	20/74 (27.0)	16/59 (27.1)	39/80 (48.8)	60/71 (84.5)	46/56 (82.1)	3.04 (1.93 to 4.21)	2.89 (1.65 to 4.00)
The decision I made was the best decision possible for me personally	41/79 (51.9)	25/74 (33.8)	17/59 (28.8)	44/80 (55.0)	61/71 (85.9)	47/56 (83.9)	2.89 (1.72 to 4.17)	3.08 (1.79 to 4.22)
I am satisfied that my decision was consistent with my personal values	40/79 (50.6)	24/74 (32.4)	18/59 (30.5)	41/80 (50.31)	65/71 (91.6)	51/56 (91.1)	3.93 (2.51 to 5.23)	3.89 (2.43 to 5.23)
I expect to successfully carry out (or continue to carry out) the decision I made	41/79 (51.9)	24/74 (32.4)	15/59 (25.4)	38/80 (47.5)	62/71 (87.3)	47/56 (83.9)	3.21 (2.03 to 4.23)	3.23 (2.07 to 4.48)
I am satisfied that this was my decision to make	41/79 (51.9)	23/74 (31.1)	16/59 (27.1)	38/80 (47.5)	64/71 (90.1)	48/57 (84.2)	2.97 (1.89 to 4.17)	3.18 (1.97 to 4.45)
I am satisfied with my decision	43/79 (54.4)	25/74 (33.8)	17/59 (28.8)	41/80 (51.3)	64/71 (90.1)	49/56 (87.5)	3.42 (2.24 to 4.62)	3.35 (2.15 to 4.73)

NOTE. Satisfaction with decision was assessed using the Satisfaction with Decision scale, which measured the rating of decision making. Questions were assessed with responses on a scale of strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree. The results are expressed as proportion of participants who responded strongly agree at 6 months postenrollment. A total of 79 (98.8%) participants in the control group and 80 (100%) participants in the intervention group completed this survey question at baseline (time of enrollment). The results are expressed as proportion of participants who responded "strongly agree" at time of assessment. A total of 74 participants (92.5%) in the control group and 71 (88.8%) in the intervention group completed this survey question at 4 months after study enrollment; 6 (7.5%) participants in the control group and 9 (11.3%) participants in the intervention group had died at the time of this 4-month assessment. A total of 59 participants (73.8%) in the control group and 56 (70.0%) in the intervention group completed this survey question at 12 months after study enrollment; 21 (26.3%) participants in the control group and 23 (28.8%) participants in the intervention group had died at the time of the 12-month assessment. The *P* value was estimated using generalized estimating equations comparing the change between groups overtime from baseline (time of enrollment) to 4 and 12 months postenrollment and adjusted city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage.

Abbreviation: GEE, generalized estimating equation.

[a]Ratios of odds ratios were estimated on the basis of responses between groups from baseline to 4 months and 12 months postenrollment using GEE-log binomial models clustered within participants with an exchangeable correlation structure. Outcomes were modeled as a function of treatment group, categorical time (4 months, 12 months, or baseline), an interaction term between treatment group and time, city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage. All ratios are expressed as referent to the control group.

intervention group participants had documentation. Compared with the control group, the intervention group had greater odds of GOC documentation at 4 months (OR, 9.20 [95% CI, 3.83 to 20.03]; $P < .001$) and 12 months (OR, 19.72 [95% CI, 8.43 to 46.12]; $P < .001$). At 4 months, 15 (18.8%) control group and 46 (57.5%) intervention group participants had AD documentation. At 12 months, 55 (68.8%) control group and 72 (90.0%) intervention group participants had documentation. Compared with the control group, the intervention group had greater odds of AD documentation at 4 months (OR, 6.53 [95% CI, 2.90 to 14.69]; $P < .001$) and 12 months (OR, 5.32 [95% CI, 1.78 to 15.93]; $P = .003$). At 4 months, 5 (6.3%) control group and 25 (31.3%) intervention group participants had POLST documentation. At 12 months, 13 (16.3%) control group and 33 (41.3%) intervention group participants had documentation. Compared with the control group, the intervention group had greater odds of POLST documentation at 4 months (OR, 4.79 [95% CI, 1.63 to 14.11]; $P = .004$) and 12 months (OR, 2.64 [95% CI, 1.15 to 6.08; $P = .02$; Fig 3; Appendix Table A3).

Health Care Use

Between baseline and 4 months, 15 (18.8%) control group and 12 (15.0%) intervention group participants had an ED visit. At 12 months, 24 (30.0%) control and 27 (33.8%) intervention participants had an ED visit. There were no statistically significant differences between groups in odds of any ED use at 4 months (OR, 0.75 [95 CI, 0.30 to 1.88]; $P = .54$) or 12 months (OR, 1.16 [95% CI, 0.54 to 2.49]; $P = .70$). However, compared with the control group, the frequency of ED use was lower among the intervention group at 4 months (IRR, 0.20 [95% CI,

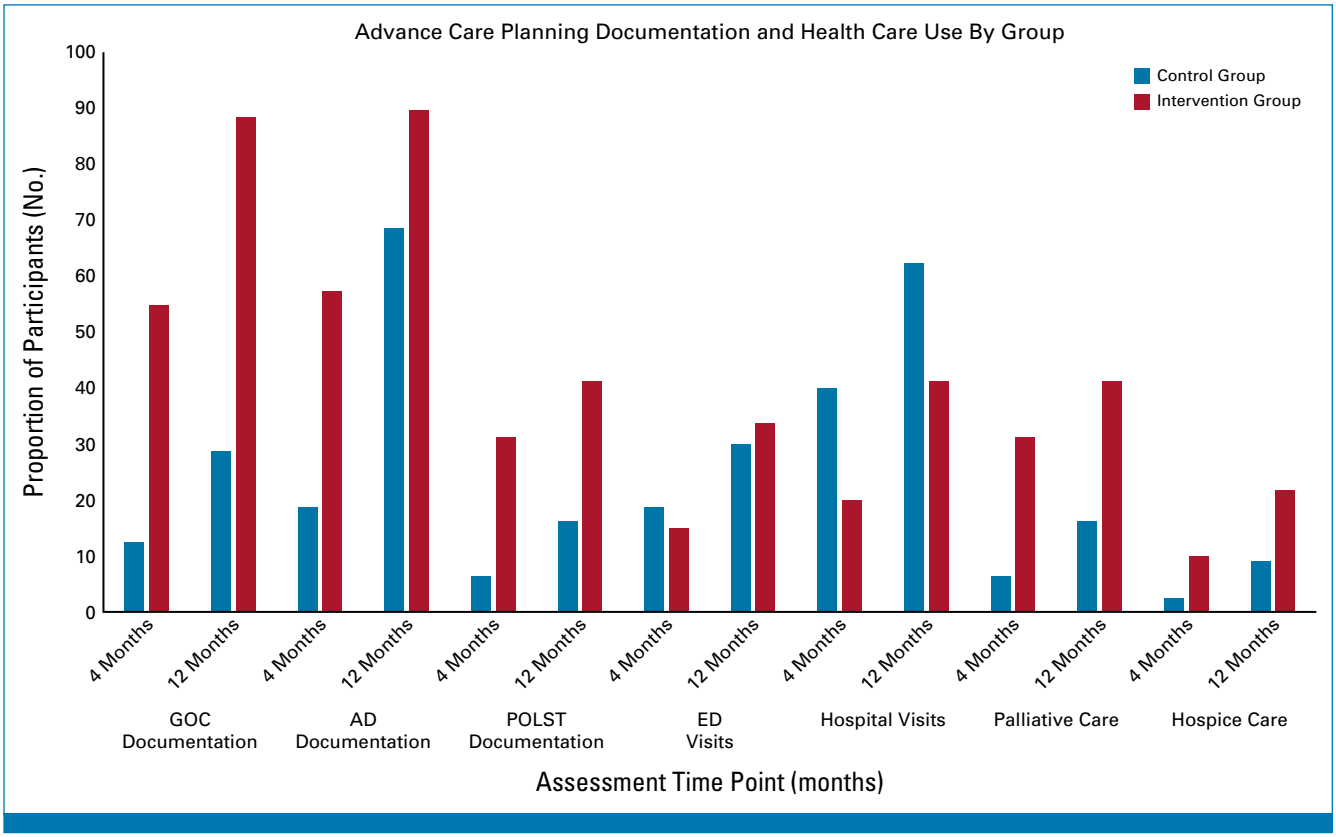

FIG 3. Advance care planning documentation and health care use by group. As compared with the control group, the intervention group had greater odds of GOC documentation at 4 months (OR, 9.20 [95% CI, 3.83 to 20.03]; $P < .001$) and 12 months (OR, 19.72 [95% CI, 8.43 to 46.12]; $P < .001$). Compared with the control group, the intervention group had greater odds of AD documentation at 4 months (OR, 6.53 [95% CI, 2.90 to 14.69]; $P < .001$) and 12 months (OR, 5.32 [95% CI, 1.78 to 15.93]; $P = .003$). Compared with the control group, the intervention group had greater odds of POLST documentation at 4 months (OR, 4.79 [95% CI, 1.63 to 14.11]; $P = .004$) and 12 months (OR, 2.64 [95% CI, 1.15 to 6.08; $P = .02$]). There were no statistically significant differences between groups in odds of any ED use at 4 months (OR, 0.75 [95 CI, 0.30 to 1.88]; $P = .54$) or 12 months (OR, 1.16 [95% CI, 0.54 to 2.49]; $P = .70$). However, compared with the control group, the frequency of ED use was lower among the intervention group at 4 months (IRR, 0.20 [95% CI, 0.11 to 0.34]; $P < .001$) and 12 months (IRR, 0.54 [95% CI, 0.35 to 0.85]; $P = .007$). Compared with the control group, the intervention group had lower odds of hospital use at 4 months (OR, 0.27 [95% CI, 0.12 to 0.61]; $P = .002$) and 12 months (OR, 0.32 [95% CI, 0.16 to 0.66]; $P = .002$) and less frequent use at 4 months (IRR, 0.45 [95% CI, 0.31 to 0.66]; $P < .001$) and 12 months (IRR, 0.41 [95% CI, 0.31 to 0.55]; $P < .001$). There were no significant differences in odds of palliative care use between groups at 4 months (OR, 5.72 [95% CI, 0.98 to 33.44]; $P = .05$) or 12 months (OR, 2.16 [95% CI, 0.71 to 6.62]; $P = .18$). There were no differences in odds of hospice use between groups at 4 months (OR, 2.04 [95% CI, 0.48 to 8.56]; $P = .33$); however, at 12 months, the intervention group had greater odds of hospice use (OR, 3.29 [95% CI, 1.17 to 9.22]; $P = .02$). AD, advance directive; ED, emergency department; GOC, goals of care; IRR, incidence rate ratios; OR, odds ratio; POLST, physician orders for life-sustaining treatment.

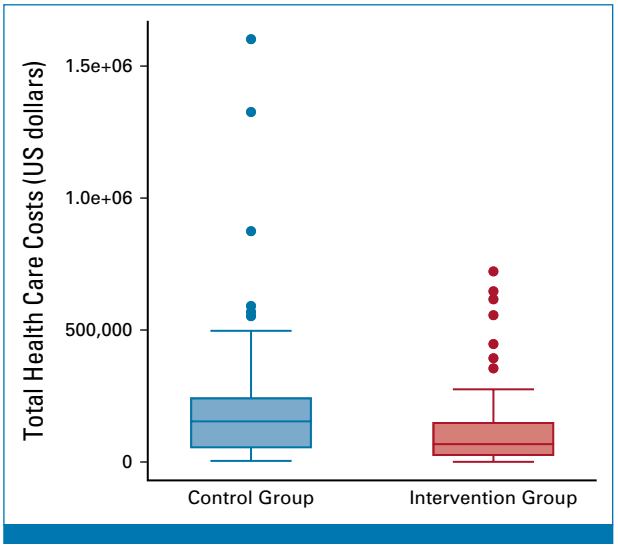

FIG 4. Total health care costs by group. At 12 months, the proportional change in total health care costs between groups referent to the control group was 0.61 (95% CI, 0.40 to 0.92); $P = .02$.

0.11 to 0.34]; $P < .001$) and 12 months (IRR, 0.54 [95% CI, 0.35 to 0.85]; $P = .007$; Fig 3, Appendix Table A4).

Between baseline and 4 months, 32 (40.0%) control group and 16 (20.0%) intervention group participants had hospital use. At 12 months, 50 (62.5%) control group and 33 (41.3%) intervention group participants had hospital use. Compared with the control group, the intervention group had lower odds of hospital use at 4 months (OR, 0.27 [95% CI, 0.12 to 0.61]; $P = .002$) and 12 months (OR, 0.32 [95% CI, 0.16 to 0.66]; $P = .002$) and less frequent use at 4 months (IRR, 0.45 [95% CI, 0.31 to 0.66]; $P < .001$) and 12 months (IRR, 0.41 [95% CI, 0.31 to 0.55]; $P < .001$). Between baseline and 4 months, 5 (6.3%) control group and 25 (31.3%) intervention group participants used specialty palliative care. At 12 months, 13 (16.3%) control group and 33 (41.3%) intervention group participants used specialty palliative care use. There were no significant differences in odds of palliative care use between groups at 4 months (OR, 5.72 [95% CI, 0.98 to 33.44]; $P = .05$) or 12 months (OR, 2.16 [95% CI, 0.71 to 6.62]; $P = .18$). Between baseline and 4 months, 2 (2.5%) control group and 8 (10.0%) intervention group participants had hospice use. At 12 months, 6 (9.2%) control group and 16 (21.9%) intervention group participants had hospice use. There were no differences in odds of hospice use between groups at 4 months (OR, 2.04 [95% CI, 0.48 to 8.56]; $P = .33$); however, at 12 months, the intervention group had greater odds of hospice use (OR, 3.29 [95% CI, 1.17 to 9.22]; $P = .02$).

Total Costs of Care

At 12 months, the intervention group had lower median total costs of care ($67,655 [USD]) than the control group ($153,980 [USD]) with a proportional change in total costs between groups of 0.61 (95% CI, 0.40 to 0.92; $P = .02$; Fig 4; Appendix Table A4).

Survival and End-of-Life Health Care Use and Total Costs of Care

At 12 months, 21 control group and 23 intervention group participants had died. Similar survival was observed between groups (Appendix Fig A1). There were few participants with end-of-life acute care use in either group. Three (14.3%) control and 1 (4.4%) intervention group participants had ED use. There were no statistically significant differences between groups in odds of ED use (OR, 0.25 [95% CI, 0.03 to 2.93]; $P = .28$) or frequency of use (IRR, 0.22 [95% CI, 0.03 to 2.02]; $P = .18$). Six (28.6%) control group and 3 (13.0%) intervention group participants had hospital use. There were no differences in odds of hospital use between groups (OR, 0.27 [95% CI, 0.05 to 1.51]; $P = .14$); however, compared with the control group, the intervention group had less frequent use (IRR, 0.22 [95% CI, 0.06 to 0.80]; $P = .02$). Six (28.6%) control group and 16 (69.6%) intervention group participants had palliative care and/or hospice use. Compared with the control group, the intervention group had greater odds of palliative care and/or hospice use (OR, 7.49 [95% CI, 1.72 to 22.51]; $P = .007$). The median total costs in the 30 days before death was $6,211 (USD) among the control group and $5,471 (USD) among the intervention group, without significant differences in proportional change between groups (OR, 0.59 [95% CI, 0.29 to 1.19]; $P = .14$; Appendix Fig A1 and Table A5).

DISCUSSION

In this randomized clinical trial, a CHW-led ACP, symptom screening, and HRSN intervention (LEAPS) improved HRQoL among low-income and racial and ethnic minoritized hourly low-wage workers with solid tumor cancers and hematologic malignancies more than usual cancer care alone. The results demonstrate LEAPS' effectiveness in overcoming persistent gaps in delivery of these services for these populations.

Despite national guidelines recommending ACP and cancer symptom management after diagnosis,[28] low-income and racial and ethnic minoritized populations are half as likely to receive such care than affluent and White populations.[29-33] The few interventions that exist are narrowly focused on either ACP or symptom management and include church-based education and clinic-based interventions.[34-38] In this study, we report the robust effect of LEAPS, a comprehensive, employer health fund-based CHW-led intervention, on HRQoL and patient activation among low-income and racial and ethnic minoritized hourly, low-wage workers, supporting LEAPS' impact on participants' improvement in quality of life and ability to advocate for and manage their health and care. As in our previous work, LEAPS reduced hospital use and frequency of both ED and hospital use at 4 and 12 months and at the end-of-life, supporting LEAPS' effects on reducing severe symptoms and

other adverse events that may lead to unplanned, costly acute care. The consequential reduction in total costs of care is likely a reflection of the effect on acute care use, hospice use, and, as studies show, patient activation.[39,40]

Limitations include our focus on one organization. Although we implemented and evaluated LEAPS in two cities, generalizability may be limited. Second, participant accrual took longer than anticipated given small numbers of eligible participants and partial enrollment during the COVID-19 pandemic. Third, we did not conduct a subgroup analysis by cancer diagnosis or treatment and had a limited end-of-life subgroup analysis given the small number of participants who died by 12 months. In addition, we did not obtain comorbidity data. Finally, we were unable to evaluate the independent intervention effects such as the HRSN component or the redesigned benefits and reimbursement models which may induce larger effects among low-income and minoritized populations and could limit generalizability.

Key study strengths are longitudinal evaluation of HRQoL which allowed us to account for potential declines because of cancer progression or clinical conditions. In our analyses, the effect on HRQoL sustained at 12 months. Second, our 100% retention was likely due to strong collaboration and years of prior work establishing bidirectional relationships with community partners. Finally, collaboration with UHH allowed claims-based analyses on health care use and costs—outcomes infrequently assessed in randomized cancer studies.

This CHW-led intervention is an effective strategy that may mitigate the impact of structural racism on ACP and cancer symptom management among low-income and racial and ethnic minoritized populations in community-based outpatient cancer clinics.

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DISCLAIMER

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The National Institutes of Health did not participate in the design and conduct of the study; collection, management, analysis and interpretation of the data; preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication. M.I.P. and K.K. had full access to all the data in this study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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CLINICAL TRIAL INFORMATION

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Effect of a Community Health Worker–Led Intervention Among Low-Income and Minoritized Patients With Cancer: A Randomized Clinical Trial

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No other potential conflicts of interest were reported.

APPENDIX

TABLE A1. Change in HRQoL Between Groups From Baseline to 4 and 12 Months

Variable	Total (N = 160)	Control Group	Intervention Group	Expected Mean Difference Between Groups From Baseline (95% CI)[a]	*P*[b]
HRQoL (FACT-G) mean ± SD, score[c]					
Baseline	73.8 ± 16.1	74.1 ± 16.5	73.5 ± 15.8	—	
4 months	75.4 ± 17.4	70.3 ± 16.8	80.7 ± 16.4	11.25 (7.28 to 15.22)	<.001
12 months	78.8 ± 16.9	73.3 ± 15.6	84.4 ± 16.5	11.29 (6.96 to 15.62)	

Abbreviations: FACT-G, Functional Assessment of Cancer Therapy-General; GEE, generalized estimating equation; HRQoL, health-related quality of life.

[a]Effect estimates were expected mean differences in HRQoL scores (see below) between groups from baseline. Effect estimates were estimated using GEE models as a function of treatment group, categorical time (baseline, 4 months and 12 months), and an interaction term between treatment group and time with an exchangeable correlation clustered within person and adjusted for city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis and cancer stage. The effect estimate column shows the difference between change in the intervention group from baseline and the change in the control group from baseline.

[b]*P* values were estimated using a type III F-test to determine significance of the interaction effect between time point and group.

[c]HRQoL was assessed using the 27-item FACT-G where scores range from 0-108 with higher scores indicating better HRQoL. A clinically meaningful delta change is four points. A total of 74 participants (92.5%) in the control group and 71 (88.8%) in the intervention group completed this survey question at 4 months after study enrollment. Missingness was only observed because of death among 6 (7.5%) participants in the control group and 9 (11.3%) participants in the intervention group who had died before this 4-month assessment. A total of 59 participants (73.8%) in the control group and 57 (71.3%) in the intervention group completed this survey question at 12 months after study enrollment. Missingness was only observed because of death among 21 (26.3%) participants in the control group and 23 (28.8%) participants in the intervention group who had died before this 12-month assessment. All participants with missingness because of death before the assessment at each time period were assigned a score of 0 (worse possible value for HRQoL) in this sensitivity analysis.

TABLE A2. Sensitivity Analysis for the Effect on HRQoL

Variable	Total (N = 160)	Control Group (n = 80)	Intervention Group (n = 80)	Expected Mean Difference Between Groups From Baseline (95%CI)[a]	*P*[b]
Baseline	73.8 ± 16.1	74.1 ± 16.5	73.5 ± 15.8	—	
4 months	68.2 ± 27.6	54.0 ± 35.1	64.9 ± 24.7	7.18 (2.18 to 16.54)	<.001
12 months	57.1 ± 38.1	60.1 ± 40.9	71.7 ± 29.9	7.93 (2.16 to 20.66)	

NOTE. HRQoL was assessed using the 27-item FACT-G where scores range from 0-108 with higher scores indicating better HRQoL. A clinically meaningful delta change is 4 points. A total of 74 participants (92.5%) in the control group and 71 (88.8%) in the intervention group completed this survey question at 4 months after study enrollment. Missingness was only observed because of death among 6 (7.5%) participants in the control group and 9 (11.3%) participants in the intervention group who had died before this 4-month assessment. A total of 59 participants (73.8%) in the control group and 57 (71.3%) in the intervention group completed this survey question at 12 months after study enrollment. Missingness was only observed because of death among 21 (26.3%) participants in the control group and 23 (28.8%) participants in the intervention group who had died before this 12-month assessment. All participants with missingness because of death before the assessment at each time period were assigned a score of 0 (worse possible value for HRQoL) in this sensitivity analysis.

Abbreviations: FACT-G, Functional Assessment of Cancer Therapy-General; GEE, generalized estimating equation; HRQoL, health-related quality of life.

[a]Effect estimates were expected mean differences in HRQoL scores (see below) between groups from baseline. Effect estimates were estimated using GEE models as a function of treatment group, categorical time (baseline, 4 months and 12 months), and an interaction term between treatment group and time with an exchangeable correlation clustered within person and adjusted for city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis and cancer stage. The effect estimate column shows the difference between change in the intervention group from baseline and the change in the control group from baseline.

[b]*P* values were estimated using a type III F-test to determine significance of the interaction effect between time point and group.

TABLE A3. Patient Activation and Advance Care Planning Documentation by Group

Variable	Total (N = 160)	Control Group (n = 80)	Intervention Group (n = 80)	Effect Estimates and ORs (95% CI)	*P*
Patient activation (PAM-13), mean ± SD, score[a]					
Baseline	53.4 ± 9.99	53.5 ± 10.3	53.4 ± 9.80	—	
4 months	59.5 ± 14.7	53.3 ± 10.1	65.9 ± 14.7	12.77 (9.07 to 16.46)	<.001
12 months	67.5 ± 14.9	57.6 ± 10.8	77.7 ± 11.2	19.63 (15.59 to 23.67)	<.001
Goals of care documentation, No. (%)[b]					
Baseline	1 (0.6)	1 (1.3)	0 (0)	—	
4 months	54 (33.8)	10 (12.5)	44 (55.0)	9.20 (3.83 to 22.03)	<.001
12 months	94 (58.8)	23 (28.8)	71 (88.8)	19.72 (8.43 to 46.12)	<.001
Advance directive documentation, No. (%)[b]					
Baseline	1 (0.6)	1 (1.3)	0 (0)	—	
4 months	61 (38.1)	15 (18.8)	46 (57.5)	6.53 (2.90 to 14.69)	<.001
12 months	127 (79.4)	55 (68.8)	72 (90.0)	5.32 (1.78 to 15.93)	.003
Physician order for life-sustaining treatment documentation, No. (%)[b]					
Baseline	0 (0)	0 (0)	0 (0)	—	
4 months	30 (18.8)	5 (6.3)	25 (31.3)	4.79 (1.63 to 14.11)	.004
12 months	46	13 (16.3)	33 (41.3)	2.64 (1.15 to 6.08)	.02

Abbreviations: GEE, generalized estimating equation; OR, odds ratio; PAM-13, patient activation measure-13; SD, standard deviation.

[a]Patient activation was assessed with the use of the 13-item Patient Activation Measure. Scores range from 0-100 with higher scores indicating greater patient activation. A total of 79 participants (98.8%) in the control group and 80 participants (100%) in the intervention group completed this survey at baseline. A total of 74 participants (92.5%) in the control group and 71 participants (88.8%) in the intervention group completed this survey at 4 months after study enrollment. Missingness was only observed because of death among 6 (7.5%) participants in the control group and 9 (11.3%) participants in the intervention group who had died before the 4-month assessment. A total of 58 participants (72.5%) in the control group and 57 participants (71.3%) in the intervention group completed this survey at 12 months after study enrollment. Missingness was only observed because of death among 21 (26.3%) participants in the control group and 23 (28.8%) participants in the intervention group who had died before this 12-month assessment. Effect estimates were expected mean differences in Patient Activation Measure scores between groups from baseline. Effect estimates were estimated using GEE models as a function of treatment group, categorical time (baseline, 4 months and 12 months), an interaction term between treatment group and time, and with an exchangeable correlation clustered within person. Models were adjusted for city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage. The effect estimate column shows the difference between change in the intervention group from baseline and the change in the control group from baseline.

[b]ORs for goals of care documentation, advance directive documentation, and physician order for life-sustaining treatment documentation were estimated on the basis of assessments 4 months and 12 months postenrollment with logistic regression models adjusted for city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage.

TABLE A4. Health Care Use and Total Costs of Care by Group

Variable	Total (N = 160)	Control Group (n = 80)	Intervention Group (n = 80)	OR, IRRs, and Proportional Change (95% CI)	*P*
Any ED visit use, No. (%)[a]					
4 months	27 (16.9)	15 (18.8)	12 (15.0)	0.75 (0.30 to 1.88)	.54
12 months	51 (31.9)	24 (30.0)	27 (33.8)	1.16 (0.54 to 2.49)	.70
Mean ED visits, mean ± SD[b]					
4 months	0.54 ± 1.79	0.83 ± 2.29	0.26 ± 1.00	0.20 (0.11 to 0.34)	<.001
12 months	0.61 ± 1.50	0.77 ± 1.99	0.44 ± 0.71	0.54 (0.35 to 0.85)	.007
Any hospital visit, No. (%)[a]					
4 months	48 (30.0)	32 (40.0)	16 (20.0)	0.27 (0.12 to 0.61)	.002
12 months	83 (51.9)	50 (62.5)	33 (41.3)	0.32 (0.16 to 0.66)	.002
Mean hospital visits, mean ± SD[b]					
4 months	0.80 ± 1.26	1.11 ± 1.35	0.49 ± 1.09	0.45 (0.31 to 0.66)	<.001
12 months	1.51 ± 1.28	2.06 ± 2.29	0.96 ± 1.27	0.41 (0.31 to 0.55)	<.001
Palliative care receipt, No. (%)[c]					
4 months	30 (18.8)	5 (6.3)	25 (31.3)	5.72 (0.98 to 33.44)	.05
12 months	46 (28.8)	13 (16.3)	33 (41.3)	2.16 (0.71 to 6.62)	.18
Hospice receipt, No. (%)[c]					
4 months	10 (6.3)	2 (2.5)	8 (10.0)	2.04 (0.48 to 8.56)	.33
12 months	22 (15.9)	6 (9.2)	16 (21.9)	3.29 (1.17 to 9.22)	.02
Total health care costs, US dollars, median (IQR)[d]					
12 months	96,635.30 (37,221.48-20,869.20)	153,980.60 (52,612.08-243,751.00)	67,654.97 (23,601.07-150,670.06)	0.61 (0.40 to 0.92)	.02

Abbreviations: ED, emergency department; GEE, generalized estimating equation; IRRs, incidence rate ratios; OR, odds ratio; SD, standard deviation.

[a]OR for any ED use and any hospitalization use were estimated using logistic regression models adjusted for city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage.

[b]IRRs were estimated using Poisson models offset for follow-up time and adjusted for city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage with each time point (4-month and 12-month estimates) modeled separately. All ratios are expressed as referent to the control group.

[c]ORs for palliative care receipt and hospice receipt were estimated on the basis of assessments 4 months and 12 months postenrollment compared with baseline (time of enrollment) using logistic regression and adjusted for city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage.

[d]Proportional change in total health care costs are expressed as referent to the control group and were modeled using a generalized linear model with gamma link-log function to account for skewed cost data after adjustment for length of follow-up, city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage.

TABLE A5. Health Care Use and Total Costs of Care by Group in the Last 30 Days of Life

Variable	Total (N = 44)	Control Group (n = 21)	Intervention Group (n = 23)	Effect Estimates	*P*
Any ED visit use, No. (%)[a]	4 (9.1)	3 (14.3)	1 (4.4)	0.25 (0.03-2.93)	.28
Mean ED visits, mean ± SD[b]	0.11 ± 0.39	0.19 ± 0.51	0.04 ± 0.21	0.22 (0.03-2.02)	.18
Any hospital visit, No. (%)[a]	9 (20.5)	6 (28.6)	3 (13.0)	0.27 (0.05-1.51)	.14
Mean hospital visits, mean ± SD[b]	0.32 ± 0.71	0.52 ± 0.93	0.13 ± 0.34	0.22 (0.06-0.80)	.02
Palliative care receipt, No. (%)[a]	22 (50.0)	6 (28.6)	16 (69.6)	7.49 (1.72-22.51)	.007
Hospice receipt, No. (%)[a]	22 (50.0)	6 (28.6)	16 (69.6)	7.49 (1.72-22.51)	.007
Total health care costs, $, USD, median (IQR)[c]	6,055 (419.82-14,169)	6,211 (2,500-18,221)	5,471 (0-10,752)	0.59 (0.29-1.19)	.14

NOTE. Estimates are based on the sample of 21 participants in the control group and 23 participants in the intervention group who died within 12 months of study enrollment.

Abbreviations: ED, emergency department; IRR, incidence rate ratios; SD, standard deviation; USD, US dollars.

[a]Odds ratios for any ED use and any hospitalization use, palliative care, and hospice receipt were estimated using logistic regression models adjusted for city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage.

[b]IRR were estimated using Poisson models adjusted for city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage. All ratios are expressed as referent to the control group.

[c]Proportional change in total health care costs are expressed as referent to the control group and were modeled using a generalized linear model with gamma link-log function to account for skewed cost data and adjusted for city, age, sex, race and ethnicity, annual household income, education level, cancer diagnosis, and cancer stage.

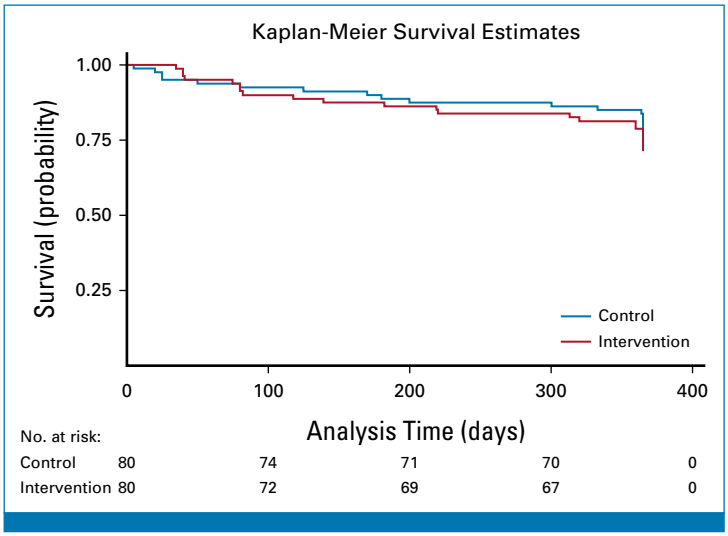

FIG A1. Survival by treatment group.