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Emergency Department–Initiated Palliative Care in Advanced Cancer:

A Randomized Clinical Trial

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Abstract

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Acquisition, analysis, or interpretation of data: Grudzen, Richardson, Johnson, Hu, Wang, Ortiz, Kistler, Chen.
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Conflict of Interest Disclosure: None reported.

IMPORTANCE—The delivery of palliative care is not standard of care within most emergency departments (EDs).

OBJECTIVE—To compare quality of life, depression, health care utilization, and survival in ED patients with advanced cancer randomized to ED-initiated palliative care consultation vs care as usual.

DESIGN, SETTING, AND PARTICIPANTS—A single-blind, randomized clinical trial of ED-initiated palliative care consultation for patients with advanced cancer vs usual care took place from June 2011 to April 2014 at an urban, academic ED at a quaternary care referral center. Adult patients with advanced cancer who were able to pass a cognitive screen, had never been seen by palliative care, spoke English or Spanish, and presented to the ED met eligibility criteria; 136 of 298 eligible patients were approached and enrolled in the ED and randomized via balanced block randomization.

INTERVENTIONS—Intervention participants received a comprehensive palliative care consultation by the inpatient team, including an assessment of symptoms, spiritual and/or social needs, and goals of care.

MAIN OUTCOMES AND MEASURES—The primary outcome was quality of life as measured by the change in Functional Assessment of Cancer Therapy–General Measure (FACT-G) score at 12 weeks. Secondary outcomes included major depressive disorder as measured by the Patient Health Questionnaire-9, health care utilization at 180 days, and survival at 1 year.

RESULTS—A total of 136 participants were enrolled, and 69 allocated to palliative care (mean [SD], 55.1 [13.1] years) and 67 were randomized to usual care (mean [SD], 57.8 [14.7] years). Quality of life, as measured by a change in FACT-G score from enrollment to 12 weeks, was significantly higher in patients randomized to the intervention group, who demonstrated a mean (SD) increase of 5.91 (16.65) points compared with 1.08 (16.00) in controls ($P = .03$ using the nonparametric Wilcoxon test). Median estimates of survival were longer in the intervention group than the control group: 289 (95% CI, 128-453) days vs 132 (95% CI, 80-302) days, although this did not reach statistical significance ($P = .20$). There were no statistically significant differences in depression, admission to the intensive care unit, and discharge to hospice.

CONCLUSIONS AND RELEVANCE—Emergency department–initiated palliative care consultation in advanced cancer improves quality of life in patients with advanced cancer and does not seem to shorten survival; the impact on health care utilization and depression is less clear and warrants further study.

TRIAL REGISTRATION—clinicaltrials.gov Identifier: NCT01358110

A report by the Institute of Medicine[1] delineated many barriers to improving cancer care at the end of life, including the historical separation of palliative or hospice care from other health care environments. The emergency department (ED) serves as the health care safety net for society's most vulnerable, with both ethnic and/or racial minorities and the poor presenting to the ED for care in disproportionate numbers.[2-4] Despite this, care within the ED has not been realigned to better reflect this population's needs or goals.

For patients with advanced cancer, visits to the ED are common,[5,6] often because patients are in physical and/or emotional crisis.[7-9] During these visits, decisions are made about the intensity of care, including whether to admit (and to what level of care) and whether to begin life-sustaining therapies, such as intubation or other invasive procedures. Although the availability of palliative care services continues to increase,[10-13] consultation typically does not occur until a week into a patient's hospital stay.[14,15] Thus, the ED presents a key decision point at which physicians set the subsequent care trajectory during a hospitalization.

Because hospice use has increased in patients with cancer at the end of life, intensive care unit (ICU) use has also increased in the last month of life, from 24% to 29%.[16] ED to ICU admissions are increasing at a rate greater than population growth and are outpacing ED use.[17] Patients' main concerns at the end of life include maintaining control, relieving burdens, and strengthening family relationships,[18] which may conflict with ICU admission. Physicians often fail to initiate discussion of patients' goals of care, despite the fact that those discussions are well received by patients and cause minimal distress.[19]

Data suggest that early palliative care consultation can improve quality of life (QOL), decrease hospital length of stay and ICU admission, and may even extend life.[14,20-24] Better matching of patients' goals of care to treatments would not only result in better concordance of ED disposition with patients' preferred site of care, but also might decrease ICU admissions at the end of life and increase referrals to hospice. A consultation prompted from the ED may be a unique point at which to ensure that care is congruent with patients' wishes and interrupt the cascade of intensive, end-of-life care that could be a marker of low-quality care. To compare QOL, depression, health care utilization, and survival for ED patients with advanced cancer, we conducted a single-blind randomized clinical trial (RCT) of ED-initiated palliative care consultation vs usual care.

Methods

Study Design

To evaluate the impact of ED-initiated palliative care consultation on QOL, depression, health care utilization, and survival in patients with advanced cancer, we conducted a patient-level, single center, single-blind pilot RCT of 136 participants. The institutional review board at the Icahn School of Medicine at Mount Sinai approved all study procedures, and every participant provided written, informed consent. Patients were offered a $20 gift card as an incentive to participate. See the trial protocol in Supplement 1.

Setting

Mount Sinai Hospital (MSH) is a quaternary care, academic referral center in New York City, and the MSH ED is an active, urban emergency department. Annually, approximately 100 000 patient visits are seen in the ED's adult and pediatric divisions. The ED provides patient care 24 hours per day, 7 days per week, to all who seek care. The trial was conducted in the flow of routine patient care.

Participants

Research assistants screened the electronic medical record ED track board for patients with our specific advanced cancer staging criteria (see eTable 1 in Supplement 2) 8 to 12 hours a day Sunday through Friday. Medical oncologists at our institution were able to opt out of participation. Of 79 full-time medical oncology faculty at MSH, all but 1 agreed to have any of their patients enrolled in the study. All voluntary medical oncologists were called in real-time prior to approaching any of their patients who were eligible to participate. Patients eligible for participation were those with a known advanced cancer that met our staging criteria, who were able to speak English or Spanish fluently, and who were being admitted to or observed in the hospital. Patients were excluded if they were unable to answer questions because of severe pain or lethargy, if they had been seen by palliative care in the past, or if they had evidence of cognitive impairment based on the 6-item screener.[25] Patients planning to leave the immediate geographic area (ie, move to another state or country) were also excluded.

Intervention

Randomization and Blinding—After the baseline survey was completed, the research coordinator then relayed the participant information to a separate research staff member (the “randomizer”) with no role in study recruitment, follow-up, or analysis. Participants were randomized via prespecified balanced block randomization in blocks of 50. If the participant was assigned to the intervention group, the randomizer then paged the palliative care consultation team to relay information about the participant (name, medical record number, ED attending, and oncologist of record) and the reason for consultation. If assigned to the usual care group, no further action was necessary. The list linking participant name and group assignment was stored on a secure network computer under password protection, and was accessible only to the randomizer. All research staff involved in recruitment and follow-up were blind to participant assignment. It was not feasible to blind participants or care providers to participant assignment. See the eFigure in Supplement 2 for the CONSORT flow diagram demonstrating subject flow through each stage of the study.

Intervention Arm—If the participant was assigned to the intervention arm, the palliative care team was consulted within a few hours. Intervention participants received a comprehensive palliative care consultation by the inpatient team on the same or following day. At MSH, inpatient comprehensive palliative care consultation consists of 3 components: (1) symptom assessment and treatment, (2) goals of care and advance care plans, and (3) transition planning. The palliative care team is composed of a physician, a nurse practitioner, a social worker, and a chaplain. The team uses validated symptom assessments to make recommendations for symptom management using National Comprehensive Cancer Network (NCCN) guidelines.[26] They communicate these recommendations to consulting physicians (in this case, the oncologist or hospitalist) verbally, either in person or by telephone, and electronically through standardized palliative care team medical chart notes. The palliative care team meets with patients, families, and care teams to identify goals of care, complete advance directives, and communicate difficult news (if requested) using standardized communication protocols. If admitted, the team sees patients daily to monitor implementation and results of treatment recommendations and to assess for new and

ongoing symptoms. Reassessment and treatment modifications occur as needed to achieve goals of care. The palliative care team conducts or assists with discussions about new or changing goals of care, communicates bad news, and adjusts treatments accordingly. The team also works with the patients' social workers and family to facilitate transition management consistent with goals of care. If the team finds ongoing palliative care needs that are expected to continue after discharge, they refer patients to the outpatient palliative care clinic.

Usual Care Arm—Participants assigned to the usual care arm completed the same baseline interviews and follow-up as intervention participants. If requested by the admitting team or oncologist of record, usual care participants may also have received a palliative care consultation.

Outcome Measures

Outcomes were specified ahead of time. The primary outcome was the measure of the change score of the QOL at 12 weeks. Secondary outcomes included survival at 1 year, health care utilization at 180 days (hospital days, hospice use, and ICU admission), and major depressive disorder at 12 weeks.

Data Collection and Management

Patient-Reported Outcomes—A face-to-face English or Spanish survey was administered to the participant in the ED prior to randomization. The survey included questions regarding demographics, including sex, race/ethnicity, marital status, income, education, religious affiliation, type of residence, history of an advance directive or designation of a health care proxy, and health insurance; functional performance status was measured using the Eastern Oncology Cooperative Group score (ECOG)[27]; QOL was measured using the Functional Assessment of Cancer Therapy-General Measure (FACT-G)[28]; and the 9-item Patient Health Questionnaire-9 (PHQ-9)[29] was used to screen for depression. Quality of life and depression were measured again at 6 and 12 weeks, either by telephone or in person during a scheduled follow-up visit. The 6-week measurement was added 1 month into the protocol because a large proportion of our first participants died before the 12-week follow-up.

Measures of Health Care Use—Measure of Health Care use outcome data was collected via the electronic medical record. Administrative data review using the Mount Sinai Data Warehouse was used for health care utilization and billing information. For the medical chart and administrative data review, a codebook was created, and the research coordinator performing medical chart abstraction was blinded to participant assignment.

Statistical Analysis

Statistical analyses were performed using SAS software (version 9.3.2; SAS Institute Inc). Descriptive statistics were used to estimate the frequencies, and means (SDs) of the study variables. Difference between the intervention group and the usual care group in baseline characteristics and outcomes were assessed with the use of 2-sided Fisher exact tests and χ^2 tests for categorical variables, and independent 2-sample *t* tests and Wilcoxon rank

tests for continuous variables. Multivariate logistic regression analyses, adjusted for baseline scores, were used to examine the effect of the intervention on depression. We used an intention-to-treat analysis. We chose a conservative method of carrying baseline values forward to account for missing depression and QOL follow-up measures. Survival time was calculated from the date of enrollment to the date of death using the Kaplan-Meier method, and the difference of survival time between the intervention and the usual care group was compared using the Log-rank test. $P < .05$ was considered statistically significant. Please refer to our published protocol for additional methodological and logistical details.[30]

Results

Baseline Characteristics of the Participants

A total of 311 patients were approached for participation out of 1872 patients who were screened for eligibility between June 2011 through April 2014; 175 patients were excluded (see the eFigure in Supplement 2 for reasons of exclusion); 136 participants were enrolled in the study and randomized to the intervention group and the usual care group in a 1:1 ratio. The baseline demographic characteristics were well matched between the 2 study groups as outlined in the Table (see eTable 2 in Supplement 2 for the full table).

Survival Analysis

Among the 69 participants in the intervention group, 41 had died by the 1-year mark; 44 of the 67 participants in the usual care group had died. Median estimates of survival in the intervention group (289 days; 95% CI, 128-453 days) were longer than the median survival in the usual care group (132 days; 95% CI, 80-302 days). However, this difference did not reach statistical significance (log-rank test $P = .20$) at the end of the trials (Figure 1C), or with censoring at 180 days or 365 days (Figure 1A and B).

Quality of Life

Participants assigned to the intervention group had significantly higher QOL outcome than the participants assigned to the usual care group. We first measured QOL at baseline using the FACT-G (Figure 2). Compared with the baseline, the participants in the intervention group had an increase of 4.78 points on the FACT-G at week 6 (SD, 12.00), while the participants in the usual care group had an increase of 1.52 points (SD, 15.00), which was not statistically significant (Wilcoxon rank test $P = .054$). Compared with the baseline, participants in the intervention group had a statistically significant increase of 5.91 points on the FACT-G at week 12 (SD, 16.65), compared with an increase of 1.08 points in usual cares (SD, 16.00; Wilcoxon rank test $P = .03$).

Mood Symptoms—Major Depressive Disorder

Major depressive disorder was coded as a binary variable (yes/no), and the proportion with depression at baseline, 6 weeks, and 12 weeks by group are demonstrated in Figure 3. We found that depression was well balanced between the intervention group and the usual care group at baseline (χ^2 test $P = .49$), and that there were no significant differences at week 6 (χ^2 test $P = .61$) or week 12 from baseline between the 2 groups (χ^2 test $P = .82$). To evaluate the intervention's effect on change in major depressive disorder, we fitted logistic

regression models controlling for baseline depression. Using the presence of depression at 6 weeks, the logistic regression analysis showed that the intervention effect was not statistically significant ($P = .97$). The results were similar for the analysis at week 12 ($P = .46$).

Health Care Utilization

Hospice Use—We compared hospice use between the intervention group and the usual care group at 180 days (see eTable 3 in Supplement 2). Although hospice use was slightly higher in the intervention group, 28% vs 25% in the usual care group, we found no significant difference in hospice usage between the 2 groups (χ^2 test $P = .93$; Fisher exact test $P = .85$).

Hospital Days—We compared hospital days between the intervention group and the usual care group both for the index-admission and up to 180 days. We truncated the hospital days at 180 days for 5 participants with a length of stay that crossed the 180-day mark. See eTable 4 in Supplement 2, which lists the summary statistics (mean [SD]) for inpatient days. We found no significant difference in hospital days between the intervention and usual care groups during the index-admission (Wilcoxon test $P = .67$). The intervention group had slightly more hospital days at 180 days than the usual care group, although this was not statistically significant (Wilcoxon test $P = .14$).

ICU Admission—We compared ICU admission between the intervention group and the usual care group during the index-admission and at 180 days. Since only 1 participant had more than 1 ICU admission, we treated the ICU admission as a binary outcome. See eTable 5 in Supplement 2 which lists 2 contingency tables for the ICU admission analysis. During the index-admission, there was no statistically significant difference between the 2 groups (see eTable 5A in Supplement 2) (Fisher exact test $P > .99$). Similarly, for the ICU admission up to 180 days, there was no statistically significant difference between the 2 groups (see eTable 5B in Supplement 2) (Fisher exact test $P > .99$).

Discussion

Herein, we present results from the first trial of ED-initiated palliative care in advanced cancer, proving that early referral to palliative care significantly improves QOL and does not seem to have a negative impact on survival. Quality of life was significantly higher in participants randomized to the intervention group, who demonstrated a statistically and clinically meaningful increase in QOL at 12 weeks ($P < .05$ using the nonparametric Wilcoxon test).[31,32] Median survival was almost 5 months longer in the intervention group. The lack of statistical significance was due to the highly variable length of survival in our cohort. It is likely that a future trial that limits enrollment to patients at a similar stage in their disease, and thus has a less variable length of survival from enrollment, would both find a similar survival benefit and reach statistical significance.

While of obvious importance to patients, these findings are also tremendously important to hospitals and policymakers who are concerned with initiating palliative care earlier in the disease course. The results of a recently completed trial of early vs delayed palliative

care in cancer by Bakitas et al[24] demonstrate a survival benefit at the 1 year mark for early-entry participants. This study demonstrates that we can now generalize from what we already know about palliative care in metastatic non–small-cell lung cancer to other advanced cancers.[20] The results presented herein also add to the knowledge base about palliative care and cancer by demonstrating similar effects with a different population and setting. Despite tremendous racial, ethnic, and socioeconomic diversity in our cohort, as well as variability in cancer type and functional status, we were able to illustrate similar improvements in QOL. In addition, participants randomized to the intervention group in our study lived 4.9 months longer than those in usual care, although this difference was not statistically significant because of the heterogeneity of survival among our participants. This should not only be reassuring to hospitals who hope to initiate palliative care triggers from the ED but also provoke further interest among policymakers hoping to find ways to decrease disparities in access to palliative care. It is well established that large disparities exist in cancer survival for racial/ethnic minorities and that these groups are more likely to access the ED for care. While integrated models of palliative care in oncology clinics are critical to beginning palliative care early in the course of disease, they may miss important, vulnerable populations who use the ED in disproportionate numbers.

The impact of palliative care on health care utilization in this study is more nuanced. We found, overall, that palliative care did not have a significant impact on hospital days, ICU admission, or hospice use, although the study was not powered to assess differences in these outcomes. In fact, although not statistically significant, hospital days at the 180-day mark were, on average, longer in the group randomized to palliative care. We are not surprised by this finding because patients present to the ED for a variety of physical, social, and psychological reasons, and addressing them during an inpatient stay takes time. It is also important to note that palliative care is not synonymous with end-of-life care, and one of the primary goals of palliative care is to align the care plan with a patient's goals, regardless of whether these goals include the pursuit of invasive, life-sustaining procedures, admission to the ICU, or discharge to hospice.

Future research must examine ways in which we can more accurately measure patient goals and evaluate whether care plans run concordant to these wishes. This is also a limitation to our work, in which we were unable to ascertain whether ICU admission or hospice referral was a reflection of a patient's goals of care or, rather, whether it simply was a reflection of what the system and team offered the patient. Another limitation inherent to the design of research in any population with limited life expectancy is missing data, insofar as many patients do not survive to complete follow-up. We accounted for this in our analysis by using the conservative methods of carrying the last value forward for missing follow-up data on depression and QOL, as was done by Temel et al.[20]

Conclusions

We found that initiating palliative care in the ED for patients with advanced cancer improved QOL and did not seem to shorten survival. Given the diversity of the ED population and its often limited access to specialty care, this is an important place to initiate palliative care consultation. The impact on depression, hospital days, ICU admission, and hospice is less

clear, and better ways of measuring whether care plans are congruent with patient goals are sorely needed.

Emergency department–initiated palliative care consultation improves QOL in patients with advanced cancer and does not seem to shorten survival; the impact on health care utilization and depression is less clear and warrants further study.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Role of the Funder/Sponsor:

The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

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Key Points

Question:

Does palliative care in the emergency department affect quality of life, depression, health care use, and survival in patients with advanced cancer?

Findings:

In this randomized clinical trial, patients with advanced cancer who were offered emergency department–initiated palliative care vs usual care had statistically significant better quality of life at 12 weeks with no significant difference in survival rates at 1 year.

Meaning:

Emergency department–initiated palliative care improves quality of life without shortening survival.

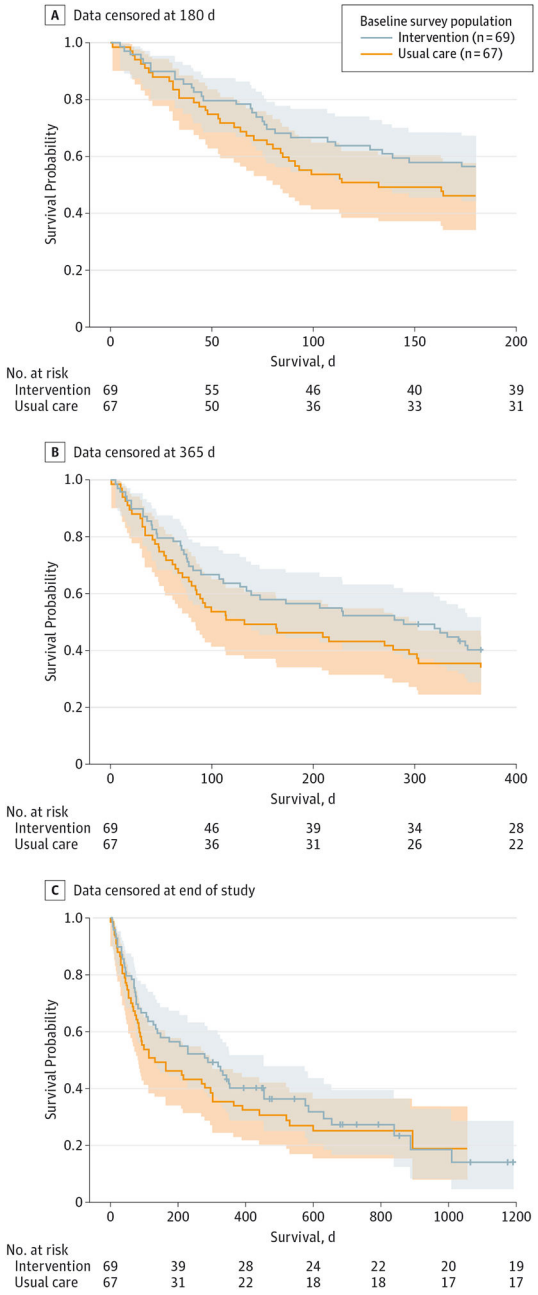

Figure 1. Kaplan-Meier Estimates of Survival According to Study Group of 136 Patients

Survival was calculated from the time of enrollment to the time of death, if it occurred during the study period, or to the time of censoring of data.

Median estimates of survival were 289 (95% CI, 128-453) days and 132 (95% CI, 80-302) days for the intervention and the usual care group, respectively.

Tick marks indicate censoring of data. Shaded areas are 95% CIs.

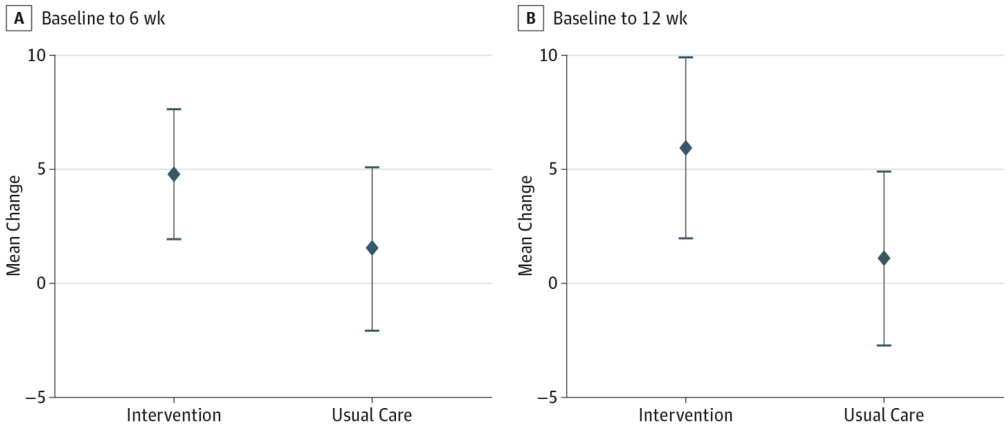

Figure 2. Mean Change in Quality-of-Life (QOL) Scores Among the Intervention and the Usual Care Groups, at 6 and 12 Weeks

Diamonds show the mean change, and error bars, the 95% CI. We assessed QOL with the use of the Functional Assessment of Chronic Illness Therapy–General Measure (FACT-G) scale, on which scores range from 0 to 108, with higher scores indicating a better QOL. Study group is the independent variable. Wilcoxon rank test showed a trend toward significant between group differences. Data are from 67 participants in the usual care group and 69 patients in the intervention group.

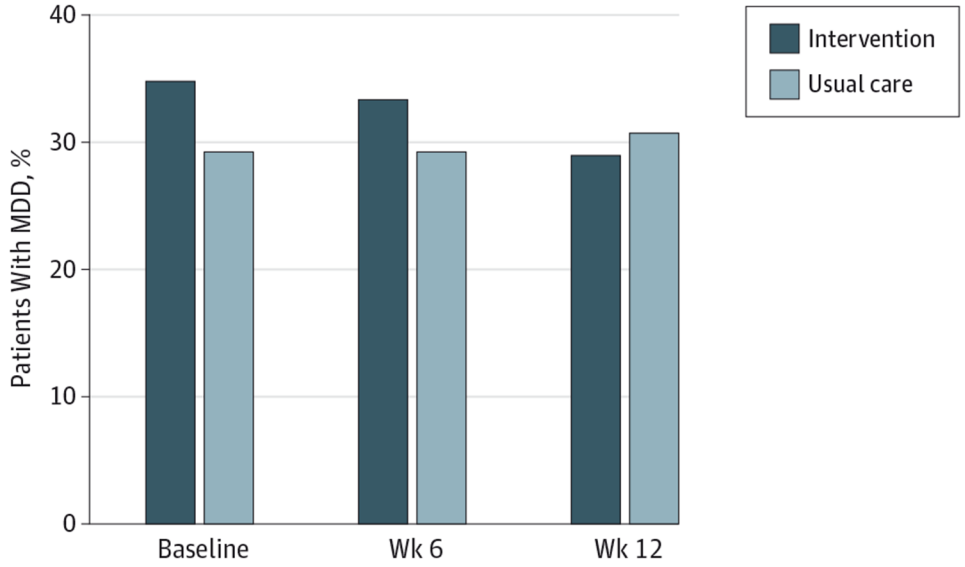

Figure 3. Mood Assessment of Major Depressive Disorder (MDD) With Outcomes at Baseline, Week 6, and Week 12

Depressive symptoms indicating the presence of MDD were assessed with the use of the Patient Health Questionnaire 9 (PHQ-9), a 9-item measure that evaluates symptoms of major depressive disorder according to the criteria of the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV). Major depressive disorder was coded as a binary variable (yes/no). A major depressive disorder was noted as a Yes if a patient reported at least 5 of the 9 symptoms of depression on the PHQ-9, with 1 of the 5 symptoms being depressed mood or a lack of pleasure. Symptoms had to be present for more than half the time over the past 2 weeks, except for the symptom of suicidal thoughts, which was included in the notation of major depressive disorder, if it was present at any time. The percentages of patients with noted MDD mood symptoms at 3 different time points, assigned to intervention group, and those assigned to the usual care group are shown. The analyses were performed with an intention to treat, and we chose a conservative method of carrying baseline values forward to account for all missing data.

Table.

Baseline Characteristics of the Study Participants[a]

Variable	Group, No. (%)		
	Usual Care (n = 67)	Intervention (n = 69)	*P* value[b]
Age, mean (SD), y	57.8 (14.7)	55.1 (13.1)	.16
Female	37 (55)	39 (57)	>.99
Race			
White	20 (30)	23 (34)	
Black	15 (23)	18 (27)	
Asian	2 (3)	4 (6)	.80
American Indian or Alaskan Native	2 (3)	1 (1)	
>1 Race	2 (3)	1 (1)	
Other	25 (38)	20 (30)	
Hispanic or Latino	29 (43)	20 (29)	.08
Education			
High school or less	36 (54)	32 (46)	.49
College or more	31 (46)	37 (54)	
Income, $			
<50 000	41 (61)	41 (62)	
≥50 000	15 (22)	19 (29)	.37
Do not know	11 (16)	6 (9)	
Health care proxy			
No	26 (39)	29 (42)	
Yes	34 (51)	37 (54)	.45
Do not know	7 (10)	3 (4)	
Living will			
No	51 (76)	47 (68)	
Yes	13 (19)	19 (28)	.48
Do not know	3 (5)	3 (4)	
Has insurance	65 (97)	67 (97)	>.99
Cancer type			

Variable	Group, No. (%)		
	Usual Care (n = 67)	Intervention (n = 69)	*P* value[b]
Breast	7 (10)	9 (13)	
Colorectal	7 (10)	9 (13)	.53
Lung	10 (15)	5 (7)	
Other	43 (64)	46 (67)	
Mood outcome, No./total No. (%)			
Major depressive disorder[c]	19 of 65 (29)	24 of 69 (35)	.12
Quality of life, total No.[d]	67	68	
FACT-G scores, mean (SD)	59.82 (16.77)	53.56 (19.61)	.06

Abbreviation: FACT-G, Functional Assessment of Cancer Therapy-General Measure.

[a]Plus-minus values are reported as means (SDs). Percentages may not total 100% because of rounding. Variables are self-reported with the exception of cancer type, which was taken from the electronic medical record during the eligibility screening process.

[b]*P* values were calculated with the use of 2-sided Fisher exact tests for categorical variables and the Wilcoxon rank tests for continuous variables.

[c]The Patient Health Questionnaire-9 (PHQ-9) is a 9-item measure that evaluates symptoms of major depressive disorder according to the criteria of the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders*. Major depressive disorder was coded as a binary variable (yes/no). A major depressive disorder was noted if a patient reported at least 5 of the 9 symptoms of depression on the PHQ-9, with 1 of the 5 symptoms being depressed mood or a lack of pleasure. Symptoms had to be present for more than half the time over the past 2 weeks, except for the symptom of suicidal thoughts, which was included in the notation of major depressive disorder, if it was present at any time.

[d]Quality of life was assessed by the use of the measure FACT-G, on which scores range from 0 to 108, with higher scores indicating a better quality of life.