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Telehealth vs In-Person Early Palliative Care for Patients With Advanced Lung Cancer
A Multisite Randomized Clinical Trial

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IMPORTANCE Numerous studies show that early palliative care improves quality of life and other key outcomes in patients with advanced cancer and their caregivers, although most lack access to this evidence-based model of care.

OBJECTIVE To evaluate whether delivering early palliative care via secure video vs in-person visits has an equivalent effect on quality of life in patients with advanced non–small cell lung cancer (NSCLC).

DESIGN, SETTING, AND PARTICIPANTS Randomized, multisite, comparative effectiveness trial from June 14, 2018, to May 4, 2023, at 22 US cancer centers among 1250 patients within 12 weeks of diagnosis of advanced NSCLC and 548 caregivers.

INTERVENTION Participants were randomized to meet with a specialty-trained palliative care clinician every 4 weeks either via video visit or in person in the outpatient clinic from the time of enrollment and throughout the course of disease. The video visit group had an initial in-person visit to establish rapport, followed by subsequent virtual visits.

MAIN OUTCOMES AND MEASURES Equivalence of the effect of video visit vs in-person early palliative care on quality of life at week 24 per the Functional Assessment of Cancer Therapy-Lung questionnaire (equivalence margin of ±4 points; score range: 0-136, with higher scores indicating better quality of life). Participants completed study questionnaires at enrollment and at weeks 12, 24, 36, and 48.

RESULTS By 24 weeks, participants (mean age, 65.5 years; 54.0% women; 82.7% White) had a mean of 4.7 (video) and 4.9 (in-person) early palliative care encounters. Patient-reported quality-of-life scores were equivalent between groups (video mean, 99.7 vs in-person mean, 97.7; difference, 2.0 [90% CI, 0.1-3.9]; $P = .04$ for equivalence). Rate of caregiver participation in visits was lower for video vs in-person early palliative care (36.6% vs 49.7%; $P < .001$). Study groups did not differ in caregiver quality of life, patient coping, or patient and caregiver satisfaction with care, mood symptoms, or prognostic perceptions.

CONCLUSIONS AND RELEVANCE The delivery of early palliative care virtually vs in person demonstrated equivalent effects on quality of life in patients with advanced NSCLC, underscoring the considerable potential for improving access to this evidence-based care model through telehealth delivery.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT03375489

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Despite therapeutic advances over the last 2 decades that have prolonged survival, many patients with advanced lung cancer report significant symptom burden, psychological distress, poor prognostic awareness, and diminished quality of life (QOL).[1-4] Patients' caregivers similarly experience high rates of distress and burden.[5,6] To address these unmet needs, national guidelines recommend the integration of palliative and oncology care from the time of diagnosis of advanced cancer.[7] Support for the guidelines comes from numerous clinical trials demonstrating the efficacy of early palliative care for improving QOL, symptoms, and other salient outcomes in this vulnerable population.[8-10]

Unfortunately, most patients with advanced cancer and their families do not receive this evidence-based model of care due to multiple barriers, including the limited availability of specialty-trained clinicians, misperceptions of the role of palliative care, and the financial burden of additional care.[11] Thus, alternative approaches for delivering palliative care are needed to enhance scalability and patient-centeredness.[12] One promising solution for helping patients overcome barriers to obtaining medical care is the provision of telehealth using video visits, which has accelerated dramatically since the COVID-19 pandemic given changes in federal policy.[13] Health care leaders recognize the benefits of telehealth for improving access to supportive oncology services, and recent studies have shown the utility of telehealth for conducting advance care planning conversations and reducing financial toxicity in patients with cancer.[14-18] Many health care facilities now have the capacity to offer video visits; however, whether the virtual modality is as effective as in-person care for improving patient outcomes remains unclear.[19] As the pandemic wanes, this comparative effectiveness question becomes increasingly crucial to inform policy decisions regarding the role and coverage of telehealth services.

The purpose of this study was to conduct a large-scale, national, multisite trial to evaluate whether the delivery of early palliative care via telehealth using video visits was equivalent to in-person visits for improving QOL in patients with advanced lung cancer. Secondary outcomes included the rate of caregiver participation in palliative care visits as well as patient- and caregiver-reported satisfaction with care. The study hypotheses were that the 2 modalities would have equivalent effects on patients' QOL, where those assigned to video visits would have a higher rate of caregiver participation and report greater satisfaction with care compared with those in the in-person group. Finally, the study explored the effect of the 2 delivery modalities on participant-reported depression and anxiety symptoms, coping, and perceptions of prognosis.

Key Points

Question Does early palliative care delivered via secure video vs in person have an equivalent effect on quality of life in patients with advanced lung cancer?

Findings In this randomized comparative effectiveness trial of 1250 adults with advanced lung cancer receiving care across 22 institutions in the US, patients assigned to receive early palliative care via video visits reported quality-of-life scores at week 24 that were equivalent to those assigned to in-person palliative care.

Meaning Findings underscore the potential to increase access to evidence-based early palliative care through telehealth delivery.

Methods

Trial Design

The REACH PC trial was an investigator-initiated comparative effectiveness randomized trial at 22 US cancer centers. The internal review boards at each site approved the trial protocol, which has been published previously.[20] The trial was registered on ClinicalTrials.gov (NCT03375489) before initiating study procedures.

Participants

Eligible patients included those who were diagnosed with advanced non–small cell lung cancer within the past 12 weeks, were not being treated with curative intent, had a documented Eastern Cooperative Oncology Group Performance Status Scale score of 0 (fully active) to 3 (capable of only limited self-care and confined to a bed or chair more than 50% of waking hours), and were able to read and respond to questions in English or Spanish. Patients were excluded if they were already receiving palliative care or hospice services or had a cognitive or psychiatric condition that prohibited study consent. Research coordinators reviewed the electronic health records to identify potentially eligible patients and approached them for study participation. All participants provided written informed consent before the COVID-19 pandemic, after which study sites also allowed electronic and verbal consent. Enrolled patients were asked to identify 1 caregiver (eg, family member or friend involved in their care) to complete self-report surveys as part of the trial, although participation was optional. Spanish-speaking participants had the option to receive Spanish-language versions of the study documents and participate in the procedures and palliative care visits with the assistance of a hospital interpreter. All study sites paused enrollment for at least 2 months during the first year of the COVID-19 pandemic and reinitiated recruitment when in-person care resumed at their institutions.

Procedures

Research staff, independent of the study team, randomly assigned participants in a 1:1 ratio to receive telehealth delivered via secure video or in-person palliative care, using computer-generated block randomization stratified by study site. Specialist palliative care physicians and advanced practice providers (138) conducted all visits, with each clinician providing care for participants in both study groups. Per the recommendations of patient, caregiver, and clinician stakeholders, participants assigned to video visits were scheduled

Table 1. Patient Baseline Characteristics

Characteristic	Video visits (n = 633)	In-person visits (n = 617)
Age, y		
Mean (SD)	65.5 (10.9)	65.5 (10.6)
Median (IQR)	65.8 (58.9-73.0)	65.8 (59.3-73.1)
Gender, No. (%)[a]	n = 633	n = 615
Men	277 (43.8)	297 (48.3)
Women	356 (56.2)	318 (51.7)
Race, No. (%)[b]	n = 630	n = 611
African American or Black	57 (9.0)	72 (11.8)
American Indian or Alaska Native	4 (0.6)	4 (0.7)
Asian	32 (5.1)	32 (5.2)
Native Hawaiian or Other Pacific Islander	2 (0.3)	4 (0.7)
White	524 (83.2)	502 (82.2)
Other[c]	21 (3.3)	10 (1.6)
Ethnicity, No. (%)[d]	n = 625	n = 605
Hispanic or Latino	29 (4.6)	30 (5.0)
Not Hispanic or Latino	596 (95.4)	575 (95.0)
Religion, No. (%)	n = 625	n = 611
Catholic	193 (30.9)	200 (32.7)
Other Christian (eg, Protestant)	301 (48.2)	273 (44.7)
Jewish	35 (5.6)	27 (4.4)
Atheist	5 (0.8)	7 (1.1)
Muslim	5 (0.8)	5 (0.8)
None	67 (10.7)	75 (12.3)
Other	19 (3.0)	24 (3.9)
Relationship status, No. (%)	n = 630	n = 612
Married/partnered	420 (66.7)	409 (66.8)
Divorced/separated	100 (15.9)	81 (13.2)
Widowed/loss of partner	67 (10.6)	73 (11.9)
Single	42 (6.7)	48 (7.8)
Other	1 (0.2)	1 (0.2)
Education, No. (%)	n = 631	n = 613
High school graduate or less	207 (32.8)	175 (28.5)
Associate degree/ technical school	190 (30.1)	188 (30.7)
Bachelor's degree	116 (18.4)	137 (22.3)
Master's, doctoral, or professional degree	118 (18.7)	113 (18.4)
Annual household income, No. (%), $	n = 595	n = 564
<25 000	141 (23.7)	120 (21.3)
25 000-49 999	124 (20.8)	104 (18.4)
50 000-99 999	156 (26.2)	155 (27.5)
100 000-149 999	84 (14.1)	98 (17.4)
≥150 000	90 (15.1)	87 (15.4)
Smoking history, No. (%)	n = 627	n = 609
>10 pack-years	382 (60.9)	381 (62.6)
Never smoker/ ≤10 pack-years	245 (39.1)	228 (37.4)
Caregiver enrolled, No. (%)[e]	272 (43.0)	276 (44.7)
Cancer type, No. (%)		
Adenocarcinoma	516 (81.5)	506 (82.0)
Squamous cell carcinoma	95 (15.0)	80 (13.0)
Large cell/large cell neuroendocrine carcinoma	4 (0.6)	11 (1.8)
Other	18 (2.8)	20 (3.2)
Cancer treatment, No. (%)		
Platinum-based doublet chemotherapy (± third agent)	257 (40.6)	277 (44.9)
Radiation	138 (21.8)	123 (19.9)
Oral-targeted chemotherapy	126 (19.9)	114 (18.5)
Immunotherapy	93 (14.7)	72 (11.7)
No treatment	8 (1.3)	18 (2.9)
Single agent IV chemotherapy	7 (1.1)	8 (1.3)
Combined radiation and chemotherapy	4 (0.6)	5 (0.8)
Cancer gene variant status, No. (%)		
ALK	28 (4.4)	26 (4.2)
EGFR	113 (17.9)	102 (16.5)
RET	11 (1.7)	7 (1.1)
ROS	6 (0.9)	0 (0)
Other or no variation	475 (75.0)	482 (78.1)
ECOG Performance Status Scale score, No. (%)[f]		
0	158 (25.0)	143 (23.2)
1	345 (54.5)	342 (55.4)
2	111 (17.5)	113 (18.3)
3	19 (3.0)	19 (3.1)
Medical comorbidity (SCQ score)[g]		
Mean (SD)	8.2 (4.0) [n = 631]	8.3 (4.1) [n = 612]
Median (IQR)	8 (5-10)	8 (6-11)
Quality of life (FACT-L score)[h]		
Mean (SD)	93.3 (20.0) [n = 618]	92.0 (20.1) [n = 606]
Median (IQR)	94.5 (79.3-108.5)	93.0 (77.5-107.5)
Mood symptoms		
Anxiety (HADS-anxiety score)[i]		
Mean (SD)	6.0 (4.0) [n = 627]	6.0 (4.1) [n = 608]
Median (IQR)	5.0 (3.0-9.0)	5.0 (3.0-9.0)
Depression (HADS-depression score)[i]		
Mean (SD)	5.7 (4.1) [n = 627]	5.9 (4.3) [n = 608]
Median (IQR)	5.0 (2.0-8.0)	5.0 (2.0-8.0)
Depression (PHQ-9 score)[j]		
Mean (SD)	6.6 (5.3) [n = 626]	7.1 (5.4) [n = 604]
Median (IQR)	6.0 (2.0-10.0)	6.0 (3.0-10.0)

Table 1. Patient Baseline Characteristics (continued)

Characteristic	Video visits (n = 633)	In-person visits (n = 617)
Coping skills (Brief-COPE score)		
Approach-oriented coping[k]		
Mean (SD)	18.3 (3.8) [n = 604]	18.1 (3.7) [n = 593]
Median (IQR)	19.0 (16.0-21.0)	18.0 (15.0-21.0)
Avoidant coping[k]		
Mean (SD)	6.3 (2.5) [n = 601]	6.4 (2.5) [n = 579]
Median (IQR)	6.0 (4.0-8.0)	6.0 (4.0-8.0)
Perceptions of prognosis, No./total No. (%)[l]		
Perceives goal of therapy is to cure cancer	215/623 (34.5)	207/600 (34.5)
Perceives cancer is curable	182/592 (30.7)	188/558 (33.7)

Abbreviations: *ALK*, anaplastic lymphoma kinase; Brief-COPE, Brief Coping Orientation to Problems Experienced Inventory; ECOG, Eastern Cooperative Oncology Group; *EGFR*, epidermal growth factor receptor; FACT-L, Functional Assessment of Cancer Therapy-Lung; HADS, Hospital Anxiety and Depression Scale; PHQ, Patient Health Questionnaire; *RET*, ret proto-oncogene; *ROS*, ros oncogene; SCQ, Self-Administered Comorbidity Questionnaire.

[a] Gender was collected by self-report, which allowed a single selection from a predetermined list: man, woman, or other/write-in. No participants selected other.

[b] Race was collected by self-report, which allowed multiple selections from a predetermined list, including an other/write-in option. Sum of percentages may exceed 100%.

[c] Indicates participant-selected other race. See eAppendix 2 in Supplement 1 for itemization.

[d] Ethnicity was collected by self-report, which allowed a single selection from a predetermined list.

[e] Participants were asked to identify 1 caregiver (eg, family member or friend involved in their care) to complete self-report surveys as part of the trial. Caregiver participation was optional.

[f] ECOG Performance Status Scale is a clinician-assessed measure of patients' functional status: 0, fully active with no restrictions; 1, able to do light work; 2, unable to work and in bed <50% of the day; 3, capable of only limited self-care and in bed >50% of the day; 4, bedridden.

[g] SCQ score range: 0-36, with higher scores indicating greater comorbidity.

[h] FACT-L scale score range: 0-136, with higher scores indicating better quality of life; minimal clinically important difference = 6.

[i] HADS scores: anxiety score range, 0-21, with higher scores indicating greater anxiety; depression score range, 0-21, with higher scores indicating greater depression.

[j] PHQ-9 score range: 0-27, with higher scores indicating more significant depression symptoms.

[k] Brief-COPE scores: approach-oriented coping score range: 6-24, with higher scores indicating greater use of approach-oriented coping strategies; avoidant coping score range: 4-16, with higher scores indicating greater use of avoidant coping strategies.

[l] Patients' perceptions of prognosis were collected by self-report using items from the Prognosis and Treatment Perceptions Questionnaire eliciting patients' goal of cancer care ("to cure my cancer" vs any other option) and patients' assessment of curability (yes or no).

for 1 initial in-person encounter to establish rapport with the clinician and then via video for subsequent visits. Participants in both groups were scheduled to meet with palliative care clinicians at least every 4 weeks, consistent with prior palliative care trials.[21,22] Telephone calls were permitted if the visit could not occur per the assigned modality within that time frame. If necessary for care, clinicians could schedule participants in either study group for an in-person or video visit. Any patients in the video visit group lacking the necessary technology received a cellular-enabled tablet computer. Study sites used the same videoconferencing software prior to the onset of the COVID-19 pandemic, after which they transitioned to their institutional platforms.

To ensure fidelity, palliative care clinicians underwent an initial comprehensive training on the use of the videoconferencing platform and principles of early palliative care, including reviewing a clinician intervention guide, and then participated in annual retraining sessions. After each participant encounter, study clinicians received a link via email to complete an electronic visit summary form to document the topics addressed, who attended, and the visit duration. These summary forms were required for face-to-face visits (in-person or video), but were optional for telephone calls. Finally, the lead study team met monthly with the site principal investigators and research staff to support recruitment, intervention delivery, and data collection.

Outcomes

Participants completed a sociodemographic questionnaire upon enrollment as well as self-reported outcome measures at baseline and again at weeks 12, 24, 36, and 48 (±3 weeks). The primary outcome time point was week 24. For the outcome measures listed below, the ranges and interpretation of the scores are listed as footnotes to **Tables 1** and **2**. The 36- and 48-week follow-up measures, communication about end-of-life care, and hospice utilization outcomes will be reported in a future manuscript.

Primary Outcome

The primary outcome was patient QOL measured via the Functional Assessment of Cancer Therapy-Lung (FACT-L) questionnaire.[23,24]

Secondary Outcomes

The secondary outcomes were patient and caregiver satisfaction with care measured by the Satisfaction and Care Delivery Questionnaire[25] and caregiver participation in study visits measured by clinician visit summary forms.

Exploratory Outcomes

The exploratory outcomes were patient and caregiver mood symptoms (Hospital Anxiety and Depression Scale and Patient Health Questionnaire-9),[26,27] patient use of approach-oriented and avoidant coping skills (Brief Coping Orientation to Problems Experienced Inventory),[28,29] caregiver QOL (CareGiver Oncology Quality of Life questionnaire),[30] and patient and caregiver perceptions of prognosis and goal of therapy (Prognosis and Treatment Perceptions Questionnaire).[31]

Statistical Analyses

We designed this study to demonstrate the equivalence of video visit and in-person palliative care with a margin of ±4 points on the FACT-L at week 24. This margin is approximately

Table 2. Regression Model Estimates of Study Group Effects on 24-Week Outcome Measures

Outcome measure	Estimated mean/proportion (SD)[a] Video visits (n = 305)	In-person visits (n = 315)	Difference (95% CI)[b]	*P* value[c]
Primary outcome test of equivalence				
Patient-reported quality of life				
FACT-L, mean[d]	99.7 (0.8) [n = 305]	97.7 (0.8) [n = 315]	2.0 (90% CI, 0.1 to 3.9)	.04
Secondary outcome tests of superiority				
Satisfaction with care				
Patient-reported SCDQ, mean[e]	41.3 (0.5) [n = 422]	41.0 (0.5) [n = 422]	0.3 (−1.0 to 1.7)	>.99
Caregiver-reported SCDQ, mean[e]	37.2 (0.7) [n = 176]	36.8 (0.7) [n = 177]	0.4 (−1.5 to 2.3)	>.99
Caregiver attendance at palliative care visits, %[f]	36.6 (1.6) [n = 576]	49.7 (1.7) [n = 549]	−13.0 (−17.6 to −8.6)	<.001
Exploratory outcome tests of superiority				
Patients				
Mood symptoms				
HADS-anxiety score, mean[g]	4.8 (0.2) [n = 309]	5.0 (0.2) [n = 318]	−0.1 (−0.6 to 0.3)	
HADS-depression score, mean[g]	4.9 (0.2) [n = 309]	5.3 (0.2) [n = 318]	−0.4 (−0.9 to 0.1)	
PHQ-9 score, mean[h]	5.2 (0.2) [n = 309]	5.5 (0.2) [n = 317]	−0.3 (−0.9 to 0.3)	
Coping skills[i]				
Approach-oriented coping, mean	18.1 (0.2) [n = 293]	18.3 (0.2) [n = 309]	−0.1 (−0.6 to 0.4)	
Avoidant coping, mean	5.8 (0.1) [n = 289]	5.7 (0.1) [n = 296]	0.2 (−0.1 to 0.4)	
Perceptions of prognosis[j]				
Perceives cancer is curable, %	31.0 (2.3) [n = 422]	27.1 (2.2) [n = 421]	4.0 (−2.2 to 10.1)	
Perceives goal of therapy is to cure cancer, %	30.9 (2.2) [n = 430]	29.1 (2.2) [n = 433]	1.8 (−4.3 to 8.0)	
Caregivers				
Quality of life				
CarGOQoL score, mean[k]	74.2 (1.0) [n = 120]	72.5 (0.9) [n = 131]	1.6 (−1.1 to 4.3)	
Mood symptoms				
HADS-anxiety score, mean[g]	7.4 (0.3) [n = 122]	7.4 (0.3) [n = 133]	0.0 (−0.8 to 0.8)	
HADS-depression score, mean[g]	5.0 (0.3) [n = 122]	5.0 (0.3) [n = 133]	0.0 (−0.7 to 0.8)	
Perceptions of prognosis[j]				
Perceives patient's cancer is curable, %	17.7 (2.9) [n = 170]	16.6 (2.8) [n = 181]	1.1 (−6.8 to 9.0)	
Perceives goal of therapy is to cure patient's cancer, %	22.9 (3.1) [n = 179]	21.1 (3.0) [n = 185]	1.8 (−6.7 to 10.3)	

Abbreviations: Brief-COPE, Brief Coping Orientation to Problems Experienced Inventory; CarGOQoL, CareGiver Oncology Quality of Life; FACT-L, Functional Assessment of Cancer Therapy-Lung; HADS, Hospital Anxiety and Depression Scale; PHQ, Patient Health Questionnaire; SCDQ, Satisfaction and Care Delivery Questionnaire; TOST, two one-sided test.

[a] All estimates, except those for satisfaction with care, caregiver attendance at palliative care visits, and perceptions of prognosis, are adjusted for baseline scores of outcome variable. Numbers in brackets reflect the number of participants in each group whose data were included in the model. The number of patients included in models for satisfaction with care and perceptions of prognosis are higher than for other participant-reported outcomes because the week 12 response was used when the week 24 response was missing (see details in the Statistical Analysis Plan in Supplement 3).

[b] Equivalence is established if the 2-sided 90% CI for the estimated difference between groups is within the prespecified equivalence margin of ±4 points (FACT-L), which corresponds to the TOST procedure for equivalence with an overall type I error rate of 5%.

[c] The *P* value for equivalence of FACT-L is based on the TOST procedure for equivalence against the prespecified margin of ±4 points (ie, the larger of the 2 *P* values from TOSTs of the estimated difference in means against null values −4 and 4). *P* values for secondary outcomes were adjusted using a Bonferroni correction that maintained an overall family-wise error rate of 5% across all 5 prespecified secondary outcomes; only 3 of 5 are reported in this manuscript (see details in the Statistical Analysis Plan in Supplement 3). *P* values are not reported for exploratory outcomes.

[d] FACT-L scale score range: 0-136, with higher scores indicating better quality of life; minimal clinically important difference = 6.

[e] SCDQ score range: 0-52 (patient version) or 0-48 (caregiver version), with higher scores indicating greater satisfaction. Patients and participating caregivers self-reported their satisfaction on separate surveys.

[f] Palliative care clinicians reported attendance by a caregiver at each visit using an electronic visit summary form.

[g] HADS scores: anxiety score range, 0-21, with higher scores indicating greater anxiety; depression score range, 0-21, with higher scores indicating greater depression.

[h] PHQ-9 score range: 0-27, with higher scores indicating more significant depression symptoms.

[i] Brief-COPE scores: approach-oriented coping score range: 6-24, with higher scores indicating greater use of approach-oriented coping strategies; avoidant coping score range: 4-16, with higher scores indicating greater use of avoidant coping strategies.

[j] Patients' and caregivers' perceptions of prognosis were collected by self-report using items from the Prognosis and Treatment Perceptions Questionnaire eliciting patients' or caregivers' goal of cancer care ("to cure my [his/her] cancer" vs any other option) and patients' or caregivers' assessment of curability (yes or no).

[k] CarGOQoL questionnaire score range: 0-100, with higher scores indicating better quality of life of the caregivers of patients with cancer.

half the difference observed in our prior palliative care trial vs usual care (7.5 points) and less than a clinically meaningful difference (6 points).[22,24,32] Assuming a standard deviation of 17.5 points, 469 patients per group would provide 95% power to detect equivalence based on a two one-sided *t* test (TOST) procedure[33] with an overall type I error rate of 5%. To account for attrition and missing data by week 24, we planned to enroll 625 patients per group.

Primary comparisons of patient-reported outcomes were made among participants who survived through week 24 (ie, a survivor's analysis), given this was the comparison of primary scientific interest and similar death rates were anticipated across groups.[34,35] The difference in week 24 means between intervention groups was estimated using a linear regression model with group assignment and baseline FACT-L score as main effects. Equivalence was established if the 2-sided 90% CI for the estimated difference between groups was within the prespecified equivalence margin of ±4 points, which corresponds to the TOST procedure for equivalence with an overall type I error rate of 5%.[33] The proportion of visits with caregiver attendance was compared using a binomial generalized estimating equation model with robust standard errors, the identity link function, and a main effect for group assignment. Self-reported satisfaction with care, anxiety and depression symptoms, use of coping skills, and caregiver QOL were compared by examining differences in week 24 means using linear regression with group assignment and baseline score (except for satisfaction with care, which participants completed only at follow-up) as main effects. Perceptions of prognosis, coded dichotomously, were compared using binomial generalized linear models with the identity link function. *P* values for secondary outcomes were adjusted using a Bonferroni correction that maintained an overall family-wise error rate of 5%. Exploratory outcomes were reported using estimates with 95% CIs and were not adjusted for multiple comparisons.

We conducted sensitivity analyses to evaluate the robustness of results for the primary outcome (see eAppendix 1 in Supplement 1 and the Statistical Analysis Plan in Supplement 3). To account for the stratification of randomization by site, we conducted a sensitivity analysis by adding a main effect for study site in the primary linear regression model. Our primary analysis excluded participants with missing FACT-L scores at week 24. To evaluate the potential impact of missing data, we conducted analyses incorporating baseline, 12-week, and 24-week longitudinal data and using multiple imputation for nonresponse (but not truncation due to death).[36] To address the potential impact of intervention contamination introduced during the COVID-19 pandemic, we conducted a per-protocol analysis using inverse probability weighting and a contamination-adjusted intention-to-treat analysis.[37,38] We conservatively defined intervention contamination (ie, not per-protocol) as any participant assigned to in-person visits who received at least 1 video visit by week 24 (in-person and telephone contacts were allowed to occur per protocol in both groups when clinically appropriate). All analyses used R statistical software version 4.3.2 (RStudio).

Results

Sample Characteristics

Between June 14, 2018, and May 4, 2023, of the 2833 patients approached to participate, 1250 (44.1%) were registered and randomized (**Figure 1**). The mean (SD) age of the patient sample was 65.5 (10.8) years, and the majority self-identified as women (54.0%), married or partnered (66.7%), White (82.7%), and not Hispanic or Latino (95.2%). Just under half of the sample (45.7%) reported having to travel 1 hour or more to the cancer clinic. Fifty-nine percent (738/1250) of patient participants identified a caregiver for potential enrollment, of whom 93.6% (691/738) were offered study participation and 79.3% (548/691) enrolled. Of enrolled caregivers, the majority were the patient's spouse or partner (64.2%). See Table 1 and eTables 1 and 2 in Supplement 1 for the patient and caregiver characteristics. Overall, 123 (9.8%) study participants died by week 12 (55 assigned to video visits; 68 assigned to in-person visits) and 246 (19.7%) died by week 24 (123 assigned to video visits; 123 assigned to in-person visits) (Figure 1).

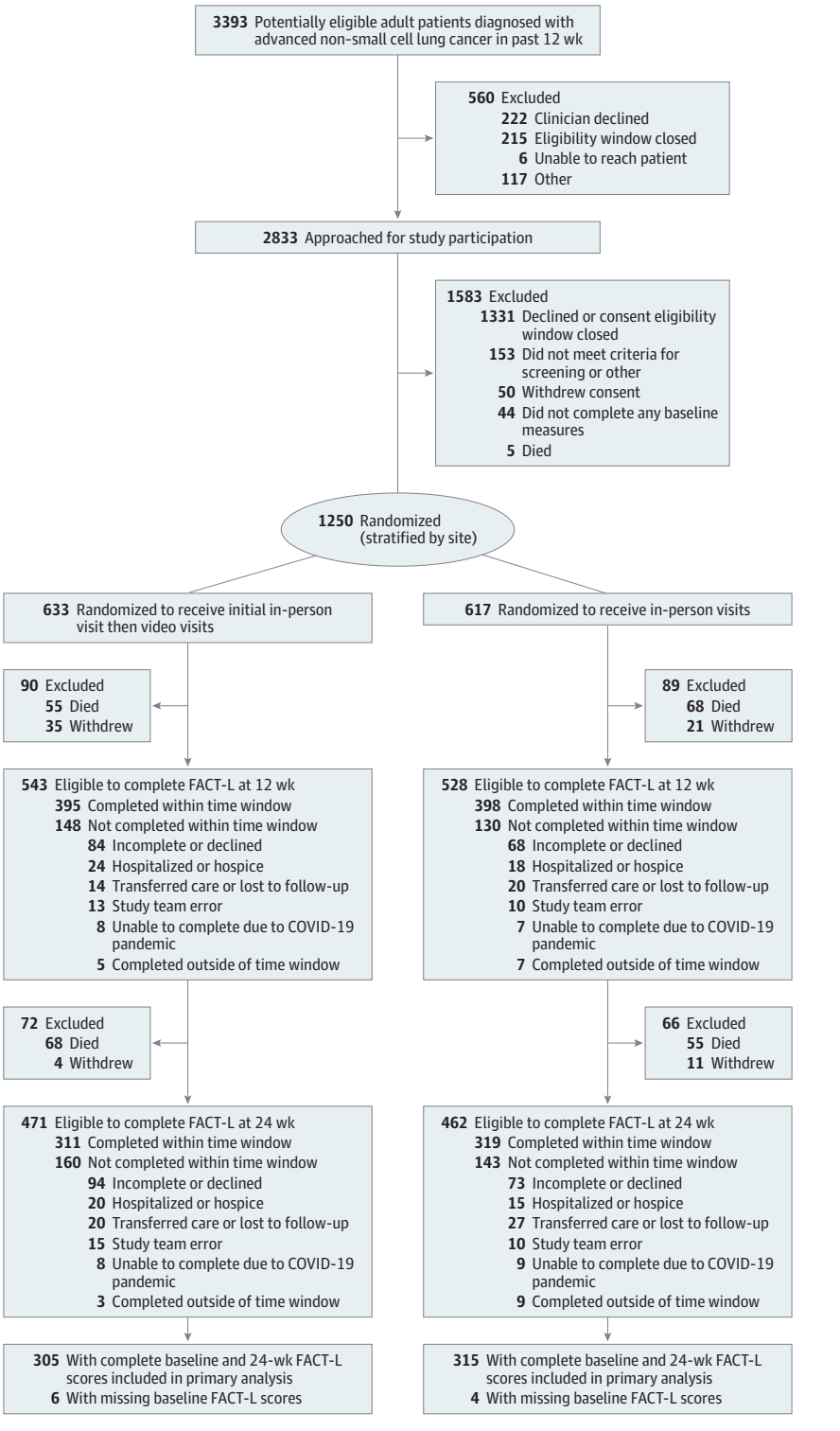
Intervention Delivery

By week 24, the mean (SD) number of palliative care encounters was 4.7 (2.5) and 4.9 (2.7) in the video visit and in-person groups, respectively (eFigure 1 in Supplement 1). Of the face-to-face encounters within the video visit group (2306), 68.6% occurred over video, 21.0% were in person due to the protocol-required initial in-person encounter, and 10.4% were in person at the request of the clinician or patient. Of the face-to-face encounters in the in-person group (2038), 94.3% were in person, whereas 5.7% occurred via video due to the COVID-19 pandemic. The study clinicians completed 93.2% (4047/4344) of the required face-to-face visit summary forms, along with an additional 1172 optional forms for telephone calls. eFigure 2 in Supplement 1 shows the proportion of topics discussed across visits by group. The median (IQR) durations for the video and in-person visits were 30 (20-39) and 35 (25-52) minutes, respectively.

Patient and Caregiver Outcomes

A plot of individual-level change in QOL scores by week 24 is shown in **Figure 2**. QOL scores on the FACT-L at week 24 for patients assigned to the video visit group were equivalent to those assigned to in-person palliative care (adjusted mean, 99.7 vs 97.7; difference, 2.0 [90% CI, 0.1-3.9]; *P* = .04 for equivalence; Table 2). The mean improvement in FACT-L scores from baseline to week 24 was 8.4 and 6.9 points in the video visit and in-person groups, respectively. Sensitivity analyses accounting for site effects, missing data, and intervention contamination all supported the primary equivalence finding or noninferiority of video visits (eTable 3 and eFigure 3 in Supplement 1). Baseline characteristics of patients with vs without intervention contamination among those assigned to in-person visits are shown in eTable 4 in Supplement 1. For the secondary and exploratory patient outcomes, study groups did not differ in patient-reported satisfaction with care, anxiety

Figure 1. Recruitment, Randomization, and Follow-Up

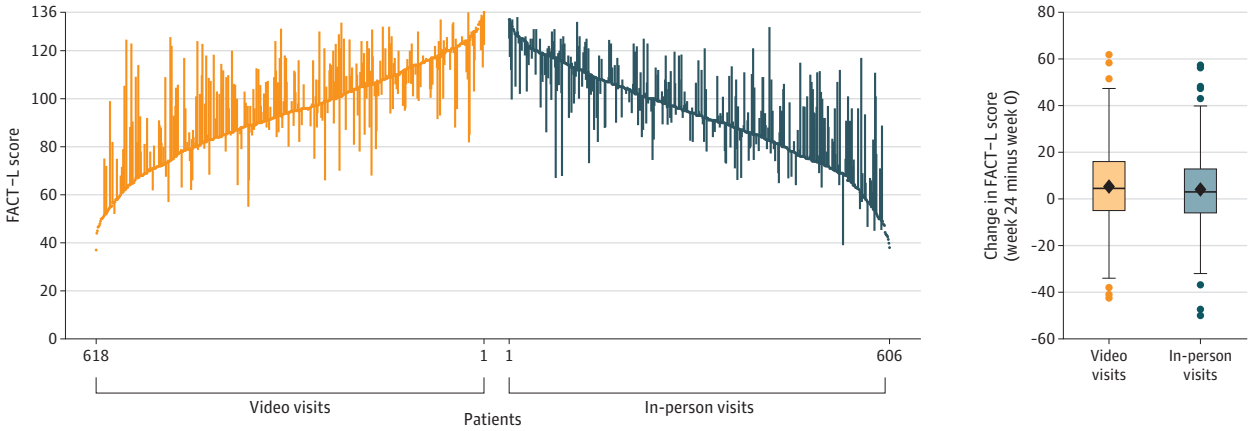


FACT-L indicates Functional Assessment of Cancer Therapy-Lung (see Table 1 footnotes for score range and interpretation).

and depression symptoms, use of approach-oriented or avoidant coping strategies, or perceptions of the primary goal of treatment and curability of their cancer (Table 2 and **Figure 3**).

The rate of caregiver participation in the palliative care visits by week 24 was lower in the video visit vs in-person group (36.6% vs 49.7%; $P < .001$). Nonetheless, study groups did not differ in caregiver-reported satisfaction with care, QOL, anxiety and depression symptoms, and perceptions of the goal of therapy and curability of the patient's cancer (Table 2).

Figure 2. Changes in Patient-Reported Quality of Life From Baseline to Week 24 by Study Group



The parallel line plot contains 1 dot with a vertical line for each participant (ordered by baseline FACT-L score) that extends from their week 0 FACT-L value (dot) to the value at week 24 (end of vertical line). Participants with FACT-L score observed at baseline but missing at week 24 are depicted as a dot without a vertical line. Participants with missing baseline FACT-L score (15 randomized to video visits, 11 randomized to in-person visits) were excluded. Descending vertical lines indicate a worsening in patient-reported quality of life over time; ascending vertical lines indicate an improvement in patient-reported quality of life. Baseline values are placed in ascending order for participants assigned to video visits and descending order for participants assigned to in-person visits. On the box plots, the tops and bottoms of the boxes indicate IQRs; center horizontal lines, medians; and diamonds, means. Whiskers extend to the highest and lowest values within 1.5 times the IQR, and dots reflect more extreme data. FACT-L indicates Functional Assessment of Cancer Therapy-Lung (see Table 1 footnotes for score range and interpretation).

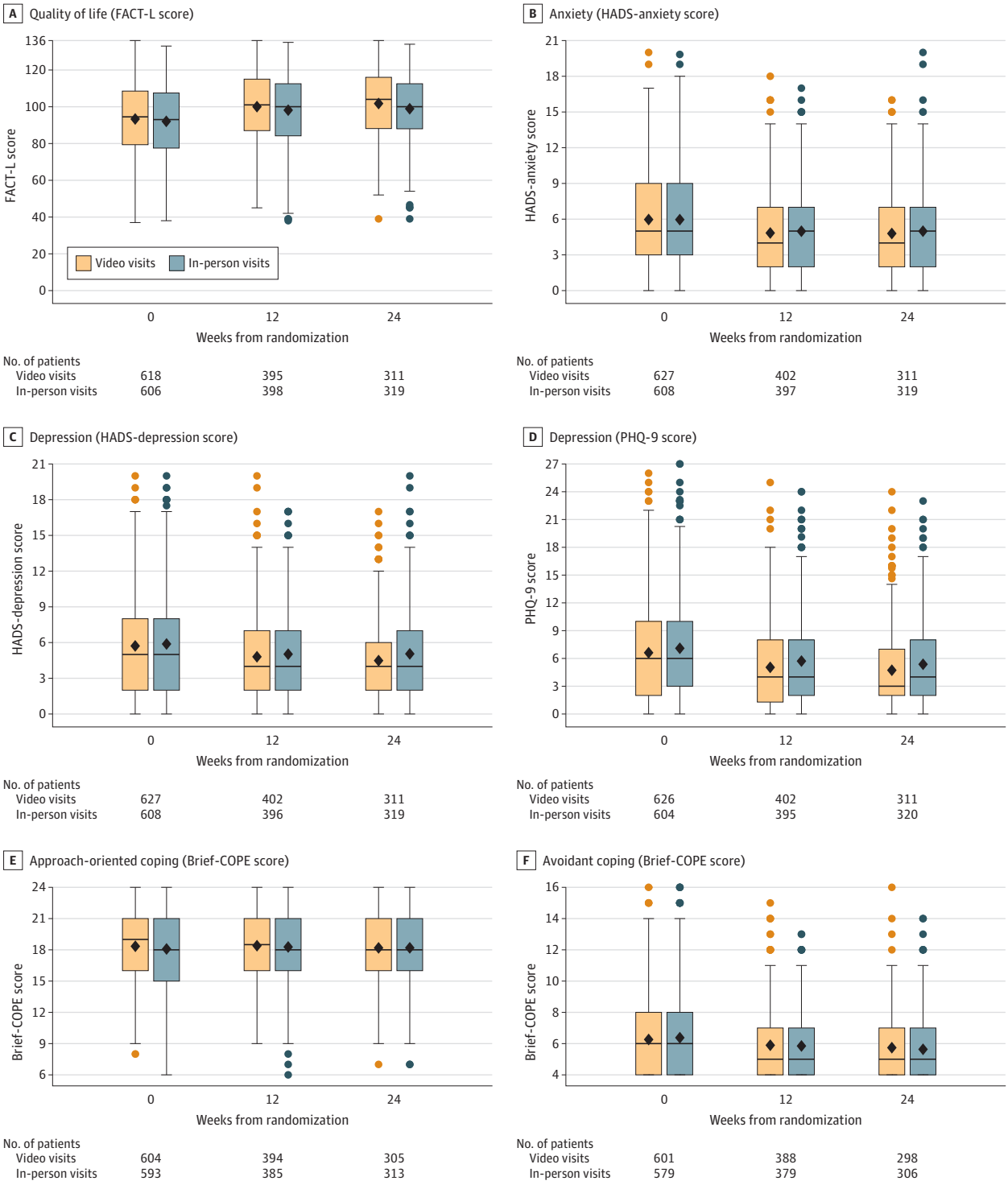
Discussion

This large-scale comparative effectiveness trial demonstrated the equivalence of the effect of delivering palliative care via video vs in person on QOL in patients with advanced lung cancer. Additionally, the QOL improvement in both study groups was similar to the initial efficacy trial of in-person early palliative care for patients with advanced lung cancer and exceeded a clinically meaningful change of 6 points.[21,24,32] Telehealth studies have largely focused on mental health and behavioral interventions, the use of telephone-delivered care, or been observational, retrospective, or pilot feasibility evaluations.[19] To our knowledge, this is the largest prospective trial to directly compare the use of video vs in-person visits to provide outpatient palliative care services. The benefits of enhancing access to palliative care via video visits for patients with advanced cancer cannot be overstated. As these findings and other studies show, video visits are associated with decreased burden related to transportation cost and travel time for patients as well as more efficient delivery of care for clinicians.[16] In a separate survey study of the implementation of these 2 palliative care delivery modalities, study clinicians underscored the mutual benefit of video visits for enhancing the continuity of care while increasing access for patients who live far from clinics, lack social support and transportation assistance, are hesitant to attend additional visits for palliative care, and/or have impairing physical symptoms.[39]

Contrary to the study's a priori superiority hypotheses for the secondary outcomes, the rate of caregiver participation in visits was higher in the in-person vs video visit group, and patient- and caregiver-reported satisfaction with care did not differ significantly between the 2 modalities. It was anticipated that caregiver attendance would be greater in the video visit group given the potential for a family member or friend to join video sessions remotely. However, this convenience may be the precise reason why the rate of caregiver participation was lower, as many patients require transportation assistance from caregivers to attend in-person visits, likely increasing their shared participation onsite. Additionally, the study hypothesized that the benefits of video visits for improving access and saving transportation time and costs would result in greater perceived satisfaction among patients and their caregivers, as shown in a 2023 report.[17] However, both study groups reported similarly high ratings on average for visit-related convenience, time, and costs as well as their relationship with the palliative care clinicians.

Prior trials have demonstrated efficacy of early palliative care in improving not only QOL, depression symptoms, prognostic understanding, and use of effective coping skills in patients, but also psychological distress in their caregivers.[22,40-42] In the present trial, the patients assigned to video vs in-person visits reported no significant differences in any of these outcomes. Moreover, despite a lower rate of participation in video vs in-person visits with palliative care, the caregivers similarly reported no significant differences in their own QOL, anxiety and depression symptoms, or prognostic understanding. Video visits may offer greater autonomy for patients and caregivers to decide when to jointly participate in visits, reducing burden on time and travel for caregivers as well. These findings highlight the potential beneficial indirect effects that palliative care may have on caregiver well-being by way of the direct effects on patients' care experiences regardless of delivery modality, although further data are needed to confirm these findings.

Figure 3. Longitudinal Patient-Reported Outcome Measures Up to 24 Weeks by Study Group



The tops and bottoms of the boxes indicate IQRs; center horizontal lines, medians; and diamonds, means. Whiskers extend to the highest and lowest values within 1.5 times the IQR, and dots reflect more extreme data. The numbers beneath the plots show the number of patients in each group who completed the patient-reported assessment. Brief-COPE indicates Coping Orientation to Problems Experienced Inventory; FACT-L, Functional Assessment of Cancer Therapy-Lung; HADS, Hospital Anxiety and Depression Scale; PHQ-9, Patient Health Questionnaire-9 (see Table 1 footnotes for score ranges and interpretation).

Limitations

Although this comparative effectiveness trial has several strengths, including its large scale to increase generalizability, rigorous randomized design, and administration of validated outcome measures, several limitations deserve consideration. First, the onset of the COVID-19 pandemic in the second year of the trial posed unanticipated intervention contamination concerns, warranting a recruitment pause across all study sites until individual institutions permitted in-person care again. Although no patients assigned to in-person visits had any video visits prior to the pandemic, some enrolled patients had no choice but to have video visits due to rapid changes in ambulatory care practices. Research staff worked diligently to return participants to their assigned modality over time, limiting the number of video visits in the in-person group as much as possible, and descriptive sensitivity analyses showed that the low rate of intervention contamination did not meaningfully alter the results. Second, the patient enrollment rate was lower and attrition rate was higher than in prior palliative care studies,[21,22] likely reflecting the increased heterogeneity in the population and treatment practices across 22 cancer centers, which was further compounded by the effects of the pandemic. The study was unable to assess potential sample selection bias, given that patients who declined participation did not provide consent for staff to collect their sociodemographic information. Third, compared to the prior trial of early palliative care for patients with advanced lung and gastrointestinal cancers in which 78.6% of patients had an enrolled caregiver,[43] markedly fewer patients in this multisite trial identified a caregiver for potential participation (59.0%). Fourth, further research is needed to increase representation of patients from diverse backgrounds in telehealth studies and to conduct subgroup analyses to determine whether intervention effects vary based on key sociodemographic variables (eg, age, education level), performance status, technological experience, and presence of a caregiver.

Conclusions

As we look to the future and policymakers debate post-pandemic regulations and reimbursement for virtual care given the planned expiration of telehealth flexibilities that have been extended to the end of 2024, the present study adds critical evidence to support ongoing access to telehealth services, especially for vulnerable populations with serious illness. Moreover, although video visits help overcome key inequities by reaching patients from distant geographic regions, many individuals with limited technology access, health literacy, and English-language proficiency, as well as those with impairments in vision or hearing, will require additional support to ensure equitable care through virtual methods.[44] This study nonetheless demonstrates that a highly morbid older population, including some with very limited technology experience, can successfully engage in video visits with minimal assistance. The equivalence of these modalities in a population with serious illness underscores the urgent need for clinicians, health care systems, and policymakers to expand equitable access to evidence-based palliative care and develop guidelines for a new standard of care that includes broad adoption of telehealth services.

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Group Information: The REACH PC Investigators are listed in Supplement 4.

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Data Sharing Statement: See Supplement 5.

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