

Advance Care Planning Video Intervention Among Long-Stay Nursing Home Residents A Pragmatic Cluster Randomized Clinical Trial

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IMPORTANCE Standardized, evidenced-based approaches to conducting advance care planning (ACP) in nursing homes are lacking.

OBJECTIVE To test the effect of an ACP video program on hospital transfers, burdensome treatments, and hospice enrollment among long-stay nursing home residents with and without advanced illness.

DESIGN, SETTING, AND PARTICIPANTS The Pragmatic Trial of Video Education in Nursing Homes was a pragmatic cluster randomized clinical trial conducted between February 1, 2016, and May 31, 2019, at 360 nursing homes (119 intervention and 241 control) in 32 states owned by 2 for-profit corporations. Participants included 4171 long-stay residents with advanced dementia or cardiopulmonary disease (hereafter referred to as advanced illness) in the intervention group and 8308 long-stay residents with advanced illness in the control group, 5764 long-stay residents without advanced illness in the intervention group, and 11 773 long-stay residents without advanced illness in the control group. Analyses followed the intention-to-treat principle.

INTERVENTIONS Five 6- to 10-minute ACP videos were made available on tablet computers or online. Designated champions (mostly social workers) in intervention facilities were instructed to offer residents (or their proxies) the opportunity to view a video(s) on admission and every 6 months. Control facilities used usual ACP practices.

MAIN OUTCOMES AND MEASURES Twelve-month outcomes were measured for each resident. The primary outcome was hospital transfers per 1000 person-days alive in the advanced illness cohort. Secondary outcomes included the proportion of residents with or without advanced illness experiencing 1 or more hospital transfer, 1 or more burdensome treatment, and hospice enrollment. To monitor fidelity, champions completed reports in the electronic record whenever they offered to show residents a video.

RESULTS The study included 4171 long-stay residents with advanced illness in the intervention group (2970 women [71.2%]; mean [SD] age, 83.6 [9.1] years), and 8308 long-stay residents with advanced illness in the control group (5857 women [70.5%]; mean [SD] age, 83.6 [8.9] years), 5764 long-stay residents without advanced illness in the intervention group (3692 women [64.1%]; mean [SD] age, 81.5 [9.2] years), and 11 773 long-stay residents without advanced illness in the control group (7467 women [63.4%]; mean [SD] age, 81.3 [9.2] years). There was no significant reduction in hospital transfers per 1000 person-days alive in the intervention vs control groups (rate [SE], 3.7 [0.2]; 95% CI, 3.4-4.0 vs 3.9 [0.3]; 95% CI, 3.6-4.1; rate difference [SE], -0.2 [0.3]; 95% CI, -0.5 to 0.2). Secondary outcomes did not significantly differ between trial groups among residents with and without advanced illness. Based on champions' reports, 912 of 4171 residents with advanced illness (21.9%) viewed ACP videos. Facility-level rates of showing ACP videos ranged from 0% (14 of 119 facilities [11.8%]) to more than 40% (22 facilities [18.5%]).

CONCLUSIONS AND RELEVANCE This study found that an ACP video program was not effective in reducing hospital transfers, decreasing burdensome treatment use, or increasing hospice enrollment among long-stay residents with or without advanced illness. Intervention fidelity was low, highlighting the challenges of implementing new programs in nursing homes.

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Nursing homes in the United States are complex health care systems, caring for approximately 3 million individuals annually, including 1.5 million frail, elderly individuals with late-stage disease. These patients often receive aggressive interventions that may be inconsistent with their preferences and of little clinical benefit,¹⁻⁵ particularly hospital transfers.^{2,6-8} Identifying effective approaches with which nursing homes can promote goal-directed care is a research, public health, and clinical priority.

Advance care planning (ACP) is a modifiable factor associated with better palliative care outcomes in nursing homes.^{1,2,9-13} However, as presently conducted, ACP is often inadequate; counseling is inconsistent, patient preferences are not routinely ascertained, and advance directives are either not documented or do not reflect the goals of care.^{1,3,9,11,14-19} Verbal explanations of hypothetical health states and treatments are difficult to envision and are hindered by literacy and language barriers. Video ACP support tools attempt to address these shortcomings. From 2009 to 2013, several small, traditional (efficacy) randomized clinical trials (RCTs) found that individuals who were shown these videos were more likely to opt for comfort care (vs life-prolonging or intermediate care) compared with individuals who were read verbal narratives of care options.²⁰⁻²⁴ In terms of more downstream outcomes, 1 pilot RCT found that patients with cancer who were shown a video by clinicians had greater ACP documentation after 30 days.²⁵ Although these videos had begun to be adopted into clinical care as early as 2012,²⁶ no rigorous trials evaluating their real-world effectiveness had been conducted, to our knowledge.

In late 2013, motivated by promising efficacy data and an evaluation of the ACP videos' effectiveness in practice, the Pragmatic Trial of Video Education in Nursing Homes (PROVEN) was designed. PROVEN was a pragmatic cluster RCT conducted in partnership with 2 nursing home systems that embedded an ACP video program into the routine care provided at intervention facilities.²⁷⁻³⁰ This report presents the effect of the intervention on PROVEN's primary outcome: hospital transfers over 12 months among long-stay (>100 days) residents with advanced dementia or cardiopulmonary disease (hereafter referred to as advanced illness). Secondary outcomes for long-stay patients with and without advanced illness include burdensome treatment and hospice use. Intervention fidelity was reported as the proportion of residents offered and shown ACP videos.

Methods

Brown University's institutional review board approved the study's conduct with a waiver of informed consent because this was a minimal-risk trial, the program was rolled out to all residents in the nursing homes as part of clinical care, and all data that were collected were done so as part of routine care. Trial design details are provided in the trial protocol in [Supplement 1](#).²⁷

Facilities and Randomization

PROVEN was conducted in 360 nursing homes (119 intervention and 241 control) across 32 states owned by 2 for-profit nursing

Key Points

Question Can an advance care planning video program embedded in nursing home health care systems affect hospital transfers, burdensome treatments, and hospice enrollment among residents with and without advanced illness?

Findings In this pragmatic cluster randomized clinical trial of 12 479 residents with advanced illness, hospital transfers, burdensome treatments, and hospice enrollment did not significantly differ between the video intervention and control group. Intervention fidelity was low and variable across facilities.

Meaning An advance care planning video program did not significantly affect hospital transfers, burdensome treatments, or hospice enrollment among residents with and without advanced illness; low intervention fidelity underscores implementation challenges in this setting.

home chains, with case mix, staffing ratios, and size characteristics typical of other for-profit nursing home chains.²⁷ Eligible facilities had more than 50 beds, as determined from the 2013 Online Survey Certification and Reporting survey,³¹ and both long-stay (>100 days) and short-stay patients as determined by the Minimum Data Set (MDS).^{32,33} Among eligible facilities, corporate leaders excluded those with serious organizational problems or an inability to transfer electronic health records. The remaining facilities underwent random assignment.

Facilities were first stratified by health care system and then tertiles based on the distribution of the primary outcome aggregated at the facility level determined from 2013 MDS data: hospitalizations per 1000 person-days alive among residents with advanced dementia, chronic obstructive pulmonary disease, or congestive heart failure (eTable 2 in [Supplement 2](#)). Facilities in each stratum were randomized into the intervention and control groups in a 1:2 ratio.

In December 2015, corporate leaders sent letters to facility administrators randomized to the intervention group describing their selection to participate in the ACP video program. Although administrators could opt out, all agreed to participate. Facility administrators in both groups were not informed they were in a research trial.

Participants

Resident enrollment began February 1, 2016, and ended May 31, 2018, with 12-month follow-up for each resident completed by May 31, 2019. The protocol dictated that all patients admitted to or living in intervention facilities during the enrollment period should be offered the opportunity to watch a video (trial protocol in [Supplement 1](#)). Thus, all patients in facilities during this period constituted the study population.

The target population for the primary outcome was long-stay nursing home residents with advanced illness, for whom the opportunity and need to improve ACP was greatest. Advanced illness was defined by the following criteria on an MDS assessment completed by nurses either at the start or during the enrollment period: (1) 65 years of age or older, (2) long-stay residence (>100 days), (3) enrollment in the Medicare fee-for-service program, and (4) either advanced dementia or

Table 1. Examples of Verbal and Visual Descriptions of Levels of Care Presented in the Advance Care Planning Videos

| Video description | Life-prolonging care | Limited medical care | Comfort care |
|---------------------------|---|--|---|
| Narration | | | |
| Goal | Prolong life | Return to level of functioning prior to illness | Maximize comfort |
| Treatment types | All available, such as CPR, mechanical ventilation, and ICU care | Conservative treatments for potentially reversible conditions, such as antibiotics and intravenous fluids; no CPR, mechanical ventilation, or ICU care | Only treatments to reduce suffering, such as analgesics and oxygen; no CPR, mechanical ventilation, or ICU care |
| Setting | Hospital | Nursing home or hospital | Usually nursing home; hospital only if needed for comfort |
| Examples of visual images | Resuscitation performed on a simulated patient, actual mechanically ventilated patient in the ICU, and patient with advanced dementia with a feeding tube | Patient in a hospital ward bed receiving intravenous therapy | Patient receiving oxygen in a nursing home bed and receiving assistance with self-care |

Abbreviations: CPR, cardiopulmonary resuscitation; ICU, intensive care unit.

cardiopulmonary disease (chronic obstructive pulmonary disease or congestive heart failure) as defined using MDS 3.0 variables.^{34,35} Advanced dementia was defined as having either Alzheimer disease or other dementia, advanced cognitive impairment (Cognitive Function Scale score of 3 or 4³⁶), and needing extensive or total assistance for eating and transferring. Advanced cardiopulmonary disease was defined as having either chronic obstructive pulmonary disease or congestive heart failure plus shortness of breath while sitting or supine and needing extensive or total assistance with walking, transferring, locomotion, or dressing. This report also presents secondary analyses among long-stay, Medicare fee-for-service residents 65 years of age or older without advanced illness.

Intervention

The intervention consisted of 5 existing 6- to 10-minute videos in English or Spanish: (1) General Goals of Care, (2) Goals of Care for Advanced Dementia, (3) Hospice, (4) Hospitalization, and (5) ACP for Healthy Patients.^{21,37-39} The Goals of Care video outlined 3 broad approaches to care: intensive medical care, basic medical care, and comfort care, accompanied by narration and images of typical treatments representing each approach (Table 1).²⁷ Goals of Care for Advanced Dementia used a similar framework but targeted proxies of residents with this condition. The hospice and hospitalization videos focused on these management options. The ACP for Healthy Patients video presented basic ACP information for relatively healthy patients admitted for time-limited recuperation. Videos were preloaded onto tablet computers (2 per facility) and were also accessible online with a password-protected weblink.

Each nursing home system employed a dedicated senior project manager to oversee their organization's program rollout. At each nursing home, 2 ACP video program champions, typically social workers, were identified and charged with showing videos to patients and families (ie, no other frontline staff were asked to show videos). The project manager partnered with the ACP champions throughout all stages of planning, training, and implementation. Project managers were aware a trial was being conducted, whereas champions were not.

Starting January 2016, 4 sequential waves of intervention nursing homes (approximately 30 per wave) underwent a 1-month training period prior to starting resident enrollment and intervention implementation. Training materials included printed toolkits, webinars, and pocket-sized reference guides. The PROVEN implementation team and project managers jointly trained champions either by webinar (primary mode in health care system 1) or in-person conference (primary mode in health care system 2). The protocol instructed the ACP champions to offer videos to all residents or their proxies (1) within 7 days of admission or readmission, (2) every 6 months, (3) when specific decisions arose (eg, transition to hospice care), and (4) under special circumstances (eg, out-of-town family visit). Champions chose which video(s) to offer. Residents and proxies were offered the opportunity to view videos on tablet computers at the facility or, if that was not feasible, online.

To monitor fidelity, a video status report was embedded into all facilities' electronic medical records. Champions were instructed to complete these reports whenever a video was offered, indicating whether it was shown once it was offered (ie, the resident could refuse). The research team linked video status reports and the nursing homes' MDS data to create fidelity reports that were distributed to intervention facilities quarterly. Every 2 months, individual ACP champions met by telephone with the project manager and PROVEN implementation team to review these reports and address implementation challenges. Additional steps taken in January 2017 to further enhance fidelity included the following: (1) champion meetings were increased to monthly meetings; (2) lists of long-stay patients who had not been shown a video were generated and reviewed at these meetings, and the group problem-solved on how to reach these individuals; and (3) project managers visited facilities to investigate reasons for nonadherence and motivate engagement.

Control nursing homes used their usual ACP procedures. Facilities in both groups could continue to use other programs intended to improve ACP or reduce hospitalizations.^{40,41}

Data Sources and Baseline Variables

Data sources included Centers for Medicare & Medicaid Services Medicare claims and nursing homes' electronic health records (MDS 3.0,³⁴ video status report). Medicare claims were accessed via the Virtual Research Data Center Workbench.⁴² Nursing homes transferred residents' electronic medical record and MDS data to the data coordinating center monthly, and these were matched with Medicare enrollment records.

The baseline characteristics of the residents were ascertained from the first MDS assessment in which residents met criteria for either the advanced illness or nonadvanced illness cohorts. Demographic data included age, sex, race/ethnicity, and length of stay (number of days). Functional status was quantified using the MDS Activities of Daily Living scale (range, 0-28, where 28 indicates total functional dependence and 0 indicates no functional dependence).⁴³ Mortality risk was measured using the MDS 3.0 Mortality Risk Score (range, 0-39, where higher scores indicate higher mortality risk).⁴⁴ Hospice enrollment at baseline was determined using Medicare claims.

Outcomes

The primary outcome was the number of hospital transfers per 1000 person-days alive among long-stay residents with advanced illness. Each resident was followed up for up to 12 months, starting with the MDS assessment date on which they first became eligible. Death dates were determined using Medicare records. If residents switched to Medicare Advantage plans, their end date was the last day of Medicare fee-for-service coverage. Hospital transfers were based on Medicare claims for admissions, emergency department visits, and observation stays, treated as mutually exclusive events. Hospital transfers per 1000 person-days alive in the long-stay residents without advanced illness was a secondary outcome.

Secondary outcomes analyzed in the advanced illness and nonadvanced illness cohorts included the proportion of residents experiencing the following over 12 months: at least 1 hospital transfer, at least 1 burdensome treatment, and hospice enrollment. Burdensome treatments determined from Medicare claims and MDS assessments (eTable 2 in [Supplement 2](#)) were tube feeding, parenteral therapy (for hydration or medication delivery), invasive mechanical intervention, and intensive care unit admission.^{1-5,45} Mortality was examined for descriptive purposes but was not a prespecified outcome. Intervention fidelity was measured as the proportion of residents offered and shown a video at least once based on champion reports.

Masking

Members of the research team (including A.E.V.) and the program managers were aware of the intervention facilities but were not involved in data programming or analyses. Control facilities were known to Brown University statisticians and analysts who were involved in randomization and in preparing Data Safety and Monitoring reports. Two of us (S.L.M. and V.M.) were masked to the identities of the control and intervention facilities.

Statistical Analysis

Variables were described using mean (SD) values for continuous variables and proportions for categorical variables. Analy-

ses followed the intention-to-treat principle. Hierarchical models were used to adjust for facility-level clustering.

To test the intervention's effect on the number of hospital transfers per 1000 person-days alive, a multilevel zero-inflated Poisson model with an indicator for assignment to the intervention was implemented.⁴⁶ A 2-sided test of the difference in marginal mean values was used to examine the null hypothesis, and SEs were calculated via bootstrapping.⁴⁷ Marginal rate differences with 95% CIs were generated. Logistic regression was used to estimate the intervention's effect on binary secondary outcomes, generating marginal risk differences and 95% CIs. Residents receiving hospice care at baseline were excluded from the hospice analysis. Sensitivity analyses adjusting for stratification variables (nursing home chain and prior hospitalization rates) were conducted for hospital transfer outcomes. $P < .05$ was considered significant.

Statistical Power and Sample Size

Sample size estimates were based on the primary outcome (hospital transfers per 1000 person-days alive over 12 months among long-stay residents with advanced illness) and guided by prior studies examining the effect of other nursing home ACP interventions on hospitalization rates.^{48,49} Computations assumed a Poisson distribution and equal number of facilities in each group.⁵⁰ Hospital transfers per person-year in the control group were estimated to be 1.51 based on the 2 health care systems' 2012-2013 MDS data. To achieve at least 90% power in testing for a 0.25-point absolute reduction in transfer rate, representing approximately a 16% relative reduction, 103 facilities per group were required. On average, 42 residents per facility were expected to meet eligibility criteria and contribute 12 months of observation, resulting in 4326 residents per group.

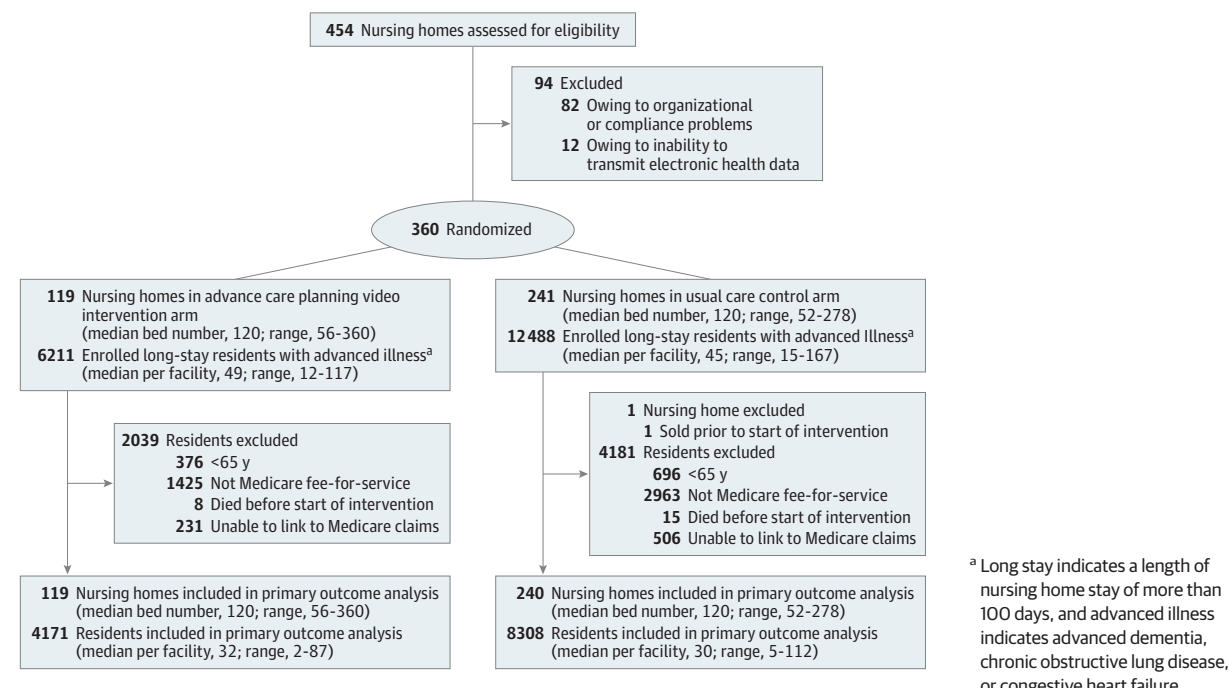
To accommodate an anticipated 10% facility nonparticipation rate, 16 additional facilities were recruited into the intervention group for a total of 119 facilities. As there were 360 eligible facilities in the 2 health care systems, the remaining 241 facilities were assigned to the control group to allow for a more precise estimate of the outcome. Thus, 4998 eligible residents were estimated to be in the intervention group, and 10 122 eligible residents were estimated to be in the control group.

Results

Facility and Resident Characteristics

A total of 454 facilities met initial eligibility criteria (356 in health care system 1 and 98 in health care system 2) ([Figure](#)). Ninety-four facilities were excluded owing to organizational problems ($n = 82$) or an inability to transfer electronic records ($n = 12$). Among the remaining 360 facilities, 119 were randomly assigned to the intervention group and 241 were randomly assigned to the control group (health care system 1 had 98 intervention and 199 control facilities, and health care system 2 had 21 intervention and 42 control facilities). One facility randomized to the control group was sold prior to the tri-

Figure. CONSORT Diagram of Nursing Homes and Residents



al's initiation, leaving 240 facilities in that group. In several facilities sold after the trial began, enrollment in the study ceased after the sale. However, because Medicare claims were used for outcome determination, no enrolled residents were lost to follow-up. The final analytic sample for the primary outcome included 4171 residents with advanced illness in the intervention group and 8308 residents with advanced illness in the control group. For secondary outcome analyses, 5764 long-stay residents without advanced illness were in the intervention group and 11 773 long-stay residents without advanced illness were in the control group.

The advanced illness cohorts were similar in both groups with respect to demographic characteristics and to mean activities of daily living and MDS 3.0 Mortality Risk Scores (Table 2).^{43,44} Approximately one-third of residents in both groups were receiving hospice care at baseline (intervention group, 1426 of 4171 [34.2%]; control group, 2875 of 8308 [34.6%]). Over 12 months, 1829 of 4171 residents (43.9%) with advanced illness in the intervention group and 3764 of 8308 residents (45.3%) with advanced illness in the control group died. The mean (SD) follow-up time was 253.1 (136.2) days in the intervention group and 252.6 (135.2) days in the control group. Residents without advanced illness were younger, less functionally dependent, at a lower risk of death, less frequently enrolled in hospice, and had lower mortality rates and longer mean follow-up times relative to the cohort with advanced illness (Table 2).

Hospital Transfers

There was no significant reduction of hospital transfers per 1000 person-day alive between the intervention (3.7; SE, 0.2; 95% CI, 3.4-4.0) and control group (3.9; SE, 0.3; 95% CI,

3.6-4.1) (rate difference, -0.2; SE, 0.3; 95% CI, -0.5 to 0.2) (Table 3). The outcome distribution was highly skewed. Only 41.1% of advanced illness residents (1704 of 4147) in the intervention facilities and 41.4% (3443 of 8308) in the control facilities experienced at least 1 hospital transfer, which did not differ significantly between groups (risk difference, -0.7%; SE, 1.5%; 95% CI, -3.7% to 2.3%). Most hospital transfers in the intervention group (3466 total transfers) were attributable to admissions (1985 [57.3%]), followed by emergency department visits (1287 [37.1%]) and observation stays (194 [5.6%]). The distribution was similar in the control group. Hospital transfer rates and the proportion of residents with at least 1 transfer did not differ significantly between groups among residents without advanced illness. Sensitivity analyses adjusting for stratification variables slightly reduced the SEs but did not change our overall conclusions for hospital transfer outcomes.

Secondary Outcomes

Among residents with and without advanced illness, the proportion experiencing any burdensome treatment (eTable 1 in Supplement 2) and enrolled in hospice did not significantly differ between groups (Table 4). Exploratory analyses stratifying the cohorts by health care system and advanced illness type also found nonsignificant differences between trial groups for all outcomes.

Intervention Fidelity

Based on the video status reports, an estimated 2320 of the 4171 residents (55.6%) with advanced illness in the intervention group or their proxies were offered the opportunity to watch a video, and 912 (21.9%) were shown a video at least

Table 2. Characteristics of Long-Stay Nursing Home Residents^a

| Characteristic | Residents, No. (%) | | | |
|------------------------------------|------------------------------------|--------------------|--------------------------|----------------------|
| | With advanced illness ^b | | Without advanced illness | |
| | Intervention (n = 4171) | Control (n = 8308) | Intervention (n = 5764) | Control (n = 11 773) |
| Baseline characteristics | | | | |
| Age, mean (SD), y | 83.6 (9.1) | 83.6 (8.9) | 81.5 (9.2) | 81.3 (9.2) |
| Female sex | 2970 (71.2) | 5857 (70.5) | 3692 (64.1) | 7467 (63.4) |
| Race/ethnicity | | | | |
| White | 3270 (78.4) | 6768 (81.5) | 4626 (80.3) | 9123 (77.5) |
| Black | 745 (17.9) | 1281 (15.4) | 947 (16.4) | 1617 (13.7) |
| Asian | 36 (0.9) | 59 (0.7) | 36 (0.6) | 93 (0.8) |
| Hispanic | 39 (0.9) | 82 (1.0) | 54 (0.9) | 143 (1.2) |
| Other ^c | 22 (0.5) | 47 (0.6) | 38 (0.7) | 68 (0.6) |
| Unknown | 8 (0.2) | 32 (0.4) | 21 (0.4) | 52 (0.4) |
| Advanced dementia | 2862 (68.6) | 5824 (70.1) | NA | NA |
| Advanced CHF or COPD ^b | 1475 (35.4) | 2772 (33.4) | NA | NA |
| Hospice care at baseline | 1426 (34.2) | 2875 (34.6) | 470 (8.2) | 1055 (9.0) |
| ADL score, mean (SD) ^d | 21.8 (3.8) | 21.9 (3.8) | 14.7 (6.8) | 15.1 (6.7) |
| MRS3 score, mean (SD) ^e | 7.6 (2.9) | 7.6 (2.8) | 4.6 (2.0) | 4.6 (2.0) |
| Follow-up characteristics | | | | |
| Died during follow-up | 1829 (43.9) | 3764 (45.3) | 1472 (25.5) | 3019 (25.6) |
| Days of follow-up, mean (SD) | 253.1 (136.2) | 252.6 (135.2) | 296.4 (114.2) | 296.1 (114.8) |

Abbreviations: ADL, activities of daily living; CHF, congestive heart failure; COPD, chronic obstructive lung disease; MRS3, MDS 3.0 Mortality Risk Score; NA, not applicable.

^a Long-stay: over 100 days in nursing home.

^b Advanced illness includes residents with advanced dementia, advanced CHF, and advanced COPD.

^c Other includes Native Hawaiian or other Pacific Islander, Native American or Alaska Native, or more than 1 race/ethnicity.

^d The ADL score (0-28) is the sum of scores in 7 domains of function including: bed mobility, dressing, toileting, transfer, eating, grooming, and locomotion. Each is scored on a 5-point scale (0, independent; 1, supervision; 2, limited assistance; 3, extensive assistance; and 4, total dependence). A score of 28 represents complete functional dependence.⁴³

^e Range, 0-39; higher scores indicate higher risk of mortality.⁴⁴

Table 3. Primary Outcome of Advance Care Planning Video Intervention Among Long-Stay Nursing Home Residents

| Outcome | Residents with advanced illness | | | Residents without advanced illness | | |
|--|---------------------------------|------------------------|--|------------------------------------|------------------------|--|
| | Rate (SE) [95% CI] | | Marginal rate difference (SE) [95% CI] | Rate (SE) [95% CI] | | Marginal rate difference (SE) [95% CI] |
| | Intervention (n = 4171) | Control (n = 8308) | | Intervention (n = 5764) | Control (n = 11 773) | |
| Hospital transfers/1000 person-days alive ^a | 3.7 (0.2) [3.4 to 4.0] | 3.9 (0.3) [3.6 to 4.1] | -0.2 (0.3) [-0.5 to 0.2] | 3.4 (0.1) [3.2 to 3.5] | 3.4 (0.1) [3.3 to 3.5] | 0.0 (0.1) [-0.3 to 0.2] |

^a Hospital transfers include admissions, emergency department visits, and observation stays.

Table 4. Secondary Outcomes of Advance Care Planning Video Intervention Among Long-Stay Nursing Home Residents^a

| Outcome | Residents with advanced illness | | | Residents without advanced illness | | |
|---------------------------------------|---------------------------------|---------------------------|--------------------------|------------------------------------|---------------------------|---------------------------|
| | % (SE) [95% CI] | | MRD (SE) [95% CI] | % (SE) [95% CI] | | MRD (SE) [95% CI] |
| | Intervention (n = 4171) | Control (n = 8308) | | Intervention (n = 5764) | Control (n = 11 773) | |
| ≥1 Hospital transfer ^b | 40.9 (1.2) [38.4 to 43.2] | 41.6 (0.9) [39.7 to 43.3] | -0.7 (1.5) [-3.7 to 2.3] | 44.8 (1.0) [42.8 to 46.7] | 45.3 (0.8) [43.8 to 46.7] | -0.5 (1.2) [-3.21 to 1.8] |
| ≥1 Burdensome treatment ^c | 9.6 (0.8) [8.0 to 11.3] | 10.7 (0.7) [9.4 to 12.1] | -1.1 (1.1) [-3.2 to 1.1] | 6.4 (0.5) [5.3 to 7.6] | 7.3 (0.4) [6.5 to 8.2] | -0.9 (0.7) [-2.3 to 0.5] |
| Enrolled in hospice care ^d | 24.9 (1.2) [22.6 to 27.2] | 25.5 (0.9) [23.3 to 27.2] | -0.6 (1.5) [-3.4 to 2.4] | 4.8 (0.4) [4.0 to 5.7] | 5.5 (0.3) [5.0 to 6.2] | -0.8 (0.5) [-1.8 to 0.3] |

Abbreviation: MRD, marginal risk difference.

^a All secondary outcomes are measured as the proportion of residents who experienced the outcome over a 12-month follow-up.

^b Hospital transfers include admissions, emergency department visits, and observation stays.

^c Burdensome treatments include tube feeding, parenteral therapy (for

hydration or medication delivery), invasive mechanical intervention, and admission to an intensive care unit.

^d Residents enrolled in hospice care at baseline are excluded from these analyses (1602 residents with advanced illness and 347 residents without advanced illness).

once (ie, the resident or proxy could refuse when offered). Facility-level rates of videos shown varied considerably across intervention nursing homes (119 facilities: 0%, 14 facilities [11.8%]; 1%-10%, 28 facilities [23.5%]; 11%-20%, 27 facilities [22.7%]; 21%-40%, 28 facilities [23.5%]; and >40%, 22 facilities [18.5%]).

Discussion

In this pragmatic cluster RCT conducted in 2 nursing home health care systems, an ACP video program was not effective in significantly reducing the number of hospital transfers,

decreasing the number of burdensome treatments, or increasing the number of hospice enrollments among long-stay residents with or without advanced illness. Intervention fidelity was low and highly variable across facilities, underscoring implementation challenges in nursing homes. The lack of effectiveness of the intervention must be interpreted in the context of what is known about the efficacy of ACP videos, low intervention fidelity, and challenges ascertaining outcomes indicative of high-quality ACP in pragmatic RCTs.

Pragmatic RCTs ideally follow traditional RCTs demonstrating the efficacy of an intervention.^{51,52} In late 2013 when PROVEN was conceived, efficacy data supporting its conduct were based largely on several small RCTs reporting increased preferences for comfort care among individuals who were shown the ACP videos by research staff and 1 pilot RCT demonstrating greater ACP documentation among patients with cancer who were shown videos by clinicians.²⁵ Findings from the Educational Video to Improve Nursing Home Care in End-stage dementia (EVINCE) trial, a traditional (efficacy) cluster RCT that examined more downstream outcomes,³⁹ emerged while PROVEN was being conducted. In the EVINCE trial, research staff showed ACP videos to proxies of nursing home residents in intervention facilities, ensuring 100% fidelity. Proxies in control facilities were read verbal narratives of care options. No difference in preferences, do-not-hospitalize orders (primary outcome), or burdensome treatments between trial groups was found. When interpreting these findings in the context of those of PROVEN, it is important to recognize that stand-alone interventions tested in efficacy trials, such as EVINCE, fundamentally change when adapted for programmatic implementation within a health care system. In fact, a main purported explanation for the EVINCE trial's negative findings was that the videos were not integrated into clinical care, as ACP must be done in practice.³⁹

Although PROVEN aimed to evaluate the effectiveness of ACP videos by integrating them into nursing homes' work flow and charging direct care clinicians with their delivery, clearly the pragmatic approach has its trade-offs. Only approximately 1 in 5 targeted residents with advanced illness (or their proxies) were shown videos. Thus "implementation error," which implies that the intervention was ineffective because most residents did not receive it, may explain our nonsignificant findings.⁵³ The low intervention fidelity also raises the consideration of a per-protocol analysis, which attempts to evaluate the intervention effect only among residents known to receive it. Per-protocol analyses are not straightforward in pragmatic RCTs.⁵⁴ Moreover, intention-to-treat analysis arguably better evaluates the intervention's effectiveness under conditions that reflect the typical messiness of a new program rollout within a health care system. Program implementation is particularly challenging in the nursing home environment; clinicians have limited bandwidth to care for an increasingly complex patient population, staff turnover is common, and quality of care is highly variable.^{8,40} Earlier quantitative and qualitative reports from PROVEN found that facilities with higher 5-star quality ratings⁵⁵ had higher fidelity rates,²⁸ as did

those with greater champion engagement in implementation (eg, higher attendance in telephone meetings) and enthusiasm for ACP practices.³⁰

In keeping with a pragmatic trial paradigm,⁵⁶ the hospital transfer rate was selected as the primary outcome as it was both important to key stakeholders (eg, health care systems, patients, and insurance programs)⁸ and ascertainable using secondary data. However, palliative care experts are increasingly advocating "care consistent with goals" as the most relevant measure of successful ACP.^{57,58} To this point, exploratory analyses of the EVINCE trial found that when comfort care was preferred, residents in intervention vs control nursing homes were more likely to have documented directives consistent with that preference (eg, do-not-hospitalize directives).^{39,59} That said, measuring goal-concordant care in the context of a pragmatic RCT is challenging, as it either requires primary data collection or an in-depth review of electronic health records.⁵⁷

Limitations

Our findings must be considered in the context of several limitations. First, hospital transfer rates decreased across US nursing homes while PROVEN was conducted.³⁵ Secular changes outside the trial that may affect outcomes are an accepted feature of pragmatic RCTs but are expected to affect trial groups nondifferentially. Second, inadequate power may have contributed to the nonsignificant findings. Fewer residents were enrolled than estimated in our sample size calculations for the primary outcome in the intervention (4171 vs 4998) and control (8307 vs 10 222) groups, possibly owing to higher than anticipated Medicare Advantage participation and mortality rates. Third, we did not have information on how the intervention may have affected decision-making for ACP. Advance directives were not consistently available, as they are not in the MDS 3.0 or systematically documented across the electronic medical records of the PROVEN nursing homes.

Conclusions

As one of the first large, pragmatic RCTs to be conducted in the nursing home setting, PROVEN's inability to demonstrate a significant effect on hospital transfer rates and other outcomes among long-stay residents is sobering. Implications should be considered from the perspectives of various key stakeholders. For corporate leaders, front-line clinicians, and frail nursing home residents, widely adoptable programs with known effectiveness in promoting high-quality ACP remain elusive. For palliative care researchers, creative approaches are needed to capture goal-concordant care in pragmatic RCTs.⁵⁷ Finally, for pragmatic trialists and implementation scientists focused on the nursing home setting, the highest level of health care system readiness and endorsement from senior and local leadership must be present before embarking on pragmatic RCTs; otherwise, low implementation fidelity may compromise interpretation of its findings.

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