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PRagmatic trial Of Video Education in Nursing Homes (PROVEN): The design and rationale for a pragmatic cluster randomized trial in the nursing home setting

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Abstract

Background/Aims—Nursing homes are complex healthcare systems serving an increasingly sick population. Nursing homes must engage patients in advance care planning, but do so inconsistently. Video decision support tools improved advance care planning in small randomized controlled trials (RCTs). Pragmatic trials are increasingly employed in health services research, although not commonly in the nursing home setting to which they are well-suited. This report presents the design and rationale for a pragmatic cluster RCT that evaluated the “real world” application of an Advance Care Planning Video Program in two large U.S. nursing home healthcare systems.

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Declaration of conflicting interests

Drs. Gutman, Gatsonis, and Mitchell have no conflicts of interest.

Dr. Mor holds stock in PointRight, Inc. an information services company whose clients are the nursing home industry; chairs the Independent Quality Committee for HRC Manor Care, Inc.; chairs a Scientific Advisory Committee for NaviHealth, a post-acute care service organization; serves as a Technical Expert panel member on several Center for Medicare/Medicaid quality measurement panels; and is a member of the board of directors of Tufts Health Plan Foundation, Hospice Care of Rhode Island, and The Jewish Alliance of Rhode Island.

Dr. Volandes is President of Nous Foundation, Inc., (www.ACPDecisions.org) a not-for profit (501[c]3) foundation that disseminates educational videos. Dr. Volandes has a financial interest in the not-for-profit, which was reviewed and is managed by Massachusetts General Hospital and Partners HealthCare in accordance with their conflict of interest policies.

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Methods—PROVEN (PRagmatic trial Of Video Education in Nursing homes) was conducted in 360 nursing homes (N=119 intervention/N=241 control) owned by two healthcare systems. Over an 18 month implementation period, intervention facilities were instructed to offer the Advance Care Planning Video Program to all patients. Control facilities employed usual advance care planning practices. Patient characteristics and outcomes were ascertained from Medicare Claims, Minimum Data Set assessments, and facility electronic medical record data. Intervention adherence was measured using a Video Status Report embedded into electronic medical record systems. The primary outcome was the number of hospitalizations/person-day alive among long-stay patients with advanced dementia or cardiopulmonary disease. The rationale for the approaches to facility randomization and recruitment, intervention implementation, population selection, data acquisition, regulatory issues, and statistical analyses are discussed.

Results—The large number of well-characterized candidate facilities enabled several unique design features including: stratification on historical hospitalization rates, randomization prior to recruitment, and 2:1 control to intervention facilities ratio. Strong endorsement from corporate leadership made randomization prior to recruitment feasible with 100% participation of facilities randomized to the intervention arm. Critical regulatory issues included: minimal risk determination, waiver of informed consent, and determination that nursing home providers were not engaged in human subjects research. Intervention training and implementation were initiated on January 5, 2016 using corporate infrastructures for new program roll-out guided by standardized training elements designed by the research team. Video Status Reports in facilities' electronic medical records permitted "real-time" adherence monitoring and corrective actions. The Centers for Medicare and Medicaid Services Virtual Research Data Center allowed for rapid outcomes ascertainment.

Conclusions—We must rigorously evaluate interventions to deliver more patient-focused care to an increasingly frail nursing home population. Video decision support is a practical approach to improve advance care planning. PROVEN has the potential to promote goal-directed care among millions of older Americans in nursing homes and establish a methodology for future pragmatic RCTs in this complex healthcare setting.

Keywords

Cluster randomized clinical trial; advance care planning; end of life; decision aids; pragmatic trial; nursing home

Introduction

Over the past three decades, nursing homes have evolved into complex healthcare systems serving nearly 4 million individuals annually. Approximately 20% of all hospitalized Medicare beneficiaries are discharged to nursing homes.¹ On any given day, approximately 1 million older persons with advanced chronic diseases are permanent nursing home residents.^{2,3} Nursing homes also commonly care for terminally ill patients. In 2009, 45% of U.S. Medicare decedents were in nursing homes during the last 90 days of life, and 28% died in that setting.⁴

Given the increasing clinical complexity and advanced disease of the population, nursing homes are often charged with guiding patients through challenging decisions about the direction of their treatment. Advance care planning is the *process* of communication between providers and patients/families to identify anticipated medical decisions and clarify treatment preferences. Ideally, advance care planning leads to *advance directives* (e.g., do-not-resuscitate, do-not-hospitalize) that come into effect when patients become incapacitated. While nursing homes are mandated to ascertain patients' advance directives,⁵ advance care planning in this setting remains suboptimal; counseling is inconsistent, care preferences are not routinely ascertained, and advance directives may not be discussed or reflect patients' goals of care.^{6–15}

Traditional advance care planning relies on verbal descriptions of hypothetical health states and treatments. This approach is limited because complex scenarios are difficult to envision, information is inconsistent, and verbal explanations are hindered by literacy and language barriers. To address these shortcomings, advance care planning video decision support tools have been developed, which have improved advance care planning in small randomized controlled trials (RCTs).^{16–23} Prior to widespread uptake, rigorous evaluation of the impact of these tools on patient outcomes when implemented as they would be in the real-world is an essential next step.

The pragmatic cluster RCT design is ideally suited to evaluate the effectiveness of advance care planning video decision support in the nursing home setting.²⁴ The intervention is standardized but flexible, and introduced at the facility-level providing the rationale for cluster randomization. Furthermore, extensive administrative and clinical data are routinely collected electronically that could be leveraged to describe patients and outcomes. In 2015, with federal funding specifically intended to promote collaborative clinical trials within healthcare systems, we partnered with two nursing home corporations to conduct “**PR**agmatic trial **O**f **V**ideo **E**ducation in **N**ursing **H**omes (PROVEN),” the first large pragmatic cluster RCT of a system-wide intervention in U.S. nursing homes. This report describes the unique aspects of PROVEN's design and factors influencing our selection of its features (Table 1).

Methods

Facility selection, random assignment, and recruitment

Two for-profit nursing home healthcare systems, operating 456 facilities (healthcare system 1, N=358; healthcare system 2, N=98) in 32 states participated. Facility selection, facility randomization, and recruitment were conducted in December 2015 using several innovative approaches.

Facilities were eligible if they had > 50 beds and served both short- and long- term patients. Such facilities were identified using 2013 data from two linked nationwide sources; size was ascertained from publically available Online Survey Certification and Reporting surveys collected annually for nursing home re-certification. Case-mix was determined from the federally-mandated Minimum Data Set.^{25,26} Nursing homes must complete Minimum Data Set assessments on each patient upon admission, quarterly thereafter, and upon discharge,

and regularly transmit these data electronically to the Centers for Medicare and Medicaid Services. Minimum Data Set assessments contain over 400 data elements ranging from demographics, diagnoses, and treatments to cognitive and physical functioning. Next, corporate leaders excluded facilities with serious organizational or regulatory compliance problems. Removing these problematic facilities from the eligibility pool prior to randomization or recruitment mitigated a potential source of selection bias.²⁷ After these exclusions, 360 (79%) nursing homes remained eligible for random assignment (healthcare system 1, N=297 (83%); healthcare system 2, N=63 (64%)).

Random assignment involved two levels of stratification (Figure 1). First, facilities were stratified by healthcare system because variation in corporate-level processes, size, clinical practice culture, and endorsement of the study could influence outcomes. Next, facilities were stratified into terciles based on the distribution of our primary outcome aggregated at the facility-level as ascertained from 2013 Minimum Data Set data: hospitalizations/person-day alive among patients with advanced dementia or cardiopulmonary disease (chronic obstructive lung disease or congestive heart failure). We considered stratifying on multiple individual facility characteristics known to influence hospitalization rates (e.g., proportion of non-white residents, region, etc.).^{28,29} However, we mitigated potential confounding by many such facility factors by simply stratifying on the recent distribution of the exact primary outcome, and thus avoided complicated procedures involving more levels of stratification.

After applying these two levels of stratification, facilities in each stratum were ordered based on government-assigned facility identification numbers by a statistician masked to the nursing homes' names. Next, 119 facility numbers were randomly generated, assigned to the intervention arm and proportionately distributed across each stratum. The remaining facilities (N=241) were assigned to the control arm and similarly distributed across strata. Our sample size calculations estimated that approximately 119 nursing homes/arm were needed. However, all 360 eligible facilities were randomized in a roughly 2:1 ratio, between the control versus intervention arms because having more control nursing homes incurred no additional personnel or costs, yet increased the precision of the estimate of secular trends in the primary outcome, which is relevant given the decline in hospitalization rates among Medicare beneficiaries in recent years.³⁰ Following random assignment, but prior to recruitment, we verified that key facility characteristics from 2013 (staffing, size, hospitalization rates) were balanced between study arms (Table 2).

We considered recruiting nursing homes either before or after random assignment. Recruitment after randomization was chosen for the following reasons: 1. It avoided the awkwardness of offering facilities the possibility of the intervention, and then denying it to those randomized to the control arm, 2. It minimized contamination by allowing control facilities to remain unaware they were part of a trial, and 3. It was the healthcare systems' preferred approach as they felt that with strong corporate endorsement, the participation rate in facilities randomized to the experimental arm would be very high. Thus in December 2015, corporate leaders sent letters to administrators of facilities randomized to the intervention arm describing their nursing homes' selection to participate in the Advance Care Planning Video Program. While administrators could opt out, all agreed to participate.

Population

In actual practice, programs intended to improve advance care planning in nursing homes, such as our intervention, would be implemented facility-wide as standard operating procedures. Thus, the study protocol dictated that all patients in the intervention facilities, regardless of length of stay or diagnoses, should be offered to watch a video.

Correspondingly, all patients cared for in the intervention and control facilities during the 18-month study period, constituted the study population.

For the primary analysis, we selected a target population of long-stay nursing home patients with advanced illness because we hypothesized the Advance Care Planning Video Program would produce a demonstrable reduction in hospitalization rates in this group. The relatively high rate of hospitalizations in these patients³¹ increased the likelihood that large numbers of outcome events would be observed within the limited time-frame of an RCT. Moreover, the opportunity to reduce hospitalizations through advance care planning was greatest among nursing home patients with advanced disease. The decision to be hospitalized should align with the patient's goals of care. For frail older patients with advanced illnesses, the primary goal of care is often comfort (versus life prolongation) and with few exceptions (e.g., hip fracture), hospitalization rarely promotes that goal. We hypothesized that by exposing these patients to the video's standardized framework for aligning treatment choices with goals of care, they were more likely to forgo future hospitalizations compared to similar patients in the control condition who did not see the videos.

Eligibility criteria for the target population were: (a) ≥ 65 ; (b) long-stay in the facility (≥ 90 days); and (c) had advanced dementia or cardiopulmonary disease. Using Minimum Data Set variables, advanced dementia was defined as having either Alzheimer's disease or other dementia, advanced cognitive impairment (score of 3 or 4 on the Cognitive Function Scale³²), 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 for walking, transferring, locomotion, or dressing. Patients were eligible for the target sub-populations if they met these criteria either at the start or during the 18-month implementation phase. Secondary aims examined outcomes in two other sub-groups: (a) short-stay (< 90 days) patients with advanced disease; and (b) short- and long-stay nursing home patients without these advanced diseases.

Intervention design, implementation, and adherence monitoring

The intervention consisted of five previously created videos that addressed common advance care planning decisions in nursing homes: (a) General Goals of Care; (b) Goals of Care for Advanced Dementia; (c) Hospice; (d) Hospitalization; and (e) Advance Care Planning for Healthy Patients. The videos were in English and Spanish, 6–10 minutes in duration, and offered to patients, family members, or both as deemed appropriate by the providers.

The General Goals of Care video outlined three broad approaches to care: intensive medical care, basic medical care, and comfort care. Narrative explanations and visual images of typical treatments representing each approach were presented. For example, for intensive

care, a resuscitation being conducted on a simulated patient and an actual ventilated patient were shown. For basic care, a patient in a hospital bed getting intravenous treatment was shown. For comfort care, a patient getting oxygen and being assisted with self-care were shown. The advanced dementia video used a similar framework but targeted family members of patients with this condition. The hospice and hospitalization videos focused on these specific management options. The Healthy Patients video was primarily educational, presenting basic advance care planning information aimed at relatively healthy patients in the nursing home for time-limited recuperation. The videos were intended to supplement, not replace, existing advance care planning counseling practices. Thus, provider training included guidance on initiating advance care planning conversations, integrating videos into discussions, and debriefing with patients and families after the video.

Intervention training and implementation began in January 2015; approximately 30 intervention nursing homes were trained in each of 4 sequential waves. The implementation strategy was collaboratively designed by the research team and corporate leaders but executed almost exclusively by the healthcare systems. Each nursing home designated two advance care planning program champions, one of whom was a social worker, charged with leading implementation at their facility. Only corporate leaders were aware the intervention nursing homes were part of an RCT. Advance care planning champions and nursing home providers were simply told the program was a new, corporate-led initiative.

In keeping with a pragmatic trial, healthcare systems and nursing homes had flexibility to tailor the implementation protocol to their specific environments. The protocol instructed nursing home staff to offer videos to patients or families at the following trigger events: (a) Within 7 days of admission or readmission; (b) Every 6 months for long-stay patients; (c) When decisions were being discussed for which there was a specific video (e.g., hospice); and (d) Special circumstances (e.g., out-of-town family visit, change in health status). Clinicians could choose which video(s) to show, with the goal-of-care video being the most widely applicable. Videos were pre-loaded onto tablet devices (two devices per facility) and available for out-of-town family members through a password-protected web link.

Training materials included two printed toolkits, webinar companions to the toolkits, and pocket-sized reference guides. One toolkit focused on protocols for providers showing the videos to patients and families; another focused on implementing the videos into the nursing home workflow. Training occurred during the month prior to the implementation for each wave and periodically thereafter. Monthly conference calls are held among advance care planning champions, corporate leaders, and researchers to review the progress of implementation and resolve difficulties.

To monitor adherence, a Video Status Report was integrated into the electronic medical records of intervention nursing homes. Providers were instructed to complete the Video Status Report each time a video was offered, even if it was not shown (e.g., patient refused). The Video Status Report documented which video(s) was shown, who watched it (e.g., family, patient), and who showed it. The research team linked Video Status Report with real-time Minimum Data Set data to generate adherence reports which were sent to corporate leaders every quarter. The reports presented adherence measures for two primary

indications for offering videos which were readily quantifiable; within 7 days of admission/readmission and every 6 months for long-stay patients. Minimum Data Set data provided the denominator (e.g., number of admissions), and the Video Status Report provided the numerator (e.g., Video Status Reports completed for the new admissions). Both healthcare systems constructed similar internal reports, albeit primarily for admissions, every two weeks using their own data for more frequent monitoring.

Control conditions

Control nursing homes used their usual advance care planning procedures. We chose not to include an “attention control” (e.g., simple hand-out to patients and families about advance directives) for the following reasons: 1. Advance care planning, in some form, was already mandatory in all nursing homes; 2. It undermined the fact that control facilities were unaware of their involvement in a trial; and 3. We wanted to compare the effect of the intervention to “real-world” conditions. In that vein, both control and intervention facilities could continue to use other programs intended to improve advance care planning or reduce hospitalizations (e.g., INTERACT,³³ POLST³⁴).

Data sources, data elements, and linkage

The data coordinating center was at Brown University. One unique feature that clearly lent itself to the conduct of pragmatic trials in nursing homes was the robust foundation of standardized electronic clinical and administrative data present in virtually all U.S. nursing homes that can be leveraged to characterize patients and outcomes. In PROVEN, three sources of such data were linked: (a) Centers for Medicare and Medicaid Services (Medicare files, Minimum Data Set^{25,26}); (b) nursing homes’ electronic medical records (Minimum Data Set, Video Status Report, and advance directives); and (c) Online Survey Certification and Reporting (Table 3).

Minimum Data Set data were used to identify eligible facilities based on their case-mix, characterize the overall study population, identify target populations, and ascertain hospitalization rates. The electronic medical records provided Video Status Report data, and advance directives information captured as physician orders in some facilities and free text in others.

The Centers for Medicare and Medicaid Services Medicare files were used to track outcomes for fee-for-service beneficiaries, including hospitalizations, procedures for burdensome interventions (feeding tubes, intravenous therapy), and hospice enrollment. The Medicare enrollment records also provided information on vital status. Minimum Data Set data from the Centers for Medicare and Medicaid Services complemented nursing homes’ Minimum Data Set data by allowing tracking of patients from participant to non-participant facilities. On the other hand, Minimum Data Set data also allowed the capture of key outcomes (e.g., hospitalizations) generally missing from Medicare claims for beneficiaries in Medicare Advantage plans. Online Survey Certification and Reporting data were used to identify eligible facilities and compare features of nursing homes randomized to the control and intervention arms prior to recruitment.

We obtained a Data Use Agreement to work directly on the Virtual Research Data Center Workbench,³⁵ which allowed access to the Centers for Medicare and Medicaid Services data within 2–3 months after events occurred, as opposed to the more typical delayed time-frame (up to two years). Each month, nursing homes transferred electronic medical record data to Brown using secure processes. Individual identifiers from these records were assembled into a “finder” file, which was uploaded onto the Centers for Medicare and Medicaid Services system to match with Medicare and Minimum Data Set files.³⁵

Masking

Members of the research (Dr. Volandes) and healthcare systems’ implementation teams were aware of the identity of the intervention facilities but are not involved in any data programming, manipulation, or outcome analyses. The identities of the control facilities were known to a few analysts at Brown involved in randomization and preparation of reports for the Data Safety and Monitoring Board. Drs. Mitchell, Mor, and the lead statistician (Gatsonis) are masked to the identities of the control and intervention facilities.

Regulatory considerations

Regulatory aspects of the PROVEN Trial involved: (a) Institutional Review Board approval; (b) Data Use Agreements from healthcare system partners and the Centers for Medicare and Medicaid Services; and (c) Data Safety and Monitoring. The Brown Institutional Review Board approved the study by expedited review and included several critical determinations without which this pragmatic trial could not be conducted. The project was deemed minimal risk, which facilitated the approval of a waiver of informed consent. PROVEN could not have been conducted without waiving informed consent as the intervention was implemented by nursing home providers as a “standard of care.” If consent was required to use patients’ data, this would have had to be done in the control and intervention nursing homes, seriously undermining the trial’s pragmatic nature. Next, because providers were not obtaining consent or collecting data for research purposes, they were deemed not involved in human subjects research, which obviated the need to obtain Federal Wide Assurance numbers for each facility. Finally, a HIPAA (Health Insurance Portability and Accountability Act) waiver for authorization was granted for release of protected health information to identify patients with specific characteristics for our analyses. Data Use Agreements were obtained from the Centers for Medicare and Medicaid Services and each healthcare system. A Data Safety and Monitoring Board was established by the National Institute of Aging. The only reportable adverse event was the occurrence of a serious distressful reaction by patients or family members while or after watching a video.

Outcomes

The primary outcome was the number of hospitalizations/person-day alive among the target group of long-stay patients with advanced dementia or cardiopulmonary disease over 12 months measured at the patient-level. This measure was chosen because of its high clinical and policy relevance and because it can be measured accurately and reliably with existing data.³⁶ Prior work has shown that 23–60% of hospitalizations of nursing home patients are avoidable, because they are either unnecessary or unwanted, and if averted, could potentially save the health care system billions of dollars annually.^{37–41} Moreover, the need to reduce

avoidable hospitalizations is greatest among frail nursing home patients with advanced illnesses, for whom the burdens of hospitalization often outweigh the benefits. Advance directives (e.g., do-not-resuscitate) were considered an inferior choice for a primary outcome because they only reflect one step in the process of advance care planning rather than the actual care received. In addition, advance directives are not always ascertained, adhered to, or accurately documented.^{6–15}

Secondary outcomes included documented advance directives, use of burdensome treatments (e.g., tube-feeding, parenteral therapy), and hospice enrollment in long-stay patients with advanced illness over 12 months. Other secondary outcomes were measured in two additional groups. Among short-stay patients with advanced dementia or cardiopulmonary disease, secondary outcomes included: (a) advance directives at any time during admission, (b) any hospitalization within 100 days of admission, and (c) hospice enrollment within 100 days of admission. Finally, among short- and long-stay patients without advanced disease, secondary outcomes included: advance directives, hospitalization, burdensome treatments, and hospice enrollment.

Although the analyses compared mortality rates between the target subpopulation of very frail patients in each arm, mortality was not a pre-specified outcome nor was an effect on mortality anticipated.

Statistical analysis

Detailed description of the analytic methods is described in the online Appendix. Analyses followed the intention-to-treat principle (i.e., all randomized facilities were included in the analyses) and adjusted in any residual imbalances in patient characteristics between arms. Analyses for the primary outcome, number of hospitalizations/person-day over 12 months among long-stay residents with advanced disease, used a zero-inflated Poisson distribution with facility random effects to test the effect of the intervention, while adjusting for clustering at the nursing home level. A two-sided test of the difference in marginal means was used to examine the null hypothesis. This approach was chosen because 2013 Medicare data from participant nursing homes demonstrated that the distribution of the outcome was very dispersed, with many patients having no hospitalizations and a sizeable percentage having more than one hospitalization.^{42,43} To estimate the effect of the intervention on binary secondary outcomes (advance directives, burdensome treatments, hospice enrollment), we used a random effects logistic model.

Statistical power and sample size requirements

Sample size estimates were based on the primary trial outcome. Using 2013 data from both healthcare systems, we estimated the number of hospitalizations among patients with advanced illness per person-year alive in the control arm to be between 1.06 and 2.12. Based on prior research,^{28,44–47} we estimated that the absolute reduction in hospitalization rates in the intervention versus control nursing homes will range from .200 to .275 points, a 16% relative reduction.

Computations for sample size estimates were based on an approach for the comparison of incidence rates that uses a Poisson distribution for the outcome.^{48,49} To achieve power of at

least 90%, given a coefficient of variation of .37 estimated with 2013 Minimum Data Set data and alpha-level of 0.05, in testing for a .25 point absolute reduction in an average hospital transfer rate of 1.51, we required 103 facilities per study arm (Table 4). However, to accommodate a possible 10% non-participation rate among nursing homes in the intervention arm, an additional 16 facilities were recruited for a total of 119 intervention nursing homes. Moreover, because there was an available total pool of 360 eligible facilities, the remaining 241 facilities were randomized to the control arm (approximate 2:1 control to intervention) since there were no personnel or budgetary costs to do so. While twice the number of control facilities only marginally increased power, as power is primarily determined by the size of the smaller group,⁵⁰ it did allow for a more precise estimate of the outcome in the control group. Data from the two healthcare systems in 2013 revealed that, over 12 months, there were, on average, 42 long-stay patients with advanced dementia or cardiopulmonary disease per facility, resulting in an anticipated 5000 patients in 119 intervention nursing homes and 10,000 patients in the 241 control nursing homes.

Discussion

PROVEN illustrates the tremendous potential of implementing pragmatic cluster RCTs in the nursing home setting, a growing and critical segment of the healthcare continuum. While standardized electronic medical records are increasingly being introduced into acute and ambulatory care settings, nursing homes have employed a uniform patient assessment and clinical data structure since 1991 with federally mandated computerization beginning in 1998.^{26,51} The availability of these data has enabled observational research and the evaluation of policy changes in this setting for over a decade,^{13,28,36,52–59} but clearly provides the ideal foundation for the conduct of rigorous pragmatic RCTs of interventions introduced into healthcare systems.

In 1987, the development of the Minimum Data Set Resident Assessment Instrument was mandated as part of the Nursing Home Reform Act.^{26,60} Designed to improve nursing homes' ability to identify residents' needs, the Minimum Data Set became the basis for calculating case-mix reimbursement, measuring quality performance, and is increasingly being used as an input into "value based purchasing".^{61–63} The availability of detailed, longitudinal, uniform, clinically relevant information is relatively unique to U.S. nursing homes. Thus, as leveraged for PROVEN, the Minimum Data Set facilitated the characterization of the broad nursing home population, identification of targeted analytic sub-groups (e.g., advanced illness), and outcomes measurement. Furthermore, the availability of nationwide Minimum Data Set data linked to Medicare records and claims (constituting nearly 95% of nursing home users) mitigated problems related to loss to follow-up, the bane of many traditional RCTs and even pragmatic RCTs reliant on electronic medical records within single healthcare systems (e.g., insurance providers).⁶⁴

Another advantage of the nursing home healthcare system as a setting for pragmatic RCTs is that existing corporate infrastructures can be used to implement the intervention, much like other system-wide quality improvement programs but with the added benefit of random assignment. Such rigorous testing allows definitive evaluation of the effectiveness of new clinical programs as they would be introduced under real-world circumstances, an approach

strongly endorsed by the Centers for Medicare and Medicaid Services and the Institute for Healthcare Improvement.⁶⁵

Large cluster pragmatic RCTs have complex and evolving ethical and regulatory considerations.^{66–70} However, PROVEN set a precedent for the conduct of such trials in the nursing home setting from a regulatory perspective. The fact that research data could be garnered from existing clinical and administrative sources, and also that interventions promoting a prevailing standard of care (e.g., videos for advance care planning) could be implemented by nursing home providers under the direction of corporate leadership as a new clinical program (i.e., not by research staff), greatly facilitated the case for minimal risk determination, waiver of individual informed consent, and lack of need for Federal Wide Assurances from every facility. Without such authorizations, the “pragmatic” nature of the trial would have been seriously impeded.

In summary, the PROVEN trial provides a paradigm for a genre of RCTs that combines the elegance of cluster-based random assignment with readily assembled and integrated uniform clinical data that allow for evaluation of a facility-wide intervention among the most appropriate patients. These attributes obviate the most expensive and labor-intensive aspects of typical traditional RCTs. Ultimately, the conduct of pragmatic trials in the nursing home setting can lead to important research advances promoting evidence-based, high quality care in this vulnerable population.

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Figure 1.
Stratification and randomization of nursing home facilities

Table 1

Unique Design Features of the PRagmatic trial of Video Education in Nursing homes (PROVEN)

Design Feature	Unique Aspects	Enabling Factors/Advantages
Facilities		
Selection	Application of size and case-mix criteria	Access to 2013 linked MDS ¹ and OSCAR ² data
	Stratify by historical rate of primary outcome Post-randomization balance of aggregated patient factors between facilities in each arm	Access to 2013 MDS ¹ data
Randomization	2:1 control to intervention ratio	Large number of available facilities; no additional personnel or budget costs
	Randomization prior to recruitment	Strong corporate endorsement to recruit intervention facilities
Recruitment	100% recruitment of nursing homes randomized to intervention arm	Strong endorsement from corporate leadership
Population	Intervention applied to all nursing home population as in “real world”; analyses focused on targeted sub-groups	MDS ¹ data can easily characterize population and identify sub-groups
Intervention		
Structure	Established efficacy from prior trial, option of 5 short videos	Loaded on easy-to-use tablets, providers choose best video (s) for individual patient
Training	Co-designed by research team and healthcare partners; multiple modalities	Well-established corporate infrastructures for staff training
Implementation	Co-designed by research team and healthcare partners but implemented by healthcare partners, two local champions at each facility	Well-established corporate infrastructures for new program roll-out, mandated by corporate leaders, advance care planning already required
Adherence	New video status report embedded in facilities’ electronic medical record	Established sophisticated facility electronic medical records, easily linked to real time MDS ¹
Data		
Sources	MDS ¹ , Medicare files, facility electronic medical records already collected for clinical and administrative purposes	Established sophisticated facility electronic medical records, data management team has extensive experience linking data sources, MDS ¹ data permits tracking of hospitalization in non-Medicare beneficiaries
Utilization	Analyses can be conducted almost in ‘real-time’	Virtual Research Data Center, monthly data transfer from facility electronic medical records
Regulatory	Minimal risk determination, waiver of informed consent, nursing home providers deemed not engaged in human subjects research	Trial could not have been conducted without waiver of informed consent, Federal-wide assurance numbers were not required for each nursing home
Analytic plan	Focused on target sub-populations	MDS ¹ data can easily characterize population and identify sub-groups
Sample size estimates	Based on Poisson distribution; 2:1 control to intervention facility ratio allows more precise estimate of the outcome in the control group	2013 MDS ¹ data provides robust estimates of primary outcome in control arm

¹MDS=Minimum Data Set

²OSCAR= Online Survey Certification and Reporting

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Table 2

2013 Characteristics of Participant Facilities Post-Random Assignment

	Intervention		Control		Total	
	Mean	SD ^b	Mean	SD ^b	Mean	SD ^b
	N = 119		N=241		N=360	
Healthcare system 1	N=98		N=199		N=297	
Healthcare system 2	N=21		N=42		N=63	
Facility Characteristics						
Facility hospitalization rate ^a	1.1	0.4	1.1	0.4	1.1	0.4
Occupancy rate	0.9	0.1	0.9	0.1	0.9	0.1
Total beds	120.2	37.9	121.1	45.5	120.8	43.1
% Medicare patients	15.1	7.4	16.2	9.2	15.8	8.7
Registered nurse full-time equivalents/100 beds	9.3	5.1	8.9	4.7	9.0	4.8
Licensed nurse practitioners full-time equivalents/100 beds	13.1	4.2	13.4	3.8	13.3	3.9
Mean Centers for Medicare and Medicaid Five-Star Rating	2.9	1.3	2.9	1.3	2.9	1.3
No. Admissions	559.5	274.8	578.2	314.9	572.0	301.9
No. Admissions/bed	4.7	2.2	4.8	2.2	4.8	2.2
No. residents in 2013	324.7	138.2	333.1	162.5	330.3	154.7
% residents with advanced cardiopulmonary disease ^c	20.5	13.1	20.0	14.3	20.2	13.9
Advanced cardiopulmonary disease ^c hospitalization rate ^a	1.4	1.1	1.4	0.7	1.4	0.9
% residents with advanced dementia	29.3	13.9	31.2	17.0	30.6	16.0
Advanced dementia hospitalization rate ^a	0.6	0.4	0.6	0.4	0.6	0.4

^a Hospitalization rate is measured as number of hospitalization/person-day alive in prior 12 months^b SD=standard deviation^c Advanced cardiopulmonary disease = advanced chronic obstructive lung disease or congestive heart failure

Data Element and Sources

Table 3

Data Element	Purpose	SOURCE			
		EMR ^a	MDS ^b	Medicare	OSCAR ^c
Facility-Level (2013 data)					
Organization	recruitment				X
Case-mix	recruitment		X		
Hospitalization rate	randomization		X		
Patient-Level					
Demographic	covariate	X	X		
Long-stay vs. short-stay	cohort definition		X		
Functional status	target sub-population identification, covariate		X		
Cognitive status	target sub-population identification, covariate		X		
Medical condition	target sub-population identification, covariate	X	X		
Insurance	covariate			X	
Advance directives	2° outcome	X			
Health services use	1° and 2° outcome	X	X	X	
Burdensome interventions	2° outcome	X	X	X	
Death	description, competing risk			X	
Video status report	intervention fidelity	X			

^aEMR=electronic medical record

^bMDS=Minimum Data Set

^cOSCAR= Online Survey Certification and Reporting

Table 4

Number of Facilities Required Per Arm

Number hospitalizations/person-day alive among long-stay residents with advanced illness ^a	Effect Size of Absolute Rate Differences			
	0.20	0.225	0.25	0.275
1.06	81	63	50	41
1.51	165	129	103	84
2.12	351	275	220	180

^a Advanced illness= advanced dementia, chronic obstructive lung disease or congestive heart failure