

A Cluster Randomized Pragmatic Trial of an Advance
Care Planning Video Intervention in Long-Stay Nursing
Home Residents with Advanced Illness: PROVEN
What Would we Have Done Differently



PRagmatic Trial of Video Education in Nursing Homes

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Objectives

- Describe PROVEN Cluster RCT Design
- Summarize main findings
- Would Design Changes have made a difference?
- Discuss implications for Dissemination

PROVEN

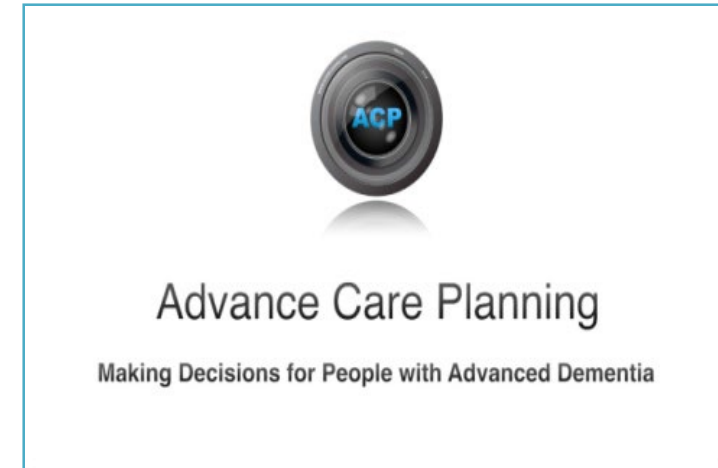
- A pragmatic cluster RCT of an advance care planning (ACP) video intervention embedded within two NH healthcare systems

Rationale

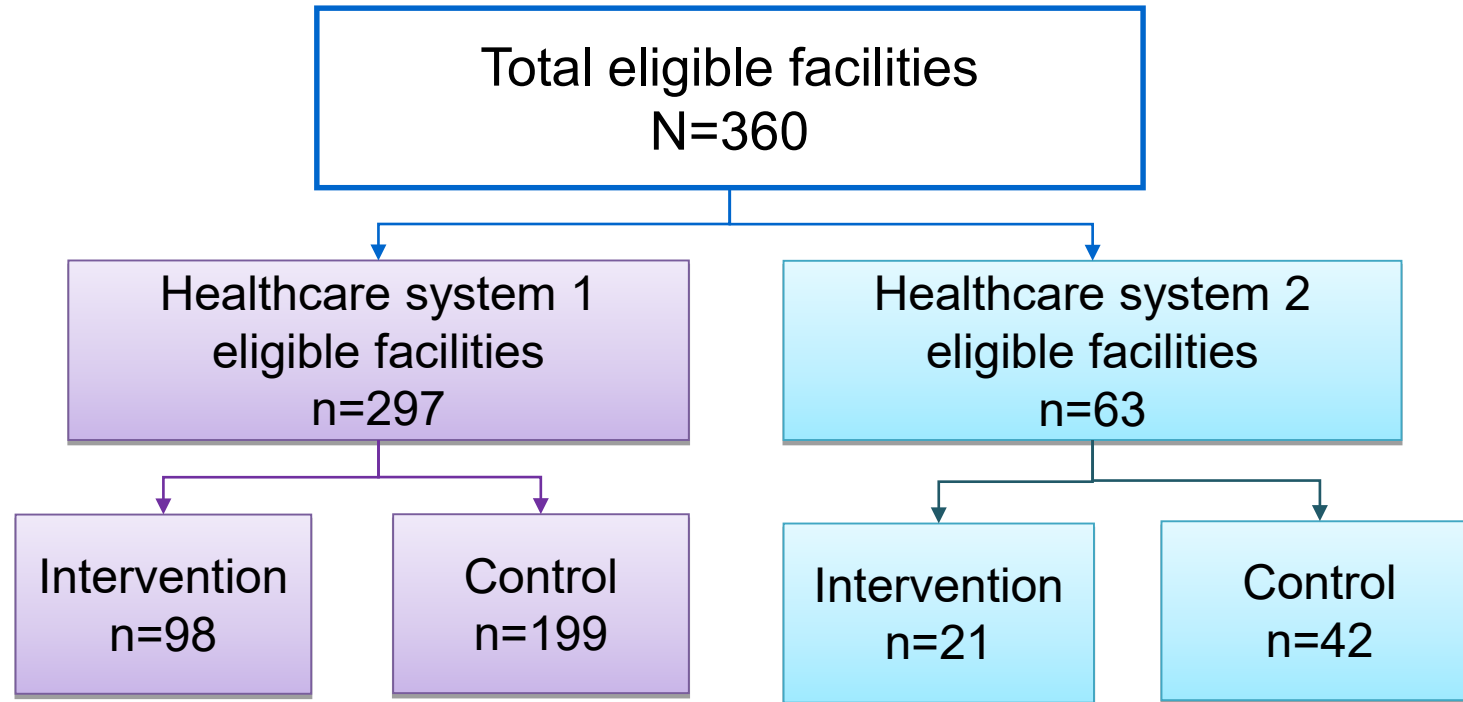
- 1.5 million NH residents with advanced illness
- Burdensome interventions, particularly hospital transfers, are common but often inconsistent with preferences and of little clinical benefit
- Advanced Care Planning (ACP) related to less intensive interventions
- BUT, hard to do and hard to scale
- Video ACP decision support tools addresses these shortcomings

Rationale: ACP Videos

- Goals of care options with visual images
 - Life prolongation, basic, comfort
- Specific conditions or treatments
- Adjunct to counseling
- 6-8 minutes



Facilities



Patient Participants

- Enrollment: 02/02/16-05/31/18
- 12-month f/u each resident; ends 06/01/19
- Population
 - All patients in NH during enrollment period
- Target population: advanced illness
 - Greatest opportunity to benefit from ACP
 - Medicare beneficiaries
 - > 65, long-stay (>100 days)
 - Advanced dementia, CHF or COPD (>50% 6 mo. Mortality)
 - Met criteria during enrollment period

Intervention

- Suite of 5 videos
- Tablet (2/NH) or on-line
- 2 Champions/NH
 - Social Worker
- Offer video to resident or proxy:
 - Baseline
 - Admission
 - Q6months
 - Ad hoc
- Could choose video
- English or Spanish



*Goals of Care for Any Patient**

This video helps patients understand and make decisions about their goals of care.



Goals of Care for Patients with Advanced Dementia

This video helps family members understand and make decisions for patients with advanced dementia.



*Decisions about Hospice**

This video helps patients and their families understand and make decisions about hospice care.



*Decisions about Hospitalization**

This video helps patients understand and make decisions about hospitalization.



*General Information about Advance Care Planning for Healthy Adults**

This video helps generally healthy patients understand and make decisions about their long-term health goals.

Monitoring Fidelity and Adaptations

- Video Status Report linked to resident-level assessment data
- Created facility reports
 - % targeted residents offered/shown a video
- Q2month calls with ACP champion, HCS senior project manager, implementation team
- January 2017 steps take to increase fidelity
 - Calls increased to q1month and made 1:1
 - List of actual residents not offered video reviewed
 - Site visits by senior project manager

PROVEN: Primary Outcome

- No. hospital transfers/1000 person-days alive among long-stay (> 100 days) Medicare beneficiaries ≥ 65 with advanced dementia, CHF or COPD
- Medicare Claims
- Transfers = admissions, observation stays, emergency room visits
- Up to 12-month follow-up

Results: Subject Characteristics

Characteristic	Intervention (N=4171)	Control (N=8308)
Age, mean (SD)	83.6 (9.1)	83.6 (8.9)
Female, %	71.2	70.5
White, %	78.4	81.5
Advanced dementia, %	68.6	70.1
Advanced CHF/COPD, %	35.4	33.4
Hospice at baseline, %	34.2	34.6
Activities of daily living score (0-28), mean (SD)	21.8 (3.8)	21.9 (3.8)
Mortality risk score (0-39), mean (SD)	7.6 (2.9)	7.6 (2.8)
Died during follow-up, %	43.8	45.3
Days of follow-up, mean (SD)	253.1 (136.2)	252.6 (135.1)

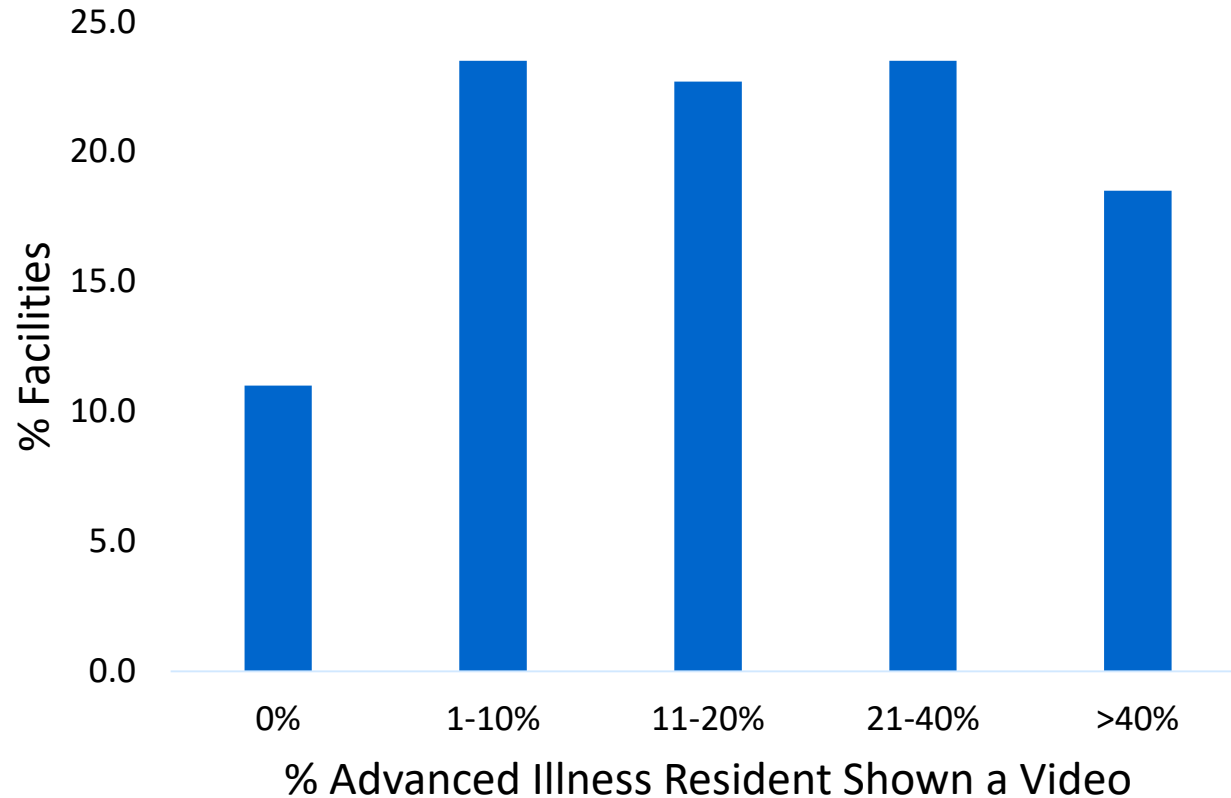
Results: Outcomes

Primary Outcome	Intervention N=4171	Control N=8308	Marginal Rate Difference (SE) (95% CI)
	Rate (SE) (95% CI)		
Hospital transfers/1000 person-days alive	3.7 (0.2) (3.4-4.0)	3.9 (0.3) (3.6-4.1)	-0.2 (0.3) (-0.5,0.2)
Secondary Outcomes	Percent (SE) (95% confidence interval)		Marginal Risk Difference (SE) (95% CI)
≥ 1 hospital transfer	40.9 (1.2) (38.4-43.2)	41.6 (0.9) (39.7,43.3)	-0.7 (1.5) (-3.7, 2.3)
≥ 1 burdensome treatment	9.6 (0.8) (8.0,11.3)	10.7 (0.7) (9.4,12.1)	-1.1 (1.1) (-3.2,1.1)
Enrolled in hospice*	24.9 (1.2) (22.6, 27.2)	25.5 (0.9) (23.3,27.2)	-0.6 (1.5) (-3.4, 2.4)

*Excluded residents enrolled in hospice at baseline

Fidelity

- 55.6% advanced illness residents (or proxies) offered a video
- 21.6% advanced illness residents (or proxies) shown a video
- Variability across facilities



Study Re-Design Thoughts: Option #1

Stratify on Facility Implementation Capacity

- **Advantages**

- Estimate Effects in facilities that actually implemented
- “peer” sharing of intervention strategies more cohesive?
- Post-hoc analysis of matched facilities and patients found positive results

- **Disadvantages**

- Under-powered?
- May Not be able to predict implementation
- How pragmatic if only applicable to ¼ of facilities?
- Complicates the analyses and perhaps the interpretation of results.

Study Re-Design Thoughts: Option #2

Focus on Very Sick Post-Acute Patients.

- **Advantages**

- Higher hospital transfer rates
- Higher acuity
- Video intervention would be more complete part of admission/orientation
- Salient for Hospital & SNF

- **Disadvantages**

- Smaller number of such patients
- More variable number of post-acute cases per facility
- Post-acute patients & families might not trust SNF on setting advance directives

Summary

- In this pragmatic cluster RCT, a ACP video intervention was not effective in significantly:
 - Reducing hospital transfers
 - Reducing burdensome interventions
 - Increasing hospice enrollment
- Fidelity
 - Low
 - Variable across facilities
- Study Design Options
 - No clear advantages