

Pragmatic Trial of Video Education in Nursing Homes (PROVEN)

Study Snapshot

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Sponsoring Institution: Brown University School of Public Health

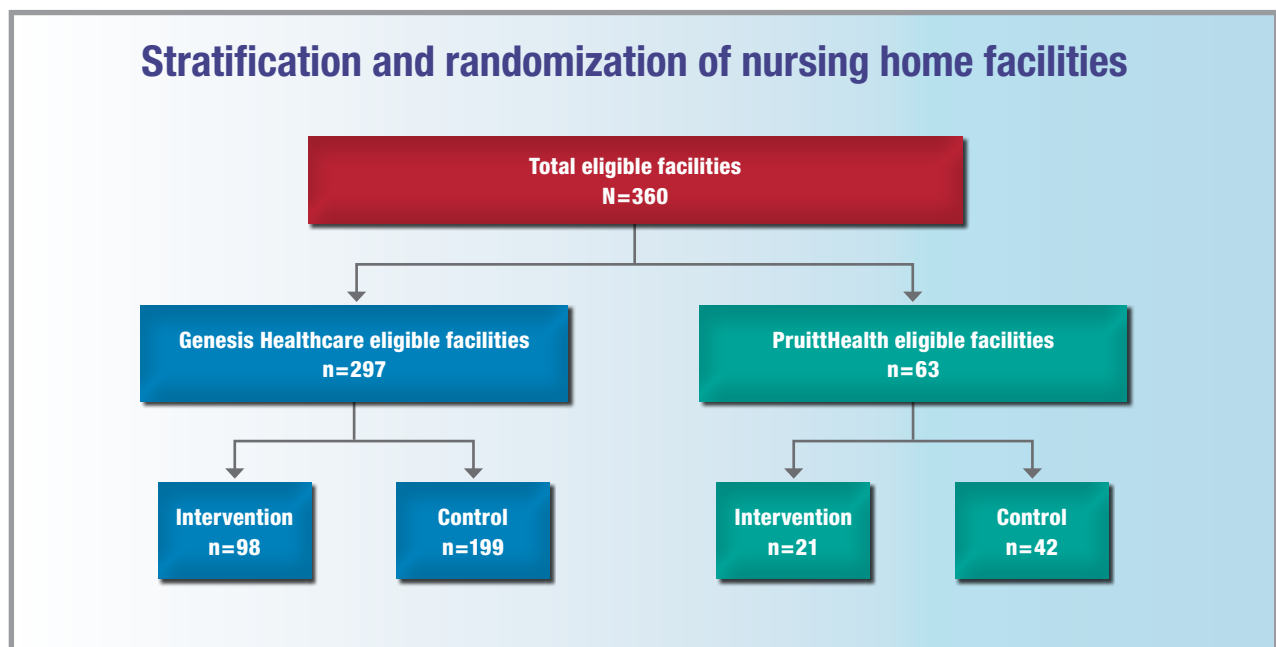
ClinicalTrials.gov: [NCT02612688](https://clinicaltrials.gov/ct2/show/study/NCT02612688)

NIH Institute Oversight: National Institute on Aging (NIA)

Abstract: Nursing homes are often charged with guiding increasingly sick patients through decisions about the direction of their treatment. Patients at nursing homes commonly receive aggressive care that may be inconsistent with their preferences and of little clinical benefit. Identifying effective approaches that nursing homes can use to better promote goal-directed care within existing resources is a research, public health, and clinical priority.

Advance care planning (ACP) is the most consistent factor associated with better palliative care outcomes. However, traditional ACP relies on verbal descriptions of hypothetical health states and treatments, which is limiting because

complex scenarios are difficult to envision and verbal explanations are hindered by literacy and language barriers. The PROVEN project has developed video-assisted ACP decision-support tools that have shown efficacy in small randomized controlled trials. While several large healthcare systems have begun to adopt the videos, outcomes have not been rigorously evaluated. The goal of PROVEN is to conduct a pragmatic cluster-randomized trial to evaluate the effectiveness of the ACP video tools by partnering with 2 large healthcare systems that operate 492 nursing homes nationwide. This work has the potential to improve the care provided to millions of older Americans.



What We've Learned So Far

Current Barriers	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/ subjects	N/A				
Engagement of clinicians and health systems			X		
Data collection and merging datasets	X				
Regulatory issues (IRBs and consent)	X				
Stability of control intervention	X				
Implementing/delivering intervention across healthcare organizations			X		

1 = little difficulty
5 = extreme difficulty

Challenge	Solution
Because the primary outcome is hospitalization rate per person day-alive, the data needed to be matched between nursing homes and hospitals and Medicare vital statistics data since nursing home data alone could have biased results.	Added additional IT resources to help link the systems.
The study team and healthcare system partners did not want to recruit facility leadership to participate in the study and then say they were assigned to control since the partners felt that all facilities would want to have the videos.	The team chose to “prerandomize” by first applying eligibility criteria to existing data on all partner facilities and then giving them the opportunity to exclude other facilities based on recent leadership changes. They next divided facilities into <i>a priori</i> strata and randomly selected the 120 treatment facilities from the pool, leaving the rest as controls. In this way, no facilities that wanted to participate were disappointed; the partners were confident that they would have a high participation rate.

Selected Publications & Presentations	
April 2017	Pragmatic Trial of Video Education in Nursing Homes: The design and rationale for a pragmatic cluster randomized trial in the nursing home setting. <i>Clinical Trials</i> , Mor et al.
March 2017	PCT Grand Rounds Presentation: Implementing PROVEN

