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

PROVEN
PRagmatic Trial of Video Education in Nursing Homes

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BROWN School of Public Health
Marcus Institute for Aging Research Hebrew SeniorLife
MGH 1811
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
• 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

Total eligible facilities
N=360

Healthcare system 1
eligible facilities
n=297

Intervention n=98
Control n=199

Healthcare system 2
eligible facilities
n=63

Intervention n=21
Control n=42
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 online
- 2 Champions/NH
  - Social Worker
- Offer video to resident or proxy:
  - Baseline
  - Admission
  - Q6months
  - Ad hoc
- Could choose video
- English or Spanish
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

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

<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>Intervention N=4171</th>
<th>Control N=8308</th>
<th>Marginal Rate Difference (SE) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital transfers/1000 person-days alive</td>
<td>3.7 (0.2) (3.4-4.0)</td>
<td>3.9 (0.3) (3.6-4.1)</td>
<td>-0.2 (0.3) (-0.5,0.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secondary Outcomes</th>
<th>Percent (SE) (95% confidence interval)</th>
<th>Marginal Risk Difference (SE) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 1 hospital transfer</td>
<td>40.9 (1.2) (38.4-43.2)</td>
<td>41.6 (0.9) (39.7,43.3)</td>
</tr>
<tr>
<td>≥ 1 burdensome treatment</td>
<td>9.6 (0.8) (8.0,11.3)</td>
<td>10.7 (0.7) (9.4,12.1)</td>
</tr>
<tr>
<td>Enrolled in hospice*</td>
<td>24.9 (1.2) (22.6, 27.2)</td>
<td>25.5 (0.9) (23.3,27.2)</td>
</tr>
</tbody>
</table>

*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

![Bar Chart]

% Facilities

% Advanced Illness Resident Shown a Video
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.**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>• Higher hospital transfer rates</td>
<td>• Smaller number of such patients</td>
</tr>
<tr>
<td>• Higher acuity</td>
<td>• More variable number of post-acute cases per facility</td>
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<tr>
<td>• Video intervention would be more complete part of admission/orientation</td>
<td>• Post-acute patients &amp; families might not trust SNF on setting advance directives</td>
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<td>• Salient for Hospital &amp; SNF</td>
<td></td>
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6/21/2022
Summary

• In this pragmatic cluster RCT, an 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