Implementation in AD/ADRD Embedded Pragmatic Clinical Trials: Examples from the Frontlines

Ab Brody, PhD, RN, FAAN
Jessica Colburn, MD
Ellen McCreedy, PhD, MPH
Panelist: Brian S. Mittman, PhD
Objectives: The learner will be able to

• Understand the implementation strategies used in 3 pragmatic clinical trials among persons living with dementia

• Gain knowledge about implementation barriers and facilitators of complex interventions in pragmatic trials

• Apply a novel framework to promote complex health intervention implementation in health care systems
Housekeeping

• All participants will be muted

• Enter **all questions** in the Zoom Q&A or **chat box** and send to All Panelists and Attendees

• Moderator will review questions from chat box and ask them at the end

• Want to continue the discussion? Look for the associated podcast released about 2 weeks after Grand Rounds.

• Visit [impactcollaboratory.org](https://impactcollaboratory.org)

• Follow us on Twitter: [@IMPACTcollab1](https://twitter.com/IMPACTcollab1)

• LinkedIn: [https://www.linkedin.com/company/65346172](https://www.linkedin.com/company/65346172)  @IMPACT Collaboratory
Implementing the The Hospice Advanced dementia Symptom management and Quality Of Life (HAS-QOL) ePCT: Lessons learned from sequential pilots and implementation of a full-scale ePCT during a pandemic

Ab Brody, PhD, RN, FAAN
Associate Professor of Nursing and Medicine, New York University Rory Meyers College of Nursing
Associate Director, Hartford Institute for Geriatric Nursing
Implementing the The Hospice Advanced dementia Symptom management and Quality Of Life (HAS-QOL) ePCT: Lessons learned from sequential pilots and implementation of a full-scale ePCT during a pandemic

This work is supported by NIH/NIA Award R61/R33AG061904 and R01AG056610
• Sequential Pilot Trial (R61 Phase)
• Stepped wedge trial (R33 Phase)
• Multi-modal Complex Intervention
• All study outcomes collected in EHR/Admin but NOT implementation outcomes or scaling to large# of sites
But what about IMPLEMENTATION

Pilot Experience Led to Augmented Intervention:

• Mobile Health Application
• Personalized Email and Mobile Push Nudges
• QAPI Templates
• Care Plans for Caregiving Strain, Acute Delirium

Simplified Some Instructions
Use Case

Need to manage large studies with thousands of clinicians
- Turnover of clinicians
- Ensuring training occurs
- Automate survey administration
- Provide nudges to clinicians to use toolbox and complete training
- Provide access to our toolbox via secure mobile health app
- Track implementation metrics such as toolbox utilization, nudge receipts and email reads
- Ensure agency contracts are completed, agencies paid, provide reporting to agencies on their clinician’s compliance/usage
Methods of Engaging Staff in Development

- Pre-Implementation huddles with executive Leadership and data managers at each hospice
- Post-champion training focus group with champions
- Post-online training program evaluations
- Follow up telephone calls with champions at 1-week, monthly thereafter
- Usability Survey
Data Architecture

Postgres Database

salesforce

heroku

django CMS

kd lms

qualified xM
Hey Ab,

Wow, how time flies! Aliviado Test is in full swing of implementing Aliviado Dementia Care. This is the week where everyone should be completing their training if they haven’t already. At this point you should be implementing the Aliviado tools in real-world care if you haven’t been already.

You did it! Congratulations on completing all your training. Now is the time to focus on putting what you learned into practice.

Communication with Persons Living With Dementia is HARD! The Communication tip sheet in the Aliviado mobile app focuses on how you can better communicate how you are trying to help them, and also better understand their needs. This can reduce agitation and make it easier to perform care tasks.

We noticed you haven’t logged into the Aliviado mobile app yet. If you need help accessing, please reply to this email and we’ll get you all setup.

Thanks for reading!

The Aliviado Team
Extra nudges for our champions

- ALIVADO
  - Training has started!
  - Show your team how they can access the Aliviado Learning Center.

- ALIVADO
  - Training has started!
  - Show your team how they can access the Aliviado Learning Center.

- ALIVADO
  - Your team is starting Aliviado Training Today!
  - Today is day 1 of Aliviado training. Make sure you are reminding your team to activate their account and login!
**Results: Aggression Care Plan**

Throughout this questionnaire you have made selections pertaining to this patient’s symptoms, possible interventions, and goals and outcomes. Your care plan is compiled below.

- The patient is experiencing chronic Aggression.
- The Aggression is distressing/harmful for the patient, the caregiver, or both.
- Defining characteristics include:
  - Kicking
  - Pushing
  - Resisting care
- Assessment method(s) used:
  - NPI-Q: Agitation or aggression
  - The behavior is distressing or stressful for the caregiver.
  - The patient is NOT redirectable

**Using PIECES**

Before implementing any interventions, review whether Aggression is being triggered or caused by PIECES: Physical, Intellectual, Emotional, Capabilities, Environmental, or Social needs/factors not being met (see Behavioral Symptom Treatment Algorithm).

<table>
<thead>
<tr>
<th>Aggression Care Plan Instructions</th>
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**Neuropsychiatric Inventory Questionnaire (NPI-Q) Score**

- This person is exhibiting at least one behavioral or psychological symptom of dementia. Listed in order of caregiver stress level:
  - **Extreme Caregiver Distress**
    - Anxiety, Severe (3 points); Extreme caregiver distress (5 points)
  - **Mild Caregiver Distress**
    - Agitation or Aggression, Moderate (2 points); Mild caregiver distress (2 points)

You should discuss with the caregiver which symptom (or two if more than one) to focus on using the ABCD method (Antecedent, Behavior, Consequence, Discussion). Utilize PIECES and the behavioral symptom treatment algorithm to inform your discussion with the caregiver.

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**Non-pharmacologic Interventions**

- **Music therapy:** Allows patients to express themselves nonverbally. Soothes and relaxes individuals.
- **Don’t argue or react defensively:** Keeps the tone of the exchange neutral.
- **Acknowledges feelings of the person with dementia:** Promotes emotional connectedness and well-being.
- **Distraction:** Helps patients to cope more effectively.

**Pharmacologic Interventions**

- Remove ANTIPSYCHOTICS or BENZODIAZEPINES (if patient is currently on an antipsychotic or benzodiazepines and does not have hallucinations/delusions or sexual disinhibition, then trial deprescribing)
- **SSRI**

**Goals and Outcomes**

- The patient will not engage in verbal or physical assaults for the duration of the day
- The patient will actively participate in care without displaying aggression for the duration of the day
- The patient will be receptive to help from others
1,395 ASSESSMENTS COMPLETED
431 CAREPLANS INITIATED
7,000 CAREGIVER EDUCATION ARTICLES VIEWED
## Implementation Data Collected

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<th>Data Type</th>
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<tr>
<td>All mobile application usage</td>
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<td>Training completion</td>
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<td>Clinician Turnover, well-being, quality of life</td>
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<td>Quarterly surveys from champions of what they have done</td>
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<td>Notes from monthly meetings with champions</td>
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<td>Care plans/Assessment Instruments Completed in EHR</td>
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Naturalistic Experiment Due to COVID-19

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COVID-19 Effects

- “Paused” the trial after first 5 hospices implemented
- Were given go ahead to restart in October but few hospices ready after engaging with them so moving to February 2021
- Gave time to further tighten up and iterate implementation using feedback from initial hospices
- Hospices are overwhelmed:
  - Staffing/turnover – 1/5 leaders and 11% of 75 champions
  - Seeing patients face to face less often
  - Siege Mode-maintaining what they can, decreased engagement/buy-in (champions and staff)
Pragmatic Trial to Improve Communication for Primary Care Patients with Alzheimer’s Disease and Related Dementias

Jessica Colburn, MD
Johns Hopkins University School of Medicine
Implementation Workgroup Lead

Principal Investigators:
Jennifer Wolff, PhD & Sydney Dy, MD
Johns Hopkins School of Public Health
Pragmatic Trial to Improve Communication for Primary Care Patients with Alzheimer’s Disease and Related Dementias

Jessica Colburn, MD
Johns Hopkins University School of Medicine
Implementation Workgroup Lead

Principal Investigators:
Jennifer Wolff, PhD & Sydney Dy, MD
Johns Hopkins School of Public Health

Project Period: 9/1/2020-9/1/2023
Funding: NIA R33AG061882
Title: Improving Communication in Primary Care
Overall Trial Design

• To evaluate the effectiveness and implementation of SHARING Choices among primary care patients age 65 years and older including those with mild to severe ADRD (Alzheimer’s Disease and Related Dementias).

• Cluster-randomized trial to compare SHARING Choices with usual care control at 55 primary care clinics.

• Our primary objective is to assess whether patients at intervention (versus control) clinics are:
  • More likely to have an advance directive or MOLST uploaded in their electronic health record at 12 months;
  • Less likely to experience potentially burdensome care within 6 months of death, from dates and services extracted from CRISP;

• We secondarily evaluate implementation and contextual factors that may facilitate or impede dissemination and sustainability in primary care.
SHARING CHOICES

1. A **letter** from the clinic introducing an initiative to prepare persons & families for Advance Care Planning

2. Patient-family **agenda-setting checklist** to align perspectives about the role of family & stimulate discussion about ACP

3. Facilitated registration to the **patient portal** (patient *and* family) as desired by the patient

4. Access to a **facilitator** trained to lead ACP discussions

5. Education and **resources about ADRD** for clinic staff
Clinic Randomization

1. Stratified by health system

- n=20 System A
- n=35 System B

2. Randomized by Characteristics:

- % age 65+
- % Black/African American
- Number of clinicians
- Urban/Suburban/Rural

- ~7 Intervention Clinics*
- ~13 Control Clinics*

- ~12 Intervention Clinics*
- ~23 Control Clinics*
Implementation Strategy

Practice Onboarding Meeting with Medical Directors/Practice Champions

Meetings with Champions to Individualize Workflow for each Clinic Site

SHARING CHOICES Introductory mailing to patients prior to a visit

ACP discussion w/facilitator
Facilitated portal access/proxy access
Documentation of ACP conversations, uploading of advance directive into chart
Pilot Experience

20 patient-family dyads from 2 systems, after 6 weeks

- 10 out of 12 people with cognitive impairment participated in ACP

Implementation Adaptations

- Shift from embedded facilitators within the clinic to centralized facilitators across sites of care
- Health systems have preferred facilitators who are trained as nurses or social workers rather than community health workers
- System adaptation to pair ACP facilitator meetings with Medicare Annual Wellness Visit
  - Greater sustainability, no added out of pocket cost for Medicare beneficiaries
- Change in primary endpoint to include MOLST/MOST as well as advance directive due to health system prioritization in the pandemic
Factors Enabling Implementation

• Flexibility at system level, site level, and facilitator level
  – System level: top-down vs bottom up approach to implementation & system-
    level resources (e.g., availability and involvement of centralized palliative care
    team)
  – Site level: some sites with prior exposure to ACP initiatives
  – Facilitator level: embedded facilitators in clinic

• Site champions to help with individualization of approaches and to
  encourage change in clinic workflow

• Alignment with system priorities
  – Statewide ACP quality metrics for Maryland PCP initiative
  – Potential for additional reimbursement with Medicare Annual Wellness Visit
  – Alignment with organizational leadership
Barriers to Implementation: COVID-19

- Increased focus on telehealth due to the COVID-19 pandemic
- Challenge of embedding facilitators into the clinic team
- Logistically difficult to schedule remote ACP conversations
- Technology challenges, ACP conversations by phone/video
- Completing and getting copies of the paperwork challenging with telehealth
- No family in clinic except in the cases of cognitive or physical disability requiring assistance, which impacts the use of the agenda setting checklist
Key Lessons Learned

- SHARING Choices is feasible among older adults with and without cognitive impairment.
- Alignment with other metrics & goals in primary care helps with buy-in and uptake.
- Flexibility is important to fit organizational culture, workflows, and priorities.
- Champions and co-designing contribute significantly to buy-in.
- Engaged partners who are mission-driven contribute to the value and success of the work.
- Prioritizing strategies that resonate with diverse populations is important.
Music & Memory: A Pragmatic Trial for Nursing Home Residents With Alzheimer's Disease (METRICAL)

Ellen McCreedy, PhD, MPH
Assistant Professor, Brown University School of Public Health

NIA R33AG057451 (PI: Mor)
Ellen McCreedy, PhD, Project Director
Jim Rudolph, MD, Implementation Lead
Miranda Olson, MS, Project Analyst
Overview

• Drugs used to manage agitated behaviors in nursing home residents with dementia increase the risk of falls and death

• Reminiscence therapies may reduce agitated behaviors resulting from social isolation or sensory deprivation by eliciting long-stored memories

• In Music & Memory, the music a resident preferred when s/he was young is put on a personalized music device (mp3 player) and played at early signs of agitation

• The purpose of the study is to assess the effectiveness of a personalized music intervention on agitated behaviors in nursing home residents with dementia.
Trial Design

- Two parallel, cluster-randomized controlled trials with different implementation strategies

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<th>Trial 1</th>
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<td>Intervention (405 residents)</td>
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<td>(27 Nursing Homes)</td>
<td></td>
<td></td>
<td>(405 residents)</td>
</tr>
</tbody>
</table>
Intervention Structure

1. Establish multidisciplinary team and project champion
2. Identify residents likely to benefit from intervention
3. Build music library, label and charge equipment
4. Identify residents preferred music
5. Start with few residents on one unit before scaling
6. Identify residents preferred music
7. Nursing staff use music with residents
8. Personalize music playlists for all 15 residents
9. Nursing staff use music to manage agitation
10. Establish multidisciplinary team and project champion
Pilot Experience

• 6-month pilot in 2018

• 4 nursing homes, one from each corporation participating in trial

• Barriers identified:
  – Technology (e.g., no broadband internet to download music)
  – Trial and error process to identify resident preferred music was time consuming
  – Lack of frontline nursing engagement resulting in lack of clinical targeting of intervention

Implementation Adaptations

1. Establish multidisciplinary team and project champion
2. Identify residents likely to benefit from intervention
3. Build music library, label and charge equipment
4. Identify residents preferred music

- Nursing staff use music to manage agitation
- Nursing staff use music with residents
- Personalize music playlists for all 15 residents
- Start with few residents on one unit before scaling
Implementation Adaptations

• Trial 1 - Fully personalized music playlists:
  – Activities staff (champion) identifies eligible residents, tests individual songs with resident to identify preferred music, downloads music to iPods
  – iPods transitioned to frontline nursing staff for use at early signs of agitation

• Trial 2 - Partially personalized music playlists:
  – Frontline nursing staff (champion) identifies eligible residents
  – Research staff load iPods using only resident age and preferred genre (no individual testing)
  – Players delivered directly to frontline nursing staff for use
Quantitative Implementation Evaluation

Jim Rudolph, MD, Implementation Lead
Director LTSS COIN Providence VA,
Associate Professor of Medicine

Miranda Olson, MS, Project Analyst

Conceptual Model

Potential moderators:
1. Comprehensiveness of policy description
2. Strategies to facilitate implementation
3. Quality of delivery
4. Participant responsiveness

Intervention ➔ Adherence:
Details of content
Coverage
Frequency
Duration

Outcomes ➔ Evaluation

Evaluation of implementation fidelity

Component analysis to identify “essential” components

# Evaluation of Implementation Fidelity

## Adherence Domain Operational Definition (facility-level variables)

<table>
<thead>
<tr>
<th>Adherence Domain</th>
<th>Operational Definition (facility-level variables)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration</td>
<td>Median minutes of music per day exposed</td>
</tr>
<tr>
<td>Frequency</td>
<td>Percent of residents receiving the intervention five or more days per week</td>
</tr>
<tr>
<td>Coverage</td>
<td>Number of residents exposed during the study window</td>
</tr>
</tbody>
</table>
| Details of Content | Intervention core features:  
  - Percent of residents chosen for intervention to address agitation  
  - Percent of songs on playlist which are unique, not on other residents’ playlists  
  - Percent of residents receiving the intervention from frontline nursing staff at least once per week |
<table>
<thead>
<tr>
<th>Adherence Domain</th>
<th>Operational Definition (facility-level)</th>
<th>Fully Personalized Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration</td>
<td>Median minutes of music per day exposed</td>
<td>29 minutes / day exposed</td>
</tr>
<tr>
<td>Frequency</td>
<td>Percent of residents receiving the intervention five or more days per week</td>
<td>13% of residents receiving music daily</td>
</tr>
<tr>
<td>Coverage</td>
<td>Number of residents exposed during the study window</td>
<td>14 residents exposed</td>
</tr>
</tbody>
</table>
| Details of Content | Intervention core features:  
• Percent of residents chosen for intervention to address agitation  
• Percent of songs on playlist which are unique, not on other residents’ playlists  
• Percent of residents receiving the intervention from frontline nursing staff at least once per week | • 31% of residents chosen to address agitation  
• 50% of songs on playlist unique to resident  
• 26% residents had intervention delivered by frontline nursing staff at least once per week |
Key Lessons Learned

- Dose matters, but so does the context in which the dose is delivered.

- Examining types of adherence may help researchers compare the effects of different implementation strategies on overall fidelity.

- Adherence in specific domains may differentially affect study outcomes.
Panelist Response

Brian S. Mittman, PhD
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Division of Health Services Research & Implementation Science, Kaiser Permanente