

NIA IMPACT
COLLABORATORY
TRANSFORMING DEMENTIA CARE

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

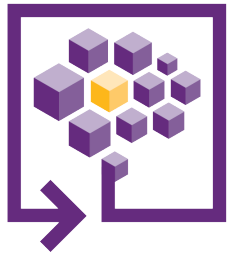
Objectives: The learner will be able to

- 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
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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

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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

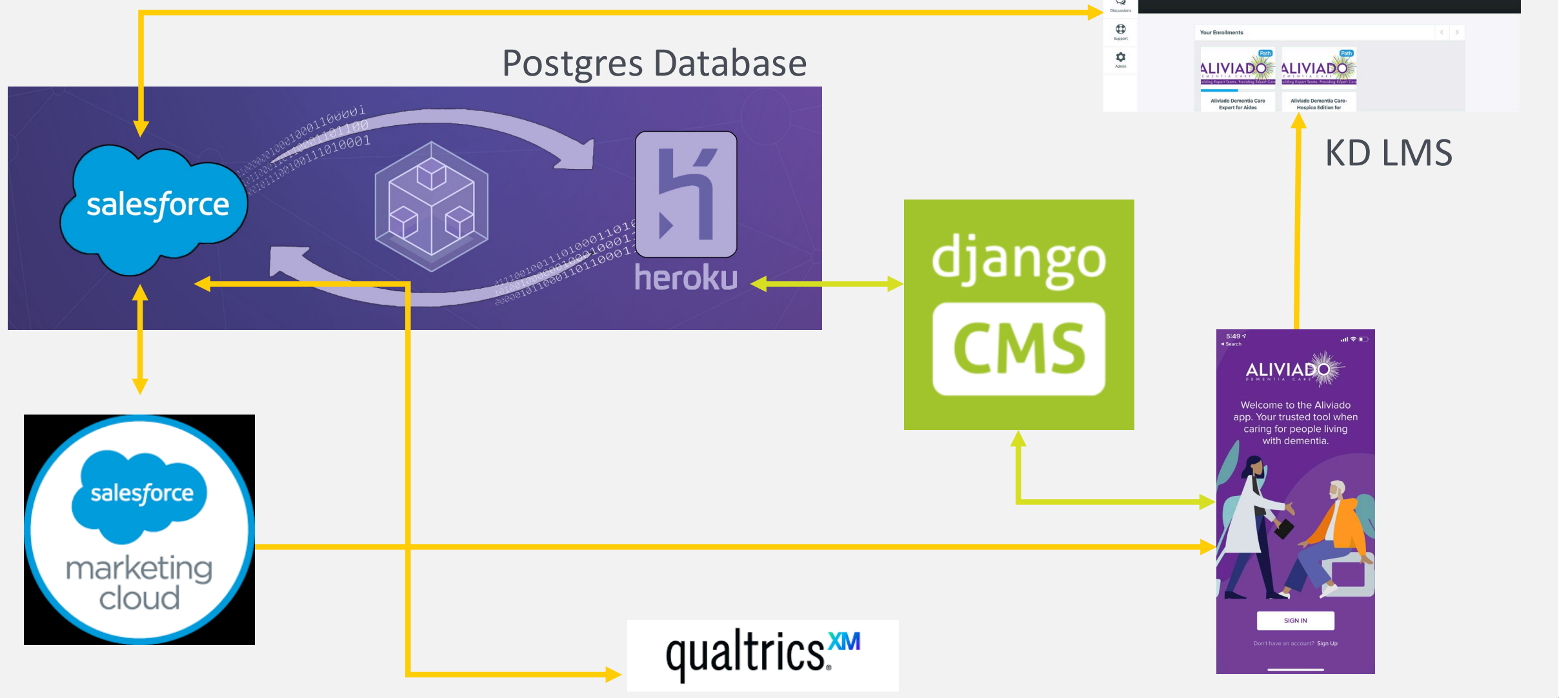
Need to manage large studies with thousands of clinicians

- 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



Sample Email



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.

Tool of the week



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.

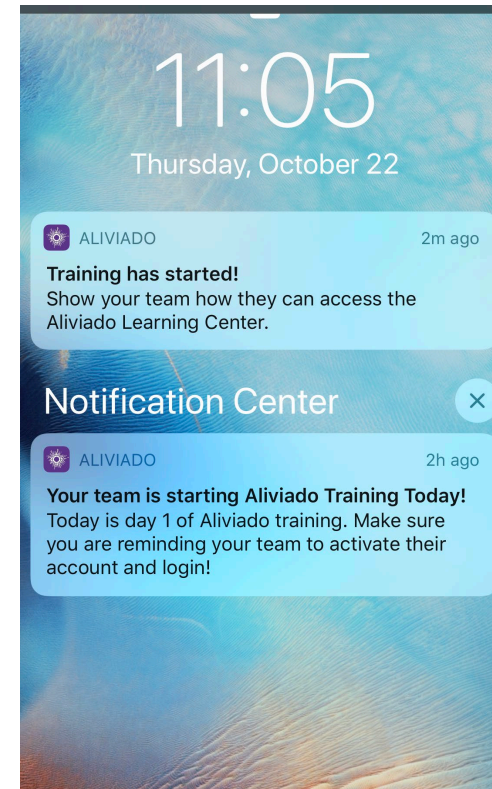
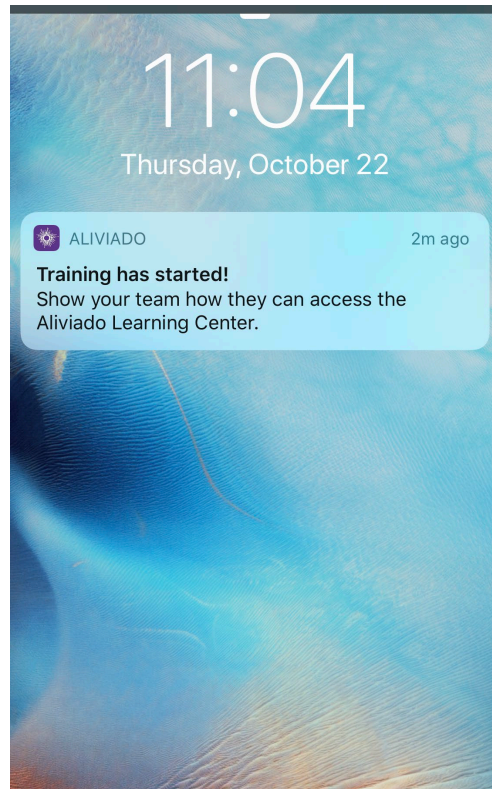
We noticed you haven't logged into the Aliviado mobile app yet. If you need help accessing, please reply to this email and we'll get you all setup.

Thanks for reading!

The Aliviado Team



Extra nudges for our champions



Mobile App



**1,395 ASSESSMENTS
COMPLETED**



431 CAREPLANS INITIATED



**7,000 CAREGIVER EDUCATION
ARTICLES VIEWED**

Implementation Data Collected



All mobile application usage



Training completion



Clinician Turnover, well-being, quality of life



Mobile Pushes sent



Emails sent/opened/links clicked



Quarterly surveys from champions of what they have done



Notes from monthly meetings with champions



Care plans/Assessment Instruments Completed in EHR

What is missing?

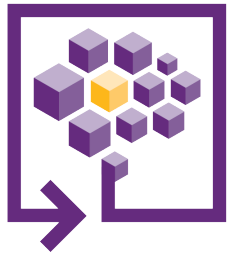
Y1M1-Y1M3	Y1M4	Y1M5	Y1M6	Y1M7	Y1M8	Y1M9	Y1M10	Y1M11	Y1M12	Y2M1	Y2M2-Y4M3
Control phase	Intervention [2-3 hospices]	Maintenance phase									
Control	Intervention [2-3 hospices]	Maintenance									
Control		Intervention [2-3 hospices]	Maintenance								
Control			Intervention [2-3 hospices]	Maintenance							
Control				Intervention [2-3 hospices]	Maintenance						
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Control							Intervention [2-3 hospices]	Maintenance			
Control								Intervention [2-3 hospices]	Maintenance		
Control									Intervention [2-3 hospices]	Maintenance	
Control										Intervention [2-3 hospices]	Maintenance

Naturalistic Experiment Due to COVID-19

Y1M1-Y1M3	Y1M4	Y1M5	Y1M6	Y1M7	Y1M8	Y1M9	Y1M10	Y1M11	Y1M12	Y2M1	Y2M2-Y4M3
Control phase	Intervention [2-3 hospices]	Maintenance phase									
Control	Intervention [2-3 hospices]	Maintenance									
Control			Intervention [2-3 hospices]	Maintenance							
Control				Intervention [2-3 hospices]	Maintenance						
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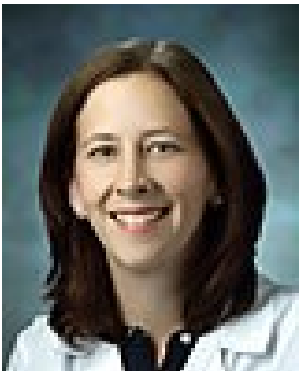
COVID-19 Effects

- “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)



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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

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Project Period: 9/1/2020-9/1/2023

Funding: NIA **R33AG061882**

Title: Improving Communication in Primary Care

Overall Trial Design

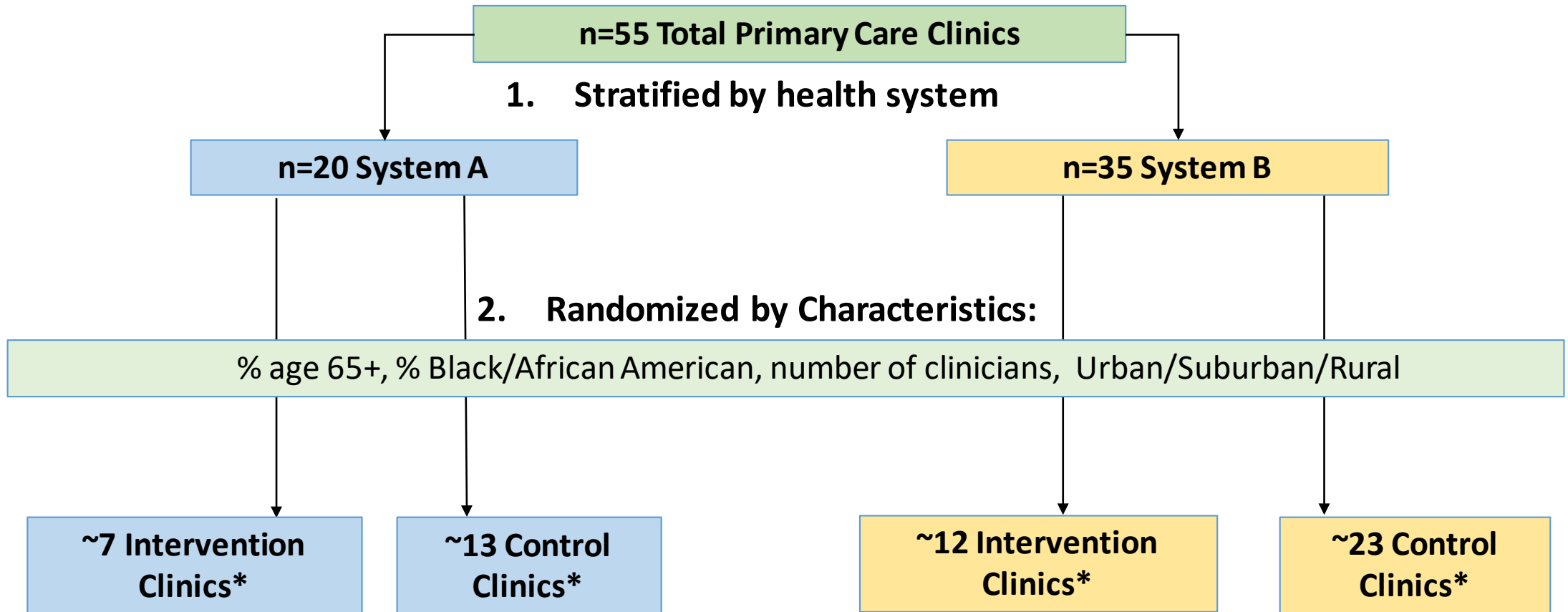
- To evaluate the effectiveness and implementation of SHARING Choices among primary care patients age 65 years and older including those with mild to severe ADRD (Alzheimer's Disease and Related Dementias).
- Cluster-randomized trial to compare SHARING Choices with usual care control at 55 primary care 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

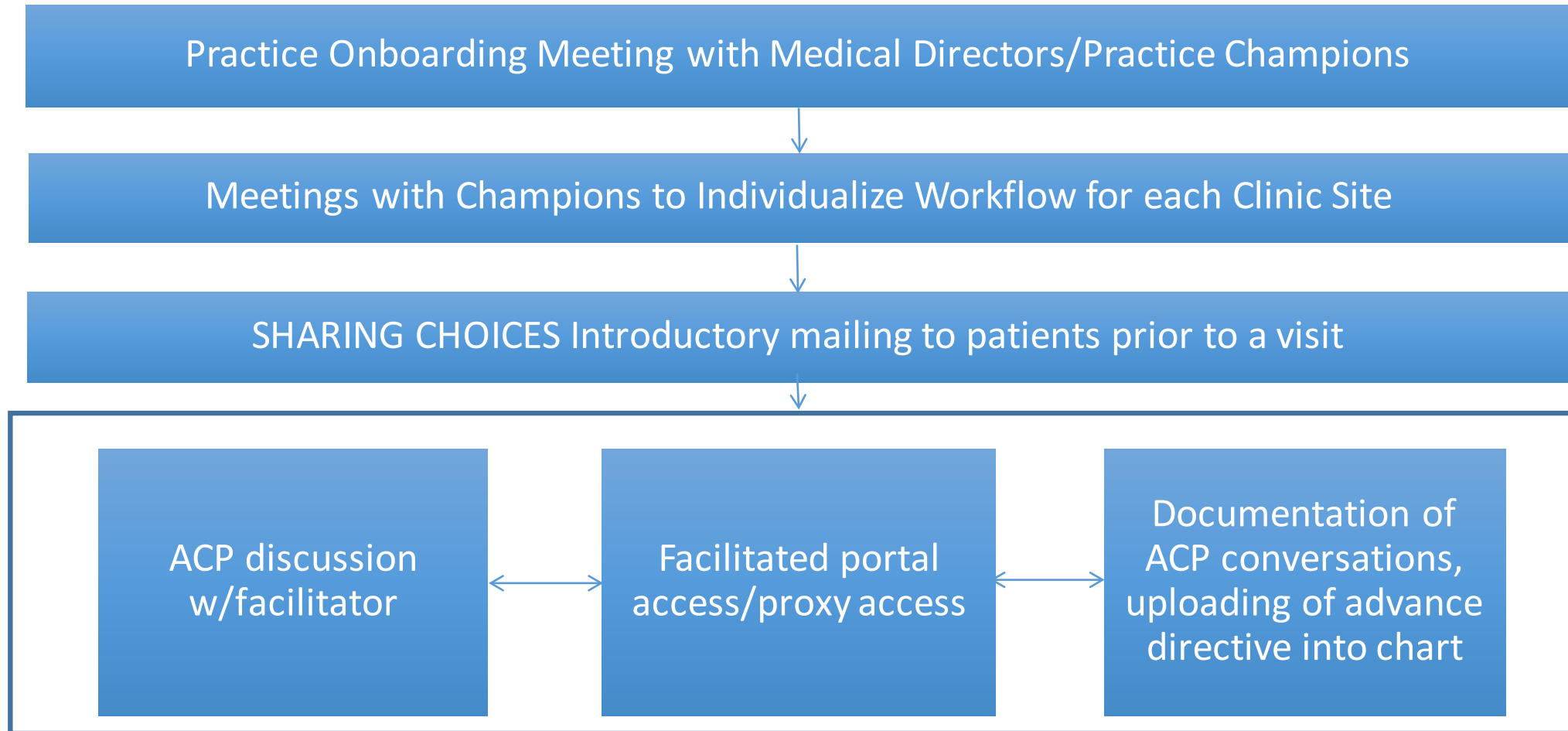
1. A **letter** from the clinic introducing an initiative to prepare persons & families for Advance Care Planning
2. Patient-family **agenda-setting checklist** to align perspectives about the role of family & stimulate discussion about ACP
3. Facilitated registration to the **patient portal** (patient *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

Intervention Structure

Clinic Randomization

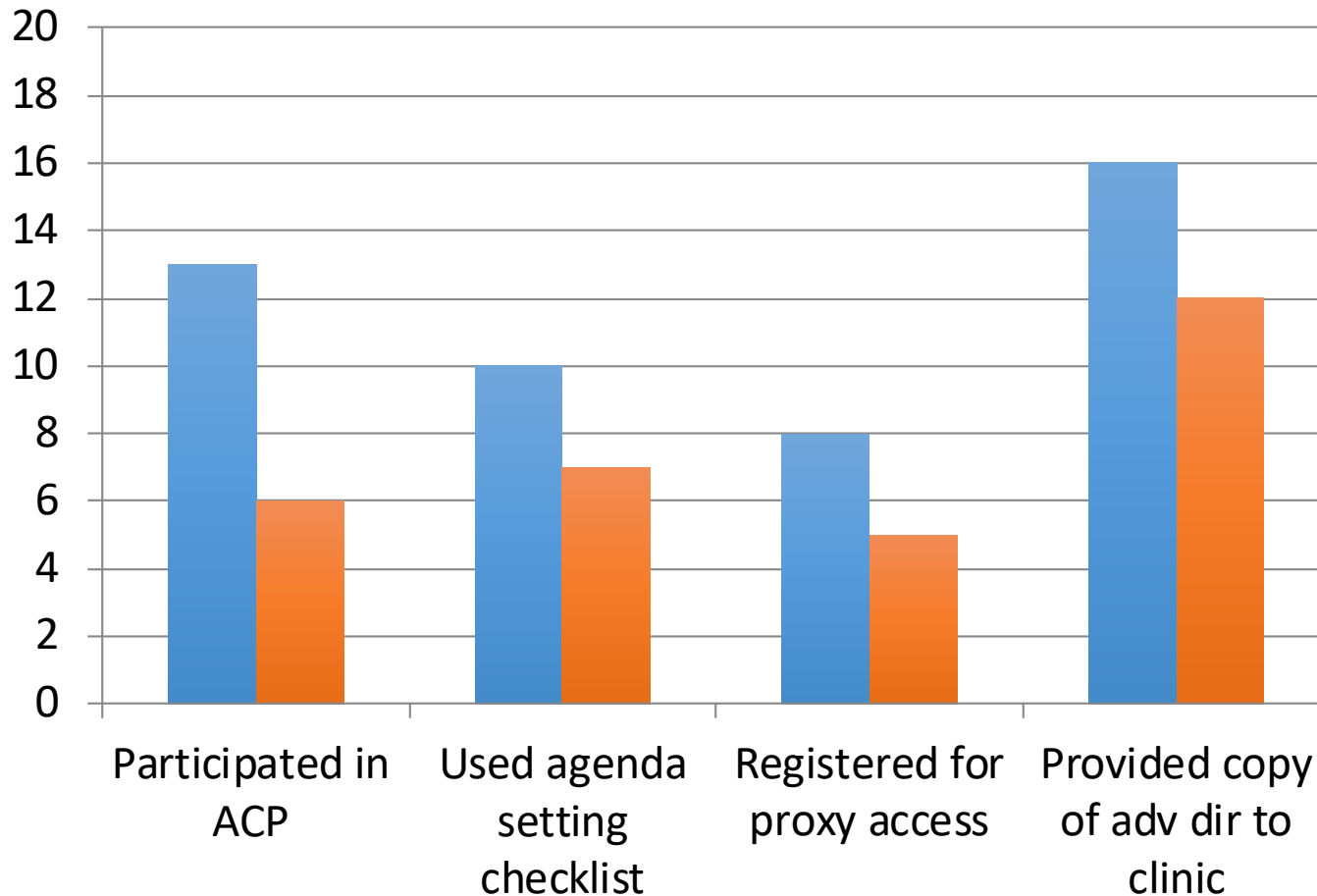


Implementation Strategy

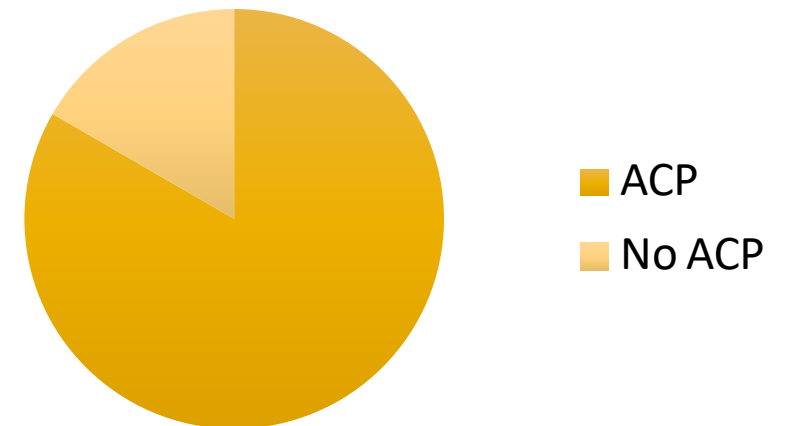


Pilot Experience

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.

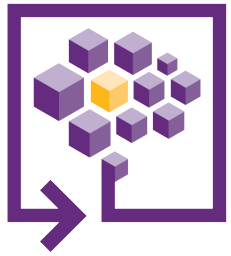
Alignment with other metrics & goals in primary care helps with buy-in and uptake.

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.



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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

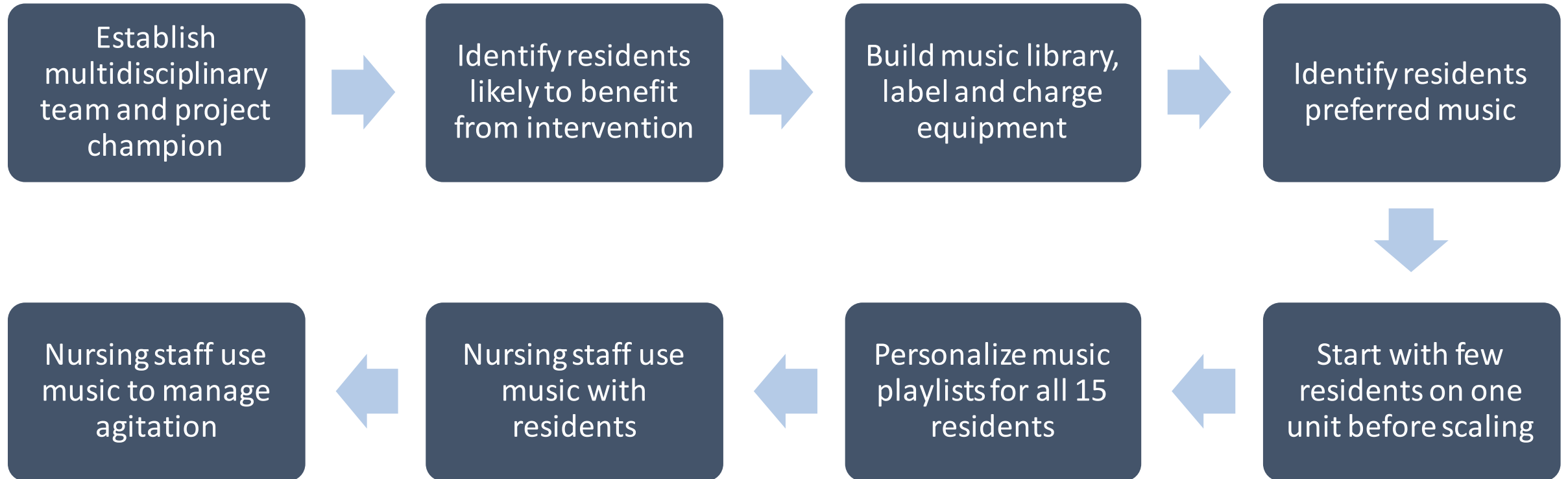
- Drugs used to manage agitated behaviors in nursing home residents with dementia increase the risk of falls and death
- Reminiscence therapies may reduce agitated behaviors resulting from social isolation or sensory deprivation by eliciting long-stored memories
- In Music & Memory, the music a resident 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

	Trial 1 (June, 2019 - January, 2020)	Pandemic (March, 2020 - current)	Trial 2 (May 2021 - December, 2021)
Wave 1 (27 Nursing Homes)	Intervention (405 residents)	Coronavirus pandemic	Intervention (405 residents)
Wave 2 (27 Nursing Homes)	Control (405 residents)	Coronavirus pandemic	Intervention (405 residents)
Wave 3 (27 Nursing Homes)	Control (405 residents)	Coronavirus pandemic	Control (405 residents)

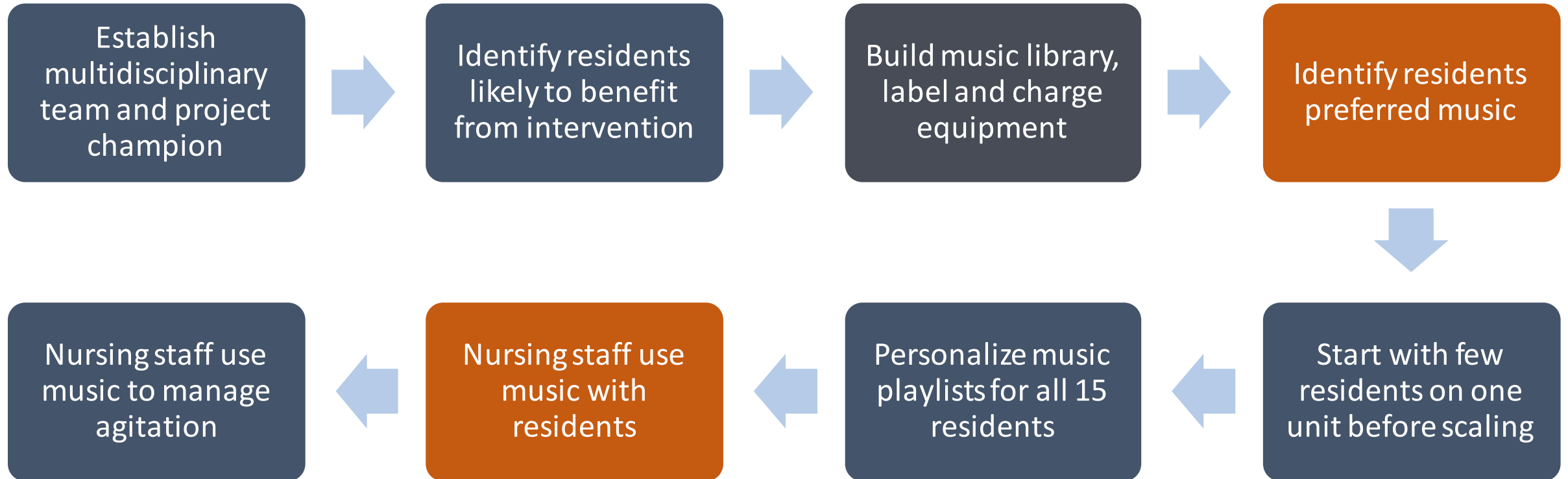
Intervention Structure



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

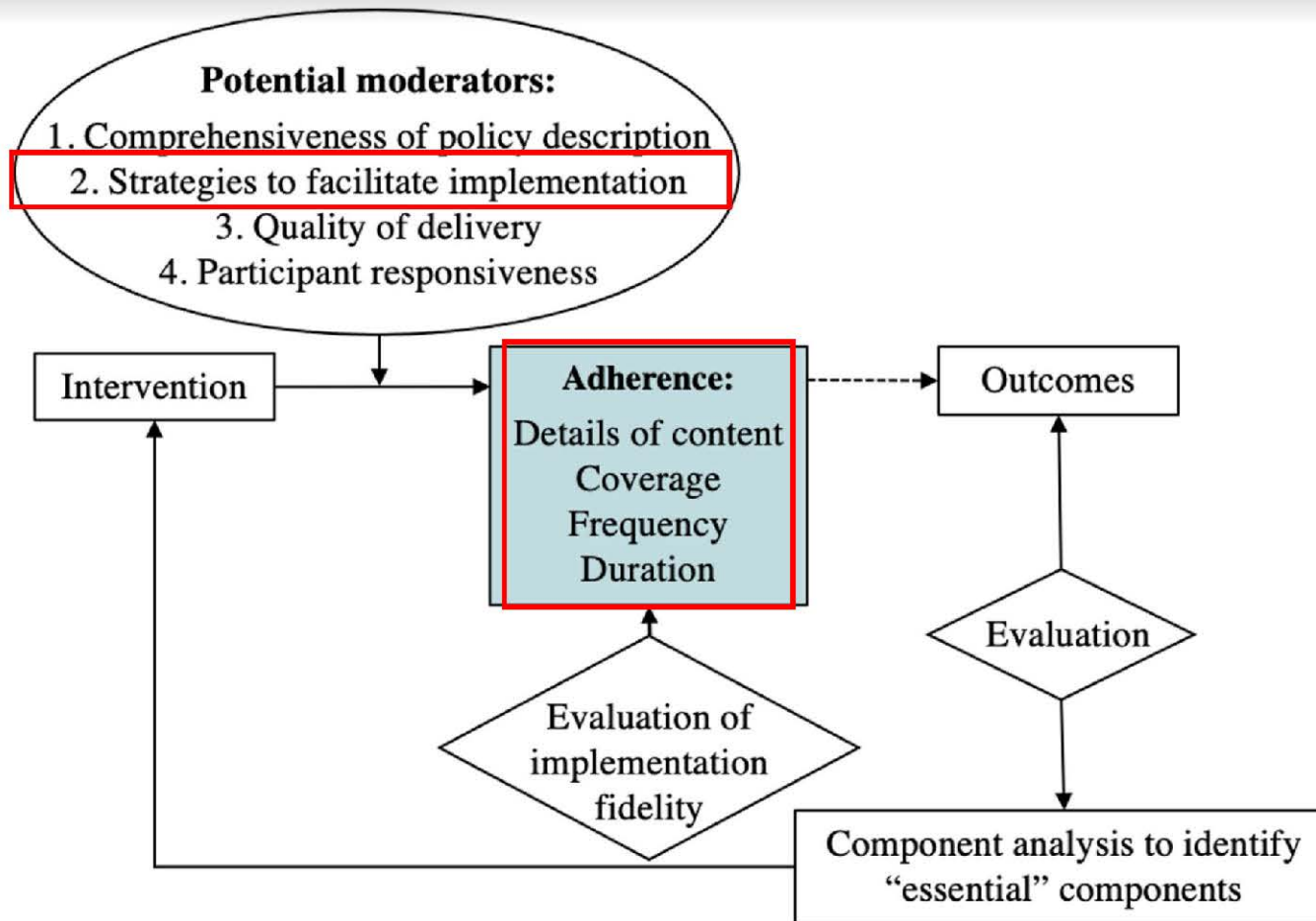
Implementation Adaptations



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

Conceptual Model



Quantitative Implementation Evaluation

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

Miranda Olson, MS, Project Analyst

Evaluation of Implementation Fidelity

Adherence Domain	Operational Definition (facility-level variables)
Duration	Median minutes of music per day exposed
Frequency	Percent of residents receiving the intervention five or more days per week
Coverage	Number of residents exposed during the study window
Details of Content	Intervention core features: <ul style="list-style-type: none">• 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

Evaluation of Implementation Fidelity

Adherence Domain	Operational Definition (facility-level)	Fully Personalized Strategy
Duration	Median minutes of music per day exposed	29 minutes / day exposed
Frequency	Percent of residents receiving the intervention five or more days per week	13% of residents receiving music daily
Coverage	Number of residents exposed during the study window	14 residents exposed
Details of Content	<p>Intervention core features:</p> <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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



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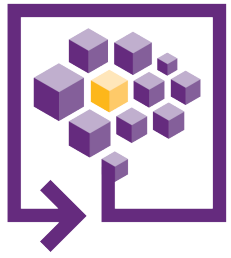
Panelist Response



Brian S. Mittman, PhD

Research Scientist III,

Division of Health Services Research &
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Q&A