


Innovations and Challenges in Performing Community-Based Dyadic Dementia Palliative Care Clinical Trials: Lessons from the Field

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DISCLOSURES

I have no relevant financial relationships to disclose that exist now or in the past 12 months

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DEDICATED TO IMPROVING HEALTH CARE FOR OLDER AMERICANS

The John A. Hartford Foundation

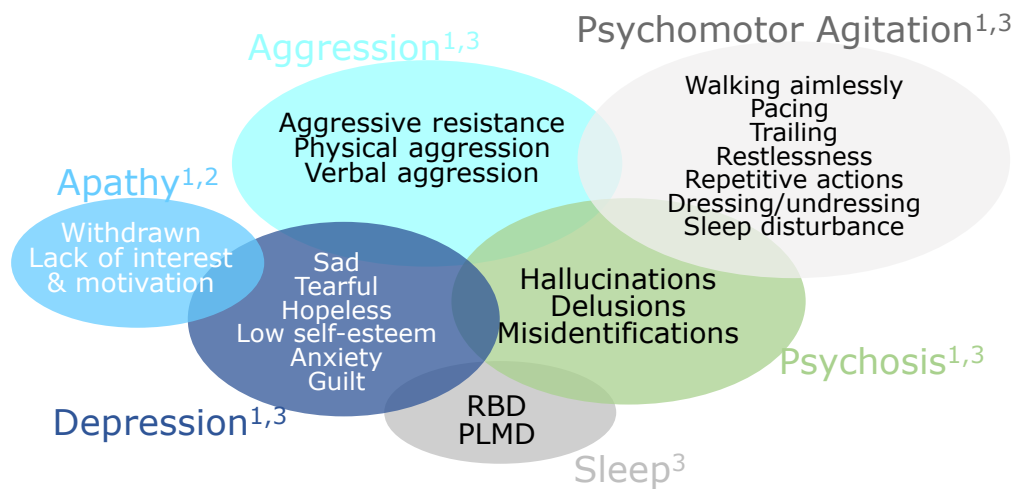


National Institutes of Health

R33AG061904
R01AG056610
U54AG063546
PCORI R-1609-36306



Behavioral and Psychological Symptoms: Behavior Clusters in Dementia and DD



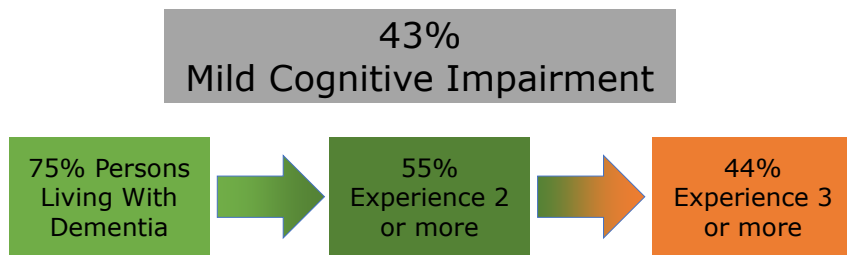
RBD=rapid eye movement (REM) sleep behavior disorder. PLMD=periodic limb movement disorder.

1. Lyketsos CG, et al. Am J Psychiatry. 2000;157(5):708-714.
2. Clarke DE, et al. J Neuropsychiatry Clin Neurosci. 2008;20(3):337-347.
3. Boyd M. Psychiatric Nursing: Contemporary practice; 2008



Background

- Symptoms of emotional distress or abnormal behavior
- BPSD are Commonly found in persons living with dementia



Significance of BPSDs

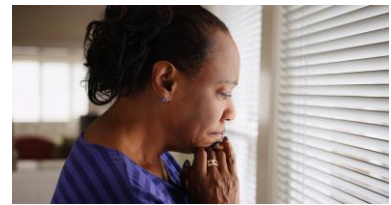
•For the Person Living with Dementia or DD

- ↓ Quality of Life
- ↓ ADLs & IADLs
- ↓ Cognition
- ↑ Institutionalization



For the Caregiver

- ↓ Health
- ↑ Depression
- ↑ Stress
- ↑ Burnout





There were no dementia specific symptom management interventions in home-based care when I started this journey in 2007

Adaptation and Piloting for Hospice Social Workers of Aliviado Dementia Care, a Dementia Symptom Management Program

Tessa M. Jones, LMSW¹, and Abraham A. Brody, PhD, RN, FPCN^{2,3}

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Feature Article

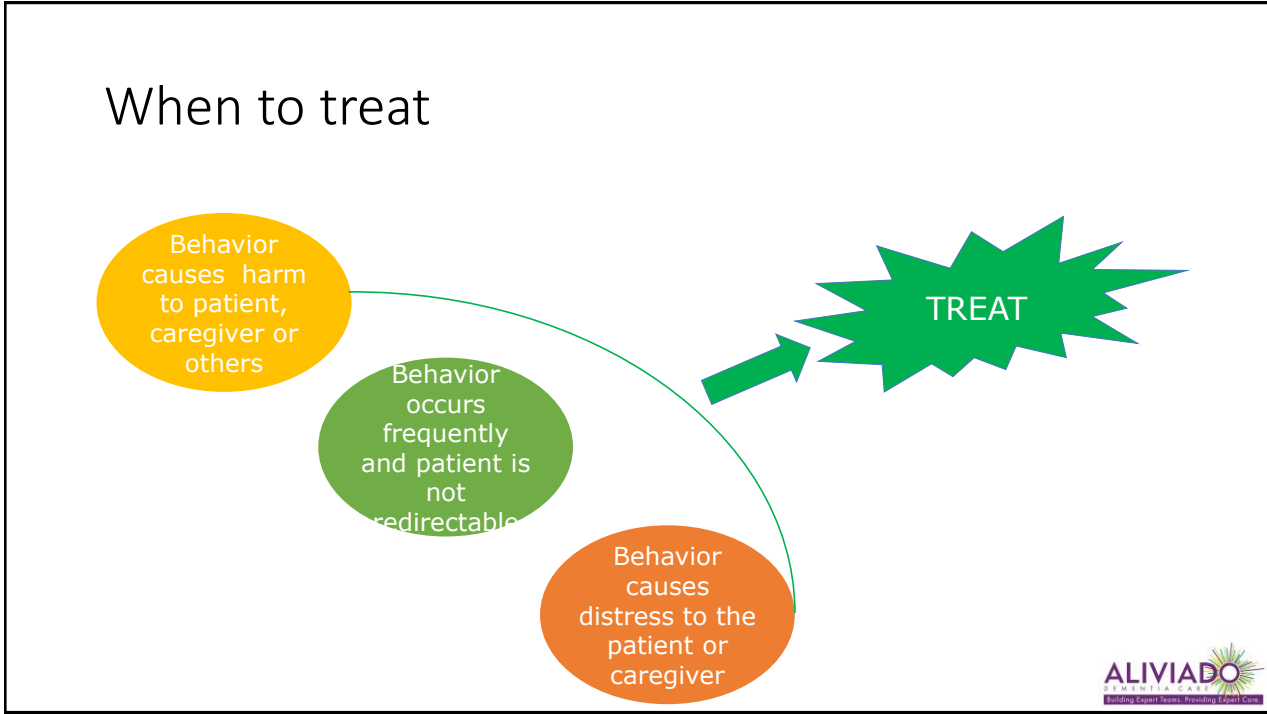
Development and testing of the Dementia Symptom Management at Home (DSM-H) program: An interprofessional home health care intervention to improve the quality of life for persons with dementia and their caregivers

Home Health Care Management & Practice
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DOI: 10.1080/02701960.2013.801342

Routledge
Taylor & Francis Group

Feasibility of Implementing a Web-Based Education Program in Geriatric Pain and Depression for Home Health Care Nurses



Please answer the following questions based on changes that have occurred since the patient first began to experience memory problems.

Circle "Yes" only if the symptom(s) has been present in the last month. Otherwise, circle "No". For each item marked "Yes":

a) Rate the SEVERITY of the symptom (how it affects the patient):
 1 = Mild (noticeable, but not a significant change)
 2 = Moderate (significant, but not a dramatic change)
 3 = Severe (very marked or prominent, a dramatic change)

b) Rate the DISTRESS you experience due to that symptom (for you):
 0 = Not distressing at all
 1 = Minimal (slightly distressing, not a problem)
 2 = Mild (not very distressing, generally easy to cope with)
 3 = Moderate (fairly distressing, not always easy to cope with)
 4 = Severe (very distressing, difficult to cope with)
 5 = Extreme or Very Severe (extremely distressing, unable to cope with)

Please answer each question carefully. Ask for assistance if you have any questions.

Delusions Does the patient have false beliefs, such as thinking he or she is being persecuted, others are stealing from him/her or planning to harm him, or in some way?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Hallucinations Does the patient have hallucinations such as false visions or voices? Does he or she seem to hear or see things that are not present?

Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

Agitation/Aggression Is the patient resistive to help from others at times, or hard to handle?


Yes No SEVERITY: 1 2 3 DISTRESS: 0 1 2 3 4 5

npITEST

Neuropsychiatric Inventory Questionnaire: Screening Test for BPSD


Neuropsychiatric Inventory
Questionnaire (NPI-Q)

By Jeffrey L. Cummings, MD



Treating BPSD

- Look for other causes first (e.g. acute delirium or terminal delirium)
 - Pain
 - Depression
 - Sleep Disturbance
 - Infection
 - Worsening medical condition
 - Dyspnea (e.g. from concomitant COPD or CHF)
 - End of life signs/symptoms



Using P-I-E-C-E-S

- Physical
- Intellectual Needs
- Emotional
- Capabilities
- Environmental
- Social

Create a Personalized
Care Plan Based on
Exhibited Behaviors and
Causes



Physical Needs

- Unmet needs-hungry, thirsty, needs to be cleaned, toileted or repositioned
- Pain
- Medical Co-morbidity issues
- Medications
- Altered Senses



Intellectual Needs

- Communication issues
- Dementia related cognitive decline
- The 5 As
 - Amnesia
 - Aphasia
 - Agnosia
 - Apraxia
 - Apathy



Emotional

- Depression
- Loss or Grief
- Recent move
- Loss of independence
- Past mental health issues (BiPolar, Schizophrenia, etc..)



Capabilities

- Reduced ability to perform ADLs and iADLs
- Ability to communicate
- Loss of social skills
- Loss of motor skills
- Loss of ability to perform complex tasks



Environmental

- Physical
 - noise
 - light
 - temperature
 - environmental design
 - clutter
 - smell
 - familiarity
- Social
 - isolation
 - lack of meaningful stimuli or contact
 - loss of privacy
 - limited/invaded personal space



Social

- Boredom
- Loneliness
- Isolation
- Providing non-supportive forms of care
 - overwhelming
 - moving too fast
 - impatience

- ignoring capabilities the pt retains
- lack of cuing or appropriate directions
- Not following personal preferences
- loss of control

Pharmacology Practice



Prescribing is Easy



Prescribing doesn't work that well to control most BPSD

Sleep Disturbance Treatment

Non-Pharmacologic

- Lighting
- Limit napping
- Exercise
- Limit alcohol
- Good sleep hygiene
- Pain and depression management
- Maintain set, patient specific sleep-wake times
- Caregiver Education Sheet available in App/Toolbox

Pharmacologic

- Trazadone (off label)
- Ensure cholinesterase inhibitor is not given in evening
- Mirtazapine if also concomitant depression and weight loss/loss of appetite

Study Design

- Stratified Cluster Hybrid III/IV Randomized Trial
 - 3 Home Health Agencies, 20 Care Teams- Intervention Teams vs Usual Care
 - Agency 1-Large, Urban-Suburban, non-profit highly diverse population, particularly AA population
 - Agency 2-Medium Size, Urban-Suburban-Rural (highly rural), non-profit, limited diversity
 - Agency 3-Small, Urban-suburban, for-profit, highly diverse population, particularly Latinx population
 - Longitudinal collection (0, 15, 30, 60 days) in the PLWD/caregiver's home

Design Considerations

Pros

- Intervention Implemented/Delivered Pragmatically
- Assessments nudged via EHR
- Highly diverse enrollment population
- Gold standard measurement
- Comparison to Pragmatic Measures

Cons

- Intervention Fidelity***
- Enrollment Challenges
- QOL (primary outcome) as a measure has limited variability
- EHRs are not flexible/extensible in community settings
- COVID-19!

***will come back to this



Pragmatic Trials for Dementia Care in Long-term Services and Support (LTSS) Settings (R61/R33 - Clinical Trial Required)

R61/R33 Exploratory/Developmental Phased Award

Reissue of RFA-AG-17-065

- August 23, 2019 - Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-137.
- July 26, 2019 - Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-128.
- November 26, 2018 - NIH & AHRQ Announce Upcoming Updates to Application Instructions and Funding Research Grant Applications. See Notice NOT-OD-18-238.

Sometimes there's an opportunity you just can't pass up



R61 Purpose

- To sequentially test and adapt Aliviado Dementia Care for use by the hospice interdisciplinary team through stakeholder input



R61 Aims

01

Establish the infrastructure necessary for implementing a pragmatic clinical trial of Aliviado Dementia Care.

02

Further tailor the Aliviado program specifically for hospice IDT members caring for PLWD receiving end of life care and adapt for wide-scale implementation in hospice.

03

Pilot test the complete protocol in 2 hospice agencies and refine the protocol further based on feedback from the pilot agencies.



R61 Methods of Engaging Staff

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, 1 month

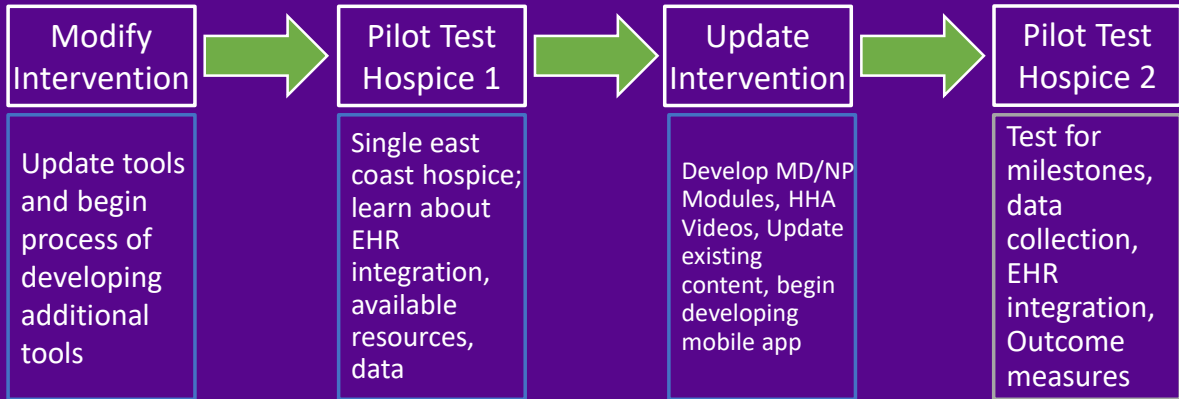
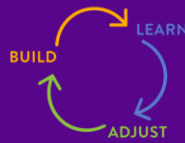


R61 Milestones

- **1) Feasibility.** Milestone: completion of all required education and training by at least 80% of eligible hospice IDT members
- **2) Applicability.** Milestone: post-implementation surveys indicating 80% of IDT members feel the program is applicable to their work and that they will implement changes in their practice
- **3) Fidelity.** Milestone: at least 75% of advanced dementia patients receiving home hospice having at least 1 care plan or assessment instrument utilized within the month following implementation.



R61 Methods



Stakeholder Engagement Led to:

- Flexibility in how we collect data because of the limited flexibility of hospice EHRs
- Creation of a mobile health app with access to the tools and tracking of results over time***
- Spanish language tools, home health aide training requested by sites
- Modification of social work and chaplain tools to even further de-medicalize




Stakeholder Engagement Led to:

- Substantial Implementation Enhancements
 - Creation of QAPI templated plans for champions
 - Continuing monthly champion calls beyond 6 months
 - Implementing automated, personalized, nudge push notifications and emails that are discipline specific and thematic




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



Mobile App



10:44

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ASSESSMENTS CARE PLANS CAREGIVING NEWS & BLOG FAVORITES

Educational Articles for Caregivers

These articles provide guidance about some of the most common challenges faced by people with dementia and their caregivers.

Filter

Advance Care Planning

This educational material helps caregivers to better understand how to talk to their loved ones and make decisions about future care.

Advance Care Planning Caregiving

Aggression When Performing Personal Care

This educational material helps caregivers to better understand agitation and aggression specifically regarding bathing and personal care and how to manage it.

Behavioral Symptoms Personal Care

ALIVIADO DEMENTIA CARE

Ab Brody
Nurse Practitioner

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- Contact Us
- Learning Center
- Privacy Policy
- Settings
- Logout

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10:43

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Apple Bee DOB: 8/2/1950 MEDICAL RECORD #: 12346

Assessments (7) Careplans (4)

Score	Assessment Date	Performed By
5	Oct 10 2020	Ab Brody
15	Sep 16 2020	Aditi Durga

Score	Assessment Date	Performed By
5	Sep 16 2020	S Lin

Score	Assessment Date	Performed By
3	Sep 16 2020	S Lin

10:43

Neuropsychiatric Inventory Questionnaire (NPI-Q) Score

5

0 1-3 4-17 18-36

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

10:49

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).

Aggression Care Plan Instructions

10:49

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.

Acknowledge 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 desprescribing)

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

Aggression Care Plan Instructions

Transitioning to the R33

- 25-site stepped wedge trial
- Stakeholder engagement related to:
 - Readiness
 - Data collection processes**
 - Further intervention modifications
 - Implementation processes
- Sites chosen to ensure geographic, profit status and racial/ethnic variability



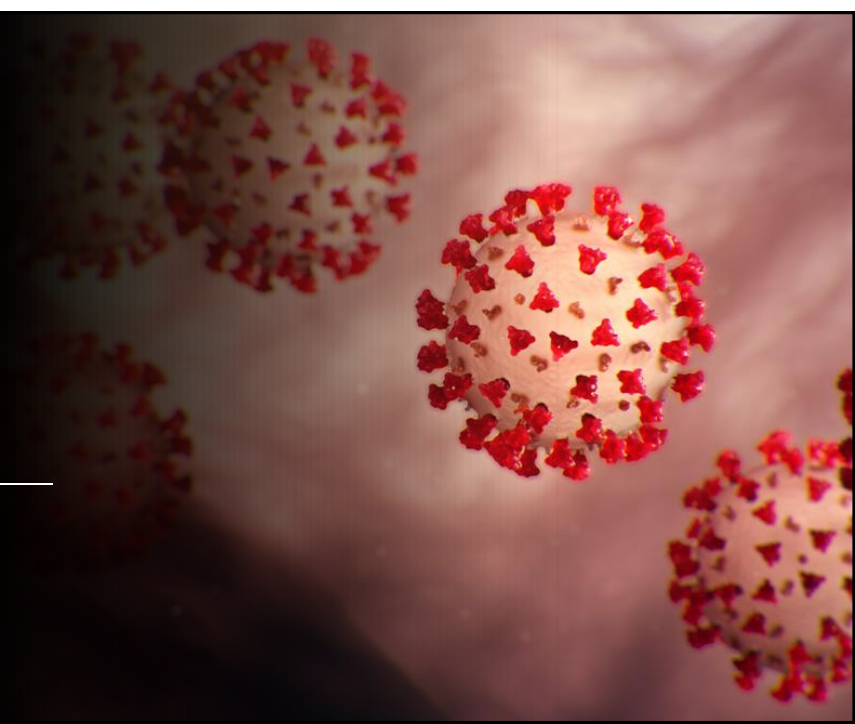
Y1M1-Y1M3	Y1M4	Y1M5	Y1M6	Y1M7	Y1M8	Y1M9	Y1M10	Y1M11	Y1M12	Y2M1	Y2M2-Y4M3
Control phase	Intervention [2-3 hospices]	Maintenance phase									
Control	Intervention [2-3 hospices]	Maintenance									
Control	Control	Intervention [2-3 hospices]	Maintenance								
Control	Control	Control	Intervention [2-3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





Data collection

- Outcome measures:
 - Antipsychotic use, disenrollment/increased level of care required (e.g. GIP, continuous care), HCAHPS
 - Will perform secondary analyses by race/ethnicity and sex
- Implementation/Fidelity measures:
 - Staff training completion
 - Tool usage (both in EHR and app)
 - Read/Open rates of nudges/emails



COVID-19

Turned our
plans upside
down

COVID-19 Effects

- “Pause” our 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 2021
- Gave time to further tighten up and iterate implementation using feedback from initial hospices



Pilot Cycle 1 Awardees



Brent Forester, MD, MSc

McLean Hospital, Mass General Brigham

Implementation of the Care Ecosystem training model for individuals with dementia in a high risk, integrated care management program



Ula Hwang, MD, MPH

Yale School of Medicine

Pathway to Detection & Differentiation of Delirium & Dementia in the Emergency Department



New R61/R33 Awards + Existing R01s and R61/R33s



Yvonne Lu, PhD, RN, FGSA

IU SON

DEMA-PRO in Home Health



Kali S Thomas, PhD

Brown Public Health

Home Delivered Meals +
Wellness Check for Persons Living
with Dementia vs Frozen Drop
Shipments

Several Others focused
on:

- Social Service Organizations
- Primary Care Communication of ACP
- Family Caregivers in Adult Day Health
- Telephonic Care



New IMPACT RFA will come out in ~February

- ~\$175k direct funds to prepare for a pragmatic trial by testing out evidence-based interventions that can be widely spread
 - Be on the lookout for the RFA and the accompanying webinars
-
- We also have a health systems core focused on having sites/providers join up to serve as sites in pragmatic ADRD trials and provide input and generate ideas to test, it CAN'T ALL COME FROM RESEARCHERS!!!



Overall Take Home Message

Implementing embedded pragmatic trials for ADRD care in the community:

Can reach more diverse populations and enhance equity

Can be more realistic and thus generalizable to real world practice than sticking in academic med centers

Addresses real world clinical problems

Need to think further about how to drive quality outside of specialty clinics

Non-pharmacologic interventions, while “harder” to implement are often more efficacious.

Quality improvement requires multiple strategies, training alone doesn't work

