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

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Pilot Care Lead, NIA IMPACT Collaboratory

DISCLOSURES

I have no relevant financial relationships to disclose that exist now or in the past 12 months
Behavioral and Psychological Symptoms: Behavior Clusters in Dementia and DD

- Aggression\(^1,3\)
  - Aggressive resistance
  - Physical aggression
  - Verbal aggression

- Psychomotor Agitation\(^1,3\)
  - Walking aimlessly
  - Pacing
  - Trailing
  - Restlessness
  - Repetitive actions
  - Dressing/undressing
  - Sleep disturbance

- Apathy\(^1,2\)
  - Withdrawn
  - Lack of interest & motivation

- Depression\(^1,3\)
  - Sad
  - Tearful
  - Hopeless
  - Low self-esteem
  - Anxiety
  - Guilt

- Hallucinations
- Delusions
- Misidentifications

- Psychosis\(^1,3\)

- Sleep\(^3\)

- RBD
- PLMD

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

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.
When to treat

- Behavior causes harm to patient, caregiver or others
- Behavior occurs frequently and patient is not redirectable
- Behavior causes distress to the patient or caregiver

TREAT
Neuropsychiatric Inventory (NPI-Q) Screening Test for BPSD

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
<table>
<thead>
<tr>
<th>Social</th>
<th>Pharmacology Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Boredom</td>
<td>Prescribing doesn’t work that well to control most BPSD</td>
</tr>
<tr>
<td>• Loneliness</td>
<td></td>
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<tr>
<td>• Isolation</td>
<td></td>
</tr>
<tr>
<td>• Providing non-supportive forms of care</td>
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<tr>
<td>- overwhelming</td>
<td></td>
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<tr>
<td>- moving too fast</td>
<td></td>
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<tr>
<td>- impatience</td>
<td></td>
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<td>• Ignoring capabilities the pt retains</td>
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<tr>
<td>• Lack of cuing or appropriate directions</td>
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<tr>
<td>• Not following personal preferences</td>
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<tr>
<td>• Loss of control</td>
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</table>
**Sleep Disturbance Treatment**

<table>
<thead>
<tr>
<th>Non-Pharmacologic</th>
<th>Pharmacologic</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Lighting</td>
<td>• Trazadone (off label)</td>
</tr>
<tr>
<td>• Limit napping</td>
<td>• Ensure cholinesterase inhibitor is not given in evening</td>
</tr>
<tr>
<td>• Exercise</td>
<td>• Mirtazapine if also concomitant depression and weight loss/loss of appetite</td>
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<tr>
<td>• Limit alcohol</td>
<td></td>
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<tr>
<td>• Good sleep hygiene</td>
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<tr>
<td>• Pain and depression management</td>
<td></td>
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<tr>
<td>• Maintain set, patient specific sleep-wake times</td>
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<tr>
<td>• Caregiver Education Sheet available in App/Toolbox</td>
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</tbody>
</table>

**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

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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

Modify Intervention
Update tools and begin process of developing additional tools

Pilot Test Hospice 1
Single east coast hospice; learn about EHR integration, available resources, data

Update Intervention
Develop MD/NP Modules, HHA Videos, Update existing content, begin developing mobile app

Pilot Test Hospice 2
Test for milestones, data collection, EHR integration, Outcome measures

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.

Thanks for reading!
The Aliviado Team

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.
### Mobile App

#### 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

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#### Neuropsychiatric Inventory Questionnaire (NPI-Q) Score

**Score: 5**  

<table>
<thead>
<tr>
<th>Score</th>
<th>Assessment Date</th>
<th>Performed By</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Oct 10 2020</td>
<td>Ab Brody</td>
</tr>
<tr>
<td>15</td>
<td>Sep 16 2020</td>
<td>Aditi Durga</td>
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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

- **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 methods 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/deficits not being met (see Behavioral Symptom Treatment Algorithm)

- **Non-pharmacologic Interventions**
  - **Music therapy:** Allows patients to express themselves nonverbally. Soothes and relieves individuals.
  - **Don’t argue or react defensively:** Keeps the tone of the exchange neutral.
  - **Achromatic 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
Transitional 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

Transitioning to the R33

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<th>Maintenance phase</th>
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<tr>
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<td>Intervention [3 hospitals]</td>
<td>Maintenance</td>
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<td>Control</td>
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<tr>
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<td>Intervention [3 hospitals]</td>
<td>Maintenance</td>
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</table>
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!!!
**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