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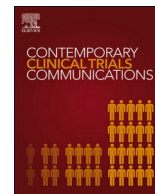
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Evaluating non-pharmacological approaches to nursing home dementia care: A protocol

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ABSTRACT

Background: The COVID-19 pandemic has underscored the daily challenges nursing home (NH) staff face caring for the residents living with Alzheimer's Disease and Related Dementias (ADRD). Non-pharmacological approaches are prioritized over off-label medication to manage the behavioral and psychological symptoms of ADRD. Yet, it is not clear how to best equip NH staff and families with the knowledge and strategies needed to provide non-pharmacological approaches to these residents.

Methods: This clustered randomized trial will compare *team-* and *problem-based* approaches to non-pharmacological ADRD care. The team-based approach includes core training for all NH staff using a common language and strategies to support continuity and sustainability. The problem-based approach capitalizes on the expertise of the professional healthcare providers to target issues that arise. A convergent mixed methods design will be used to examine (a) comparative effectiveness of the two approaches on long-term NH resident outcomes and (b) whether either approach is protective against the negative consequences of COVID-19. The primary outcome is the percentage of ADRD residents with off-label antipsychotic medication use, which will be evaluated with an intent-to-treat approach. Staff and family caregiver perspectives will be explored using a multiple case study approach.

Conclusion: This trial will be the first-ever evaluation of team- and problem-based approaches to ADRD care across multiple NHs and geographic regions. Results can provide health system leaders and policymakers with evidence on how to optimize ADRD training for staff in an effort to enhance ADRD care delivery.

1. Introduction

Of the 1.4 million nursing home (NH) residents in the United States (US), half of residents have a diagnosis of Alzheimer's Disease and Alzheimer's Disease Related-Dementias (ADRD) [1]. As the disease progresses, behavioral and psychological symptoms are common. These symptoms originate from disruptions in the resident's daily routine, difficulty communicating personal needs, and environmental overstimulation or sensory deprivation [2–4]. If untreated, these behavioral and psychological symptoms result in negative side effects (e.g., injuries

to self or others, limited food intake, accidental falls) increasing the risk of hospitalization and death [4,5]. Historically, off-label antipsychotic medications have been used to manage these symptoms, despite negative side effects and concerns about this approach from the NH stakeholder community (e.g., patient advocates, family, policy makers) [6–8]. Prior to the emergence of COVID-19, national initiatives were introduced to reduce off-label medication use and enhance non-pharmacological strategies to manage the sources of the behaviors, optimize care, and enhance the resident's quality of life [4,8–15].

Studies examining *team-based* and *problem-based* non-

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pharmacological approaches to ADRD care found resident benefits (e.g., reduced frequency of behaviors, use of psychotropic medications) [4, 9–14,16]. The *team-based approach* emphasizes a common understanding of the disease process, resident abilities, and cognitive stages, regardless of job role [10,17–19]. This approach includes core training for all NH staff using a common language and strategies to support continuity and sustainability. The *problem-based approach* capitalizes on the expertise of the professional healthcare providers to target issues that arise [18,20]. These providers then educate direct care providers and family caregivers (e.g., adult child) in the resident-specific care plan [21]. Yet, these two approaches have not been compared to each other, and it is not clear if there is a difference in outcomes given the variation in NH contexts [22].

Since COVID-19 emerged, there is growing concern that the use of off-label antipsychotics may again be on the rise to manage behavioral and psychological symptoms of ADRD. Strategies that are used as part of a non-pharmacological comprehensive, multi-dimensional plan (e.g., group activities, consistent routine) may be hindered due to COVID-19 related infection control policies and staffing shortages. As a result, COVID-19 has only accelerated the urgency to answer the clinical dilemma, *which type of comprehensive, non-pharmacological approach is the most successful in limiting behavioral and psychological symptoms of ADRD and thereby reducing the administration of off-label psychotropic drugs in residents living with ADRD*. To address this dilemma, this protocol describes how we will: (a) assess comparative effectiveness of a *team- and problem-based* approach to ADRD care on NH residents before and after the emergence of COVID-19, (b) provide insight into family and staff perspectives on implementation and effectiveness, and (c) provide recommendations for revisions to nursing home policies and regulations regarding non-pharmacological approaches to dementia care and emerging events impacting care delivery for ADRD residents (e.g., natural disaster, highly contagious infections). This protocol follows Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 guidelines [23].

2. Design and methods

The study protocol was designed and initiated prior to the emergence of the COVID-19 pandemic. At that time, 80 NHs had been recruited, randomized to one of the two ADRD care approaches (*team-vs. problem-based*), and staff training delivered. In March 2020, all research related communication between the research team and NHs stopped due to a communication moratorium put in place due to COVID-19. As the pandemic evolved, the research team worked with the funders to develop a strategy for moving forward with the study. This strategy included determining which facilities were able to re-engage, of which 53 agreed to re-engage. This manuscript presents the peer-reviewed funder approved protocol, which was finalized in April 2022.

2.1. Study design and setting

The study will employ a clustered randomized pragmatic comparative effectiveness study, using a mixed-methods convergent design [24], to compare a *team-* and *problem-based* approach to non-pharmacological ADRD care. This trial takes place in NHs within the US and is led in collaboration with an Advisory Committee.

2.2. Advisory committee

The 18-member Advisory Committee represents communities critical to NH care such as ADRD resident advocates, families, professional healthcare providers (e.g., registered nurse, social worker), direct service providers (e.g., certified nursing assistants, dietary staff), and administrators, who provide guidance on all aspects of study execution, interpretation, and dissemination. Prior to the COVID-19 pandemic, the committee participated in a one-day in-person kick-off meeting in which

a shared governance structure was established [25]. After which, the committee has and continues to participate in monthly meetings.

2.3. Conceptual framework

Recent implementation studies have utilized multiple frameworks to inform distinct aspects of implementation [26]. As such, this study is informed by two frameworks, including Donabedian's 3-component model of quality and the Health Equity Implementation Framework [27,28]. Donabedian's model guided the analysis to determine whether key resident-centered outcomes differ between the two non-pharmacological approaches to ADRD care (Fig. 1). The Health Equity Implementation Framework informed the study design (Appendix A) to ensure the study does not systematically exclude facilities that care for patient populations that have experienced inequities in ADRD care [29,30].

2.4. Eligibility criteria

Facility-level inclusion criteria requires eligible NHs to (a) not have existing ADRD program targeting reduction of off-label antipsychotic medication use, (b) serve an average of ≥ 60 long-term care residents with ADRD, (c) be Centers for Medicare & Medicaid Services' (CMS) certified facility (e.g., conduct regularly scheduled resident assessments), and (d) comply with CMS's annual staff ADRD care training requirement (i.e., 4 h) [31–33]. NHs in states that require more than 4 h of dementia-specific training annually were excluded [34].

Eligible NH residents will include those that (a) have an existing diagnosis of ADRD or a Cognitive Function Scale [35] score indicating Mild, Moderate, or Severe Cognitive Impairment, (b) are 65 years of age or older, and (c) are long-stay residents (>100 days). We will exclude post-acute care patients admitted for a brief stay (<100 days) and respite stay patients.

Eligible family caregivers will be the primary contact for an older adult living with ADRD in a participating NH (e.g., relative, spouse, partner, neighbor) [21]. Eligible staff must be employed by a participating NH and included all staff categories, (a) **professional healthcare providers**, including licensed staff with professional degrees, such as registered nurses, licensed practical nurses, rehabilitation practitioners (e.g., occupational [OT], physical, speech therapists [SLP]), certified therapeutic recreation specialist, dieticians (b) **direct care providers** (i.e., staff with licenses or certifications), such as certified nursing assistants [CNA], activities department staff, nutrition services personnel (e.g., kitchen staff, dining services); (c) **ancillary support staff**, including environmental services workers (e.g., maintenance, housekeeping) and administrative staff (e.g., reception, billing department, medical records); and (g) **administrators**.

2.5. Nursing home recruitment

A multi-pronged approach was used prior to COVID-19 to recruit NHs across four geographical regions of the US (i.e., Northeast, South, Midwest, West). Recruitment efforts included: organizational leadership messaging, which conveyed support of the project, informational materials disseminated to individual NH administrators, establishment of open office hours for administrators to learn more about the study from the investigators, and personal telephone calls to NH administrators. Further, Advisory Committee members leveraged their existing knowledge of and relationships with the NH community to assist in the dissemination of study information to support recruitment efforts.

2.6. Randomization

A clustered randomization approach was used, in which NHs were randomized to one of the two approaches to limit the staff burden (Fig. 2). The randomization scheme used stratification by region and

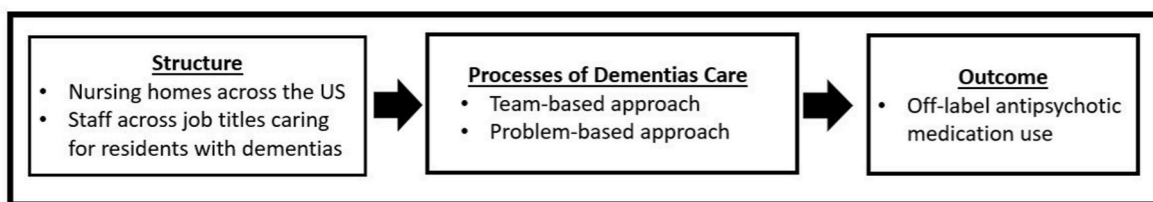


Fig. 1. Conceptual framework.

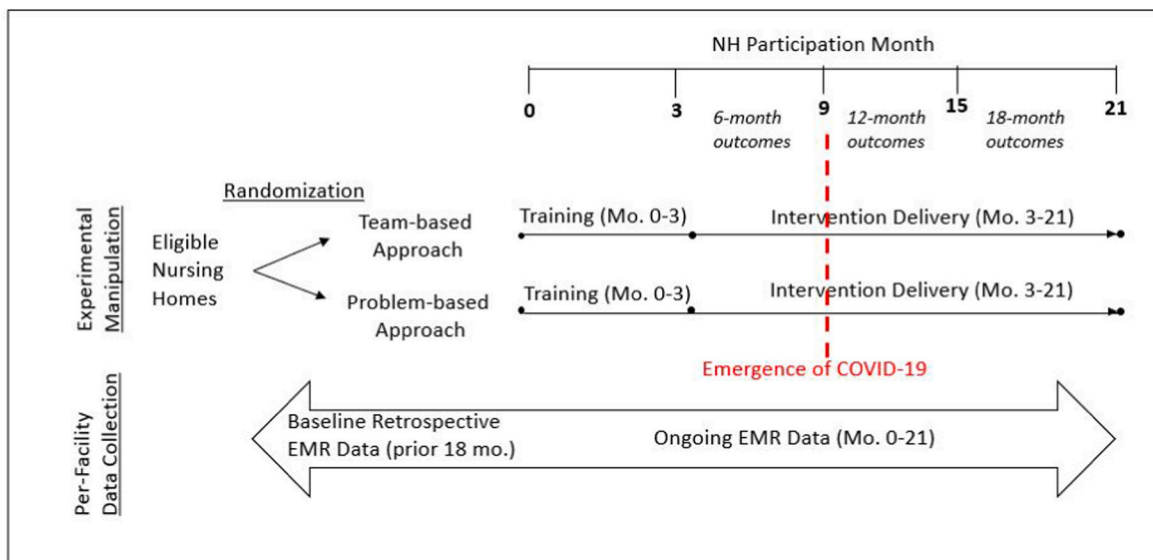


Fig. 2. Overview of experimental design.

blocking so that each region would have equal numbers of facilities randomized to each condition. To prevent selection bias, the project biostatistician (a) performed the randomization procedure after a NH consented to participate and (b) is blinded to the allocation sequence. The researchers analyzing the data will be blinded to the NH’s allocation. The trainers, NH staff, and residents are blinded to the study hypotheses and do not have access to the research data.

2.7. US nursing home ADRD care context

National regulatory policies require all CMS certified NH to (a) provide staff with annual dementia training and (b) conducted regularly scheduled resident assessments utilizing the Minimum Data Set (MDS) 3.0 [36]. When changes in a residents’ physical or mental health are identified during these assessments, a care plan must be initiated that can include pharmaceutical or non-pharmacological components. It is at this phase, the execution of the care plan, that this protocol examines: how to best execute non-pharmacological care plans for residents (Fig. 3). These two approaches were embedded within existing standards of care and leveraging existing staff, who are responsible for implementing staff education programs (refer to Appendix B for a case vignette, which highlights the differences in the two approaches). Administrators appointed a staff person to serve as a *NH change champion* to reinforce the care approaches with other staff. Monthly arm-specific (a) office hours and (b) fliers with additional ADRD care strategies were provided by two study team members. These individuals supported the clinical delivery of the two approaches, neither of which will be involved in the data analysis.

Team-based approach for integrated care begins with facility-wide staff training on ADRD. The training provides a common language and shared knowledge base for all facility staff (i.e., health care providers,

direct care providers, ancillary staff, administrators). The care process for each eligible resident includes four stages. (a) An evidence-based cognitive and functional assessment of the resident’s abilities and needs is conducted by an OT, nurse, SLP, or social worker [37]. This includes completing the global deterioration scale (GDS) assessment [38] and/or the Brief Interview for Mental Status (BIMS) [39]. (b) Assessment findings are interpreted, resulting in a designation of the resident’s cognitive level (i.e., stage) along with a summary of individualized resident-centered strategies [40]. The resident is assigned a specific color indicating the GDS level, with indicators of the assigned color placed in the resident’s room, chart, and other conspicuous locations. Additionally, a stage-specific summary of resident-centered strategies is completed by the OT or SLP, placed in the CNA logbook, and a copy is given to the family during training, if the family is available and participates in care of the resident. (c) The NH implements a coordinated strategy customized for each of the four stages across all staff, which includes family training. These strategies include pre-determined multifactorial approaches (e.g., resident in stage 5: always approach the resident from the front and provide discrete choices, “do you want to wear a blue or green sweater”) to assist all staff and family members in making appropriate decisions related to the residents’ environment, daily routine, and communication needs [41]. Additional individualized strategies that target highly specific resident needs may also be noted. (d) The skilled practitioners conduct quarterly screenings for changes in cognitive abilities to reassess each resident’s cognitive stage and intervention needs.

Problem-based approach relies on the expertise of individual professional healthcare providers involved in the care of the resident to evaluate, develop care plans, and provide resident-specific training to direct care providers and family [17,42,43]. In this approach, multiple, discipline-specific evaluations (e.g., OT, SLP) are completed to identify a

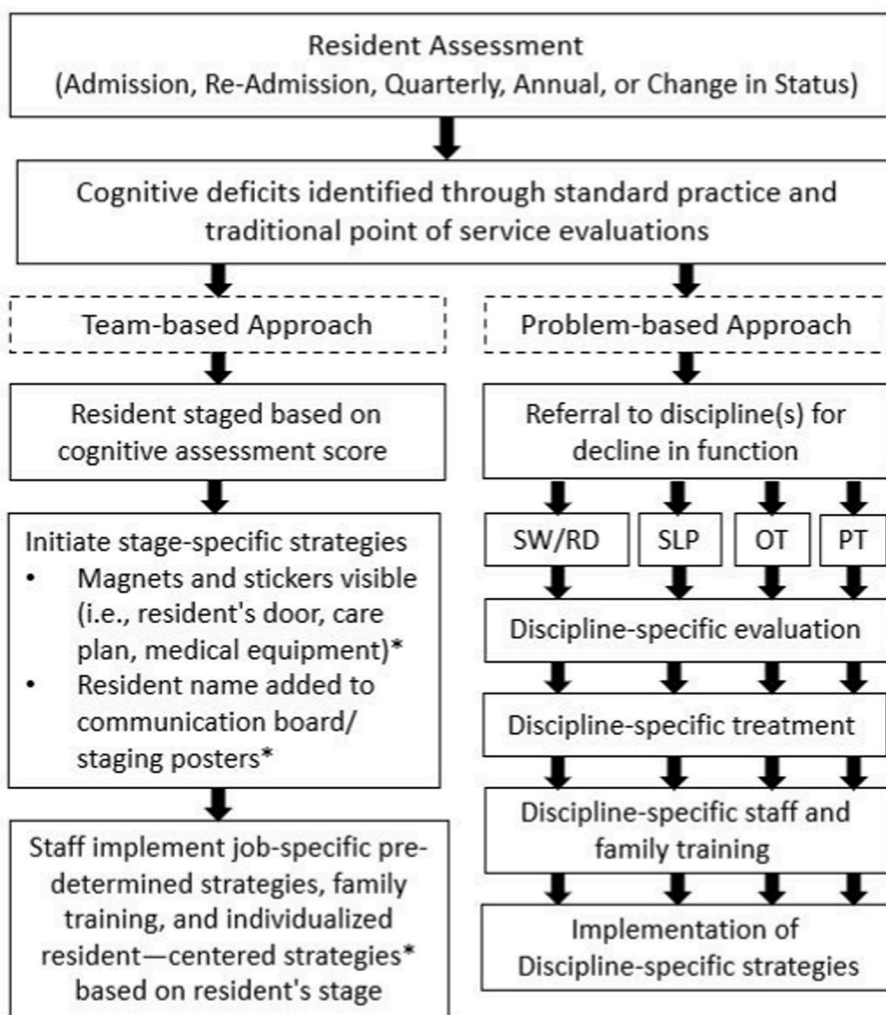


Fig. 3. Overview of Intervention

Notes: *Indicates that examples of these materials are included in the Appendix; SW= Social Work; RD = Recreation Department Staff; SLP= Speech Language Pathologist; OT= Occupational Therapist; PT= Physical Therapist.

resident’s needs and guide the development of individual care plans to be carried out by the care team. Personnel from each discipline train the direct care providers who are responsible for the resident’s daily care through in-service training, restorative nursing plans, and/or maintenance programs. Upon completion of resident-specific staff training, each discipline will transition the resident from their respective services to ongoing care delivered by the direct care providers, ancillary staff, and family if present.

2.8. Training

Team-based approach training was comprised of five modules. The first training module was presented in-person in the NH and included an overview of the training program, the team-based approach to care, and collateral materials provided to staff for quick reference (e.g., pocket reference cards). At the start of the first module, each participant completed a demographic sheet and the Alzheimer’s Disease Knowledge Scale [44] to ascertain baseline knowledge. Each of the four subsequent modules were scheduled as synchronous web-based training. Multiple days and times were offered to cover all work schedules and shifts across the 24-h-day. Post-tests were completed by participants once all modules were completed. Recorded webinars were made available to NHs to promote sustainability and implementation by embedding the videos into new staff orientation programs.

At the conclusion of each on-site training visit, the clinical trainer who delivered the training completed a modified version of the Organizational Readiness to Change Assessment (ORCA) [45]. The adapted tool, reflecting the context and facilitation scales of the ORCA, captured indicators of each NH’s environment and the processes of facilitating implementation.

Problem-based approach training was comprised primarily of asynchronous web-based learning via the organization’s learning management system. Topics for training were selected based on clinical content and the needs of the facility. Training was delivered to meet the CMS Conditions of Participation requirements for ADRD training [36].

2.9. Fidelity monitoring

Fidelity across arms. Medical record documentation will be used to track rehabilitation evaluations and services (e.g., type, intensity, frequency) in both arms of the study (Table 1). This documentation also captures whether resident and/or caregiver training is provided.

Team-based approach specific fidelity. Prior to COVID-19, we deployed a monthly fidelity monitoring survey to capture approach specific actions not captured in the medical records (i.e., resident-related, facility-related, staff-related), which was completed by NH change champions. The month 6 survey was held because of the COVID-19 communication moratorium.

Table 1
Summary of fidelity measures.

Fidelity Measures	Data Source	Study Arm	
		T	P
Provision of rehabilitation evaluation and services fidelity measures			
Receipt of rehabilitation evaluations	Rehab EMR	X	X
Intensity of rehabilitation services	Rehab EMR	X	X
Resident/caregiver training provided	Rehab EMR	X	X
Resident-related fidelity measures			
Number and distribution of residents staged in GDS 4, 5, 6, 7/total number of long-term residents with dementias	Monthly surveys	X	
Facility-related fidelity measures			
Presence of visible posters that identify resident stage	Monthly surveys	X	
Use of activity boxes	Monthly surveys	X	
Number of visible magnets or stickers with correct stage of resident	Monthly surveys	X	
Number of residents who have a Functional Maintenance Program in accessible location	Monthly surveys	X	
Staff-related fidelity measures			
Number of staff using trigger cards	Monthly surveys	X	

Note: T = team-based approach, P= Problem-based approach.

Remediation. When any of the fidelity measures fell below 80%, we used a systematic approach to support the NHs in the team-based approach to discuss emergent barriers, foster partnership, and problem solve solutions. The virtual coaching meetings included study team members responsible for supporting clinical delivery, facility change champion, and NH staff. An Advisory Committee member with expertise in clinical implementation of this program supported coaching sessions by sharing lessons learned.

2.10. Quantitative data collection and Analysis Plan

Data sources and abstraction. This project will utilize an extensive set of resident-level variables from the NH MDS 3.0 (age, gender, race/ethnicity, cognitive function, outcomes), rehabilitation medical record data, and staffing data from Payroll Based Journal [46,47], NH characteristics from CMS Care Compare [48] and LTCFocus [49] (e.g., bed size, occupancy rate, CMS Survey Rating, CMS Staffing Rating, CMS Quality Rating, Quality Measures, region) and NH COVID-19 cases and deaths during the pandemic (Table 2) [50]. MDS and EMR data will be extracted by the NH organizations and transferred to a secure server for data linking, cleaning, and analysis.

Outcomes. The primary outcome will be the percent of residents living with ADRD who received one or more off-label antipsychotic medications in the past 7-days at the time of MDS assessment [51,52]. Current research indicates that a 12% reduction in use among those receiving the drugs represents a meaningful change [8,53,54].

The secondary resident-level outcomes will consist of several MDS-based variables [51,55], including the percent of residents who (a) experienced undesirable (5%) weight loss in the last 30-days accounting for the resident not being on a physician-prescribed weight-loss program, (b) experience an accidental fall since last assessment, (c) exhibit any behavioral and psychological symptoms, (i.e., behavioral symptoms, wandering behaviors, rejection of care, depressive symptoms) and (d) are physically restrained. Sensitivity measures will include the number of days of off-label antipsychotic medication use, the number of accidental fall events, and the frequency of behavioral symptoms.

Other outcomes include staff and resident safety measures that were reported by NHs through monthly surveys prior to the emergence of COVID-19, including monthly rate of (a) resident-to-resident altercations, (b) resident-to-staff altercations, (c) nursing staff days out of work, and (4) nursing days on light duty in a 30-day period. These outcomes

Table 2
Variables for quantitative data analysis.

Domain	Data Source	Description of variables
NH Characteristics		
Size/occupancy	CMS Care Compare	<ul style="list-style-type: none"> • Number of certified beds • Occupancy rate
Insurance/acuity	LTCFocus	<ul style="list-style-type: none"> • % of residents under Medicaid • % of residents under Medicare • Average Acuity Index
CMS 5-Star Ratings	CMS Care Compare	<ul style="list-style-type: none"> • Survey Rating • Staffing Rating • Quality Rating
CMS Long-Stay Quality Measures	CMS Care Compare	<ul style="list-style-type: none"> • % of long-stay residents with/ had: <ul style="list-style-type: none"> • Increased in need for help with ADL • Pressure ulcer • Lost too much weight • Catheter inserted and left in bladder • Urinary tract infection • Depressive symptoms • Physically restrained • Fall(s) with injury • Received antipsychotic medication • Ability to move independently worsened • Received antianxiety/hypnotic medication
Staffing levels	Payroll Based Journal	<ul style="list-style-type: none"> • Nursing hours per resident per day • Rehabilitation staff hours per resident per day
COVID indicators	CMS NH COVID-19 data	<ul style="list-style-type: none"> • Resident COVID cases • Resident COVID deaths
Region		<ul style="list-style-type: none"> • Northeast, South, Midwest, West
Resident Characteristics		
Resident demographics	MDS 3.0	<ul style="list-style-type: none"> • Age • Gender • Race/ethnicity
Cognitive Function	MDS 3.0	<ul style="list-style-type: none"> • Cognitive Function Scale
Frequency of clinical assessment	MDS 3.0	<ul style="list-style-type: none"> • Number of assessments within study period
Primary Outcome Measures		
Antipsychotic medication use	MDS 3.0	<ul style="list-style-type: none"> • % of residents with antipsychotic medication use
Behavioral and psychological symptoms of dementia	MDS 3.0	<ul style="list-style-type: none"> • % of residents with behavioral symptoms • % of residents with rejection of care • % of residents with wandering
Secondary Outcomes Measures		
Resident outcomes	MDS 3.0	<ul style="list-style-type: none"> • % of residents with unintended weight loss • % of resident with fall(s) • % of resident with moderate or severe depression • % of resident with physical restraint use
Staff outcomes	Monthly survey	<ul style="list-style-type: none"> • # of resident-to-resident altercations • # of resident to staff altercations • Staff days on light duty • Staff days out of work due to injury

will be examined in the 6-month exploratory analysis. Due to the communication moratorium put in place as COVID-19 emerged, we will not have access to these data after the emergence of COVID-19.

Analysis Plan. Descriptive analyses will include calculating appropriate central tendencies (e.g., mean) for each outcome variable. We will

examine outcomes separately before and after the emergence of COVID-19. First, we will conduct an exploratory analysis using the first six months of implementation data (September 16, 2019–March 15, 2020) to compare the changes in outcomes across the two study arms from the 6-month baseline period, prior to the emergence of the pandemic. Second, we will conduct exploratory analysis of outcomes after the emergence of the pandemic spanning implementation months (a) 7–12 (March 16, 2020–September 15, 2020) and (b) 13–18 (September 16, 2020–March 15, 2021).

We will use the intention-to-treat analytic approach. To assess validity of randomization, we will compare resident characteristics and outcomes by arm for the 6-month baseline period prior to training (December 16, 2018 to June 15, 2019). If no baseline differences in resident and NH characteristics and outcomes are found, we will compare outcomes during each of the three implementation periods. If baseline differences are identified, we will implement a Difference-in-Difference analytic model, controlling for baseline resident characteristics with NH fixed effects. Both linear probability models and logistic models will be implemented.

Given the exacerbation of national healthcare staffing challenges throughout the pandemic and concerns that staffing shortages may impact both approaches, we will explore the relationship between staffing levels and the effect of interventions using the Payroll Based Journal. Analytic models will account for changes in staffing levels when examining the outcome measures. These quantitative findings will then be augmented with staff interviews to contextualize the results of the two approaches, exploring staffing levels and the evolving pandemic.

Power calculations for exploratory analysis were conducted for the primary outcome (i.e., receipt of one or more off-label antipsychotic medications). Given an estimated baseline rate of 20% for medication usage with 2173 NH residents across the two arms and an intraclass correlation coefficient of 0.05, a two-sided hypothesis test with $\alpha = 0.05$ will provide approximately 57% power to detect an effect size of a 4.4%-point difference (i.e., a 22% difference from 20% at baseline to follow-up) and 80% power to detect an effect size of a 5.7%-point difference [56]. Even if there is no statistically significant difference, current research indicates that a 12% reduction in use among those receiving the drugs represents a meaningful change [8,53,54,57].

2.11. Qualitative data collection

We will conduct a multiple case study approach to explore family caregivers and NH staff perceptions regarding the care approaches before and after the emergence of the COVID-19 pandemic [58]. Each NH will constitute a case, so we can explore the perspectives of staff and family caregivers in order to characterize the structures and processes within each case that help us to understand the approaches. Recruitment and interview procedures are guided by our Advisory Committee with input from Administrators to ensure recruitment materials meet the needs of each NH. Interviews will be conducted via phone or web-based application, audio recorded, transcribed, and blinded [59,60]. Participants will each be offered a \$50 honorarium.

Family caregiver interview objective and guide development. To document caregivers' experiences with the care approaches, a sample of 30 family caregivers [61] will be recruited to engage in semi-structured interviews, each lasting approximately 1 h. Purposive sampling will be used to promote representation of NHs across geographic region and approach.

Interviews will explore the caregiver's (a) experiences with the care their family member receives (e.g., acceptability, satisfaction, preferences), as well as their perceived (b) caregiver burden (c) quality of resident-family interactions before and after the care approach was implemented and (d) the impact of COVID-19 on family caregiver experiences.

Family caregiver recruitment. Fliers will be placed in (a) high traffic locations so family members can see them during scheduled visits

and (b) NH electronic family newsletters distributed via e-mail. Additionally, staff will be provided with scripts to use during virtual video meetings with families to share information about the study.

Family caregiver analytic plan. A grounded theory approach integrating open, axial, and selective coding will be used [62,63]. Analysis will be considered complete when no new or relevant data emerges regarding a category, when category development is dense, and when the relationships between categories are well established and validated. We will employ negative case and constant comparative analysis to assure that codes and themes are robust [64]. We will identify themes, patterns, and relationships that emerge within and across NHs and care approaches [65].

Staff interview objective and guide development. We will seek a wide range of staff perspectives, including professional healthcare providers, direct care providers, ancillary support staff, and administrators. Interview guides will be used to explore a series of a priori concepts related to the two approaches, including the staffs' perceptions of the (a) adequacy, acceptability, satisfaction of the training; (b) staff burden, (c) application of training (e.g., quality of resident-staff interactions, care delivery during the COVID-19 pandemic), (c) barriers and facilitators to delivering the approach (e.g. impact of COVID-19 regulations, staffing shortages); (d) recommendations for modifications. These insights will inform refinement of the approaches, future implementation and sustainability, and efforts to reconceptualize care in a post-COVID-19 emergence healthcare environment.

Staff recruitment. We will use a multi-prong recruitment approach to reach staff, including (a) electronic fliers to be disseminated via email and (b) printed fliers that will be posted at key locations (e.g., time clock) for staff that do not check work email within their daily workflow. Interviews will be scheduled outside of work hours at a time of the employee's choosing in an effort to foster a safe and comfortable environment, thereby ensuring that all participants are empowered to express their thoughts [60].

Staff interview analytic plan. We will use a three-phase team-based rapid qualitative analysis approach [66]. We will explore patterns and variations in themes within and across cases and care approaches [60].

2.12. Mixed methods integration

We will then integrate staff and family perspectives with quantitative findings [24]. We will use two integration methods, including (a) weaving data via narrative approaches (i.e., describing qualitative and quantitative data by theme or concept) and (b) joint displays, which capitalize on visual displays to present the integrated data [67]. We will examine coherence of the data integration to determine whether data from both sources (a) confirm the other, (b) expands upon each other, or (c) contradicts each other [67]. We anticipate that the family and staff perspectives will enhance our understanding of the quantitative findings by (a) contextualizing the results examining the effectiveness of the two approaches on outcomes prior to and after the emergence of COVID-19, (b) highlighting similarities and differences in perspectives within and across arms of the study, and (c) explaining any unexpected findings in our quantitative data analyses (or vice versa).

3. Discussion

The COVID-19 pandemic has altered NH care delivery, further exacerbating existing factors that contribute to the likelihood of prescribing anti-psychotic medications and the exacerbation of residents' behavioral and psychological symptoms of ADRD. The infection control policies that were put in place to minimize viral spread have further perpetuated the challenges associated with caring for this vulnerable resident population, including the delivery of non-pharmacological approaches to dementia care [68,69]. This new "normal" created a tension between life safety and an individual's quality of life, particularly for residents with ADRD [70]. More specifically, these infection control

policies have had a cascade of negative effects (e.g., mood, function, quality of life) among NH residents and staff, as well as being emotionally traumatic for families who cannot visit their family member living with ADRD during the lockdown [70–74]. By constraining the delivery of key strategies that are the foundation of non-pharmacological approaches to dementia care, including engaging in meaningful group activities and supporting the residents' daily routine, there is a need to examine the effect of these two non-pharmacological approaches to dementia care on the use of anti-psychotic medications and other patient outcomes.

In response, this study seeks to address two critical questions (a) is there a difference between these non-pharmacological approaches with respect to limiting behavioral and psychological symptoms of ADRD and thereby reducing administration of off-label psychotropic drugs? And (b) are either of these non-pharmacological approaches' protective against the negative consequences of COVID-19 for residents living with ADRD? Thus, there is a pressing need for a comparative effectiveness study to directly evaluate these two non-pharmacological care approaches within the real-world context, taking into account the emergence of the COVID-19 pandemic [22]. Resulting evidence will provide NH leaders and policy makers with guidance on staff dementia care training, national training standards, and implementation of non-pharmacological approaches to dementia care aimed to enhance quality of care and patient outcomes.

The COVID-19 pandemic has amplified gaps in our long-term care systems, The nursing home community, policy makers, patient advocates, and others have raised concerns about the negative impact COVID-19 related policies have had on the residents, staff, and families. The co-occurrence of the COVID-19 pandemic during this study will generate results that can inform revisions to and development of new policies for emergent events that disrupt care delivery and nursing home operations. The lessons that emerge from this study can be applied to a variety of emergent events that disrupt care beyond a global pandemic, including natural disasters (e.g., tornados, floods, hurricanes), facility closures, and rapidly spreading infections [75–78].

This study represents the first-ever evaluation of team- and problem-based approaches to ADRD across multiple NHs and US geographic regions. The study is designed to provide real-world evidence using a pragmatic trial with high internal and external validity. This approach included leveraging existing data, which is captured across nursing homes and organizations as part of daily workflow of nursing home care (e.g., Minimum Data Set). Yet, there are limitations to the reliance on this standardized data, which relies on a 7-day look back period for antipsychotic medication use. Given variability in format (paper, electronic) of resident-level medication dispensing across facilities a daily record was outside the scope of this project. While the lived experiences of NH residents will not be reflected in this study and only 53 of the original 80 NHs will be captured, the perspectives from a broad range of NH community partners (e.g., direct service providers, ancillary staff, administrators, and families) will provide a rich description of the care those living with ADRD will receive and how training impacts care delivery before and after COVID-19.

The results will give (a) healthcare providers the evidence they require to develop care plans given their specific clinical practice context, while also providing (b) administrators with evidence to guide implementation of a resident-centered, community-driven ADRD care approaches in their NH, and (c) equipping policy makers, NH leaders, and system leaders with evidence to inform responses to events that disrupt NH operations and care delivery. Finally, this study can inform future NH implementation studies, including strategies for success, sustainability, lessons learned, and how to best support staff and administrators while they are participating in implementation studies to enhance retention.

4. Available data and materials

Not applicable. This paper presents the study protocol and does not contain any data or results.

Authors' contributions

All authors have made substantial contributions to the conception or design of the study protocol; and drafting the protocol or revising it critically for important intellectual content; AND providing final approval of the version to be published; AND agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Trial registration number

NCT03442322.

Ethical approval

The protocol was approved by the University of Pittsburgh Institutional Review Board. The study will be conducted in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). We will comply with informed consent procedures and maintain the privacy rights of human subjects involved in the study as specified in the protocol approved by the institutional review board. This article does not contain any studies with animals performed by any of the authors.

Consent for publication

Not applicable. This paper presents the study protocol and does not contain any data or results.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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