NYU School of Medicine
NYU LANGONE MEDICAL CENTER

THE HOSPICE ADVANCED DEMENTIA SYMPTOM MANAGEMENT AND QUALITY OF LIFE TRIAL (HAS-QOL)

Principal Investigator	Abraham Aizer Brody, PhD, RN, FAAN, FPCN NYU Rory Meyers College of Nursing 433 First Avenue, Room 504 New York, NY 10010 212-992-7341 Ab.Brody@nyu.edu
Co-Investigators	Tara Cortes, PhD NYU Rory Meyers College of Nursing 433 First Avenue, Room 502 New York, NY 10010 212-998-5320 tc13@nyu.edu Bei Wu, PhD NYU Rory Meyers College of Nursing 433 First Avenue, Room 520 New York, NY 10010 212-992-5951 bei.wu@nyu.edu Keith Goldfeld, PhD NYUSOM Population Health 227 East 30th Street New York, NY 10016 212-263-4249 Keith.goldfeld@nyumc.org
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Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

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List of Abbreviations

ADRD	Alzheimer's Disease and Related Disorders
AE	Adverse Event/Adverse Experience
BPSD	Behavioral and Psychological Symptoms of Dementia
CFR	Code of Federal Regulations
CRF	Case Report Form
DHHS	Department of Health and Human Services
DSM-H	Dementia Symptom Management at Home Program
DSKA	Dementia Symptom Knowledge Assessment
DSMB	Data and Safety Monitoring Board
FFR	Federal Financial Report
FWA	Federalwide Assurance
GCP	Good Clinical Practice
HHA	Home Health Aide
HHC	Home Healthcare
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IDT	Interdisciplinary Team
IRB	Institutional Review Board
MOP	Manual of Procedures
N	Number (typically refers to participants)
NIA	National Institute on Aging
NIH	National Institutes of Health
NPI-Q	Neuropsychiatric Inventory Questionnaire
OHRP	Office for Human Research Protections
OHSR	Office of Human Subjects Research
PI	Principal Investigator
PWD	Persons With Dementia
QA	Quality Assurance
QC	Quality Control
QOL	Quality of Life
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
US	United States

Protocol Summary

Title	The Hospice Advanced dementia Symptom Management and Quality of Life Trial (HAS-QOL)
Brief Summary	As the population ages, the incidence rate of Alzheimer's Disease and Related Disorders (dementia) is expected to triple. The National Alzheimer's Plan recognizes that while the number of persons with dementia (PWD) is increasing substantially, the healthcare and long term care systems are unprepared to provide high quality, effective and efficient care to the PWD and their caregivers. PWD often have many behavioral and psychological symptoms of dementia (BPSD) including agitation, depression and sleep disturbances, that affect both the quality of life of the PWD and the caregiver. Unfortunately, due to a lack of programs to insert evidence-based care into the community, and hospice system specifically, PWD receive inappropriate and even harmful care. We have developed the Dementia Symptom Management at Home (DSM-H) Program to implement dementia friendly care for PWD and their caregivers in the community. Initially developed for use in home healthcare, we have modified the program for use in hospice. The DSM-H Hospice Edition is a systems level change program that includes workforce training, and agency level workflow changes.
Objectives	Through the 1-year R61 phase we will accomplish the following: Aim 1: Establish the infrastructure to implement a pragmatic clinical trial of the DSM-H Hospice Edition. We will establish a steering committee that will oversee all facets of the trial and integrate the work of the following work groups: 1. Intervention refinement; 2. Intervention implementation; 3. Measurement; 4.Statistical methods; 5. Data management; 6. Stakeholders; 7. Human subjects and data safety. Aim 2: Tailor the DSM-H Hospice Edition specifically for hospice IDT members caring for PWD and adapt for wide-scale implementation in hospice. We will further refine the intervention focusing specifically on ensuring the following: 1. The content and training align specifically with hospice IDT members caring for PWD at the end of life; 2. The content can be implemented in a wide-scale fashion in hospice agencies. Aim 3: Pilot test the complete protocol and DSM-H Hospice Edition in 2 hospice agencies and refine further based on feedback from the pilot agencies. The agencies themselves are not engaging in research but performing a performance improvement process and providing feedback, and the data received will be deidentified so that we will not have any personally identifiable information.
Methodology	pre-post study
Endpoint	None
Study Duration	1 year

Participant Duration	1 month
Population	Hospice clinicians (RNs, Social Workers, Chaplains) Persons with dementia newly admitted for hospice care.
Study Sites	This is a single site study with NYU being the only site. Study activities will take place at MJHS Hospice and Providence Trinity Care Hospice.
Number of participants	200 persons with dementia 400 clinicians
Description of Study Procedure	This pre-post study will implement the intervention at two hospice agencies, and test clinicians and hospice aides prior to and after implementation for knowledge of dementia care, and test whether the hospices implement assessment instruments or care plans included in the intervention.
Statistical Analysis	Persons with dementia: Descriptive Statistics Clinicians: descriptive statistics and Paired t-tests

1 Key Roles

Principle Investigator
Abraham Aizer Brody, PhD, RN, FAAN, FPCN
Associate Professor of Nursing and Medicine
NYU Rory Meyers College of Nursing
NYU School of Medicine
433 First Avenue, Room 504
212-992-7341
Ab.Brody@nyu.edu

2 Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

Dementia consists of a group of serious illnesses with a high symptom burden that significantly affect both persons with dementia (PWD) and their caregivers[1,2]. In the advanced stage, the PWD becomes eligible for hospice, whose goal is to alleviate suffering through symptom and psychosocial care delivered by an interdisciplinary team (IDT). Hospice provides routine home care (1-2 visits/week, more than 95% of hospice care[3]), continuous care (24h/d in-home nursing during symptom crises), inpatient care (when advanced symptoms require intensive management), and respite care (when caregivers need respite to avoid burnout, usually in a nursing home). Continuous care has been shown to significantly reduce inpatient care use and hospital mortality, allowing for more hospice patients to die at home[4,5]. Professional quality, job satisfaction, burnout and turnover are important for interdisciplinary hospice care workers.[1]

Hospice was developed initially for persons with advanced cancer living at home, but of the 1.4 million hospice recipients, 16.5% have a principal diagnosis of dementia[3]. PWD have the longest hospice length of stay (Mean 105 days, Median 56 days) and make up an outsized portion of spending (23.9%)[3]. Evidence-based practices exist for managing behavioral and psychological symptoms of dementia (BPSD), such as aggression and depression, but they have not been implemented, reducing hospice's effectiveness in supporting PWD and caregivers[6]. Hospices often fall back on antipsychotics (prescribed in 64.6% of cases)[7], which are usually ineffective at treating BPSD, cause serious adverse events, and can reduce quality of life (QOL). Furthermore, hospices may be ineffective in managing pain in this population due to the difficulty assessing PWD for pain. This can worsen BPSD and QOL. The National Alzheimer's Plan[8] recognizes poor care and lack of caregiver support as two core areas in need of change. In hospice, there is a clear and convincing case for action through wide- scale adoption of effective, evidence-based systems-level change programs.

2.1.1 DSM-H

We developed the Dementia Symptom Management at Home Program (DSM-H) to assist home healthcare agencies to implement systems-level evidence-based practice change for PWD and their caregivers and found improved clinician abilities and patient outcomes[2,3]. The DSM-H is a multi-component, evidence-based intervention. While much of the DSM-H carries over from home healthcare to hospice, some of the program needed refinement for regulatory content, and clinical care content, and addition of a home health aide (HHA) program. We have made these adaptions for hospice care and tested them with strong clinician outcomes through two separate extramural awards. The next logical step is to refine and test the program for effectiveness in a large pragmatic clinical trial.

2.1.2 Provision of Hospice

Hospice is a care model that provides care for persons with serious illness with a life expectancy of less than 6 months. Care can be provided across settings, though the majority is provided in the home. The aim of hospice care is to provide symptom, psychosocial, and spiritual support to the patient and family. Hospice consists of an interdisciplinary team (IDT) that primarily includes nurses, social workers, spiritual counselors, physicians, advanced practice nurses, HHAs and volunteers. When a patient elects to receive hospice through the Medicare Hospice Benefit, all of the care for their terminal condition is paid through hospice, which receives a per-diem reimbursement from Medicare. Patients may not receive curative care for their terminal condition. Hospices provide most of their care through routine home care services, which are a mix of visits, usually weekly to biweekly, by nurses, social workers, spiritual counselors and HHAs. If symptoms become severe and require more intensive care, patients may receive either *continuous care*, which is care by a nurse in the home for the duration of the symptom crisis, or *general inpatient care*, which is short-term acute care services in a hospital or inpatient hospice. Should caregivers become burned out while serving in hospice, the hospice can also provide short-term respite care in a nursing home to prevent permanent institutionalization. Continuous care can reduce hospital transfers, inpatient care, hospital death and hospice discharge, however it is not always offered[4,5]. Many PWD would prefer to die at home[6], and hospice services can assist in achieving this goal through continuous care if it was made available more readily.

2.1.3 Hospice agencies are particularly underprepared to care for PWD leading to sub-optimal outcomes

16.5% of the over 1.4 million hospice patients annually have a primary diagnosis of dementia[7], and many more have dementia as a secondary diagnosis[8], including 18.8% of cancer patients[9]. However, many hospice providers lack even basic training in their care due to a dearth of validated programs[10]. Furthermore, the disseminated nature of the workforce makes developing these programs more complex. Clinicians also have a negative view of caring for PWD, and do not recognize that substantial evidence exists showing differences in their care needs.[11-23]. Family members of PWD thus report significant unmet needs related to both symptom management and information about symptoms and the dying process, although at lower rates than those not receiving hospice [24]. Moreover, hospice has not shown to improve care quality for PWD[25].

2.1.4 Hospice care in the home for PWD is particularly understudied

Precise estimates regarding place of care for PWD receiving hospice are difficult to find, but it has been reported that about 25% of care occurs at home and about 50% in nursing homes[25]. However, the majority of extant research on hospice care for PWD is situated in the nursing home and is typically focused on demographics[26,27], current care provided[25,28-31], and bereaved family perceptions of care[24,32-34]—not on interventions for improving quality.

2.1.5 Behavioral and Psychological Symptoms of Dementia (BPSD) are ineffectively treated

BPSD are one of the most common and distressing symptoms in the PWD, occurring in over 40% of cases[35]. BPSD include agitation, depression, delusions, hallucinations, personality changes and aggression. BPSD are associated with weight loss[36], functional disability[37], caregiver burden and burnout[38], nursing home admission[39], and progression of dementia[40]. While multiple non-pharmacologic interventions are available and been found effective for the treatment of BPSD[41,42], they are often not used. Pharmacologic interventions are mostly ineffective in PWD unless they are targeting the underlying cause. For instance, aggression and resistance to care are often treated by antipsychotics, but antipsychotics do not treat the cause of these BPSD and have significant side effects including sedation that lower the quality of life (QOL), as well as adverse events including stroke, and death, even with short-term use[43-45]. There is a “black box” warning on use in PWD, indicating that antipsychotics should only be used in cases of last resort where the patient is a danger to self or others, experiencing concerning psychosis, or in need of palliative sedation for terminal sedation where the patient is in the last days of life[46]. In hospice, antipsychotics are widely overused; 61% of PWD nationwide are prescribed an antipsychotic[29].

2.1.6 Pain is under-recognized and under-treated in PWD receiving hospice

Though no estimates have been recorded of the incidence of pain in the community-dwelling PWD, the estimated incidence rate in older adults is over 50%[47] due to high prevalence of painful conditions. However, pain is often not treated or undertreated in the communitt[48-50], and PWD are less likely to report pain and receive less pain medication[51]. Elderly patients are also significantly less likely to discuss or label pain sensation and more likely to be stoic in the face of pain, regardless of cognitive ability[50]. While guidelines for the treatment of pain in PWD exist[52], PD are often inappropriately treated, even when identified as having pain[48]. Poor recognition and management of pain is associated with delirium, agitation, falls, decreased function, and increased hospitalization and mortality [53-56]. In hospice patients specifically, lower rates of standing analgesic orders[25] have been found, despite similar rates of pain (if not intensity) compared to other hospice populations. There have been conflicting reports regarding family perception of the quality of pain management[24,33,57]. Furthermore, recent studies have shown limited efficacy for opioids in some of the most common forms of pain PWD may present with such as osteoarthritis[58]. Yet given hospice's culture and initial organization around cancer care and relief of suffering, where opioid use is the standard of care, PWD may receive opioids for these forms of pain where efficacy is questionable and side effects are common, including delirium, constipation, reduced cognition, nausea, and urinary retention[59].

2.1.7 PWD receiving hospice have significantly longer lengths of service

PWD receiving hospice have significantly longer lengths of service than other populations receiving hospice (mean 105 days vs 69.5 overall, median 56 days vs 23 overall)[60] but have poor care quality. Because of the long length of service, if care quality improved, the benefit for PWD and their caregivers could be highly significant. If symptoms could be managed in the home through proactive routine or continuous care, the need for temporary respite care (e.g. care in a nursing home due to caregiver burnout), and inpatient care could be reduced. It could also help more PWD die in their home. This would both lead to better patient- and family-centered care and reduce costs. In one of the few studies looking at the breakdown of type of hospice care in PWD, 22% of PWD required continuous care and 25% required inpatient care in the last 7 days of life[61].

2.1.8 Caregivers are largely marginalized and ignored as part of the healthcare system

Caregivers are largely marginalized and ignored as part of the healthcare system and not provided the training or assistance they need to successfully care for PWD[62]. Informal caregivers, including family, friends, neighbors, and other acquaintances provide 83% of the care to PWD living in the community[63], representing 15.9 million people providing 18.1 billion hours of care[64]. The primary tasks informal caregivers provide include activities of daily living (ADLs) and instrumental ADLs, medication management and administration, adherence to treatment regimens, interfacing with the medical team, managing BPSD, finding support services, and hiring and managing paid caregivers[64]. These tasks are known to cause caregivers stress, burden, and burnout and worsen their physical and mental health, including 2-3 times greater risk of developing depressive symptoms (40%)[64]. Furthermore, the biologic variable of sex plays an important role in informal caregiving, as caregiving is performed significantly more by female individuals (68%)[65], and they spend between 2-3 times more hours providing care than male caregivers[64]. Caregivers who are older, female, spouses, or live in the same household with the PWD experience higher rates of caregiver burden[65]. Caregivers of PWD receiving hospice feel more supported than those whose loved ones are not receiving hospice, but they still have significant unmet needs[24,28]

2.1.9 There are significant racial and ethnic disparities in PWD and their caregivers

First and foremost, minorities have significantly higher prevalence of dementia[66]. One of the most cited study found a 2-3 fold higher risk in African-Americans and Hispanics compared to non-Hispanic whites (9.1%, 7.5%, 2.9% respectively in the 65-74 age cohort with even higher disparities as age increases)[67]. In addition to higher prevalence rates, African-American and Hispanic caregivers frequently believe cognitive impairment is a normal

part of aging[68] and present for initial diagnosis with higher rates of symptoms[69]. Overall, Hispanics have been found to have higher rates of BPSD than other groups[70], but both African-Americans and Hispanics have lower rates of institutionalization[71,72] and are less likely to be discharged to hospice following a hospitalization[73]. Therefore caregivers in these populations require more community-based support and training to counteract the longer duration of caregiving.

2.1.10 Interprofessional community education and training programs in dementia have not focused on advanced dementia care or hospice

Our systematic review of the literature in interprofessional education in dementia[74] found 17 publications of 15 studies. Eight examined provider knowledge and attitudes, and 7 showed improvement after an educational intervention.[75-80] Three showed some level of sustainability. Separately, 8 studies examined patient outcomes, 7 of which showed positive patient outcomes, including improved caregiver satisfaction, recognition of depression and reductions in patient decline, BPSD, and inappropriate use of antipsychotics[75,81-86]. **While these studies found positive outcomes and improved knowledge and attitudes of clinicians, many did not use standardized instruments, the interventions were highly variable, and none were performed in hospice.**

2.1.11 Existing relevant interventions

While no interventions have focused on an interprofessional intervention to improve QOL of the PWD-informal caregiver dyad utilizing home hospice, several interventions have been implemented in the home, **outside of hospice service delivery.** For instance, the COPE program focuses on enhancing the PWD's functional capacity and improving caregiver skills in managing dementia. It includes 10 visits by an occupational therapist along with 1 telephone contact by an advanced practice nurse[87]. The intervention is highly effective and has been implemented in the Connecticut Medicaid program[88]. The weakness of this approach is that in-person contact is solely with an occupational therapist, and few hospice visits are provided by occupational therapists, reducing the ability to implement more broadly in the existing hospice service delivery model. Another program the MIND at Home program developed by Samus, which provides care coordination services linked to an RN and geriatric psychiatrist and dementia education and caregiving strategies. It is currently being studied in an NIA-funded R01 and CMMI demonstration project. This interprofessional program has shown considerable strength in its pilot in reducing transition from home and improving QOL[89]. However, caregivers did not report improvements in BPSD, and it is not delivered through hospice. The REACH, REACH II, and REACH VA trials have examined a flexible caregiver support intervention that has been implemented nationwide outside of hospice and found to improve QOL, particularly in minority populations, and reduce healthcare utilization and costs[90,91]. The Aging Brain Care Model focuses on population health management in PWD and depression through an interprofessional team, finding reductions in caregiver stress and potential for scalability[92]. Multiple interventions specifically for advanced dementia have been implemented in the nursing home setting around BPSD[93-95], advanced care planning[96], or tube feeding[97], though have not been translated for use in hospice. Lessons learned from these interventions have been used in developing the initial DSM-H intervention[2] and updating the DSM-H for use in hospice. **The DSM-H Hospice Edition is intended to reduce the significant quality of care gap in hospice for PWD and their caregivers, improving QOL, decreasing antipsychotic use and the impact of BPSD, and the subsequent need for emergent care, while increasing bereaved caregiver satisfaction.**

2.2 Name and Description of the Quality Improvement Program

The DSM-H Hospice Edition, is an evidence-based practice quality improvement program that combines training, mentorship, workflow enhancements, assessment instruments, a BPSD treatment algorithm, and caregiver teaching pamphlets for clinical staff in hospice agencies.

Figure 1. DSM-H Hospice Edition Components

Training			Resources		
IDT Champions 2 days, in person, dementia content +QAPI content; Systems- and team-level change agents					
HHAs 4 hours, online, interactive	Skilled IDT members 5 hours, online, interactive	Providers 1 hour online, interactive	Caregiver education pamphlets English & Spanish	BPSD treatment algorithm	Care plans & assessment instruments

2.2.1 Champions training

Consists of two full days of interactive in-person didactic content, case studies, and role-playing simulated cases for members of the IDT at each agency. There are three core components of the champion training: leadership, care of the PWD and caregiver, and communication within the team and with the PWD-caregiver dyad. The leadership content is modeled after the Hartford Institute for Geriatric Nursing's highly successful NICHE program, which provides implementation training on geriatric principles for acute care hospitals and has been implemented in over 650 hospitals nationwide and internationally[98]. The leadership content also includes quality assurance and performance improvement (QAPI) methods for ensuring effective implementation. Dementia-specific content mirrors non-champion training (see below) in more depth. The third component, dyadic person-centered team based care is based on three well validated programs, AHRQ TeamSTEPPS[99] and SBAR[100] for healthcare team communication and the antecedent-behavior-consequence method of problem solving[101] to help the IDT work with caregivers to identify and solve the most problematic behaviors. Champions also participate in monthly troubleshooting calls with the coordinating center. Champions serve as the change leaders in their agency to "hardwire" systems-level practice change.

2.2.2 Non-champion clinician training

All skilled IDT members (e.g. RNs, social workers, and spiritual counselors) undergo five, one-hour modules of online interactive learning (CEUs provided) available over one month. This ensures completion of the modules without burdening staff or requiring them to take a lower patient workload, which could have significant fiscal impact on the agency and reduce the likelihood of involvement. The content aligns with the champion course but in less detail. Module 1: Defining and distinguishing types of dementia; assessing patients for dementia; basic non-pharmacologic and pharmacologic interventions for decline in PWD; working with PWD to complete care tasks. Module 2: Assessing PWD for pain; non-pharmacologic and pharmacologic strategies for treating pain in the PWD. Module 3: Understanding, assessing and recognizing BPSD, acute delirium, and terminal delirium in PWD. Module 4: Non-pharmacologic and pharmacologic interventions for managing BPSD and terminal delirium in PWD. Module 5: Dyadic team-based care concepts derived from AHRQ TeamSTEPPS, SBAR, and the patient-family centered antecedent-behavior-consequence model of problem solving. The nursing version includes more pharmacologic intervention information and the IDT version includes basic pharmacologic information and more psychosocial care modalities.

Hospice provider training All MDs, NPs, and PAs undergo a 1 hour online training module, focusing on the treatment algorithm; differentiating acute delirium, terminal delirium, and chronic worsening of BPSD; care plans that will be activated by IDT members, and their role in improving quality as part of the IDT.

2.2.3 HHA training

Training must be provided to all HHA annually by the hospice. HHA training for PWD described in D.3. is 4 hours and includes 1) dementia basics; 2) Alzheimer's and dementia progression; 3) communication and providing effective care; 4) promoting wellness in a safe environment; 5) providing care to PWD with BPSD. The piloted version was instructor-led, but we received feedback from HHA and agencies that they are performing their continuing education online, so in the R61 phase we will convert this program to a video/online program.

2.2.4 Validated instruments

Instruments are integrated into the electronic health record (EHR) and workflow to allow for better

assessment of cognition, pain, and BPSD and are validated in both English and Spanish. The tools are reviewed in the training components. Instruments included are the mini-cog[102] to screen for cognitive impairment, NPI-Q[103] for BPSD, the Cornell Scale for Depresion in Dementia[104] in moderate/severe dementia, the Geriatric Depression Scale-Short Form[105] for depression in mild dementia, the PAINAD[106] for pain assessment in moderate/severe dementia, and the caregiver strain index[107].

2.2.5 Interprofessional care plans

Interprofessional care plans that guide overall care for PWD with specific plans for pain, 7 BPSD categories (aggression, apathy, depression, psychomotor agitation, psychosis, sexual disinhibition, sleep disturbance), and terminal delirium, are available to clinicians. These care plans provide assessment and management guidance to clinicians and are consistent with the information taught in the online and champion education programs. For instance, in PWD with sleep disturbance, care plans describe evidence-based practices around implementing appropriate sleep hygiene and habits, stimulating patients during the day through activities, and environmental changes to improve sleep quality. Each plan is associated with tailored caregiver education pamphlets in English and generalized Latin American Spanish that can be reviewed on site electronically and provided on paper.

2.2.6 BPSD treatment algorithm

A BPSD treatment algorithm is provided that reinforces the education, care plans, and caregiver education pamphlets. The algorithm takes clinicians through a differential process to determine whether the event is likely acute delirium, terminal delirium, or a worsening of a chronic BPSD; and then through potential triggers for the symptom, non-pharmacologic and pharmacologic approaches, and monitoring parameters.

2.3 Clinical Data to Date

2.3.1 Development and Implementation of the DSM-H for Home Healthcare.

As part of Dr. Brody's National Palliative Care Research Center Career Development Award, Dr. Brody developed the DSM-H. The development utilized the NIH ORBIT Model for Behavioral Intervention Development[108] and later on the Structural Model for Caregiving Stress[109]. The DSM-H focuses on assisting skilled HHC clinicians to identify and managing behavioral symptoms associated with dementia, and work as a team with the primary care provider and informal caregiver. In this initial trial, two registered nurse, physical therapist, and occupational therapist educators (6 total educators) at the study site were trained as "champions" and received 14 hours of in-person, case based interprofessional instruction over two days in dementia care; the remaining 209 RNs, PTs, and OTs received 4.5 hours of modular, on-line interactive learning training. Champions served as resources for other clinicians and helped ensure smooth implementation and completion of the program. In addition to the education, participants were provided with resources and workflow changes including previously validated assessment tools for assessing and managing symptoms in PWD, and care plans based on evidence based practice for PWD. As a measure of program evaluation, Drs. Brody and Galvin developed the Dementia Symptoms Knowledge and Attitudes Survey to be utilized as a pre- and post-test. The survey incorporates three well-validated instruments for assessing clinician knowledge and attitudes regarding pain[110], depression[111] and agitation[112] in PWD, with an investigator-derived set of four questions about confidence in treating each of these symptoms in PWD. The survey had an excellent internal consistency in HHC clinicians (Cronbach alpha=.94) and took an average of 15 minutes to complete. In our sample of 209 clinicians, we found significant improvements in knowledge, attitudes and care confidence in treating PWD following program completion that varied by specialty. Overall, clinicians showed the most improvement in knowledge (20.9%) and confidence (27.1%) in managing BPSD from baseline with additional gains in knowledge (14.8%) and confidence (36.1%) in managing depression and knowledge (5.9%) and confidence (26.5%) in managing pain ($p<.0001$)[2]. Additionally, on the post-test evaluation, 97% of RNs and 100% of PTs and OTs stated the education was highly applicable to their work setting and helped them care for patients.

Based on feedback from this initial trial of the DSM-H, Dr. Brody refined the clinical education programs to reduce pharmacology content and increase content on recognition of dementia and non-pharmacologic management and working with caregivers. Drs. Brody and Galvin performed a site controlled trial of the DSM-H at 2 divisions of a large HHC agency and retrospectively collected OASIS and chart data for PWD on admission and at the first 60-day re-certification or discharge from HHC. Overall, during the study period 158 PWD were seen by the control site and 174 by the intervention site. Overall, patients were older, primarily spoke English or Spanish, were either Medicare or dual Medicare/Medicaid insured, and were admitted either from home or the acute care setting (See Appendix A). There were fewer black/African American participants in the control, the only clinically significant difference (34.2% vs 51.7%; p=.0002). Overall, we found in multivariate analysis that recognition of pain, depression, and behavioral symptoms, were all clinically and statistically significantly higher in the intervention group, and there were significantly increased odds of analgesics use (OR=2.01; p<.05) and decreased odds of antipsychotic use (OR-0.53; p<.05) in the intervention cohort[3]. These results show the DSM-H has the potential to be improve patient care and the QOL of PWD receiving HHC.

2.3.2 Conversion of the DSM-H for Home Hospice

Dr. Brody, during the first part of his Robert Wood Johnson Nurse Faculty Scholars Award converted the materials of the DSM-H for use in hospice care. During this conversion, he worked with two hospice and palliative social workers to alter materials for the setting and change in personnel, as hospice primarily is served by registered nurses, social workers, and chaplains, whereas home healthcare is served by registered nurses and physical and occupational therapists. Upon completing the conversion, he pilot tested the educational models with a nationwide sample of hospice social workers for face validity.

2.4 Rationale

While significant focus has been placed on implementing solutions for use in the acute care, nursing home, and primary care settings, few studies have focused on improving symptom management and caregiving training for PWD through hospice. Dr. Brody has adapted interprofessional, evidence-based practices, from other settings to hospice, creating the DSM-H Hospice Edition. It is a multi-component performance improvement program that consists of clinician training, patient- and family-centered assessment instruments, patient-caregiver dyadic centered care plans, a BPSD assessment and treatment algorithm, and caregiver teaching sheets. We now seek to test the efficacy of the DSM-H Hospice Edition in a behavioral pilot cluster randomized controlled trial in the hospice setting.

2.5 Potential Risks & Benefits

Known Potential Risks

This is a minimal risk study and that the agencies themselves are not engaging in research but performing a performance improvement process and providing feedback, and the data we receive will be de-identified other than zip code and service dates so that we will not have minimal personally identifiable information.

The performance improvement program itself is inherently not risky (**minimal risk**) as it is an implementation of evidence-based practices. The primary risk to patients AND clinicians is loss of confidentiality. We minimize the risk by maintaining the data in a secured fashion (see section 11). These vulnerable populations are included as the focus of the research is in improving the quality of care PWD receive, and the applicability of the DSM-H Hospice Edition to hospice workers and their knowledge. The DSM-H could affect hospice workers professional quality of life.

As the potential risks are minimal and there are potential direct benefits to subjects in the performance improvement cohort, including improved PWD QOL and symptom management, the potential benefits of this study far outweigh the minimal risks to this study. The value in this study is that if feasibility, applicability and fidelity are found, a large-scale pragmatic trial will be performed in 25 hospices nationwide to examine the effectiveness of the intervention, thus leading to the disseminated to some of the over 4,000 active hospice

agencies in the country to improve the quality of care in these settings and QOL for hundreds of thousands of PWD and their caregivers.

2.5.1 Known Potential Benefits

Potential benefits to patients in the intervention includes improved quality of care and quality of life, including reduction in pain and BPSD, and reduced healthcare utilization, which could lead to lower out of pocket costs.

3 Objectives and Purpose

3.1 Primary Objectives

We developed the Dementia Symptom Management at Home Program (DSM-H) to assist home healthcare agencies to implement systems-level evidence-based practice change for PWD and their caregivers and found improved clinician abilities and patient outcomes. The DSM-H is a multi-component, evidence-based intervention. While much of the DSM-H carries over from home healthcare to hospice, some of the program needed refinement for regulatory content, and clinical care content, and addition of a home health aide (HHA) program. We have made these adaptions for hospice care and tested them with strong clinician outcomes through two separate extramural awards. The next logical step is to refine and test the program for effectiveness in a large pragmatic clinical trial. Through the 1-year R61 phase we will accomplish the following:

Aim 1: Establish the infrastructure to implement a pragmatic clinical trial of the DSM-H Hospice Edition. We will establish a steering committee that will oversee all facets of the trial and integrate the work of the following work groups: 1. Intervention refinement; 2. Intervention implementation; 3. Measurement; 4. Statistical methods; 5. Data management; 6. Stakeholders; 7. Human subjects and data safety.

Aim 2: Tailor the DSM-H Hospice Edition specifically for hospice IDT members caring for PWD and adapt for wide-scale implementation in hospice. We will further refine the intervention focusing specifically on ensuring the following: 1. The content and training align specifically with hospice IDT members caring for PWD at the end of life; 2. The content can be implemented in a wide-scale fashion in hospice agencies.

Aim 3: Pilot test the complete protocol and DSM-H Hospice Edition in 2 hospice agencies and refine further based on feedback from the pilot agencies.

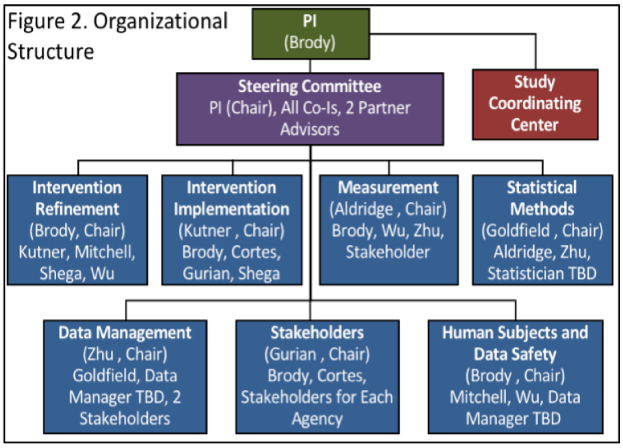
4 Study Design and Endpoints

4.1 Description of Study Design

4.1.1 Aim 1: Establish the infrastructure to implement a pragmatic clinical trial of the DSM-H Hospice Edition.

We will establish a steering committee that will oversee all facets of the trial and integrate the work of the following work groups: 1. intervention refinement; 2. intervention implementation; 3. measurement; 4. statistical methods; 5. data management; 6. stakeholders; 7. human subjects and data safety.

Organizational structure. The project will be led by Dr. Brody, who is responsible for the entire grant, including rigorous implementation and protection of human subjects. However, the proposed work requires a team science approach for expertise in content (clinical geriatrics, palliative care, hospice), clinical trials design and management, implementation science, and health services research. The steering committee will oversee integration of the work of the work groups (see Fig. 2). The study will be operationalized through the study coordinating center, which reports to the PI and includes a data manager, instructional technologist and a postdoctoral associate in the first two years of the grant during implementation and the last year during analysis. The study staff will support the work groups and steering committee and be integral in implementing the trial.



Steering committee. The steering committee is a group of highly experienced investigators and healthcare leaders who have the experience to implement and complete a large-scale, complex, pragmatic clinical trial in PWD in the community. The committee will be chaired by the PI, Dr. Abraham Brody, PhD, RN, FAAN. Dr. Brody is an Associate Professor of Nursing and Medicine at NYU and Associate Director of the Hartford Institute for Geriatric Nursing, one of the pre-eminent geriatric nursing research and model dissemination institutes in the United States. He is a geriatric and palliative board certified nurse practitioner with significant experience in implementation science, clinical trials, demonstration research, and clinical experience in the home setting, including a current semi-pragmatic multi-site cluster randomized trial of the DSM-H in home healthcare (R01 AG056610) as PI and multiple NIH-funded home- and community-based trials randomized at both the individual and cluster level as a co-investigator (R01 AG052557, R01 NR016461, R01 NR016461) PCORI (R-1609-36306) and CMS/Hartford Foundation (1C1CMS331334/No#).

Other members of the steering committee are:

- Dr. Tara Cortes, PhD, RN, FAAN, Clinical Professor and Executive Director of the Hartford Institute for Geriatric Nursing, who is an expert in disseminating interprofessional models of care
- Dr. Bei Wu, PhD, Professor and Research Director of the Hartford Institute for Geriatric Nursing, a gerontologist with expertise in health services research and interdisciplinary clinical trials in PWD
- Dr. Susan Mitchell, MD, Professor at Harvard School of Medicine and Director of Palliative Care Research at the Institute for Aging Research, one of the foremost experts in research in PWD, particularly in the advanced stage, with a focus on performing pragmatic cluster clinical trials
- Dr. Jean Kutner, MD, MPH/MSPH, Chief Medical Officer and Professor at the University of Colorado Anschutz Campus and Co-PI of the NINR-funded Palliative Care Research Cooperative Clinical Trials Network
- Dr. Melissa Aldridge, PhD, Associate Professor and Vice Chair for Research at the Brookdale Department of Geriatrics and Palliative Medicine, and a pre-eminent hospice quality health services researcher
- Dr. Carolyn Zhu, PhD, Associate Professor and Director of the Data Core at the Mount Sinai Alzheimer's Disease Research Center, an expert in data management and pharmaco-economics;
- Dr. Keith Goldfeld, DrPH, Assistant Professor in the Department of Population Health at NYU School of Medicine, a biostatistician with significant experience analyzing cluster stepped wedge clinical trials,

including in PWD

- Advisors: Dr. Joseph Shega, MD, Nationwide Medical Director for Vitas Hospice, and Associate Professor at University of Central Florida, with expertise on care quality for PWD and their caregivers receiving hospice care

- Ms. Mollie Gurian, JD, MPH, the Chief Strategy Officer of the National Partnership for Hospice Innovation, an expert in health policy, innovation, and coalition leadership in hospice care

These above individuals will not engage in research (e.g. will not have access to data, will not perform any recruitment).

Work groups. Each work group will be chaired by a member of the steering committee, and additional members will come from the core investigative team and partner agencies. Each committee will be staffed by either the project director or post-doctoral associate during years 1-2, and then the project director in the remaining years. Groups will meet at the frequency necessary to complete the assigned charge throughout the R61 phase of the trial.

4.1.2 Aim 2: Tailor the DSM-H Hospice Edition specifically for hospice IDT members caring for PWD and adapt for wide-scale implementation in hospice.

We will further refine the intervention focusing specifically on ensuring (1) that the content and training align specifically with hospice IDT members caring for PWD at the end of life and (2) that the content can be implemented in a wide-scale fashion in hospice agencies.

*Aligning existing content with the hospice IDT***.** The intervention refinement and stakeholder work groups will refine the DSM-H Hospice Edition. For existing content, the intervention refinement group will review and edit all materials. The stakeholder work group will provide an additional review of this edition.

Revising the HHA training as an online program. The intervention refinement work group and our project staff will convert our HHA training program for PWD to an online format to allow for wider dissemination. This will include short, skills-based videos recorded at the NYU Rory Meyers College of Nursing Simulation Center with standardized patients and HHA actors depicting scenarios in which HHAs assist the PWD with care tasks while exhibiting BPSD. The videos will be embedded within interactive learning modules at a 6th grade reading level and include embedded questions and remediation. The modules will follow the curriculum from the successful in-person training we developed. We will storyboard and script the simulation videos and interactive learning modules, and the stakeholder group will review them prior to producing.

4.1.3 Aim 3: Pilot test the complete protocol and DSM-H Hospice Edition in 2 hospice agencies and refine further based on feedback from the pilot agencies.

Pilot testing the revised DSM-H Hospice Edition. Following revision, we will perform a pilot implementation in 3 IDTs at MJHS Hospice and Palliative Care, a large local hospice that serves a diverse patient population across New York City and Long Island.

Testing the refined intervention components for skilled IDT members. We will test the components of the refined intervention for skilled IDT members. We will perform a summative evaluation through pre-post testing using the DSKA, which has established content and face validity and internal consistency to measure the intervention's effects on knowledge, confidence and attitudes[2]. We will also perform a formative evaluation with completers regarding the applicability of the content through both quantitative and qualitative survey feedback. Data will be collected in Qualtrics survey software. We will also conduct a short focus group with champions to obtain feedback on the revised champion training. For this focus group we will use field notes rather than recording, as the goal is not to perform a thorough scientific qualitative analysis but obtain feedback on what did and did not work in terms of applicability, relatability to the IDT and implementability. The Focus groups and DSKA are being used for program evaluation and not research.

Testing the online HHA training for usability and applicability. Second, we will evaluate HHA knowledge and confidence, using the same tool we used in its initial development, to ensure that the effect of the online program is at least as good as in person program. We will also complete a standard systematic usability evaluation through anonymized screen recording, analyzing answers to embedded questions within the modules, and a formative evaluation by users (i.e., HHA who complete and do not complete the program)[113].

Testing the methods for collecting and merging patient-level data from the hospice agency. We will not receive identified data. The measurement, data management, and human subjects and data safety work groups will refine the specifications and protocol for securely transferring data from hospices to the study coordinating center. In this pilot, we will test collection of data from one month prior to implementation to one month after implementation. The data manager will clean and analyze the data descriptively and report back to these work groups and the statistical analysis work group for refinement of the analytic plan and to ensure that all the necessary elements are present and usable.

Further refinement of intervention components and data collection. Following initial pilot testing the respective committees will review data regarding the intervention, implementation, measurement, data management, statistical analysis, and data safety. The stakeholder work group will also review information on how the intervention affects stakeholders. Should further refinement of any of these components be required the respective work groups will meet to make changes that will be submitted to the steering committee for integration.

Second pilot test. Following integration of all necessary revisions, we will perform a second pilot at Providence Trinity Care Hospice in Torrance, CA. We chose this hospice because it is culturally and geographically different from MJHS, has a smaller daily census, and serves a suburban area with a high population of Spanish speakers. We will perform the same pilot testing as described in 4.1.3.a, unless the work groups seek additional or different data points.

4.1.4 Additional activities

During the R61 phase, the work groups and steering committee will complete additional activities to prepare for the R33: 1. Update and finalize sites to participate in the trial with our partner agencies; 2. Update power analysis and adjust methodology accordingly; 3. Finalize data management plan and infrastructure; 4. Finalize analytic plan; 5. Perform randomization; 6. Prepare timeline for individual sites and engage with the agencies in preparatory work. 7. Obtain data use agreements from each site; 8. Set up Data Safety Monitoring Board; 9. Obtain approval for R33 phase from IRB; 10. Register in clinicaltrials.gov; These activities will be carried out by the appropriate work groups and the steering committee.

4.2 Study Endpoints

4.2.1 Milestones

Transition from the R61 (this protocol/IRB) to the R33 phase (separate second phase where new IRB application will be submitted) will be based on readiness for implementation as measured by *feasibility, applicability, and fidelity thresholds* achieved at the second pilot hospice agency.

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) Fi**delity.** 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.

During this R61 year, we are also required by the NIH to submit an IRB for the full R33 pragmatic clinical trial.

5 Study Enrollment

5.1 Inclusion Criteria

CLINICIANS/AIDES; All English speaking interdisciplinary team (IDT) members employed or contracted by the agency who are receiving DSM-H online or champion training greater than 18 years of age will be eligible.

PWD: All PWD who are newly admitted to a participating hospice during the timeframe following implementation of the intervention who are over the age of 50 will be eligible.

5.2 Exclusion Criteria

None

5.3 Strategies for Recruitment and Retention

5.3.1 Clinicians

The NYU study team will send an IRB approved recruitment email to all eligible clinician subjects inviting them to the study. Upon entering the learning management system or champion training to complete their training, all eligible clinician subjects will be prompted as whether they would like to participate (online for online training, and privately, in person by a NYU study staff member for champion training). For training, they may forgo this research and move straight to taking the training. All subjects completing online training will be consented electronically through electronic survey data collection using a standardized consent approved by the NYU School of Medical IRB at onset of fidelity data collection and a waiver of documentation will be requested, as the act of taking the survey will serve as their consent.

In the last question of the initial survey clinicians will be asked if they want to complete an additional optional survey questionnaire. If they choose to participate they will be provided a link to complete these questions. Upon completion of this survey they will receive a $25 gift card. Those who choose to complete this survey will be sent an addition follow up survey three months afterwards. At the end of this survey they will be asked if they would like to complete a telephone interview. If they say yes, they will be contacted to schedule to call. They will receive an additional $50 gift card to complete the phone interview. Total remuneration for the professional quality of life optional questions if both surveys and telephone interview are completed is $100.

For clinicians who complete online training, they will be prompted following completion of the training to complete a post-survey (DSKA or HHA assessment). They will be prompted up to 3 times to complete the survey. Following the third time, we will not request further completion and will not contact the subject again unless they contact us. These same procedures will be used for additional optional survey and telephone interview about professional quality of life.

For champions who are serving in focus groups, we will notify all champions prior to the champion training that at the end of the training we will perform a focus group that is voluntary. They will then have the opportunity privately to notify us ahead of time that they do not want to participate, or can notify us in person at any time throughout the champion training. As the focus groups are for program evaluation and not research purposes, we will not consent clinicians.

5.3.2 Persons with Dementia

We will seek to obtain de-identified data (with exception of dates of service and zip codes) of PWD who receive care from the hospices who participate in the study in order to determine the fidelity of the study (See milestone 3 above). We will seek a waiver of consent and authorization for this population as NYU will not be performing

any research directly with this population. The only contact between the PWD/surrogate in this study would be to perform informed consent, and would not be practical given the dispersed nature of the subject population and number of subjects we'd have to contact. In addition to IRB approval, a Data Use Agreement will be executed to obtain this data.

5.4 Total Number of Participants and Sites

An estimated 400 clinicians and 200 PWD will serve as participants at the two hospice agencies.

5.5 Participant Withdrawal or Termination

5.5.1 Reasons for Withdrawal or Termination

Given the nature of the study, we do not see any reason a PWD would withdraw as they would not be actively participating in research and only their de-identified data other than dates of service and zip codes provided to the investigators.

Regarding clinician subjects, the primary reason for withdrawal would be leaving employment or not completing the online training.

Clinician subjects are free to withdraw from participation in the study at any time upon request. An investigator may terminate participation in the study if:

- The subject is unable to complete training or the individual leaves the hospice agency during the time period of the study.

5.5.2 Handling of Participant Withdrawals or Termination

Given the minimal risk nature of this study, should individuals choose to withdraw from the study, we will not continue to follow-up or follow them in any form.

6 Study Quality Improvement Program

6.1 Study Behavioral or Social Quality Improvement Program

The DSM-H Hospice Edition as described in section 2.2 is a quality improvement program that has been adapted from and heavily based on the pre-existing DSM-H HHC edition. The adaptation took into account regulatory and clinical team differences between the two. The original DSM-H was tested in several HHC agencies in New York and the hospice edition's educational components were tested with a nationwide sample of hospice social workers. The DSM-H Hospice edition is a multi-modal quality improvement program for improving the quality of care provided to PWD-informal caregiver dyads through hospice. The initial DSM-H home health edition training was initially created through participatory research with an interprofessional team of clinicians, and then refined through feedback from clinicians who completed the training. It has been culturally tailored for use in diverse settings and tested with multiple minority communities in New York, including multiple Hispanic groups and African-Americans and Caribbean blacks. This new hospice edition is based on the prior home health edition. The DSM-H Hospice Edition quality improvement program presented in this section is not in and of itself a study intervention. We are solely in this study measuring the outcomes of the quality improvement program, however include the components of the program here so it is easier to understand the research protocol around the study of outcomes.

6.1.1 Procedures for Training Quality Improvement Teams and Monitoring Fidelity

Because there are multiple care teams receiving the performance improvement program, and we need to understand how well the program is implemented in order to assess the research outcomes, we will measure

fidelity of implementation (e.g. clinician exposure to the performance improvement program) as well as differences across control and performance improvement teams through assessing registered nurse, physical and occupational therapist knowledge, attitudes and confidence using Dr. Brody's previously validated dementia symptom knowledge and attitudes survey at baseline, 3 months, and 1 year[2], and through measuring the number of care plans initiated, caregiver teaching sheets provided to caregivers, and assessment instruments used at each site throughout the trial.

7 Study Procedures and Schedule

7.1 Study Procedures/Evaluations

7.1.1 Study Specific Procedures

7.1.1.1 Clinician Knowledge, Confidence, Attitudes

We will implement the DSM-H Hospice Edition first at MJHS, then make iterative changes for usability and applicability based on feedback from our stakeholder workgroup and the MJHS hospice participants, and implement at Providence Trinity Hospice.

To assess knowledge of the clinicians, the DSKA (skilled clinicians) or HHA assessment (hospice aides) will be collected prior to and post online training via Qualtrics survey. It takes approximately 15 minutes to complete the former and 10 minutes the latter. The DSKA includes baseline demographics (first survey only for an individual) and 79 likert style items regarding their knowledge, confidence and attitudes towards pain, depression and behavioral symptom assessment and management in persons with dementia. We have administered, and clinicians have completed the DSKA hundreds of times in the past four years in intervention and control settings and it has a Cronbach Alpha of .94.

The HHA assessment takes approximately 10 minutes to complete and following demographic also includes 17 true false and likert style questions regarding knowledge and confidence in managing care tasks in PWD. We have administered this survey to over 1100 HHA in the past two years and it has strong internal consistency and validity.

7.1.1.2 Optional Professional Quality of Life

We will implement the professional quality of life survey at pilot site 2 to assess professional quality of life of the clinicians before and after DSM-H hospice training. It takes approximately 10 minutes to complete the surveys. The survey instruments include the professional quality of life (ProQOL-5), which is a 30 question self-report questionnaire measuring professional quality of life on a 5-point Likert scale. about how frequently the participant experienced the things being asked about in the last 30 days. The scale starts at one indicating never and goes to five indicating very often. It measures professional quality of life on three subscales including compassion satisfaction, burnout and secondary traumatic stress. Higher scores on the burnout and secondary traumatic stress indicate higher risk for burnout and higher secondary traumatic stress, respectively. Higher scores on the compassion satisfaction scale indicate greater satisfaction in your ability to be an effective caregiver at your job.[114] A 9-item Well-being Index (WBI) will be used to identify U.S. workers in distress and stratify quality of life. The WBI is a successful screening tool to identify distress and identify those with high well-being among nurses[115,116] and among a variety of workers. [115] Supplemental questions asked will be taken from the National Sample Survey of Registered Nurses question numbers: 36, 66, 67. The last question included is a retention question that asks: "Do you plan to be with your employer one year from now?" Yes or No.

7.1.1.3 Applicability to the setting

In addition to asking clinicians and hospice aides about their knowledge, confidence and attitudes, we will also ask them about the applicability of the program through a series of questions via the online survey (see questions under other materials).

We will also perform a focus group with all champions who consent to participate. The focus group will be held in the same room where the champion training was performed at the end of that day and will take approximately 20 minutes to complete. The focus group will ask three open ended questions about the champions training, with follow-up questions based on response. These questions are: what did you feel were the best parts of the champion training and why; what did you feel were the parts you liked least about the champion training and why; how do you think it will help you change the practice of clinicians in your agency; what would you change about the champions training?

7.1.2 Standard of Care Study Procedures

PWD subjects who are in the control group will receive usual care as provided by the hospice agency.

7.2 Study Schedule

7.2.1 Screening

The NYU study team will be provided a list of all staff by the hospice agency who are in the applicable care teams at the participating hospices. We will then invite them to take part in this research study consisting of pre- and post-training survey assessments. The initial survey will ask them the eligibility questions at the beginning following review of the consent document, and should they not click the eligible options will be directed to the end of survey where a message will be performed stating they are not eligible. All eligible clinician subjects will continue on to the remainder of the pre-training survey assessment.

7.2.2 Pre-Training Assessment

At baseline the HHA will take the HHA assessment, and skilled clinicians will take the DSKA assessment. They will then at completion receive access to their respective training modules. Champions will be scheduled to take the in-person training together.

7.2.3 Post-Training Assessment

Following completing the online training modules, the clinician subjects will proceed to the appropriate post-training assessment.

7.2.4 Collection of Hospice Record

Following completion of the pilot, we will collect de-identified data of eligible PWD other than zip codes and dates of service. This is pre-existing routinely collected data by the agencies of all PWD who are receiving care at the participating hospice agencies. We will primarily be looking to describe the population as well as determine how many assessment instruments or care plans have been initiated, and types and frequency of symptoms, and pharmacologic and non-pharmacologic interventions utilized.

7.2.5 Withdrawal/Early Termination Visit

Clinician subjects can withdraw from the study at any time, and will not have to complete the assessment instruments, though they may be required by the hospice agency to complete the training as an operational initiative.

8 Assessment of Safety

8.1 Staff (Clinicians)

There is minimal risk to the healthcare staff as the content is not sensitive in nature and the surveys do not significantly relate to measures on which staff are measured for job accountability. The greatest risk to staff is the loss of confidentiality. We will not share any data collected back to the agency. For reporting purposes in conference proceedings, abstracts and manuscripts, data will be aggregated to ensure lack of identifiability to the staff level.

8.2 Persons with Dementia

We will not be monitoring efficacy or effectiveness during the R61 pilot phase of this evidence-based practice intervention, and therefore will not be actively monitoring for adverse events.

8.2.1 Data Safety and Monitoring

The Principle Investigator will ensure overall safety of the subjects in the R61 pilot phase on a daily basis and will be responsible for all reporting. The study statistician will be responsible for running reports on data safety, consistency and outcomes and reviewing them with the study PI.

8.2.2 Frequency and Reporting

As this is a R61 pilot and not a clinical trial, and outcomes are around feasibility, acceptability and fidelity, we will not perform routine reporting other than the annual continuing review. If we find through our analyses any negative outcomes the PI will report them within 24 hours to the IRB and NIH program officer.

9 Clinical Monitoring

Clinical site monitoring will not be conducted during this R61 pilot project.

10 Statistical Considerations

10.1 Statistical and Analytical Plans (SAP)

A formal SAP will not be completed for this study.

10.2 Statistical Hypotheses

There are no hypotheses for this R61 pilot phase. Instead, we have milestones we must achieve in order to proceed to the R33 phase of the grant (to be submitted under separate IRB):

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.

10.3 Analysis Datasets

We will maintain separate data sets nested by site for skilled clinicians, hospice aides, and PWD.

10.4 Description of Statistical Methods

10.4.1 General Approach

Data Analysis will be performed using SAS 9.4[117]. We will perform basic descriptive tests to examine baseline characteristics of the patient populations and clinician populations. We will perform paired t-tests to examine differences in knowledge, confidence and attitudes from baseline, as well as tests of validity and reliability.

10.4.2 Adherence and Retention Analyses

We will perform sensitivity analyses to examine whether there are differences in those who are retained in the study vs those who withdraw/are terminated. As this is a cluster randomized trial, adherence is related to the quality improvement program implementation at the care team level and therefore falls under fidelity monitoring. We will examine differences in DSKA scores submitted by hospice clinicians across control and quality improvement program care teams through paired t-tests and repeated measures ANOVA.

10.5 Sample Size

This study will utilize a convenience sample for both PWD and clinicians based on those available and eligible at the time of implementation as this is a R61 pilot phase study.

11 Source Documents and Access to Source Data/Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial. It is acceptable to use CRFs as source documents. If this is the case, it should be stated in this section what data will be collected on CRFs and what data will be collected from other sources.

All clinician data, which has no PHI, will be collected using Qualtrics, which is hosted by NYU Data Services. All de-identified data sets (other than zip codes and dates of service) will be maintained on a secure MCIT managed research drive.

Access to study records will be limited to IRB-approved members of the study team. The investigator will permit study-related monitoring, audits, and inspections by the IRB/EC, the sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

12 Quality Assurance and Quality Control

QC procedures will be implemented beginning with the data entry system and data QC checks that will be run on the database will be generated. Any missing data or data anomalies will be communicated to the site(s) for clarification/resolution.

The PI will verify that the R61 pilot phase study is conducted and data are generated, documented (recorded), and reported in compliance with the protocol, and GCP in coordination with the study statistician.

NYU will provide direct access to all source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by local and regulatory authorities.

13 Ethics/Protection of Human Subjects

13.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, and/or the ICH E6.

13.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

The following consent materials are submitted with this protocol:

Study Information Survey Header-Clinician
Application for Waiver of Documentation of Informed Consent-Clinician
Application for Waiver of Authorization and Informed Consent-PWD

13.3 Informed Consent Process

13.3.1 Consent/Assent-PWD

Because we are only obtaining data that is routinely collected by the participating hospices as part of the care provided, we will be seeking waiver of authorization and informed consent. Therefore, there will be no recruitment or retention per se as we will only be obtaining de-identified data other than dates of service and zip codes from PWD and caregivers who have received care at a participating hospice.

13.3.2 Consent-Clinicians

We will seek a waiver of documentation of consent and provide a statement at the beginning of the Qualtrics survey using a standardized consent statement approved by the NYU School of Medical IRB at onset of collection of fidelity surveys as we will only be performing a pre-post survey that is minimal risk in nature and obtaining signed consent would not be feasible.

13.4 Participant and Data Confidentiality

13.4.1 Data security-PWD

There will be no prospectively collected data for this trial and no prospective assignment of individuals and therefore, this trial does not require use of REDCap or TrialMaster for data collection. This study uses QA methodologies, and therefore falls under item 12 of table 1 of NYU EDC Policy dated 4-18-18, which allows for use of an MCIT managed network drive. Therefore, all retrospective data provided by participating hospice agencies will be collected through secure, NYU approved data transfer methods from the hospice agency, and data will be secured on an MCIT managed networked research drive that is encrypted behind the NYU Langone Health Firewall that is partitioned and solely accessible by the research team members authorized by the PI. Login using unique credentials is required with two factor authentication.

13.4.2 Data security-Clinicians

No PHI will be collected from clinicians. All clinician related survey data will be collected using NYU Qualtrics. In order to access completed data in Qualtrics, you must use your NYU login credential and 2 factor authentication to access through a secure portal. Once data is collected and being prepared for analysis, it will be downloaded into a NYU Box folder owned by the PI that will only be accessible to the appropriate study personnel. NYU Box is controlled by NYU and only accessible through NYU login credentials and 2 factor authentication. It is approved by NYU College of Nursing IT and Campus IT for maintaining sensitive information, though we are not collecting PHI. Data will be collected through the Qualtrics survey by the clinician either on a personal or agency owned device but entered data are not retained on the device. Data collected by Qualtrics is secure and encrypted end-to-end.

13.4.3 Research Use of Stored Human Samples, Specimens, or Data

- Intended Use: Data collected under this protocol may be used to study dementia or hospice care
- Storage: Only approved investigators will have access to the study data.

13.5 Future Use of Stored Specimens

Not Applicable

14 Data Handling and Record Keeping

14.1 Data Collection and Management Responsibilities

All data other than the consent forms will be collected and maintained electronically in on an MCIT-managed network drive.

Data collection is the responsibility of the study staff at the site under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink is required to ensure clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line, and initial and date the change. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.

Copies of the electronic CRF (eCRF) will be provided for use as source documents and maintained for recording data for each participant enrolled in the study. Data reported in the eCRF derived from source documents

should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official electronic study record.

Clinical data (including AEs, concomitant medications, and expected adverse reactions data) and clinical laboratory data will be entered into RedCap, a 21 CFR Part 11-compliant data capture system provided by the NYU Langone School of Medicine and NYU College of Nursing. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

14.2 Study Records Retention

Study documents will be retained for the longer of 3 years after close-out, 5 years after final reporting/publication.

14.3 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, GCP, or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH E6:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the site PI/study staff to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity.

All protocol deviations must be addressed in study source documents.

Protocol deviations must be reported to the local IRB per their guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

14.4 Publication and Data Sharing Policy

The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a clinical trials registration policy as a condition for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE policy, and the Section 801 of the Food and Drug Administration Amendments Act of 2007, requires that all clinical trials be registered in a public trials registry such as ClinicalTrials.gov, which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. For interventional clinical trials performed under NIH IC grants and cooperative agreements, it is the grantee's responsibility to register the trial in an acceptable registry, so the research results may be considered for publication in ICMJE member journals. The ICMJE does not review specific studies to determine whether registration is necessary; instead, the committee recommends that researchers who have questions about the need to register err on the side of registration or consult the editorial office of the journal in which they wish to publish.

The trial will be registered through clinicaltrials.gov prior to starting.

The investigators will follow policy on making available an anonymized, publicly available data set following conclusion of the study.

15 Study Finances

15.1 Funding Source

This study will be financed through the National Institutes of Health.

15.2 Costs to the Participant

There will be no costs to participate.

15.3 Participant Reimbursements or Payments

There will be no reimbursements or payments to participants.

16 Study Administration

16.1 Study Leadership

The steering committee includes the Principle Investigator, 3 additional NYU co-investigators, 4 subject experts at other universities, two hospice stakeholder representatives (Dr. Joe Shega, MD of Vitas Hospice and Ms. Molly Gurian, JD, MPH of the National Partnership for Hospice Innovation) and a caregiver stakeholder representative (TBN). The Steering Committee will govern the conduct of the study.

17 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership in conjunction with the NIA has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by the NYU Langone Conflict of Interest Management Unit (CIMU) with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All NYULMC investigators will follow the applicable conflict of interest policies.

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19 Attachments

These documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents may not require protocol amendments.

- Consent Language for Survey-Clinician
- Application for Waiver of authorization and consent-PWD
- Application for Waiver of Documentation of Consent-Clinicians
- Vulnerable Populations: Cognitive Impaired Subject Appendix
- Dementia Symptom Knowledge Assessment-Clinicians
- Home Health Aide Assessment-Clinicians

20 Ancillary Study

Impact of a dementia care expert care program on burnout, job satisfaction and turnover rate for interdisciplinary hospice care teams

Aims

Purpose: To evaluate the influence of the Aliviado dementia care training on professional quality of life and well-being of the hospice staff

Quantitative Aim:

1. To examine the association between a dementia care expert care program on burnout, job satisfaction and turnover rate for interdisciplinary hospice care teams

Qualitative Aim:

2. To explore interdisciplinary hospice teams' experiences with burnout, job satisfaction and turnover when providing care to persons with dementia

Mixed Methods Aim:

3. Compare the qualitative results to findings from the quantitative surveys (ProQOL and well-being) and gain insight into the reasons behind varying scores

Background

Hospice provides expert medical care, pain management, and emotional and spiritual support tailored to individuals living with a terminal illness [1]. In 2016, 1.43 million Medicare beneficiaries were enrolled in hospice care for one day or more; among which 18% had a principal diagnosis of dementia [1]. As the dementia progresses, persons with dementia (PWD) tend to display a plethora of behavioral changes, collectively termed Behavioral and Psychological Symptoms of Dementia (BPSD). Research conducted with professional caregivers of PWDs showed that understanding PWDs' behavior and behavioral change is a crucial factor to achieve and sustain good working relationships between professionals and PWDs receiving care [2]. Helping hospice professionals understand BPSD has great potential in sustaining good working relationships between professionals and PWDs, and subsequently improve hospice staff's professional quality of life (QoL). Research also shows that the role of homecare workers supporting PWDs up to the end of life remains under-researched, with unmet needs for informational, technical and emotional support [3]. The Aliviado Dementia Care-Hospice Edition provides training and a toolbox to hospice professionals on dementia behavioral symptom assessment and management. To understand the potential impact of the Aliviado Dementia Care-Hospice Edition on hospice staff's professional QoL, we propose the addition of the following measures that will be collected at the existing baseline survey, and during a new 6 months post-intervention survey.

Methods

Design

This ancillary study will use a mixed method model and will utilize a pre-post methodology in pilot 2 described in the primary study. Quantitative survey questions from the validated instruments outlined below will be inserted in the existing baseline survey. A new, optional, 6 month survey timepoint will be added, with an additional option at the end

of the 6 month survey to check a box stating they would be interested in participating in a telephonic based qualitative interview.

Quantitative Measures

The quantitative measurements that will be used to evaluate burnout and job satisfaction include:

1) Professional Quality of Life (ProQOL-5)—The ProQOL is a 30 question self-report questionnaire measuring professional quality of life measured through a 5-point Likert scale that asks questions about how frequently the participant experienced the things being asked about in the last 30 days. The scale starts at one indicating never and goes to five indicating very often. It measures professional quality of life on three subscales including compassion satisfaction, burnout and secondary traumatic stress. Higher scores on the burnout and secondary traumatic stress indicate higher risk for burnout and higher secondary traumatic stress, respectively. Higher scores on the compassion satisfaction scale indicate greater satisfaction in your ability to be an effective caregiver at your job (Stamm, 2009 & 2010).
    a. The concise ProQOL manual . Pocatello, ID. *Retrieved from ProQOL. org*. https://proqol.org/ProQol_Test.html (See measure below P.2)
2) 9-item Well-being Index (WBI)—The WBI is an index used to identify U.S. workers in distress and stratify quality of life. The WBI is a successful screening tool to identify distress and identify those with high well-being among nurses (Dyrbye, Johnson, Johnson, Satele & Shanafelt, 2019) and among a variety of workers (Dyrbye, Satele & Shanafelt, 2016).
    a. *Retreived from https://www.mededwebs.com request form.* (See measure below P. 5).
3) Supplemental questions asked will include:
    a. National Sample Survey of Registered Nurses question numbers: 36, 66, 67,
    b. Retention Question: Do you plan to be with your current employer one year from now? Yes or No

Qualitative Measures

Qualitative Interview. Example questions in the table below.

Questions	**Follow Up Probes**	**Comments/Field Observations**
Tell me about your experience with the Aliviado training	What did you expect to gain from the training? What part of the training was most helpful? Any barriers or facilitators to completing the online training?	
Tell me about your ability to care for persons with dementia (PWD) in the hospice setting	What have you done differently since the training? What changes have you experienced in your job after the training?	
Tell me about your satisfaction with your current professional role responsibilities	How has the training influenced your feelings of compassion? How much stress do you experience daily at work? How has your stress changed since the training?	
Tell me about how you feel about being able to provide	How much patience do you have when you provide care for PWD?	

compassionate care on a daily basis	How do you feel your job supports your ability to provide compassionate care?	
What aspects of your job or patient caseload impact your ability to carry out your job?	How are these aspects influencing your desire to stay in your current role?	
Is there anything else you would like to share that I did not ask about?		

All qualitative interviews will conducted by telephone and tape recorded. Transcripts will be created from the recordings.

Inclusion/Exclusion Criteria
Per Primary Study

Number of Subjects
Quantitative: Per Primary Study
Qualitative:

Analytic Plan
Survey data will be analyzed quantitively. Descriptive and frequency statistics will be used to demographic data. Paired T-test will be used to analyze between pre and post survey results. Data from qualitative interviews will be coded using open coding methodology. The team members will code the interviews separately and will compare coding to reach interrater reliability. Codes will then be merged into categories. From the categories themes will be identified. A similar team member checking will also occur during the development of categories and themes.

Participant Burden
This ancillary study will include 43 additional questions, each question is on a simple Likert-scale and is not open ended. These questions will not add significant participant burden as it is anticipated answering these questions will take approximately 15 min. The qualitative interviews will occur post-training and will occur at the convenience of the participant over the phone by willing participants. Answering these questions will take approximately 45- 60 minutes.

Participant Incentives
Participants will receive a $25 gift card for completing the 6-month survey, and an additional $50 gift card for completing the telephonic interview.

Consent Procedures
The existing informational header for the quantitative surveys (waiver of written documentation) has been updated to reflect the addition of this ancillary study. A separate waiver of written consent will be requested for the qualitative study. During the qualitative interview, potential subjects will be emailed the informational header ahead of time and telephone consent will be performed (see waiver of written documentation-ancillary study request).

Data Safety
All data downloaded from the survey system will be maintained in accordance with the Data Safety Plan as outlined above and in concordance with NYULH data management policies. All identified data will be maintained on the MCIT research mounted drive. All de-identified data will be maintained on NYU Box per NYU campus data security protocols.

Potential Risks and Benefits
This ancillary study presents no greater risk that the original study (minimal risk). The greatest risk is of loss of confidentiality. Prior experience with these measures have not found to cause any harm, and data will not be provided back to the subjects' employer. There are no potential benefits to the subject, but generalized knowledge will be obtained that can potentially assist in reducing hospice workforce burden and burnout.