Northwell Health

RESEARCH PROTOCOL

Protocol Title:	Reducing Behavioral and Psychological Symptoms of Dementia
Principal Investigator:	Liron Sinvani
Primary Contact Name:	Suzanne Ardito
Primary Contact Phone:	(516) 241-1580
Primary Contact E-mail:	SArdito@northwell.edu
Date Revised:	03/01/2021
IRB Number:	19-0800
NCT Number:	NCT04179721

Guidelines for Preparing a Research Protocol

Instructions:

- You do not need to complete this document if you are submitting an *Application for Exemption* or *Application for a Chart Review*.
- Do not use this template if:
  - Your study involves an FDA regulated product. In this case, use the *Clinical Trial Protocol Template.*
  - Your study has a protocol from a sponsor or cooperative group. In this case, use the *Protocol Plus*.
  - Your study is a registry or repository for data and/or samples, In this case, use *Protocol Template – Registry Studies.* .
- If a section of this protocol is not applicable, please indicate such.
- Do not delete any of the text contained within this document.
- Please make sure to keep an electronic copy of this document. You will need to use it, if you make modifications in the future.
- Start by entering study information into the table above, according to these rules:
  - Protocol Title: Include the full protocol title as listed on the application.
  - Investigator: include the principal investigator's name as listed on the application form
  - Date Revised: Indicate the date at which the protocol was last revised
  - IRB Number: Indicate the assigned IRB number, when known. At initial submission, this row will be left blank.
- Once the table information in entered, proceed to page 2 and complete the rest of the form.

↓ Continue to next page to begin entering information about this study ↓

1. PREVIOUS STUDY HISTORY

Has this study ever been reviewed and rejected/disapproved by another IRB prior to submission to this IRB?

☒ No ☐ Yes – if yes, please explain:

2. BRIEF SUMMARY OF RESEARCH

- *The summary should be written in **language intelligible to a moderately educated, non-scientific layperson**.*
- *It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, with an emphasis on what will happen to the subjects, and a discussion of the results.*
- *This section should be ½ page*

Persons with Alzheimer's Disease and Related Dementias (ADRD) currently account for 3.2 million hospital admissions per year and have over three times more hospitalizations than those without cognitive impairment. Yet, hospital caregivers are currently ill-prepared to manage patients with ADRD, with less than 5% reporting mandatory dementia care training. Three-quarters of hospitalized persons with ADRD display Behavioral and Psychological Symptoms of Dementia (BPSD), associated with functional and cognitive decline, increased resource consumption, institutionalization, premature death, and caregiver burden. The *overall objective* of this project is to test the feasibility and preliminary efficacy of an innovative model of care, the **PES-4-BPSD**, for reducing BPSD by empowering **Patient Engagement Specialist (PES)** to deliver dementia care for acutely-ill patients with ADRD. Traditionally, mental health assistants with training in crisis-prevention techniques provide care to psychiatric patients. On the intervention unit, these mental health assistants, as PES, purposefully engage patients with BPSD. In our pilot study, we found that patients with cognitive impairment admitted to the PES unit were significantly less likely to require constant observation, chemical and physical restraints, suggesting improved management of BPSD. Our *central hypothesis* is that the PES-4-BPSD intervention will improve the ability of PES to create an "enabling" milieu that addresses the factors leading to BPSD and improves the experience of hospital caregivers. Guided by a social-ecological framework, the PES-4-BPSD model incorporates: dementia education and training, environmental modifications-cohorting, increased staffing-PES, and staff support. Our multidisciplinary research team is well-positioned to accomplish the following aims: *Aim 1: Determine the preliminary efficacy of the PES-4-BPSD intervention for reducing BPSD during hospitalization* and *Aim 2: Evaluate whether dementia care training improves the perceived ability of PES staff (intervention) and nurse assistant staff (control) to care for hospitalized persons with ADRD*. For Aim 1, we

will conduct a non-randomized preliminary efficacy trial of the PES-4-BPSD intervention enrolling N=158 patients (79 control and 79 intervention). The primary outcome will be the presence (through a multi-modal approach) of BPSD during hospitalization using the Neuropsychiatric Inventory-Questionnaire (NPI-Q). In Aim 2, we will use survey methodology in a repeated measures design to evaluate within and between-group differences in attitudes, experience, and satisfaction toward managing patients with ADRD. Measures will be completed at baseline (T1), immediately following training (T2), and at end of the intervention period (T3). In response to the 2017 NIA Workshop, "Innovating the Next Generation of Dementia and Alzheimer's Disease Care Interventions", this proposal will be the first to study an innovative model of care utilizing PES as specialized hospital caregivers for reducing BPSD in the hospital setting. Our findings will lay the essential groundwork for a multi-site trial of PES-4-BPSD, and will inform the development of a program that can be easily implemented in other hospitals. Providing care for persons with dementia in the hospital setting is considered standard of care. However, it is well known that hospitalized persons with dementia have worst outcomes compared to those without dementia. The dementia training that will be provided for the staff on the control and intervention units will consist of ways to optimize the care already being provided (e.g. better ways to communicate with persons with dementia, ways to avoid restraints). The training will consist of 7 in-service modules for dementia care. The training is meant to improve the care for persons with dementia by providing the staff education on dementia care. The training will not change/alter the care but simply optimize the care already being provided. The training delivery is considered standard of care and is the way all hospital training is provided to hospital staff. The modules will be presented on both the intervention and control units to all nursing and NA/PES staff. The 7 modules will include: 1) overview of dementia and dementia care; 2) addressing unmet needs; 3) avoiding restraints; 4) communicating with persons with dementia; 5) delirium; 6) the impact of the physical environment; 7) connecting to the family caregiver. The in-service sessions will be given on all nursing shifts, therefore covering all staff. The training should not be considered as altering the care. The care provided to persons with dementia remains the same (considered standard of care), the approach to getting that care will be optimized. Persons with dementia are frequently admitted to the hospital and cared for by NA/PES/nursing staff. The care provided will be the same, the training will simply enhance the care already provided. The hypothesis is that the personnel on the units that receive the training will have more confidence to provide this care. Both the intervention and control units are already functioning, we are providing training to optimize the care. This study aims to evaluate whether the presence of PES is necessary to improve care for hospitalized persons with dementia. It is important to note that this R21 is a feasibility, exploratory trial that will inform future larger efficacy trials.

3. INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

- *Describe and provide the results of previous work by yourself or others, including animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the compound or device to be studied.*
- *Include information as to why you are conducting the study and how the study differs from what has been previously researched, including what the knowledge gaps are.*
- *Describe the importance of the knowledge expected to result*

Patients with Alzheimer's disease and related dementias (ADRD) are frequently admitted to the hospital and have poor outcomes. Persons with dementia currently account for 3.2 million hospital admissions per year; they have over three times more hospitalizations than persons without cognitive impairment.[1–3,24] Hospitalization in these patients is a seminal event that often leads to delirium, lasting functional and cognitive impairment, institutionalization, premature death, increased resource consumption, and family caregiver (FCG) distress.[4–7,13,25–31] ***There is a need for interventions to improve the experience and outcomes of hospitalization for both the patient and the family caregiver.***

Three-quarters of hospitalized persons with ADRD display behavioral and psychological symptoms of dementia (BPSD). For persons with dementia, the unfamiliar, complex environment of the hospital and lack of meaningful cognitive and physical stimulation results in BPSD (agitation, depression, apathy, repetitive questioning, psychosis, aggression, sleep problems, and wandering) that precipitate poor outcomes.[16,17] BPSD in the hospital setting stems from patient factors (unmet needs, e.g. pain, fear, nutrition, toileting), hospital caregiver factors (stress, lack of dementia knowledge, communication issues), and environmental factors (lack of activity and structure).[17] ***There is a need for an intervention that addresses the multi-factorial contributants to BPSD***.

Hospital Caregivers (HCGs) are currently ill-prepared to prevent and manage BPSD. HCGs are currently ill-prepared to prevent and manage BPSD and experience low job satisfaction, stress and burnout.[10–14,32–34] BPSD in the hospital setting is commonly associated with the use of psychoactive drugs and physical restraints, all associated with adverse events and increased mortality.[9,35–40] The use of special observation (e.g. CO, sitters), usually performed by nurse assistants, has been expanded for the management of older adults with behavioral symptoms.[13,41] In addition to the unsustainable cost, CO by staff without training in dementia care and a clear understanding of their role results in poor patients outcomes.[13,41,42] A National UK audit found that less than 5% of acute hospital staff receives mandatory training in dementia and less than a third of hospital providers considered staffing as sufficient.[14] ***There is a need for innovative and practical approaches to improve dementia care of the acute care workforce.***

Theoretical Basis. The PES-4-BPSD model will be implemented within a social ecological in-patient framework that promotes specialized care for patients with ADRD. The framework consists of four domains (social climate, care system processes, policies and procedures, physical design) and assumes that: (a) people cannot be understood apart from their environmental context, and (b) physical as well as social and organizational environments must be studied.[18–20] The social-ecological framework has been used to study hospitalized older adults with dementia.[20] *The components of the PES-4-BPSD address the factors that predispose hospitalized patients with ADRD to develop BPSD, namely: policies and procedures (dementia education and training); physical design (environmental modifications including cohorting, use of common area, limit noise, lights); care system processes (increased staff ratio for non-medical needs with PES); and social climate (providing staff support to improve staff attitude and empathy with group sessions).*[20]

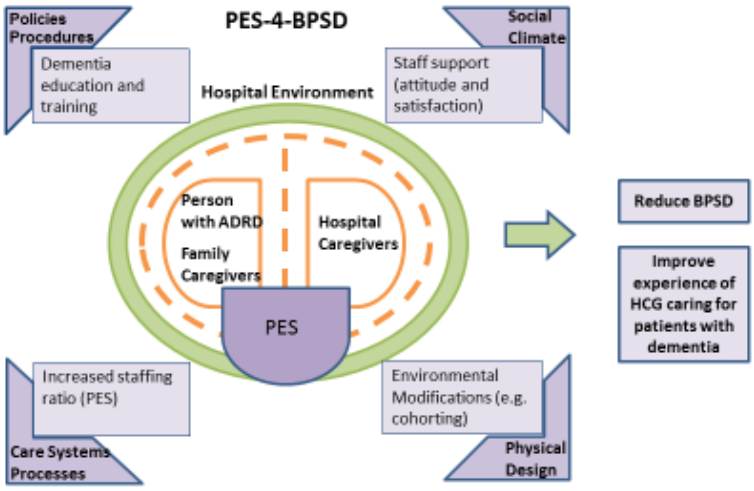

Figure 1. The PES-4-BPSD model. Within the context of the social ecological framework, we pose that the PES-4-BPSD intervention will decrease BPSD (Aim 1) and improve HCG experience in caring for hospitalized persons with dementia (Aim 2) by creating an "enabling" milieu for both patients and hospital caregivers.

Scientific Premise. Persons with dementia occupy 25% of hospital beds.[3] The quality of their care is a national concern.[23,43] HCGs report lack of knowledge, skills and confidence in caring for people with dementia.[10–14] There is limited evidence about the most effective approaches to supporting HCG to deliver better care; two review articles have suggested that patients and HCGs might benefit from increasing involvement of mental health staff who have chosen to work with patients with psychiatric conditions.[13,44] We pose that the PES-4-BPSD model, a multi-component intervention of mental health assistants with dementia training on a dedicated unit, will decrease BPSD and improve HCG experience in caring for hospitalized persons with dementia by creating an "enabling" milieu for both patients and HCG.

Innovation. The status quo for caring for hospitalized patients with dementia results in poor outcomes and distress for patients, FCGs, and HCGs. Our proposal is innovative as it represents a substantive departure in the following ways: 1) it is the first study to explore the effectiveness of a new and enhanced model that adapts mental health assistants into Patient Engagement Specialists (PES) for the care of

hospitalized persons with ADRD; 2) this study focuses specifically on BPSD, which is a critical outcome not only for patients, but also for FCGs and HCGs; and 3) it evaluates a dementia training program that can be used in the real-world setting.

Preliminary Studies. In our pilot study, we demonstrated the feasibility of utilizing PES to provide care for acutely-ill patients with BPSD.[15] Patients admitted to the intervention unit (with PES) had lower in-hospital mortality (1.1% vs. 2.9%, p=.048) and decreased LOS (5.0 vs. 5.8 days, p=.004). They were also less likely to have an order for: constant or enhanced observation (12.0% vs. 45.8%, p<0.001 and 22.1% vs. 79.6%, p<0.001, respectively), benzodiazepines (26.3% vs. 38.0%, p<.001), psychotropics (41.2% vs. 54.0%, p<.001), and restraints (3.2% vs. 6.9%, p=0.01). Decreased LOS and use of CO (5.94 FTE reduction) resulted in cost benefits.

4. OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

- *A concise statement of the goal(s) of the current study.*
- *The rationale for and specific objectives of the study.*
- *The goals and the hypothesis to be tested should be stated.*

We propose an NIA Stage I study of an innovative model of care that aims to reduce behavioral and psychological symptoms of dementia (BPSD) during hospitalization and improve the experience of hospital caregivers working with persons with Alzheimer's Disease and Related Dementia (ADRD).

Our *long-term goal* is to implement and disseminate an innovative model of care, the **PES-4-BPSD**, which aims to reduce BPSD by empowering **Patient Engagement Specialist (PES)** to provide specialized dementia care for acutely-ill patients with ADRD. PES are mental health assistants with training in crisis prevention techniques, who provide care to psychiatric patients, under nursing supervision. On the intervention unit, which cohorts older patients with cognitive impairment and behavioral symptoms, these mental health assistants purposefully engage patients with BPSD, as an added layer of staff. In our pilot study, we found that patients with cognitive impairment admitted to the PES unit were significantly less likely to require constant observation (CO) (12.0% vs. 45.8%, p<0.001), chemical (41.2% vs. 54.0%, p<.001) and physical restraints (3.2% vs. 6.9%, p=0.01), suggesting improved management of BPSD.[15] Furthermore, the decreased use of CO on the unit led to a reduction of 5.94 FTEs over 1 year. The PES in our study, however, had not received dementia care training. Given our promising findings, we now seek to refine the model by providing PES personnel with dementia care training and operational tasks geared to the care of hospitalized patients with ADRD.

The *overall objective* of this application is to test the preliminary efficacy of the PES-4-BPSD model to reduce BPSD in hospitalized patients with ADRD. Our *central hypothesis* is that the PES-4-BPSD intervention will reduce BPSD by improving the ability of PES to create an "enabling" milieu that addresses the factors leading to BPSD in the hospital, namely: patient factors (unmet needs), hospital caregiver factors (lack of dementia knowledge, communication issues) and environmental factors (lack of activity and structure).[16,17] Guided by a social-ecological framework, the PES-4-BPSD model incorporates: policies and procedures (dementia education and training), physical design (environmental modifications-cohorting), care system processes (increased staffing-PES), and social climate (staff support).[18–20] The attention control condition will consist of a medicine unit that also cohorts older adults in which patient care is performed by nurse assistants, rather than PES. To test the added layer of PES staff, nurse assistants on the control unit will receive equivalent dementia training. Our multidisciplinary research team is well-positioned to complete the following aims:

Aim 1: Determine the preliminary efficacy of the PES-4-BPSD intervention for reducing BPSD during hospitalization. We will conduct a non-randomized preliminary efficacy trial, enrolling N=158 patients (79 control and 79 intervention). The primary outcome will be presence of BPSD as measured by a patient's total score on the Neuropsychiatric Inventory-Questionnaire (NPI-Q) during hospitalization.[21] A multi-modal approach (chart review and questionnaires) will be used to determine the presence and severity of BPSD. Secondary measures will include length of stay (LOS), BPSD management practices during hospital, and family caregiver satisfaction on discharge.[14] The study will inform approaches to ensure treatment fidelity, use of outcome measures, and effect size estimates for a larger cluster-randomized trial.

Aim 2: Evaluate whether dementia care training improves the perceived ability of nursing staff, **PES staff (intervention) and nurse assistant staff (control) to care for hospitalized persons with ADRD.** We will use survey methodology in a repeated measures design to evaluate within and between-group differences in attitudes, experience, and satisfaction toward managing patients with ADRD.[11,22] Measures will be completed at baseline (T1), immediately following training (T2), and at end of the intervention period (T3).

5. RESOURCES AVAILABLE TO CONDUCT THE HUMAN RESEARCH

- *Explain the feasibility of meeting recruitment goals of this project and demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period*
    - *How many potential subjects do you have access to?*
- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol and their trial related duties and functions*

Aim 1: This study plans to enroll an equal number of patients (n=79) from the control unit and from the intervention unit. This study predicts a 50% recruitment rate and approximately 158 patients and FCGs will be approached on each unit (316 in total). Based on our preliminary results, the median length of stay for persons with dementia in the hospital is 5 on the intervention unit and 5.8 days on medicine units. After initial recruitment, all data will be collected through chart review and staff questionnaire, there will be minimal requirements from the patient and FCGs. In addition, a follow-up phone call to the FCGs will occur within 48 hours of discharge to assess satisfaction with care. Therefore, attrition in the hospital, once patients and FCGs are recruited should be minimal, as they will be in the hospital. Telephone numbers for the FCGs will be obtained on recruitment and verified on discharge. The PI, with the support of the research team, will spend 12 weeks to implement the program for the PES staff. Based on the John A. Hartford Institute for Geriatric Nursing and the National Alzheimer Association publications "Try This: Best Practices in Nursing Care for Persons with Dementia," and the "Person-Centred Care Training Programme for Acute Hospitals (PCTAH)", the PES staff will receive weekly 20 minute sessions.[32,34,51,52] Sessions will cover the following: types and impact of dementia, providing person-centered care, identification of and meeting people's emotional and physical needs, effective communication, connecting to the FCG, the impact of the physical environment, and redefining and supporting behaviors staff may describe as challenging. To ensure all PES receive training, sessions will be repeated during 3 shifts changes. Once recruitment begins, the PI will hold monthly 20 minute group sessions, to reinforce training and discuss challenging patient behaviors; meant to improve the attitude and empathy of HCGs towards patients.

Aim 2: All nursing staff on both units, PES staff on the intervention unit and nursing assistants on the control unit are eligible to participate in the study. The control unit has a total of 40 nurses and 39 nurse assistants and the intervention unit has a total of 20 nurses and 21 PES personnel that are eligible to participate. Following approval by Northwell's IRB, the research coordinator/assistant with no authority over the staff will directly approach eligible staff, nurses on both units, nursing assistants on the control units and PES personnel on the intervention unit, to participate in the study, emphasizing that participation is voluntary, with an option to opt out of the study at any point without repercussion/effect on the their employment. All information collected on employees will be restricted to the research team and will not be accessible or discussed with persons in supervisory positions. Their participation/non-participation will not affect their job at Northwell Health. Reimbursements of $25 will be offered over three installments corresponding to the completion of the two surveys at the three time points. A total of $75 will be given if completing the two surveys across the three time points.

6. RECRUITMENT METHODS

- *Describe the source of potential subjects*
- *Describe the methods that will be used to identify potential subjects*
- *Describe any materials that will be used to recruit subjects. A copy of any advertisements (flyers, radio scripts, etc.) should be submitted along with the protocol.*
- *If monetary compensation is to be offered, this should be indicated in the protocol*

Aim 1 study plans to enroll an equal number of patients (n=79) from the control unit and from the intervention unit. This study predicts a 50% recruitment rate and approximately 158 patients and FCGs will be recruited on each unit (316 in total). Based on our preliminary results, the median length of stay for persons with dementia in the hospital is 5 on the intervention unit and 5.8 days on medicine units. After initial recruitment, all data will be collected through chart review and staff questionnaire, there will be minimal requirements from the patient and FCGs. If FCG participant expresses interest in the study, daily NPI-Q collection via staff and EMR will begin. In addition, a follow-up phone call to the FCGs will occur within 48 hours of discharge to assess satisfaction with care. Therefore, attrition in the hospital, once patients and FCGs are recruited should be minimal, as they will be in the hospital. Telephone numbers for the FCGs will be obtained on recruitment and verified on discharge. FCG participants will be compensated a total of $30 for their participation ($20 at enrollment, $10 upon complete of the discharge follow-up) via ClinCard which will be given directly if interviewed in person or sent via mail if interviewed remotely.

For Aim 2 of our study, all nursing staff on both units, PES staff on the intervention unit and nursing assistants on the control unit are eligible to participate in the study. Following approval by Northwell's IRB, the consenting investigator will directly approach eligible staff, nurses on both units, nurse assistants on the control units and PES personnel on the intervention unit, to participate in the study. Participants will be reimbursed for their time. Reimbursements of $25 will be offered over three installments (total $75) corresponding to the completion of the two surveys at the three time points.

7. ELIGIBILITY CRITERIA

- *Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation.*
- *Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. You cannot include these populations in your research, unless you indicate such in the protocol*

- *Similarly, detail exclusionary criteria: age limits, special populations (minors, pregnant women, decisionally impaired), use of concomitant medications, subjects with other diseases, severity of illness, etc.*

Aim 1: All patients 65 years and older who have an acute medical admission to either the control unit (Geriatric Care Model) or intervention unit (PES-4-BPSD). Inclusion criteria: age 65 and above, FCG is English-speaking/reading, documentation of dementia in the medical record (based on ICD-9 codes). For patients without a prior history of dementia documented in the EMR, an AD8 score of greater than or equal to 2 will be required. The AD8 is an eight item, informant-based interview, used to screen for dementia. (57)

Exclusion criteria: patients who are known to be terminally ill and/or receiving hospice or surgery; LOS of less than 48 hours, no documentation of dementia in the medical record (based on ICD-9), FCG is not English-speaking/reading.

Aim 2: Inclusion criteria: All nursing staff (nurses on both units; PES on the intervention unit; and nursing assistant staff on the control unit).
Exclusion criteria will include staff who decline to participate in the study and staff that are not permanently based on either the intervention or control units

8. NUMBER OF SUBJECTS

- *Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained), randomized and complete the research procedures.*
- *If your study includes different cohorts, include the total number of subjects in each cohort.*
- *If this is multisite study, include total number of subjects across all sites.*

Aim 1 of the study plans to enroll n=158, an equal number of patients (n=79) from the control unit and from the intervention unit.

Aim 2 of the study plans to enroll all nursing and PES staff on the intervention unit (n=21) and nursing and nursing assistants on the control unit (n=26) who meet eligibility criteria.

9. STUDY TIMELINES

- *Describe the duration of an individuals participation in the study*
- *Describe the duration anticipated to enroll all study subjects*
- *The estimated date of study completion*

Participants in Aim 1 of our study will be enrolled for their entire stay in the control or intervention unit. They will be followed-up within 48 hours after

discharge for a phone interview. The duration anticipated to enroll study subjects for Aim 1 is 12 months.

Participants in Aim 2 of our study will be enrolled for 16 months. The duration anticipated to enroll study subjects for Aim 2 is 1 month.
The proposed length of the study period will be 2 years.

10. ENDPOINTS

- *Describe the primary and secondary study endpoints*
- *Describe any primary or secondary safety endpoints*

Aim 1: The primary endpoint of Aim 1 is the number, frequency, and severity of BPSD symptoms as assessed by repeated measures of the Neuropsychiatric Inventory-Questionnaire (NPI-Q) during a single acute hospital admission. Secondary endpoints will include length of stay, management practices of BPSD during stay on unit, and FCG satisfaction on discharge.

Aim 2: The primary endpoints will consist of whether:

1) Baseline nurses, patient engagement specialists (PES) and nurse assistant experience different with regard to caring for patients with dementia;
2) Training improves the experience of nurses, PES and nurse assistant staff; and
3) Nurses, PES and nurse assistant staff differ in the how they respond to dementia care training.

Secondary endpoints will include the interaction of the nurses, PES and nursing assistant demographics (age, sex, race, ethnicity, education, and work experience) position (nurses vs. PES vs. nurse assistant) and previous exposure to dementia training on the attitude and satisfaction of staff.

11. RESEARCH PROCEDURES

- *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
- *Include any screening procedures for eligibility and/or baseline diagnostic tests*
- *Include procedures being performed to monitor subjects for safety or minimize risks*
- *Include information about drug washout periods*
- *If drugs or biologics are being administered provide information on dosing and route of administration*
- *Clearly indicate which procedures are only being conducted for research purposes.*
- *If any specimens will be used for this research, explain whether they are being collected specifically for research purposes.*
- *Describe any source records that will be used to collect data about subjects*
- *Indicate the data to be collected, including long term follow-up*

Aim 1: Prior to patient recruitment, a 3 month dementia training program will be implemented on both the intervention and control units. On the intervention unit, training will target the PES and on the control to the nurse assistants. The 3 month dementia training program is based on the John A. Hartford Institute for Geriatric Nursing and the National Alzheimer Association publications Try This: Best Practices in Nursing Care for Persons with Dementia, ACT on Alzheimers guide to dementia friendly hospitals, and the Person-Centred Care Training Programme for Acute Hospitals (PCTAH), the research team will provide PES staff with weekly 20 minute sessions. The sessions will the following topics: types and impact of dementia, providing person-centered care, identification of and meeting peoples emotional and physical needs, effective communication, connecting to the FCG, the impact of the physical environment, and redefining and supporting behaviors staff may describe as challenging. In order to ensure all staff get the training, sessions will be repeated 3 times per week during change of shift. Once patient recruitment begins, the PI will hold monthly 20 minute group sessions, to reinforce training and discuss challenging patient behaviors.

Following the implementation of the dementia care training, eligible patients will be offered the opportunity to participate in the study. A waiver of consent will be obtained to pre-screen potential participants for age and history of dementia. For those eligible, the research coordinator/assistant (RC/RA) will contact the legally authorized representative (LAR) and FCG (who might be the same person) to provide study information and offer the opportunity to participate. If enrolled in person, written informed consent will be obtained in a private space and stored in a secure location. If enrolled via phone, verbal consent will be obtained and documented in REDCap and a copy of the consent will be mailed or emailed to the participant. If FCG participant expresses interest in the study, daily NPI-Q collection via staff and EMR will begin. Once a participant has been enrolled in the study, demographic information will be obtained from the EMR and verified by FCG, including: age, gender, race/ethnicity, marital status, education, work status, current living situation, medical comorbidities, and reason for admission. A member of the research team will conduct a short interview with the FCG to verify patient background information and obtain baseline (1 month prior to admission) functional status (Barthel Index), dementia severity cognitive (Clinical Dementia Rating Scale)(5 stages of severity: no 0, questionable 0.5, mild 1, moderate 2, and severe 3), and behavioral symptoms using the Neuropsychiatric Inventory Questionnaire (NPI-Q).

A member of the research team will then complete daily NPI-Qs to determine the number of behaviors and symptoms for each patient on a daily basis. The data collector will use a multi-modal approach drawing from electronic medical record (EMR) notes and interviews with nursing staff regarding the patients behavior and treatment over the past 24 hours (72 hours, if reviewing after a weekend). Delirium will be assessed daily by the RC using EMR keywords (e.g., forget, agitated), which will be used as a covariate. A final EMR chart review will be conducted

collection information such as length of stay, discharge disposition, in-hospital mortality as well as total usage practices for management of BPSD: use of special observation (1:1 or enhanced), restraints, psychoactive medications, psychiatric evaluation. Within 48 hours of discharge, family caregivers (FCG) will be interviewed regarding satisfaction with care using the Carer Questionnaire Data from the National Audit of Dementia Round 3.

Aim 2: Following recruitment into the study, participants will complete a short demographics survey. Participants will then complete the baseline (prior to training) surveys: Approaches to Dementia Questionnaire (ADQ) and Staff Experience of Working with Demented Residents Scale (SEWDR). The ADQ is a 19-item scale designed to evaluate staff attitudes to people with dementia and providing dementia care.[22, 31] The SEWDR is a 21-item scale measuring staff satisfaction in their experiences working with people with dementia as well as their work environment.[11] A five-point Likert scale is used for both surveys. The total score for the ADQ ranges from 19 to 95 and 21 to 105 for the SEWDR, with higher scores indicating a more positive attitude or greater satisfaction, respectively. The total score for the ADQ and SEWDR will serve as primary outcomes.
Providing care for persons with dementia in the hospital setting is considered standard of care. However, it is well known that hospitalized persons with dementia have worst outcomes compared to those without dementia. The dementia training that will be provided for the staff on the control and intervention units will consist of ways to optimize the care already being provided (e.g. better ways to communicate with persons with dementia, ways to avoid restraints). The training will consist of 7 in-service modules for dementia care. The PI and the research team will spend 3 months implementing the education and training program, which will consist of weekly 20 minute sessions. The training is meant to improve the care for persons with dementia by providing the staff education on dementia care. The training will not change/alter the care but simply optimize the care already being provided. The modules will be presented on both the intervention and control units to all nursing and NA/PES staff. The 7 modules will include: 1) overview of dementia and dementia care; 2) addressing unmet needs; 3) avoiding restraints; 4) communicating with persons with dementia; 5) delirium; 6) the impact of the physical environment; 7) connecting to the family caregiver. The dementia care training program is based on the John A. Hartford Institute for Geriatric Nursing and the National Alzheimer Association publications "Try This: Best Practices in Nursing Care for Persons with Dementia", ACT on Alzheimer's guide to dementia friendly hospitals, and the Person-Centred Care Training Programme for Acute Hospitals (PCTAH).
The in-service sessions will be given on all nursing shifts, therefore covering all staff. In order to ensure all nursing, nurse assistants, and PES staff get the training, sessions will be repeated 3 times per week during shift change. The training is being given to everyone on the unit, but the research only involves those that provide consent. The staff (nurses, NA and PES) that give consent will participate in Aim 2 (completing the survey at the 3 time points). Since all staff will get the in-service sessions on both the intervention and control units, this should not “muddy

the waters". The training should not be considered as altering the care. The care provided to persons with dementia remains the same (considered standard of care), the approach to getting that care will be optimized. Persons with dementia are frequently admitted to the hospital and cared for by NA/PES/nursing staff. The care provided will be the same, the training will simply enhance the care already provided. The hypothesis is that the personnel on the units that receive the training will have more confidence to provide this care.

12. STATISTICAL ANALYSIS

- *Describe how your data will be used to test the hypotheses.*
- *State clearly what variables will be tested and what statistical tests will be used.*
- *Include sample size calculations.*
- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

Aim 1: Analysis of covariance (ANCOVA) will be used to compare the primary outcome (mean NPI-Q total score) between intervention and control patients. Significance will be evaluated based on a two-sided test, with α=.05. To control for potential confounding, the model will include a set of covariates selected a priori (patient age, gender, race/ethnicity, marital status, CCI, LOS, days of delirium, dementia severity, baseline NPI-Q score for the month prior to hospital admission, and NPI-Q score from ED to arrival on the unit). Based on a two-sample t-test and a type I error rate of .05, a sample size of 63 patients per group will provide at least 80% power to detect a difference of 3 units in mean NPI-Q score, assuming the outcome has a sd of 6.0. A mean difference of 3 has been shown to be clinically significant. It has been shown that ANCOVA comparing groups of (1-R2) ·n subjects has the same power as a t-test comparing n subjects, where R2 equals the multiple correlation between the selected covariates and the outcome variable (R2 ranges from 0-1). We will enroll 79 patients per group (158 total) in order to account for 20% attrition. Differences in the intervention effect across patient subgroups will be assessed individually by testing the significance of the interaction between the intervention and the subgroup variable of interest in separate multiple linear regression models. We will assess whether sex, race, age, delirium days, and dementia severity modify the intervention effect for the primary NPI-Q score.

As a secondary analysis, we will compare intervention and control patients on the mean number of NPI-Q behaviors (range 0-12) occurring during hospitalization using Poisson regression. Secondary BPSD management outcomes (i.e. use of restraints, CO, etc.) will be treated as binary (yes/no) variables and compared between intervention and control patients using logistic regression. Differences in LOS will be assessed based on a Cox proportional hazards regression model. Poisson regression will be employed to assess differences in the mean number of delirium days. Regression models for secondary outcomes will be adjusted for the covariates described previously. The difference in the proportion of intervention and control patients treated with antipsychotics will be assessed with a chi-square

test. Differences in FCG satisfaction between intervention and control will be assessed based on responses to question 8 of the National Audit of Dementia Carer questionnaire ("Overall, how would you rate the care received by the person you look after during the hospital stay?"). Patient responses (excellent, very good, good, fair, and poor) will be compared using the Mann-Whitney U test. Lastly, we will report study feasibility measures that will be used to inform the planning of a future multi-site trial of the PES-4-BPSD intervention, namely: 1) number/percent of intervention and control unit patients meeting study eligibility criteria; 2) recruitment rate; 3) attrition rate 4) mean and standard deviation of the primary outcome (NPI-Q total score).

Aim 2: We will provide descriptive statistics to summarize the demographic characteristics of nurses, PES and nursing assistants. For each measurement scale, we will perform a two-factor mixed ANOVA where ADQ/SEWDR score is the within subject factor having 3 levels (T1, T2, T3), and group is the between subject factor having 3 levels (nurses, PES, nurse assistant). We will assess the significance of the interaction between the two factors in order to determine whether nurses, PES and nurse assistant staff differ in their change in ADQ/SEWDR scores across the 3 time points. Post hoc tests will be used to compare scores between nurses, PES and nurse assistants at T1, and to assess whether the scores of each group differ across the 3 time points.

13. SPECIMEN BANKING

- *If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens*
- *List the information that will be stored with each specimen, including how specimens are labeled/coded*
- *Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.*

N/A

14. DATA MANAGEMENT AND CONFIDENTIALITY

- *Describe the data and specimens to be sent out or received. As applicable, describe:*
  - *What information will be included in that data or associated with the specimens?*
  - *Where and how data and specimens will be stored?*
  - *How long the data will be stored?*
  - *Who will have access to the data?*
  - *Who is responsible for receipt or transmission of data and specimens?*
- *Describe the steps that will be taken to secure the data during storage, use and transmission.*

The principal investigator (Dr. Liron Sinvani), co-investigator (Dr. Marie Boltz), and research team will be responsible for maintaining our data and maintaining security. We will use standard IRB-approved and HIPAA-compliant measures to maintain confidentiality, privacy and data security. Data privacy and security procedures will include: (1) training staff on data sensitivity and protocols for safeguarding confidentiality, (2) storing and processing sensitive hardcopy in a secured, centralized location, (3) securing sensitive hardcopies in locked files when not in use, (4) removing names, addresses, and other direct identifiers from hardcopy and computer-readable data when they are no longer necessary for patient tracking and then using encrypted codes for subsequent identification of participants, (5) destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been completed, (6) capturing and storing follow-up assessments in REDCap, a secure web-based HIPAA compliant application designed to support data capture for research studies, and (7) using restricted logon identification and password protection computer protocols for all computerized entry, retrieval, and analysis. We have developed a clear and concise privacy and security plan. Northwell is well suited to develop such a plan as we are currently engaging in similar health technology projects that secure the electronic submittal of health information from patient to health system.

15. DATA AND SAFETY MONITORING PLAN

A specific data and safety monitoring plan is only required for greater than minimal risk research. For guidance on creating this plan, please see the Guidance Document *on the HRPP website.*

Part I – this part should be completed for all studies that require a DSMP.
Part II – This part should be completed when your study needs a Data and Safety Monitoring Board or Committee (DSMB/C) as part of your Data and Safety Monitoring Plan.

Part I: Elements of the Data and Safety Monitoring Plan

- *Indicate who will perform the data and safety monitoring for this study.*
- *Justify your choice of monitor, in terms of assessed risk to the research subject's health and well being. In studies where the monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and rationale for selection*
- *List the specific items that will be monitored for safety (e.g. adverse events, protocol compliance, etc)*
- *Indicate the frequency at which accumulated safety and data information (items listed in # above) will be reviewed by the monitor (s) or the DSMB/C.*
- *Where applicable, describe rules which will guide interruption or alteration of the study design.*
- *Where applicable, indicate dose selection procedures that will be used to minimize toxicity.*
- *Should a temporary or permanent suspension of your study occur, in addition to the IRB, indicate to whom will you report the occurrence.*

The proposed project is a low-risk study. The study team will review the data on a weekly basis. The work will be conducted with approval from the Human Research Protection Program (HRPP).

As per Northwell Health HRPP policies, the PI is required to notify the HRPP promptly of any unanticipated problems involving risks to subjects or others that might occur. The PI will monitor the progress of the study and safety of participants on an ongoing basis. The procedures of this study, such as regular meetings with research staff, will ensure discussion and reporting of all possible outcomes including any, though unlikely, adverse events. If the adverse event is due to the study and is unexpected, the PI will draft a safety report and send a copy to the HRPP. The HRPP committee will serve as an objective review mechanism. This policy/procedure means that any potential conflict of interest inherent in the PI being the sole reviewers of serious adverse advents is avoided.

Plans for assuring adherence with requirements regarding the reporting of adverse events (AEs). All serious AEs (e.g., medical occurrences resulting in death) that occur during the study defined by the given protocol, regardless of the relation to the research, must be reported to the HRPP by telephone, e-mail, or fax within 24 hours of the investigator's awareness of the occurrence of the event. The PI will report SAEs to the HRPP and will disseminate information to other agencies as necessary. These initial reports are followed by a safety report which is a written account of the serious AE determined by a sponsor/investigator to be both related to the treatment under investigation and to be unexpected in nature. Serious AEs will be summarized annually in the HRPP application for continuation or termination of research. All expected non-serious AEs that occur at a greater frequency or severity than anticipated and all unexpected non-serious AEs will be reported to the HRPP within 15 working days of the investigators becoming aware of the event. These AEs are also summarized annually in the HRPP application for continuation or termination of the research.

Part II: Data and Safety Monitoring Board or Committee

- *When appropriate, attach a description of the DSMB.*
- *Provide the number of members and area of professional expertise.*
- *Provide confirmation that the members of the board are all independent of the study.*

We plan to use a Safety Monitoring Committee (SMC) for this study. A SMC will be created to provide oversight and monitoring to ensure the safety of participants and the integrity of the data. Upon review and approval by the National Institute on Nursing Research (NINR) Program Official (PO), we plan the SMC to be chaired by a researcher (Renee Pekmezaris, PhD) who has extensive expertise in data safety and monitoring, clinical trials, and dementia caregiving research including bioethical considerations. The additional members of the DMSB will include a biostatisticians (Cristina Sison, PhD) who has experience on a SMC, a geriatrician (Gisele Wolf-Klein, MD) with extensive experience in care of older adults with dementia and a senior administrative manager for research (Tiffany Harvin, MBA).

Given their clinical and research expertise, Drs. Pekmezaris and Wolf-Klein will be responsible for monitoring for adverse events and their potential relationship to the intervention. Dr. Sison and Ms. Harvin will ensure data security and privacy protections. Ms. Harvin will also be responsible for submitting necessary reports to the PI and if needed to IRB as well as NINR staff. The PI will be responsible for compliance with the SMC plan. The SMC will convene prior to the enrollment of subjects and then quarterly for the duration of the study. The group will meet prior to subject recruitment and then every 6 months for the duration of the study via web conferencing. Telephone conferencing and email may be used for additional interactions as needed. At the end of each meeting the committee will make recommendations to NIH, institutional review board(s) and the PI and investigative team concerning continuation or conclusion of the trial.

16. WITHDRAWAL OF SUBJECTS

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent*
- *Describe procedures for orderly termination*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

Subjects will not be withdrawn from the study (both Aim 1 and Aim 2) without their consent.
Aim 1: Patients do not have ability to remove themselves from the intervention unit, but can choose to not participate in the study and withdraw from the study at any point, even following discharge from the hospital. If they do opt out, the treatment will not be altered in any way. On the control unit, patients and FCGs still benefit for dementia care training for nurse assistant staff. While patients and FCGs cannot remove themselves from the unit, they can decline to participate in the study and can withdraw at any point, even after discharge.
Aim 2: While nurses, PES and NA personnel cannot remove themselves from the intervention or control units, they can choose not to participate in the study and can withdraw at any point throughout the entire study. This will not alter their job in any way. If a nurse, PES or NA choose from withdraw from the study, data on the patients they are caring for may still be collected. This should not interfere with their job in any way.

17. RISKS TO SUBJECTS

- *Describe any potential risks and discomforts to the subject (physical, psychological, social, legal, or other) and assess their likelihood and seriousness and whether side effects are reversible. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*
- *Include risks to others , like sexual partners (if appropriate)*

- *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to results*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

Aim 1: Risks to subjects
The primary potential risk of participating in this study is breach of confidentiality. Northwell Health and the research team will take all possible steps to ensure the security of the collected information. Inclusion in the intervention unit does not qualify as more than minimal risk because all standard of care practices are still present on the unit; the implementation of the intervention only adds an additional layer of trained healthcare professionals whose presence has been shown to be beneficial. Patients do not have ability to remove themselves from the intervention unit, but can choose to not participate in the study and withdraw from the study at any point, even following discharge from the hospital. If they do opt out, the treatment will not be altered in any way. On the control unit, patients and FCGs still benefit for dementia care training for nurse assistant staff. While patients and FCGs cannot remove themselves from the unit, they can decline to participate in the study and can withdraw at any point, even after discharge. If the RC observes concerning behavior, she will alert the nurse or another staff member immediately. If the RC is called by the patient, the RC will alert the unit staff. The RC will have direct telephone numbers to Dr. Sinvani (PI) and Dr. Warner-Cohen (clinical psychologist) and can contact them at any time.
Aim 1 Protections against Risk We do not expect any adverse events directly attributable to the presence of the PES-4-BPSD intervention on the unit or with the dementia care training for nurse assistant staff on the control unit.

The primary risk of this study is loss of confidentiality. The researchers take the issue of confidentiality very seriously. IRB-approved and HIPAA compliant measures will be used to maintain patient confidentiality, privacy and data security. Extensive efforts will be undertaken to maintain study participants' confidentiality and privacy. All study materials will be stored in locked file cabinets to which only study personnel will have access.

Northwell Health has policies and procedure in place to protect ePHI with reasonable administrative, technical, and physical safeguards to ensure the confidentiality, integrity and availability of the PHI and to prevent unauthorized and inappropriate access, use or disclosure of the data. Along with the organizational administrative, technical and physical safeguards and IRB approved measures, data privacy, security and confidentiality activities will include but not limited to -
Training staff on data sensitivity and protocols for safeguarding confidentiality;
Storing and processing sensitive hardcopy in a secured, centralized location;
Securing sensitive hardcopies in locked files when not in use; which only study personnel will have access.

Removing names, addresses, and other direct identifiers from hardcopy and computer-readable data when they are no longer necessary for patient tracking and then using encrypted codes for subsequent identification of participants;
Destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been completed (Disposal Policy for Protected Health and Confidential Health System Information – policy no 800.47); and
Using restricted logon identification and password protection computer protocols for all computerized entry, retrieval, and analysis.

Additionally, all personnel will be instructed in the ethics of electronic data access. All database servers are housed in Northwell Health's secure data center and are subject to institutional policies on security, backup, recovery and control. Passwords for data files are managed in accordance with institutional policies.

Aim 2: Risks to subjects
The primary risk to the nursing staff, PES staff and nurse assistant staff participating in the study is a breach in confidentiality. However, to protect subjects' privacy all data will be de-identified and stored on HIPPA compliant drives or applications such as REDCap.

There is a risk of a negative impact on mood, anxiety levels, and emotions of participants due to the increased stress of being asked to evaluate their own care abilities and experiences. To address this, the PI and an on-site clinical psychologist (Dr. Jessy Warner-Cohen) will be available to provide staff support. The training and support provided to both groups (nurses, PES and nurse assistants) is anticipated to increase staff self-efficacy and experience in caring for patients with dementia.

Aim 2 Protections Against Risk
The researchers take the issue of confidentiality very seriously. IRB-approved and HIPAA compliant measures will be used to maintain patient confidentiality, privacy and data security. Extensive efforts will be undertaken to maintain study participants' confidentiality and privacy. All study materials will be stored electronically and in locked file cabinets to which only study personnel will have access.

Northwell Health has policies and procedure in place to protect ePHI with reasonable administrative, technical, and physical safeguards to ensure the confidentiality, integrity and availability of the PHI and to prevent unauthorized and inappropriate access, use or disclosure of the data. Along with the organizational administrative, technical and physical safeguards and IRB approved measures, data privacy, security and confidentiality activities will include but not limited to -

Training staff on data sensitivity and protocols for safeguarding confidentiality;
Storing and processing sensitive hardcopy in a secured, centralized location;
Securing sensitive hardcopies in locked files when not in use; which only study

personnel will have access.
Removing names, addresses, and other direct identifiers from hardcopy and computer-readable data when they are no longer necessary for patient tracking and then using encrypted codes for subsequent identification of participants;
Destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been completed (Disposal Policy for Protected Health and Confidential Health System Information – policy no 800.47); and
Using restricted logon identification and password protection computer protocols for all computerized entry, retrieval, and analysis.

Additionally, all personnel will be instructed in the ethics of electronic data access. All database servers are housed in Northwell Health's secure data center and are subject to institutional policies on security, backup, recovery and control. Passwords for data files are managed in accordance with institutional policies.

18. RESEARCH RELATED HARM/INJURY

- *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated problems that may be known to be associated with the research.*
- *If the research is greater than minimal risk, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

We do not expect any adverse events directly attributable to the presence of the PES-4-BPSD intervention on the unit or with the dementia care training for nurse assistant staff on the control unit.

The PI and an on-site clinical psychologist (Dr. Jessy Warner-Cohen) will be available to provide psychological resources to Aim 2 participants due to the risk of a negative impact on mood, anxiety levels, and emotions of participants due to the increased stress of being asked to evaluate their own care abilities and experiences.

While we do not anticipate any adverse events, in the case of a study-related adverse event, in accordance with Northwell Health guidelines, this protocol will employ the following mechanisms for adverse event reporting: 1) alert IRB of any and all reports of adverse events; 2) inform all members of the study team of any and all reports of adverse events. If three or more adverse events are reported, the study team will assess potential causes of the adverse events and, if events are clearly linked to study participation, discontinue the study.

19. POTENTIAL BENEFIT TO SUBJECTS

- *Explain what benefits might be derived from participation in the study, noting in particular the benefit over standard treatment (e.g. a once-a-day administration instead of four times a day, an oral formulation over an IV administration).*
- *Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained*

Aim 1:
The presence of PES personnel on the intervention unit has been shown to be beneficial to patient care in a prior study.[16] For the control unit, dementia care training has not been associated with any harm to patients, FCGs, or HCGs and can potentially improve care.

Aim 2:
Nurses, PES and nurse assistants who choose to participate in this study will benefit from training that is directly relevant to their employment. The implementation of this model aims to improve the experience of HCGs in caring for hospitalized persons with dementia – by improving their knowledge of dementia as well as tools to better engage persons with dementia. Patients on the intervention unit will benefit from the presence of staff that have been specifically trained in the management of BPSD and the care of patients with ADRD.

20. PROVISIONS TO PROTECT PRIVACY INTERESTS OF SUBJECTS

- *Describe the methods used to identify potential research subjects, obtain consent and gather information about subjects to ensure that their privacy is not invaded.*
- *In addition consider privacy protections that may be needed due to communications with subjects (such as phone messages or mail).*

Aim 1:
A waiver of consent will be obtained to pre-screen potential participants for age and history of dementia or nurse report of confusion. Patients will be identified as being potential participants through either the electronic records system or nurse report. No PHI will be shared; all information will only be linked to a unique number that cannot be traced back to the participant. For those eligible, the research coordinator (RC) will contact the legally authorized representative (LAR) and FCG (who might be the same person) to provide study information and offer the opportunity to participate. Patient information will be password protected and kept on a PHI protected file on the health system's server. This database is password protected and HIPAA compliant. All hard copies of documents (such as the original consents) will be kept in a locked cabinet that only the Northwell Health research staff will be able to access.

Aim 2: All nurses on the control and intervention units as well as nursing assistants on the control unit and PES personnel on the intervention unit will be eligible to participate in the study. Potential participants will be informed of the study.

Consent for both aims will be obtained in a private space.

21. COSTS TO SUBJECTS

- *Describe any foreseeable costs that subjects may incur through participation in the research*
- *Indicate whether research procedures will be billed to insurance or paid for by the research study.*

n/a

22. PAYMENT TO SUBJECTS

- *Describe the amount of payment to subjects, in what form payment will be received and the timing of the payments.*

FCG participants will be compensated a total of $30 for their participation ($20 at enrollment, $10 upon complete of the discharge follow-up) via ClinCard which will be given directly if interviewed in person or sent via mail if interviewed remotely.

Reimbursements of $25 will be offered to participants of Aim 2 over three installments (total $75) corresponding to the completion of the two surveys at the three time points (baseline, after training, and at end of intervention.

23. CONSENT PROCESS

If obtaining consent for this study, describe:

- *Who will be obtaining consent*
- *Where consent will be obtained*
- *Any waiting period available between informing the prospective participant and obtaining consent*
- *Steps that will be taken to assure the participants' understanding*
- *Any tools that will be utilized during the consent process*
- *Information about how the consent will be documented in writing. If using a standard consent form, indicate such.*
- *Procedures for maintaining informed consent.*

Aim 1:
A waiver of consent will be obtained to pre-screen potential participants for age and history of dementia or nurse report of confusion. For those eligible, the research coordinator (RC) will contact the legally authorized representative (LAR) and FCG (who might be the same person) to provide study information and offer the opportunity to participate. If the LAR is not present, the EMR will be reviewed for contact information to speak with the LAR via phone. The research team member will offer the participant's LAR a study packet in person or electronically via email link to REDCap (study information, a copy of the consent form, research team contact numbers), explain all aspects of the study, and state that participation of the study is voluntary, that the participant or his or her legal representative may opt out at any time, and that the decision to decline to participate or to opt out will not affect the patient's treatment. If FCG participant expresses interest in the study, daily NPI-Q collection via staff and EMR will begin. If enrolled in person, written informed consent will be obtained in a private space and stored in a secure location. If enrolled via phone, verbal consent will be obtained and documented in REDCap and a copy of the consent will be mailed or emailed to the participant. FCGs, who may or may not be the same person as the LAR, will be consented in the same manner. Once consented, the Research Coordinator/Research Assistant will proceed with research surveys. In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify the subject. All data included in the publication will be de-identified.

Aim 2: The consenting investigator will directly approach eligible staff nurses on both units, nursing assistants on the control unit and PES personnel on the intervention unit, to participate in the study. Potential participants will be informed of the study. The investigator will emphasize that the study is voluntary, that the participant has the right to opt out of the study at any point without repercussion, and that the decision to decline to participate or to opt out of the study will not in any way affect their employment. Consent will be requested by a member of the research team trained in Northwell Health's consent procedures. The RC will be someone who could not be interpreted to be in a position of power or influence over the participant

In the state of NY, any participants under the age of 18 are considered children. If your study involves children, additional information should be provided to describe:

- *How parental permission will be obtained*
- *From how many parents will parental permission be obtained*
- *Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided*
- *Whether or not assent will be obtained from the child*
- *How will assent be documented*

- *Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects.*

n/a

If the study involves cognitively impaired adults, additional information should be provided to describe:

- *The process to determine whether an individual is capable of consent*
- *Indicate who will make this assessment*
- *The plan should indicate that documentation of the determination and assessment will be placed in the medical record, when applicable, in addition to the research record.*
- *If permission of a legally authorized representative will be obtained,*
  - *list the individuals from who permission will be obtained in order of priority*
  - *Describe the process for assent of subjects; indicate whether assent will be required of all, some or none of the subjects. If some, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, provide an explanation as to why not*
  - *Describe whether assent will be documented and the process to document assent*
  - *Indicate if the subject could regain capacity and at what point you would obtain their consent for continued participation in the study*

The Comprehension Assessment Form was initially being used to determine whether an individual was capable of consenting to participate in the study; however, due to the requirement for documented history of dementia and the severe nature of the illness, patients are unable to understand and give consent. Therefore, it would be least disruptive to the patient to forgo the Comprehension Assessment Form and for the RC to go directly to the LAR to present study information and obtain consent. All patient observations are obtained through family caregiver, hospital caregivers, and electronic medical records as to not disrupt the patient.

If the study will enroll non-English speaking subjects:

- *Indicate what language(s) other than English are understood by prospective subjects or representatives*
- *Indicate whether or not consent forms will be translated into a language other than English*

- *Describe the process to ensure that the oral and written information provided to those subjects will be in that language*
- *If non-English speaking subjects will be excluded, provide a justification for doing so*

na

24. WAIVER OR ALTERATION OF THE CONSENT PROCESS ☐ N/A

Complete this section if you are seeking an alteration or complete waiver of the consent process.

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to the subject:*
- *Explain why the waiver/ alteration will not adversely affect the rights and welfare of subjects*
- *Explain why it is impracticable to conduct this research if informed consent is required*
- *Explain why it is not possible to conduct this research without using the information or biospecimens in an identifiable form*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

We are seeking a waiver of consent to pre-screen potential participants for age and history of dementia; patients will be identified as being potential participants through the electronic records system. Once potential participants have been identified and express interest in the study, daily NPI-Q collection via staff and EMR will begin. If enrolled in person, written informed consent will be obtained in a private space or through REDCap (if contacted via phone) and stored in a secure location. If enrolled via phone, verbal consent will be obtained and documented in REDCap and a copy of the consent will be mailed or emailed to the participant. FCGs, who may or may not be the same person as the LAR, will be consented in the same manner In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify the subject. All data included in the publication will be de-identified.

Complete this section if you are obtaining informed consent but you are requesting a waiver of the documentation of consent (i.e., verbal consent will be obtained). *To proceed with a waiver based on these criteria, each subject must be asked whether they wish to have documentation linking them to this study.* ***Only complete subsection 1 OR subsection 2.***

SUBSECTION 1

- *Explain how the only record linking the subject to the research would be the consent document.*

- *Explain how the principal risk of this study would be the potential harm resulting from a breach in the confidentiality*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

N/A

SUBSECTION 2

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk.*
- *Confirm that the research only involves procedure for which consent is not normally required outside the research context.*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

We do not anticipate any risk of harm to the subjects. The study involves no more than minimal risk because all standard of care practices are still present on the unit; the implementation of the intervention unit only adds an additional layer of trained healthcare professionals whose presence has been shown to be beneficial. The primary risk of this study is loss of confidentiality. The researchers take the issue of confidentiality very seriously. IRB-approved and HIPAA compliant measures will be used to maintain patient confidentiality, privacy and data security. Extensive efforts will be undertaken to maintain study participants' confidentiality and privacy. REDCap will be used to store data.

.

25. WAIVER OF HIPAA AUTHORIZATION ☐ N/A

Complete this section if you seek to obtain a full waiver of HIPAA authorization to use and/or disclose protected health information.

- *Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:*
- *Describe your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time.*
- *Indicate why it is not possible to seek subjects' authorization for use or disclosure of PHI.*
- *Indicate why it is not possible to conduct this research without use or disclosure of the PHI.*
- *Indicate if PHI will be disclosed outside NSLIJ Health System, and if so, to whom. Note: PHI disclosed outside NSLIJ Health System, without HIPAA authorization needs to be tracked. Please see guidance at www.nslij.com/irb for information about tracking disclosures.*

N/A

Complete this section if you seek to obtain a partial waiver of the patient's authorization for screening/recruitment purposes *(i.e., the researcher does not have access to patient records as s/he is not part of the covered entity)*

Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.

- *Describe how data will be collected and used:*
- *Indicate why you need the PHI (e.g.PHI is required to determine eligibility, identifiers are necessary to contact the individual to discuss participation, other)*
- *Indicate why the research cannot practicably be conducted without the partial waiver (e.g. no access to medical records or contact information of the targeted population, no treating clinician to assist in recruitment of the study population, other)*

Data will be collected from electronic health records. PHI is needed to determine eligibility of potential subjects, identifiers are necessary to contact the individual to discuss participation in the study.

26. VULNERABLE POPULATIONS:

Indicate whether you will include any of these vulnerable populations. If indicated, submit the appropriate appendix to the IRB for review:

- ☐ *Children or viable neonate*
- ☒ *Cognitively impaired*
- ☐ *Pregnant Women, Fetuses or neonates of uncertain viability or nonviable*
- ☐ *Prisoners*
- ☒ *NSLIJ Employees, residents, fellows, etc*
- ☐ *poor/uninsured*
- ☐ *Students*
- ☐ *Minorities*
- ☒ *Elderly*
- ☐ *Healthy Controls*

If any of these populations are included in the study, describe additional safeguards that will be used to protect their rights and welfare.

Informed consent will be obtained from the LAR/FCG of all patients participating in the study prior to any information gathering (except for 4 pre-screening items). Patients will be identified as being potential participants through the EMR (based on age and history of dementia). The research coordinator, trained in Northwell Health's consent procedures will approach the LAR and FCG on the medical unit (or contact them via phone, if unavailable in person during research hours). The person obtaining consent will discuss the study with the patient's legal representative to obtain consent. If the LAR is not present, the EMR will be reviewed for contact information to speak with

the LAR via phone. The research team member will offer the participant's legally authorized representative (LAR) a study packet (study information, a copy of the consent form, research team contact numbers), explain all aspects of the study, and state that participation of the study is voluntary, that the participant or his or her legal representative may opt out at any time, and that the decision to decline to participate or to opt out will not affect the patient's treatment. If enrolled in person, written informed consent will be obtained in a private space and stored in a secure location. If enrolled via phone, verbal consent will be obtained and documented in REDCap and a copy of the consent will be mailed or emailed to the participant. FCGs, who may or may not be the same person as the LAR, will be consented in the same manner.

While an individual with dementia is at increased risk of hospital acquired complications such as delirium and functional decline, the intervention and control units do not pose an increased risk. Inclusion in the intervention and control units does not qualify as more than minimal risk because all standard of care practices are still present on the unit; the implementation of the intervention unit only adds an additional layer of trained healthcare professionals whose presence has been shown to be beneficial. Patients do not have ability to remove themselves from the intervention unit, but can choose to not participate in the study and withdraw from the study at any point, even following discharge from the hospital. If they do opt out, the treatment will not be altered in any way. On the control unit, patients and FCGs still benefit from dementia care training for nurse assistant staff. While patients and FCGs cannot remove themselves from the unit, they can decline to participate in the study and can withdraw at any point, even after discharge. If the RC observes concerning behavior, he will alert the nurse or another staff member immediately. If the RC is called by the patient, the RC will alert the unit staff. The RC will have direct telephone numbers to Dr. Sinvani (PI) and Dr. Warner-Cohen (clinical psychologist) and can contact them at any time.

We do not expect any adverse events directly attributable to the presence of the PES-4-BPSD intervention on the unit or with the dementia care training for nurse assistant staff on the control unit. While the RC will be on the intervention and control units to collect NPI-Q information, they will not have any direct interactions with the patients. If the RC observes concerning behavior, she will alert the nurse or another staff member immediately. If the RC is called by the patient, the RC will alert the unit staff. The RC will have direct telephone numbers to Dr. Sinvani (PI) and Dr. Warner-Cohen (clinical psychologist) and can contact them at any time. The PI plans to hold weekly meetings with the PES and nursing assistants to conduct patient reviews to support treatment fidelity and safety.

The primary risk of this study is loss of confidentiality. The researchers take the issue of confidentiality very seriously. IRB-approved and HIPAA compliant measures will be used to maintain patient confidentiality, privacy and data security. Extensive efforts will be undertaken to maintain study participants' confidentiality and privacy. Only study team members that are on the Institutional Review Board (IRB) approved protocol will have access to the data that will be saved on a secured Northwell Health

drive. Individuals will be provided with a simple and timely means to access the collected data. They will meet the minimum and mandatory requirement to access the identifiable information as per the standards set by Northwell Health. Access and use of the data will be strictly monitored by the Principal Investigator (PI) and the research team. Northwell Health's Administrative Policy and Procedure Manual policy number 800.42 titled Confidentiality of Protected Health Information particularly addresses the access and use of the electronic protected health information (ePHI). The purpose of this policy is to establish the general requirements for protecting the confidentiality of protected health information (PHI) while allowing the use, access and disclosure for the purpose of providing high quality care at Northwell Health. PHI is any oral, written or electronic individually identifiable health information collected or stored by a facility. PHI includes also any demographic information and any information that relates to past, present or future physical or mental condition of an individual.

Northwell Health has policies and procedure in place to protect ePHI with reasonable administrative, technical, and physical safeguards to ensure the confidentiality, integrity and availability of the PHI and to prevent unauthorized and inappropriate access, use or disclosure of the data. Along with the organizational administrative, technical and physical safeguards and IRB approved measures, data privacy, security and confidentiality activities will include but not limited to -

1. Training staff on data sensitivity and protocols for safeguarding confidentiality;
2. Storing and processing sensitive hardcopy in a secured, centralized location;
3. Securing sensitive hardcopies in locked files when not in use; which only study personnel will have access.
4. Removing names, addresses, and other direct identifiers from hardcopy and computer-readable data when they are no longer necessary for patient tracking and then using encrypted codes for subsequent identification of participants;
5. Destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been completed (Disposal Policy for Protected Health and Confidential Health System Information – policy no 800.47); and
6. Using restricted logon identification and password protection computer protocols for all computerized entry, retrieval, and analysis.

Additionally, all personnel will be instructed in the ethics of electronic data access. Everything will follow the strict Health care Information and Technology – Privacy and Security rules, regulations, policies and procedures, and protocols established at Northwell Health based on the industry standards. Application and data access will be controlled by appropriate authentication and authorization measures. It is the policy of the health system to use encryption safeguards on Sensitive and Highly Sensitive data as defined in the Data Classification Policy (900.12), such as ePHI, to ensure data authenticity and integrity where reasonable and appropriate, and in accordance with applicable laws and regulations.

The purpose of the Data Encryption and Integrity Policy (900.25) from the administrative policy and procedure manual is to state what cryptographic techniques are acceptable and how cryptography will be used at Northwell Health.

Facility Access Controls Policy (100.99) identifies the security plan to safeguard its facilities from unauthorized physical access and to safeguard the equipment from unauthorized physical access, tampering, and theft while ensuring that environmental safeguards are in place to protect the confidentiality, access and integrity of protected health information as commensurate with data criticality and risk assessment. This is to ensure and prevent from unauthorized physical access and to safeguard the equipment and business documents including, but not limited to, clinical and business documents from unauthorized physical access, tampering and theft.

We will establish and ensure that appropriate limits on the type and amount of information collected, used, and/or disclosed are in place. This will increase privacy protections and is essential to building trust in electronic exchange of individually identifiable health information because it minimizes potential misuse and abuse. Northwell Health's Information System Review and Audit Controls Policy (900.27) will allow us to maintain a comprehensive internal security control and audit program, and established procedures and record keeping activities to ensure proper legal, ethical and business practices. This will complement the user authentication process and acts as a deterrent to internal abuse by making users aware that audit trails, access reports, and security incident tracking reports are produced, reviewed and, where applicable, investigated. These internal security controls may take various forms including regular information system activity review. These reviews incorporate logon monitoring, audit trails and logs, access reports, and manually produced security incident tracking reports for network and ePHI systems.

It is the policy of health system to have departmental procedures (e.g. human resource, corporate security and information services) to grant, modify and revoke access, permissions and rights to health system networks, systems, applications, facilities and physical locations to staff based on their roles and responsibilities.

We plan to use a Safety Monitoring Committee (SMC) for this study. A SMC will be created to provide oversight and monitoring to ensure the safety of participants and the integrity of the data. Upon review and approval by the National Institute on Nursing Research (NINR) Program Official (PO), we plan the SMC to be chaired by a researcher (Renee Pekmezaris, PhD) who has extensive expertise in data safety and monitoring, clinical trials, and dementia caregiving research including bioethical considerations. The additional members of the DMSB will include a biostatisticians (Cristina Sison, PhD) who has experience on a SMC, a geriatrician (Gisele Wolf-Klein, MD) with extensive experience in care of older adults with dementia and a senior administrative manager for research (Tiffany Harvin, MBA). Given their clinical and research expertise, Drs. Pekmezaris and Wolf-Klein will be responsible for monitoring for adverse events and their potential relationship to the intervention. Dr. Sison and Ms. Harvin will ensure data security and privacy protections. Ms. Harvin will also be responsible for submitting necessary reports to the PI and if needed to IRB as well as NINR staff. The PI will be responsible for compliance with the SMC plan. The SMC will convene prior to the enrollment of subjects and then quarterly for the duration of

the study. The group will meet prior to subject recruitment and then every 6 months for the duration of the study via web conferencing. Telephone conferencing and email may be used for additional interactions as needed. At the end of each meeting the committee will make recommendations to NIH, institutional review board(s) and the PI and investigative team concerning continuation or conclusion of the trial.

The group will meet at least annually via web conferencing. Telephone conferencing and email may be used for additional interactions as needed. The first meeting of the SMC will be prior to recruitment of participants and will focus on review of the study protocol and recruitment plan, consideration of participant burden, and a review of our plan for participant safety and comfort. The subsequent meetings will focus on the progress of the study with regard to data quality and timeliness, participant consent, accrual and retention of participants, participant risk versus benefit, performance of intervention units, and any adverse events that occur during the course of the study to date. One or more major adverse events will also trigger a SMC meeting. At the end of each meeting the committee will make recommendations to NIH, institutional review board(s) and the PI and investigative team concerning continuation or conclusion of the trial.

Vulnerable Subjects
The study will consider long-term care residents as eligible for the study. For nursing home patients who are eligible for study, the RC will present study information to the patient's LAR and family caregiver. Participation in the study is voluntary and patients/caregiver may decline. Given the prevalence of dementia in the nursing home setting, it will be important to include this patient population.

All subject information will be kept confidential and only shared with the research staff. All Northwell Health employees will be assured that there will be no consequences to their job status should they chose to participate or not to participate in this study. In addition, no one in a supervisory position over an employee will be involved in obtaining consent. No one with authority in, or affiliation to, the control and intervention units will have access to identifiable data.

27. MULTI-SITE HUMAN RESEARCH (COORDINATING CENTER)

If this is a multi-site study where you are the lead investigator, describe the management of information (e.g. results, new information, unanticipated problems involving risks to subjects or others, or protocol modifications) among sites to protect subjects.

N/A

28. REFERENCES/BIBIOGRAPHY

Provide a reasonable list of references directly related to the study. Any diagrams for new medical devices or brief reprints from journals might also prove useful.

References

1. Phelan EA, Borson S, Grothaus L, Balch S, Larson EB. Association of incident dementia with hospitalizations. Jama. 2012;307(2):165–172. PMID:22235087 PMCID: PMC3312921 DOI: 10.1001/jama.2011.1964

2. Feng Z, Coots LA, Kaganova Y, Wiener JM. Hospital and ED use among Medicare beneficiaries with dementia varies by setting and proximity to death. Health Aff (Millwood). 2014;33(4):683–690. PMID:24711331 DOI: 10.1377/hlthaff.2013.1179

3. Alzheimer's Association. 2017 Alzheimer's disease facts and figures. Alzheimers Dement. 2017;13(4):325–373.

4. Stern Y, Tang M-X, Albert MS, Brandt J, Jacobs DM, Bell K, et al. Predicting time to nursing home care and death in individuals with Alzheimer disease. Jama. 1997;277(10):806–812. PMID:9052710

5. Andrieu S, Reynish E, Nourhashemi F, Shakespeare A, Moulias S, Ousset PJ, et al. Predictive factors of acute hospitalization in 134 patients with Alzheimer's disease: a one year prospective study. Int J Geriatr Psychiatry. 2002;17(5):422–426. PMID:11994930 DOI:10.1002/gps.624

6. Wancata J, Windhaber J, Krautgartner M, Alexandrowicz R. The consequences of non-cognitive symptoms of dementia in medical hospital departments. Int J Psychiatry Med. 2003;33(3):257–271. PMID:15089007 DOI:10.2190/ABXK-FMWG-98YP-D1CU.

7. Fick DM, Steis MR, Waller JL, Inouye SK. Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults. J Hosp Med. 2013;8(9):500–505. PMID: 23955965 PMCID: PMC3928030 DOI: 10.1002/jhm.2077

8. Sampson EL, White N, Leurent B, Scott S, Lord K, Round J, et al. Behavioural and psychiatric symptoms in people with dementia admitted to the acute hospital: prospective cohort study. Br J Psychiatry. 2014;205:186–196. PMID: 25061120 PMCID: PMC4432387 DOI: 10.1192/bjp.bp.113.130948

9. White N, Leurent B, Lord K, Scott S, Jones L, Sampson EL. The management of behavioural and psychological symptoms of dementia in the acute general medical hospital: a longitudinal cohort study. Int J Geriatr Psychiatry. 2017;32(3):297–305. PMID: 27019375 PMCID: PMC5324689 DOI: 10.1002/gps.4463

10. Hessler JB, Schäufele M, Hendlmeier I, Junge MN, Leonhardt S, Weber J, et al. Behavioural and psychological symptoms in general hospital patients with dementia, distress for nursing staff and complications in care: results of the General Hospital Study. Epidemiol Psychiatr Sci. 2018;27(3):278–287. PMID: 28065176 DOI: 10.1017/S2045796016001098

11. Åström S, Nilsson M, Norberg A, Sandman P-O, Winblad B. Staff burnout in dementia care—relations to empathy and attitudes. Int J Nurs Stud. 1991 Jan 1;28(1):65–75. PMID: 1856035

12. Coffey A, Tyrrell M, Buckley M, Manning E, Browne V, Barrett A, et al. A multicentre survey of acute hospital nursing staff training in dementia care. Clin Nurs Stud. 2014;2(4):39.

13. Dewing J, Dijk S. What is the current state of care for older people with dementia in
general hospitals? A literature review. Dementia. 2016;15(1):106–124. PMID: 24459188 DOI: 10.1177/1471301213520172

14. Royal College of Psychiatrists. National Audit of Dementia Care in General Hospitals 2016-2017: Third Round Report Audit [Internet]. Healthcare Improvement Quality Partnership; 2017 Jul. Available from: https://www.hqip.org.uk/resource/national-audit-of-dementia-care-in-general-hospitals-2016-2017-third-round-of-audit-report/

15. Sinvani L, Warner-Cohen J, Strunk A, Halbert T, Harisingani R, Mulvany C, et al. A Multicomponent Model to Improve Hospital Care of Older Adults with Cognitive Impairment: A Propensity Score-Matched Analysis. J Am Geriatr Soc. 2018;66(9):1700-7. PMID: 30098015 DOI: 10.1111/jgs.15452

16. Kales HC, Gitlin LN, Lyketsos CG, Assessment DEP on the, Dementia M of the NS of. Management of neuropsychiatric symptoms of dementia in clinical settings: recommendations from a multidisciplinary expert panel. J Am Geriatr Soc. 2014;62(4):762–769. PMID: 25731881 PMCID: PMC4707529

17. Kales HC, Gitlin LN, Lyketsos CG. Assessment and management of behavioral and psychological symptoms of dementia. bmj. 2015;350(7):h369. PMID: 24635665 PMCID: PMC4146407 DOI: 10.1111/jgs.12730

18. Parke B, Chappell N. Transactions between older people and the hospital environment: a social ecological analysis. J Aging Stud. 2010;24(2):115-24.

19. Parke B, Hunter KF, Bostrom A-M, Chambers T, Manraj C. Identifying modifiable factors to improve quality for older adults in hospital: a scoping review. Int J Older People Nurs. 2014;9(1):8–24. PMID: 23067226 DOI: 10.1111/opn.12007

20. Parke B, Hunter KF, Marck PB. A novel visual method for studying complex health transitions for older people living with dementia. Int J Qual Methods. 2015;14(4):1609406915614150. PMID: 23219329 DOI: 10.1016/j.ijnurstu.2012.11.005.

21. Kaufer DI, Cummings JL, Ketchel P, Smith V, MacMillan A, Shelley T, et al. Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. J Neuropsychiatry Clin Neurosci. 2000;12(2):233–239. PMID: 11001602 DOI: 10.1176/jnp.12.2.233.

22. Lintern TC. Quality in dementia care: evaluating staff attitudes and behaviour. [PhD Thesis]. Prifysgol Bangor University; 2001.

23. Dementia Caregivers. Innovating the Next Generation of Dementia and Alzheimer's Disease Care Interventions: Addressing the Needs of Persons Living with. 2017

24. Bynum JP, Rabins PV, Weller W, Niefeld M, Anderson GF, Wu AW. The relationship between a dementia diagnosis, chronic illness, medicare expenditures, and hospital use. J Am Geriatr Soc. 2004;52(2):187-94.

25. Shankar KN, Hirschman KB, Hanlon AL, Naylor MD. Burden in caregivers of cognitively impaired elderly adults at time of hospitalization: a cross-sectional analysis. J Am Geriatr Soc. 2014;62(2):276–284. PMID: 14728626

26. Boltz M, Chippendale T, Resnick B, Galvin JE. Anxiety in family caregivers of hospitalized persons with dementia: contributing factors and responses. Alzheimer Dis Assoc Disord. 2015;29(3):236. PMID: 25635341 PMCID: PMC4714710 DOI: 10.1097/WAD.0000000000000072

27. Boltz M, Chippendale T, Resnick B, Galvin JE. Testing family-centered, function-focused care in hospitalized persons with dementia. Neurodegener Dis Manag. 2015;5(3):203–215. PMID: 26107319 PMCID: PMC4529403 DOI: 10.2217/nmt.15.10

28. Bloomer M, Digby R, Tan H, Crawford K, Williams A. The experience of family carers of people with dementia who are hospitalised. Dementia. 2016;15(5):1234–1245. PMID: 25394556 DOI: 10.1177/1471301214558308

29. Feast A, Orrell M, Charlesworth G, Melunsky N, Poland F, Moniz-cook E. Behavioural and psychological symptoms in dementia and the challenges for family carers: systematic review. Br J Psychiatry J Ment Sci. 2016;208(5):429–434. PMID: 26989095 PMCID: PMC4853642 DOI: 10.1192/bjp.bp.114.153684

30. Jamieson M, Grealish L, Brown J-A, Draper B. Carers: The navigators of the maze of care for people with dementia—a qualitative study. Dementia. 2016;15(5):1112–1123. PMID: 25305279 DOI: 10.1177/1471301214554930

31. Burgstaller M, Mayer H, Schiess C, Saxer S. Experiences and needs of relatives of people with dementia in acute hospitals—A meta-synthesis of qualitative studies. J Clin Nurs. 2018;27(3–4):502–515. PMID: 28639361 DOI: 10.1111/jocn.13934

32. Surr CA, Smith SJ, Crossland J, Robins J. Impact of a person-centred dementia care training programme on hospital staff attitudes, role efficacy and perceptions of caring for people with dementia: A repeated measures study. Int J Nurs Stud. 2016;53:144–151. PMID: 26421910 DOI: 10.1016/j.ijnurstu.2015.09.009

33. Scerri A, Innes A, Scerri C. Dementia training programmes for staff working in general hospital settings–a systematic review of the literature. Aging Ment Health. 2017;21(8):783–796. PMID: 27662075 DOI: 10.1080/13607863.2016.1231170

34. Surr CA, Gates C, Irving D, Oyebode J, Smith SJ, Parveen S, et al. Effective dementia education and training for the health and social care workforce: a systematic review of the literature. Rev Educ Res. 2017;87(5):966–1002. PMID: 28989194 PMCID: PMC5613811 DOI: 10.3102/0034654317723305

35. Jones C, Bäckman C, Capuzzo M, Flaatten H, Rylander C, Griffiths RD. Precipitants of post-traumatic stress disorder following intensive care: a hypothesis generating study of diversity in care. Intensive Care Med. 2007;33(6):978–985. PMID: 17384929 DOI: 10.1007/s00134-007-0600-8

36. Nirmalan M, Dark PM, Nightingale P, Harris J. Editorial IV: physical and pharmacological restraint of critically ill patients: clinical facts and ethical considerations. Br J Anaesth. 2004;92(6):789–792. PMID: 15145832 DOI: 10.1093/bja/aeh138

37. Lyketsos CG, Colenda CC, Beck C, Blank K, Doraiswamy MP, Kalunian DA, et al. Position statement of the American Association for Geriatric Psychiatry regarding principles of care for patients with dementia resulting from Alzheimer disease. Am J Geriatr Psychiatry. 2006;14(7):561–573. PMID: 16816009 DOI: 10.1097/01.JGP.0000221334.65330.55

38. Schneider LS, Dagerman K, Insel PS. Efficacy and adverse effects of atypical antipsychotics for dementia: meta-analysis of randomized, placebo-controlled trials. Am J Geriatr Psychiatry. 2006;14(3):191–210. PMID: 16505124 DOI: 10.1097/01.JGP.0000200589.01396.6d

39. Gill SS, Bronskill SE, Normand S-LT, Anderson GM, Sykora K, Lam K, et al. Antipsychotic drug use and mortality in older adults with dementia. Ann Intern Med. 2007;146(11):775–786. PMID: 17548409

40. Jeste DV, Blazer D, Casey D, Meeks T, Salzman C, Schneider L, et al. ACNP White Paper: update on use of antipsychotic drugs in elderly persons with dementia. Neuropsychopharmacology. 2008;33(5):957. PMID: 17637610 PMCID: PMC2553721 DOI: 10.1038/sj.npp.1301492

41. Dewing J. Special observation and older persons with dementia/delirium: a disappointing literature review. Int J Older People Nurs. 2013;8(1):19–28.

42. Moyle W, Olorenshaw R, Wallis M, Borbasi S. Best practice for the management of older people with dementia in the acute care setting: a review of the literature. Int J Older People Nurs. 2008;3(2):121–130. PMID: 20925901 DOI: 10.1111/j.1748-3743.2008.00114.x

43. US Department of Health and Human Services. National Plan to Address Alzheimer's Disease: 2016 Update [Internet]. ASPE. 2016 [cited 2018 Jun 5]. Available from: https://aspe.hhs.gov/report/national-plan-address-alzheimers-disease-2016-update

44. Handley M, Bunn F, Goodman C. Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review. BMJ Open. 2017;7(7):e015257. PMID: 28713073 PMCID: PMC5541590 DOI: 10.1136/bmjopen-2016-015257.

45. Boltz M, Capezuti E, Shabbat N. Building a framework for a geriatric acute care model. Leadersh Health Serv. 2010;23(4):334–360.

46. Boltz M, Capezuti E, Kim H, Fairchild S, Secic M. Factor structure of the geriatric institutional assessment profile's professional issues scales. Res Gerontol Nurs. 2010;3(2):126–134. PMID: 20055337 DOI: 10.3928/19404921-20091207-98

47. Boltz M, Capezuti E, Shuluk J, Brouwer J, Carolan D, Conway S, et al. Implementation of geriatric acute care best practices: Initial results of the NICHE SITE self-evaluation. Nurs Health Sci. 2013;15(4):518–524. PMID: 23656606 PMCID: PMC3949432 DOI: 10.1111/nhs.12067

48. Sinvani L, Kozikowski A, Pekmezaris R, Akerman M, Wolf-Klein G. Delirium: A Survey of Healthcare Professionals' Knowledge, Beliefs, and Practices. J Am Geriatr Soc. 2016;64(12):e297-e303. PMID: 27879983 DOI: 10.1111/jgs.14544

49. Galvin JE, Roe CM, Xiong C, Morris JC. Validity and reliability of the AD8 informant interview in dementia. Neurology. 2006;67(11):1942–1948. PMID: 17159098 DOI: 10.1212/01.wnl.0000247042.15547.eb

51. The Hartford for Geriatric Nursing. Dementia [Internet]. ConsultGeri. [cited 2018 Jun 5]. Available from: https://consultgeri.org/try-this/dementia

52. Alzheimer's Association. 50 Ways to Become a Dementia Friendly Hospital [Internet]. [cited 2018 Jun 5]. Available from: http://preview.alz.org/stl_archive_6_29_2017/documents/50_Ways_To_Become_A_Dementia_Friendly_Hospital.pdf

53. van Doorn C, Bogardus ST, Williams CS, Concato J, Towle VR, Inouye SK. Risk adjustment for older hospitalized persons: a comparison of two methods of data collection for the Charlson index. J Clin Epidemiol. 2001;54(7):694–701. PMID: 11438410

54. Pfeffer RI, Kurosaki TT, Harrah CH, Jr., Chance JM, Filos S. Measurement of functional activities in older adults in the community. J Gerontol. 1982;37(3):323-9.

55. Hughes CP, Berg L, Danziger W, Coben LA, Martin RL. A new clinical scale for the staging of dementia. Br J Psychiatry. 1982;140(6):566–572. PMID: 7104545.

56. Puelle, Margaret R., et al. "The language of delirium: keywords for identifying delirium from medical records." Journal of gerontological nursing 41.8 (2015): 34-42.

57. Morris JC. The Clinical Dementia Rating (CDR): current version and scoring rules. Neurology. 1993;43(11):2412-4. PMID: 8232972

58. Knight ADRC Washington University in St. Louis. Clinical Dementia Rating 2003 [Internet] [cited 2018 Dec 20}. Available from: http://alzheimer.wustl.edu/adrc2.

59. Mao H-F, Kuo C-A, Huang W-N, Cummings JL, Hwang T-J. Values of the minimal clinically important difference for the Neuropsychiatric Inventory Questionnaire in individuals with dementia. J Am Geriatr Soc. 2015;63(7):1448–1452. PMID: 26046666 DOI: 10.1111/jgs.13473

60. Borm GF, Fransen J, Lemmens WA. A simple sample size formula for analysis of covariance in randomized clinical trials. J Clin Epidemiol. 2007;60(12):1234–1238. PMID: 17998077 DOI: 10.1016/j.jclinepi.2007.02.006

61. Boltz M, Chippendale T, Resnick B, Galvin JE. Testing family-centered, function-focused care in hospitalized persons with demenita. Neurodegener Dis Manag. 2015; 5(3):203-15. PMID: 26107319 PMCID: PMC4529403 doi: 10.2217/nmt.15.10