POISED IRB Protocol May 10, 2021
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PURPOSE OF STUDY AND BACKGROUND

Objective

Dementia is a common problem for older patients presenting to emergency departments (EDs) and for their family caregivers who often lack the support, understanding, and skills to manage the myriad of problems that may be related to the need for that ED visit. The purpose of the **P**rogram of **I**ntensive **S**upport in **E**mergency **D**epartments for **C**are **P**artners of **C**ognitively **I**mpaired **P**atients (POISED-CPCIP, hereon referred to as POISED) randomized controlled trial is to use previously established quality improvement methods of root cause analysis to uncover reasons for ED use and to focus on caregiver (CG) activation within a program of dementia care management. Study goals are to reduce recurrent ED visits and improve caregiver symptoms of depression, anxiety and need for social support. POISED, a 4-year study, will test whether a novel care management intervention for family CGs of ED users with cognitive impairment and likely Alzheimer's disease and related dementias will reduce ED use at 3 and 6 months over the intervention period. In addition to ED use, we will test whether CGs exposed to the intervention will experience greater improvements (compared to controls) in family caregiving confidence in managing the healthcare needs of the care recipient (CR), and improved anxiety, depression and sense of social support.

Background

The United States spends more than $100 billion providing care for the millions of individuals and their family caregivers (CGs) affected by Alzheimer's disease and related dementias (ADRD).[1,2] By 2050, 11–19 million people in the U.S. will have ADRD with the associated projected annual Medicare costs exceeding one trillion dollars.[3,4] Most patients with ADRD have suboptimal management of their cognitive, behavioral and functional disability and this is made worse by under-recognition.[5] The unmet needs of family CGs challenge chronic disease management and necessitate high levels of acute care.[6-9] Compared with those without dementia, patients with ADRD visit the emergency department (ED) more often, are more likely to return within 30 days, and are more likely to die after an ED visit.[10] Despite such concerns, the role of ADRD as a factor in ED use is likely unrecognized, not typically addressed, and may be much larger than anticipated.[10,11]

An ED visit represents a "sentinel event"—either a failure in managing a chronic condition or the occurrence of new symptoms or problems—and is typically prompted by the need for urgent attention.[12-14] Although the presenting symptom provides a sharp focus for ED care and is usually addressed before the patient is sent home, EDs do not deploy strategies to uncover or address symptom precipitants or root causes—those key contextual factors that contribute to ED use. Among those contextual factors are the presence of unrecognized dementia or cognitive impairment in the patient and the caregiving situation at home. In general ED care does not address the needs of CGs (used here to mean key family and friends of persons with ADRD) in managing the presenting problem and the ED discharge plan at home. Concerns about the needs of CGs of persons with ADRD have motivated the development of dementia care management programs. However, such programs do not focus specifically on high-risk or high-need patients, do not use the need for ED care of patients with comorbid chronic disease as an organizing principle to engage and empower CGs in their healthcare management, and do not view CGs as care partners. Moreover, care management programs are not typically

offered at the crisis-point of an ED visit. Whereas some EDs now use cognitive assessment as part of their routine evaluation, the efficacy of dementia care management initiated at the point of an ED visit has not been tested.

This proposal benefits from the recent decisions of two large academic institutions to include cognitive screening as part of ED care for older patients.

Of note, cognitive screening is not part of the experimental design; thus, patients are not being consented to undergo cognitive screening.

We propose to conduct a randomized controlled trial of care management, POISED, for caregivers of patients who fail a cognitive screening test at the point of an ED visit and are discharged to home. We will randomize dyads—family caregivers and their care-recipient (CR) patients—to POISED or to a usual care control group. Within POISED, we will identify root causes of ED visits (using root cause analysis, RCA) and apply this to focused care management protocols and interventions.

Specific Aims
The specific aims of this proposal are to:

1) **Test whether the POISED intervention will reduce recurrent acute care use over 6 months when compared with post-ED care for dyads without POISED.** *We hypothesize that recurrent acute care use over 6 months will be less for CRs whose family CGs participate in POISED.*

2) **Test whether the 6-month POISED intervention will improve family caregiver "activation" in managing the health care of care recipients compared with post-ED care without POISED at 3 and 6 months.** *We hypothesize that* POISED *will improve family CG activation in managing the health care of CRs.*

3) **Test whether POISED will improve caregiver psychosocial outcomes compared with post-ED care without POISED at 3 and 6 months.** *We hypothesize that CG depression, anxiety, and experience of social support will improve more for CGs who are enrolled in POISED than for those referred to other care management programs.*

Potential Impact: Studying this approach may lead to low cost strategies to reduce high cost acute care use and related improvements in CG ability to assist in chronic disease management for CRs with dementia. Related impacts are improved health of CRs and psychosocial well-being of CGs.

METHODS

Setting: The study will be conducted in two cities, New York and Indianapolis, in the EDs of their respective academic institutions—NYU Langone Medical Center and Indiana University Health University Hospital. The NYU Ronald O. Perelman Center for Emergency Services sees >60,000 patients annually. In 2015 the numbers of ED patients >75 years who were discharged to home were >3700 in the NYU ED and 2400 patients in the Indiana University Eskanazi and Methodist EDs.

Aim1: Recruit and randomize a sample of 900 patient-caregivers (CGs) dyads (1800people total) presenting to the ED and test whether the POISED intervention will reduce recurrent acute care use over 6 months when compared with post-ED care for patients and CGs without POISED.

Study Design: We will randomize subjects to either usual care or interventional groups where we will perform an initial assessment and provide a novel care management intervention for family CGs of ED users with cognitive impairment and likely ADRD.

Inclusion/Exclusion Criteria for Care Recipients:
Inclusion criteria for participation in care management or usual care are as follows:
1) Must be 75 years and older
2) Must be in the emergency department for care at the point of recruitment
3) Must be English- or Spanish-speaking
4) Must have a family member or friend who provides caregiving assistance
5) Must have a plan to be discharged to home
6) Must have scored < 4 on the MiniCog™[15-19] or if using caregiver assessment by IQCODE[20, 21], must be > 3.4
7) Must have capacity to consent or have a proxy.

Exclusion criteria for participation in care management or usual care are as follows:
1) Care recipient (CR) is a resident of a nursing home or other supportive facility
2) CR scores ≥ 3 on the MiniCog™ or the caregiver assessment by IQCODE was < 3.4
3) Caregiver (CG) declines participation
4) CR is not being discharged to home
CR does not allow their family member or emergency contact to be contacted
Note: If the care recipient lacks capacity and we cannot obtain consent from their proxy, we will not access those data or include them in any analyses. Please note that a caregiver can still participate in the study with the assent of the care recipient, without the use of the health care data.

Inclusion/Exclusion Criteria for Care Givers of Affected Patients:
Inclusion criteria for telephone survey and potential care management are as follows:
- Family or informal caregiver (herein described as "caregiver") of a person must be identified by that patient or self-identified as that individual who provides most of assistance among potentially other family members or friends of the care recipient (patient in the ED)
- For a caregiver to be eligible for inclusion the care recipient must be living in the community; however, later facility placement will not exclude that caregiver from continued participation.
- Caregiver must be English- or Spanish-speaking
- Caregiver must be able to speak on a telephone to be eligible for randomization
- Caregiver must have adequate hearing to communicate by phone
- Caregiver must demonstrate capacity to consent to research participation.
- Caregiver must be at least 21 years old

Exclusion criteria for potential telephone survey are as follows:
1) Caregiver does not have adequate knowledge of identified patient and/or does not participate in that member's healthcare decisions
2) Caregiver is not English or Spanish speaking

3) Caregiver does not have adequate hearing to participate in telephone survey and is therefore not eligible for randomization.
4) Caregiver is not able to speak on a telephone
5) Caregiver is less than 21 years old

Recruitment: Potential subjects will be identified from the ED on the basis of the cognitive state of the ED patient. Family caregivers will be identified and approached in the ED and if not present, will be contacted by phone and offered participation in the study. Potential subjects (caregivers) are identified by the treating team who have no direct involvement in the research. As is typical for these kind of clinical studies, the treating team, using clear inclusion and exclusion criteria will ask potential subjects whether or not a research assistant (RA) (from the POISED team) can speak with them to tell them about an opportunity to participate in a study. The treating team is never informed as to whether a potential subject agrees to participate or refuses after meeting with the RA. Caregivers and/or care recipients who are in the ED will be approached only after we (the POISED team) are given permission from the ED staff who will alert the research assistant of a potential caregiver-care recipient dyad. Caregivers and their care recipients will be informed that declining to participate will in no way impact their care in the emergency department or elsewhere and that the treating medical staff will not know about their decision as to their agreement or refusal of participation.

After ED staff have completed cognitive assessment using the Mini-Cog™ and given us permission for to speak to the dyad, we will approach and offer participation to CGs and ED patients > 75 years who have scored <=3/5 on the Mini-Cog™ and have plans to be discharged home. A score of >3.4 on the Short IQ-CODE (a proxy tool used by ED staff) will identify those few who cannot complete the Mini-Cog™. We will consent CGs and care-recipients at the time of ED visit. (See Recruitment, Consent, and Assent). If the care recipient lacks capacity, we will attempt to consent to identify and consent the Care Recipient via a proxy (See Recruitment, Consent and Assent) If there is no available or identified CG, we will attempt to identify and consent the CG at a later date either by phone (using an IRB approved verbal consent telephone script with waiver of written documentation of consent) or in person using an IRB approved consent form to obtain written consent. Please note that the study team will maintain a deidentified record (using a linking code) of who had been approached (in person or by phone), whether they had declined or accepted to participate in the research, and at what time and on what date this conversation took place.

Phone Recruitment: In the event that ED recruitment and assessment cannot be done in person, a Phone Recruitment Protocol will take effect. Potential subjects will be identified from the ED on the basis of a recent admission to a participating ED site location, using the EMR. Family caregivers will be identified by the patient, or via the EMR (i.e. Emergency Contact). In order to contact a family caregiver, the person who was the ED patient will need to be called by telephone first, If the patient gives any indication of not wanting research staff to call their family member or emergency contact, research staff will not attempt to call that person and the patent and care partner will no longer be eligible to participate. A recruiter will attempt to contact the patient within 48 hours of their discharge from the ED to assess willingness to participate and our interest in contacting the designated care partner. When a Mini-Cog cannot be administered in person, the study team member will contact a Care Partner (if no refusal by the patient to do this) and will conduct the IQCODE with that care partner. After assessment for eligibility, informed consent will be obtained over the phone.

Randomization: A web-based randomization scheme will be used to randomize participants to intervention or usual care groups in blocks of four or six stratified by: site (NYU or IU), English or Spanish speaking, whether the care partner lives with the CR, and Mini-Cog™ score less than or equal to 3 (or IQCODE of >3.4).
. We assume a positive IQ-CODE score (>3.4) with an inability to complete a Mini- Cog™ is equivalent to a Mini-Cog™ score of 0.

*Initial assessment phase***:** The POISED care management team consisting of specially-trained nurses functioning as care managers (CMs) and para-professionals in the role of care manager assistants (CMAs) will conduct a biopsychosocial/environmental needs assessment by phone within 48 hours of emergency room discharge if not possible during the ED stay. These team members are clinical professionals delivering a clinical service. They are not research staff or delivering experimental procedures. This assessment includes a demographic and psychosocial interview focused on achieving problem identification. The program uses standardized assessment tools including "Managing Your Loved One's Health" (MYLOH™) for chronic disease management[22] and BEHAVE 5+ to identify problem behaviors common in advancing dementia that have been associated with caregiver strain, challenges to caregiving at home and in long-term care. BEHAVE 5+ also identifies proven behaviors common in prescribing of psychotropic medications to people with dementia.[23] (See Appendix 3) If the consented CG is not available, we will attempt to complete the CG questions at a later date either by phone or in person.

Root Cause Analysis: Starting with the ED visit and working backwards in time, the team will explore and identify problems or branch-point situations that progressed to the need for ED care. Using a logic tree as a cause and effect approach to create a timeline of events leading to ED visit[24,25] and asking the question, "how could this occur?" or "why" based on the "Five-Whys" strategy,[26] the CM team will ask "why" for each successive answer, starting with "why did you come to the ED." Answers will be applied to medical record review looking for other possible triggers and opportunities for intervention. This brainstorming/investigative process to improve quality is also deployed by patient safety teams investigating adverse events.

Usual Care Group: The comparison group, those randomized to usual care (UC), will receive referrals to services at the time of enrollment. The usual care group will not receive the POISED structured assessment, attention to chronic disease management, or RCA related to the ED visit. Similar to intervention group, we will provide UC patients with a laminated card showing the Stress Thermometer™ [23] (Appendix 5) for use in follow-up interview assessments.

Specific Aim 1 Measures – Emergency Department (ED) Use: We will obtain consent from patients to enable review of their medical records. We will identify all ED visits for the year prior to the index ED visit/study enrollment and for one year after enrollment. We will also search all-payer databases (APD) New York and the Indiana State Network for Patient Care to identify any episode of ambulatory or acute care that occurred within the 6 months of enrollment (6-month intervention and 6-month follow-up) and the 12 months prior to enrollment. Using the Care Recipient medical records, we will determine any prior diagnoses of dementia. We will also use the Care Recipient's medical records to determine comorbidity and root cause for ED use.

A one-item survey question will identify any additional visits that might have occurred outside the indicated state regions. For descriptive purposes, ICD discharge diagnoses will be included for any ED use. We will structure continuous variables that describe the number of ambulatory and/or acute care episodes.

Aim 2: Develop a collaborative care plan with the interventional group and schedule follow up testing to assess whether the 6-month POISED intervention will improve family caregiver "activation" in managing the health care of care recipients compared with post-ED care without POISED at 3 and 6 months.

Strategy: The POISED care management team consisting of specially-trained nurses functioning as care managers (CMs) and para-professionals in the role of care manager assistants (CMAs) will work to create an individualized care plan through the lens of cognitive impairment with an emphasis on coordinating care with the patient's primary care provider (PCP) and achieving relevance with the goals and capacity of the family CG and CR.

First Follow up Visit: After review of all findings from prior data and the first encounter, the CM and CMA create an initial plan and identify areas needing further assessment at the first home visit (within 2 weeks after enrollment). That visit enables the CM team to conduct some additional cognitive and functional testing while the RN uses the time to address more sensitive issues that the CG may be uncomfortable discussing in the presence of the CR. The results of this initial assessment and home visit are forwarded to the CR's PCP with requested feedback and further direction as needed

Collaborative Care Plan Development Phase: After the initial assessment is completed by the POISED care management team, any urgent issues are addressed, and consulting with the program geriatrician (Dr. Chodosh at NYU and Dr. Boustani at Indiana University) and the PCP as needed, the CM rules in or out the diagnosis of dementia and its subtypes. The CM team maps out a proposed care plan and schedules a second home visit.

During the second home visit, the CM team reviews the identified problem list and seeks input from the CR and CG on this list and prioritizing those problems, issues or topics felt most important to be addressed first. From this consensus, the CM discusses a proposed plan of care and tailors interventions to the patients, and then explains the diagnosis, natural history, and the prognosis of dementia; implements care protocols; reviews, explains, and distributes corresponding educational handouts for the dyad; and connects patients and family CGs to in-home services and community resources as needed.

Specific Aim 2 Measures – CG Activation in Health Care Management of CR: After consenting the CG, we will measure caregiver activation, a multi-dimensional construct developed by Borson and colleagues that includes CG knowledge, skills, and confidence to manage a range of tasks and tackle challenges common to dementia health care management.[27] Domains include recognizing, anticipating, and managing day-to-day symptoms and challenges for CR health; managing CR medications; recognizing and managing sudden changes in CR health; accessing health services and advocating for the CR in the health care space; and managing CG self-care. Four-level item responses range from "agree completely" to "disagree completely" with an additional option, "not my job". We will use the total score to measure activation.

Aim 3: Test whether POISED will improve caregiver psychosocial outcomes compared to post-ED care without POISED at 3 and 6 months.

Strategy: Follow-up regularly in a scheduled manner with resources and interventions to continue supporting CG and CR

The follow-up phase: During the follow-up phase, the POISED care management team (primarily the CMA) will continue to interact with the CG and CR either face-to face at their home, through video, telephone, email, fax, or mail. The minimum amount of CMA contact during this time will be by telephone and will be weekly for the first month, twice monthly calls during the second and third months, and monthly calls for the following 3 months.

Interaction intensity will be dictated by presenting needs and circumstances. During these interactions, the CM or CMA will answer any questions generated from previous visits; collect CR and family CG feedback; have the family CG complete a brief assessment to identify need for specific care protocols; and facilitate family CGs' participation in an array of community services that are already available in either the New York or Indianapolis areas. The CM (nurse) will reconcile medications and review medication adherence at the initial and second home visit. Medication questions will be referred to the study pharmacist.

Throughout the duration of the follow-up phase, the team will continue to work with the CG/CR and the patient's primary care provider to monitor, implement, and adjust the individualized care plan as needed. Both NYU and IU have significant caregiver support resources, such as CG support groups, respite care, and individual telephone counseling support. The programs benefit from already developed field-tested services from prior work by both Chodosh and Boustani (and in clinical application by Borson and Connor). Specific POISED features are highlighted here and included in Appendix 4

Specific Aim 3 Measures – Psychosocial States as Important Predisposing and Time-Varying Enabling and Need Characteristics: These include CG depression, anxiety, experience of social support, and stress. We will use the Patient Health Questionnaire–9 (PHQ-9)[28-30] and Generalized Anxiety Disorder Scale (GAD-7)[31,32] to determine the impact of the POISED intervention on CGs' mood and anxiety at baseline, 3 months, and 6 months.

Experience of social support will be measured using the Medical Outcomes (MOS) Social Support Survey — Abbreviated.[33] This is a four-item survey measure that uses a five-point Likert scale. Respondents are asked how often each kind of support is available if needed. The Stress Thermometer™[23] a visual thermometer with a five-level analogue scale to indicate the level stress chosen by the CG, will measure CG stress. Every enrolled CG will be given a laminated card with the stress thermometer at the time of ED discharge to use during interviews.

We will use the HABC-monitor to adjust for dementia symptom severity.[34] The HABC-Monitor is a CG survey tool for monitoring three CR symptom domains (cognitive, functional, and behavioral/psychological) and a CG quality of life measure.

PROTECTION OF HUMAN SUBJECTS

Risk to Subjects

Patients with cognitive impairment / likely dementia and their family / informal caregivers are a vulnerable group; however, the procedures employed in this clinical trial are low risk and have been successfully employed without incident in a number of other studies by this research team as well as by other investigative teams. In some parts of the country, dementia care management is a standard of care practice. The procedures are non-experimental but have never been tested in an ED-based population as the point of entry. This study poses minimal risk to subjects, since the study does not involve tests or treatments beyond that which they would normally receive as part of their normal care.

Care management programs are now considered non-experimental. However it is not known whether using the ED as the point of initiation will cause any undue stress or burden to the families or caregivers. Research coordinators will be trained in order to minimize any foreseeable risk.

Recruitment, Consent and Assent

Cognitive assessment is a usual care procedure for these emergency departments as part of the evaluation of patients 75 years and older who present to their emergency department. Eligible caregivers provide care for patients to be discharged home who perform poorly on the screening assessment defined by specific cut-points as abnormal (MiniCog^{TM} < 3). If the patient is unable to be assessed but identified by the caregiver as having impairment consistent with likely dementia (IQCODE > 3.4) the caregiver will be considered eligible (see inclusion/exclusion criteria above, see page 3).

The first stage of recruitment and consent is to determine the eligibility of the caregiver. The caregivers of the eligible patients are considered for study recruitment and the caregivers will be approached in the ED or by phone (if Phone Recruitment in effect) and offered research participation. Only caregivers of those patients scheduled to be discharged home will be considered eligible for participation. If a caregiver is not present in the ED and a patient provides permission to contact that person, we will conduct consent procedures by telephone.

The second stage of recruitment and consent is consent of the Care Recipient for access to health records. After it is determined that the Care Recipient has an eligible Caregiver, the Care Recipient will be approached regarding allowing the research team access to their medical records. Capacity is determined for the CR for consent using a common sense procedure. This is possible because the request in question is easy to understand procedure (collecting information from the health record). We anticipate that most will demonstrate capacity to decide regarding use of their medical records. For those who do not, we will use a proxy consent –the caregiver if that person is next of kin (defined based on hierarchy: spouse, child, sibling, nephew or niece) in the absence of a DPOA for healthcare or by consenting the proxy who is DPOA but not present, which again will require discussion of the consent process via telephone using an IRB approved script and mailing the original consent for to be signed or returned via mail, fax, or SendSafe email procedure for e-consentIf the care recipient does not want us to use his/her medical records we will of course not do so and for those subjects, and this will be missing data. This is a minimal risk study with a chart review being completed 6 months later; we will not require capacity to be reassessed at the end of the 6 months. We request consent at the beginning of the study because this is an element of the research protocol and both caregivers and care recipients need to be aware and agree with participating given this approach. Loss of capacity after giving permission does not negate this consent and require a new consent procedure but a caregiver (legal healthcare proxy) under these circumstances, can override the consent at any point in the study if in the future, the proxy does not want us to have access to the chart at the end of 6 months. The Care Recipient, as the consenting individual, can also always rescind their earlier consent. Please note that at the time of capacity assessment, the only clinical information that we have on this patient is that they have performed below a pre-specified cut point on a simple 2 minute cognitive screening test. This result neither indicates a definitive diagnosis of dementia, nor any level of severity of cognitive impairment.

The third stage of consent is for participation in care management or usual care and randomization into one of two treatment arms – receipt of the **P**rogram of **I**ntensive **S**upport in **E**mergency **D**epartments for **C**are **P**artners of **C**ognitively **I**mpaired **P**atients (POISED-CPCIP) or usual care. The Caregiver can be included regardless of CR health record consent.

Randomization will occur after completion of the baseline interview. Here, the caregiver will consent for himself or herself. Capacity will be determined for the Caregiver. For the care recipient, we will use an assent procedure, in which the Care Recipient has authority to decline participation on behalf of the Caregiver.

Vulnerable Populations

Care Recipient: The study will involve caregivers of patients with cognitive impairment and the healthcare data of those with cognitive impairment. The risk for care recipients are minimal due to the nature of their part of the study, which is limited to a chart review. To protect individuals with cognitive impairment, the research assistant will require consent from the caregiver and will assent the care recipient for the participation of their Caregiver in a care management program, and care recipient consent for health record access. If the care recipient refuses participation through any form of rejection, then that dyad will not be considered for the study. Care recipients subjects in this study insofar as they have given the research team permission to access their health records. Because we are working with family caregivers, care recipients may or may not be indirectly involved with the clinical support given to caregivers. Although we have never been required to involve the care recipients in consent procedures for the purpose of involving the caregivers as participants in other similar funded trials, we are offering (out of respect to these individuals) the opportunity to have them decline our involvement with their caregiver even if the caregiver wants to participate. However, because we are collecting information from their chart, a consent procedure will be necessary for this small component. The Care Recipient will have the right to decline participation on the part of their family caregiver even if they do not have capacity to do so. Moreover, they can decline participation at any time during the study duration and we will no longer include that caregiver in our research procedures or use their data. This approach is in keeping with our commitment to ensuring the highest level of respect for these individuals.

If the caregiver does not have the capacity to consent, we will not enroll that dyad. Please see the approach to addressing capacity to consent in the evaluation consent form and in additional text below ("Subject Capacity"). Protection of vulnerable subjects includes utilizing highly-trained RAs who will be available to answer all questions and who will provide written materials that are at a 6th grade reading level. Assessment of capacity is a common-sense procedure that does not require professional level expertise. This is a minimal-risk study and the approach, as articulated in the "evaluation to sign consent" form, is a well-worn procedure used in countless studies where some subjects may have some degree of cognitive impairment. Several studies of subjects even with early to moderate Alzheimer's disease have demonstrated the appropriateness and validity of this approach and for many, their capacity to decide about research participation. We do not anticipate significant levels of cognitive impairment among caregivers given their caregiving roles. Capacity determination is conducted by research assistants who will be trained in this approach as we have done in several other IRB-approved studies.

Protection Against Risk

We will obtain all data by computerized assisted interview instruments (CATI) that enable all answers (data) to be stored in electronic files. These files are physically separate from any identifiable data. These data will be kept on password-protected encrypted servers stored and protected under the supervision of NYU DataCore staff until transferred to the study statistician at Indiana University. Data transfer will be done through encrypted password protected discs with a unique linking ID kept by the study team in locked files and used later for analytic assignment of the randomization status. In the event that NYU has completed its plans for an

information portal that enables direct data acquisition within a secure encrypted environment, we will amend our IRB application accordingly and request that this on-line system be utilized.

Data collected by care managers at both NYU and IU sites and in subjects' homes is specific to the care management and not the research study per se. Nonetheless, care managers (who are also research credentialed) will protect these data (clinical information) on encrypted, password protected tablet computers using encrypted files. Care management data will be downloaded to site servers on a weekly basis.

All electronic data will be entered into and stored on a secure NYU School of Medicine server that will be accessible only by IRB approved study personnel. The secure server is maintained by NYU Medical Center's IT department and protected by the Medical Center firewall. Hard copy data will be double-locked and accessible only to the PI and research assistants. Only group-level information without personal identifiers will be included when presenting results or submitting manuscripts for publication.

Potential Benefits to Subjects

We anticipate that participants will receive some benefit either from dementia care management or usual care. Subjects in either arm will be offered social services and facilitated access to receipt of services. Subjects in either arm will have greater opportunity to receive additional evaluation for their care recipient by being provided with clear referral information. Caregivers (subjects) are often isolated and suffer from loneliness and partipating in this study will mitigate that isolation to greater or lesser degrees. Therefore, we anticipate that all participants will receive some potential benefit regardless of the arm into which they are randomized. All subjects will be offered referral for diagnostic assessment regardless of treatment assignment and the ED assessments will be sent to primary care physicians.

Process of Consent

Potential subjects will be identified from the ED on the basis of the cognitive state of the ED patient. Family caregivers will be identified and approached in the ED and if not present, will be contacted by phone and offered participation in the study. Caregivers and/or care recipients who are in the ED will only be approached only after giving permission to ED staff who will alert the research assistant of a potential caregiver-care recipient. Should phone recruitment be in effect, the family caregiver will be identified through the EMR or via patient and will complete the IQCODE to determine eligibility. Should the family caregiver screen into the study via IQCODE, they will be offered participation in the study.

Trained Research Associates (RAs) will approach caregivers presenting to the Emergency Department with eligibility criteria. The RAs will also provide the caregiver and care recipient with the consent form that contains all pertinent study and contact information, and will describe the nature of the study to the dyad. The care recipient will be asked to explain their understanding that we will be accessing their medical records to obtain data through the Evaluation to sign consent (ESC) form, and then verbally consented to participate. Because this is a simple procedure to understand, we anticipate that most will demonstrate capacity. For those who do not, we will use a proxy consent – typically the caregiver if that person is next of kin (defined based on hierarchy: spouse, child, sibling, nephew or niece) in the absence of a DPOA for healthcare or by consenting the proxy who is DPOA but not present, which will require telephone and waiver of written consent. This will require telephone verbal consent with waiver of written documentation of consent, as well as written authorization submitted via mail

or fax. If the care recipient does not want us to use his/her medical records we will of course not do so and for those subjects, and this will be missing data.

The caregiver will be asked to summarize the study, using the Evaluation Signed Consent (ESC) form, and consent to participate. The RAs will determine if the caregiver understands the study and that participation is voluntary and will not affect the care the Care Recipient receives in the Emergency Department.

This procedure for both the Care Recipient and Care Partner will be completed by phone when recruitment is not permitted in person (Phone Recruitment Protocol).

In the case that in-person documentation is limited, (for example, when all contact is made over phone) an e-consent process will be in effect. In this process, the research staff will complete the same verbal informed consent process with CG and CR. If informed consent is obtained, the research staff will e-sign the PDF or Word document to indicate that informed consent was obtained. The research staff will offer the CG and CR to receive a copy of their signed consent form by mail or via SendSafe email.

Family CGs will receive the care management. CGs are research subjects and will therefore be consented. Permission to use healthcare data (See Emergency Department Patient Assent Form) will be obtained from care recipients through a consent process. The Caregiver may participate regardless of the Care Recipients ability to consent, Therefore the Care Recipient will be assented regarding the participation of the Caregiver in the study. The care recipient will be assented even if the care recipient does not appear to understand our request. If the care recipient refuses through any form of rejection, then that individual does not assent to the study. We will thank both individuals for their time and remove them from eligibility as research subjects. This process is an approach we have used for over 15 years of dementia caregiver human subject research.

Caregiver consent covers participation in four evaluation survey/interviews and agreement to be randomly assigned to receive care management (POISED) or continue with care as usual. The baseline survey will be either in person or by telephone for both the IU and NYU EDs, depending upon the availability of the caregiver. We will conduct subsequent 3 and 6 month research interviews by telephone. Only caregiver names, telephone numbers, and addresses without other identifying data will be provided to the interviewer in a secure manner using encrypted password protected files.

Subject Capacity
After going through the consent process with the caregiver and care recipient, we will determine capacity. The RA will ask the following questions:

Capacity Assesment for CG
“We have just reviewed what it means to participate in this study. I am going to ask you a few questions just to make sure you understand what we will be doing once we begin.

1. What would you be doing if you agree to take part in this study? (Examples of acceptable answers: “Take part in an interview/survey,” or “Answer questions about hearing.”)

oPerson is able to answer this oPersonisnotabletoanswerthis

2. What can you do or ask me to do if you are uncomfortable with a particular question in the survey? (Examples of acceptable answers: “Ask to skip the question.” “Ask you to read another question.”)

   o Person is able to answer this oPersonisnotabletoanswerthis

3. What can you do if you decide after we start that you do not want to participate in the study? (Examples of acceptable answers: “Tell you that I do not want to answer any more questions.”)

   oPerson is able to answer this oPersonisnotabletoanswerthis

Capacity Assesment for CR

“We have just reviewed what it means to take part in this study. I am going to ask you a few questions just to make sure you understand.

1. What will the researchers be doing if you agree to take part in this study? (Examples of acceptable answers: “Taking information from my medical record,” or “Going into my records.”)

   oPerson is able to answer this oPersonisnotabletoanswerthis

2. What can you do or ask me to do if you are uncomfortable being a subject in the study? (Examples of acceptable answers: “Ask to leave the study.” “Ask to speak to the principal investigator”)

   o Person is able to answer this oPersonisnotabletoanswerthis

3. What can you do if you decide after we start that you do not want to participate in the study? (Examples of acceptable answers: “Tell you that I do not want to be in the study.” Or “Tell you to delete my information from the study.”)

   oPerson is able to answer this oPersonisnotabletoanswerthis

Subject/Representative Comprehension

Caregivers themselves may have cognitive impairment. To determine that the subject/subject’s authorized representative understood the information presented, the investigator will ensure the representative has a factual understanding of information presented to them assessed through the Evaluation to Sign Consent (ESC) described above. If the legally authorized representative is determined by the investigator to have the decisional capacity to consent the patient, he/she

will be able to consent that patient. However, if the representative is not deemed to have the capacity to consent the patient the patient will be excluded from enrollment in this study.

Documentation of Consent
Documentation of consent will be obtained through the consent form. Otherwise if consent is obtained verbally, written documentation of consent will be waived.

Costs to the Subject
There are no expected costs to subjects related to the study.

Payment for Participation
Caregivers will receive a $40 gift card by mail as payment for their time and effort in completing interviews at 0, 3, and 6 months.

Data Collection and Documentation
Data will come from three sources. First, the web-based tracking system contains data entered by the POISED care management team. The care management team documents the initial and follow-up visits using RedCap. The CM team focuses on problem clarification and reviews the assessment findings, the medical record, medication lists, ED discharge plans and pharmacist consultation. These data will provide us with extensive information on the process and content of care for those randomized to POISED. This system is specifically designed to support and monitor clinical care and was used in prior clinical trials. We will add fields that support the care processes of the POISED intervention, including the results of assessment instruments, the content of the tailored intervention, and clinical observations such as dyads' level of participation.

Second, we will obtain data on health services use including all diagnostic testing and medication use and use of inpatient and outpatient services from 1 year prior to study enrollment to 1 year after enrollment (2-year duration) from NYU's EPIC system and the Indiana Network for Patient Care (INPC). Data are obtained from the electronic medical record by a team of data managers employed by NYU (DataCore) and Regenstrief Institute in support of clinical research, including demographic information and date of birth..

Third, primary outcome measures will come from telephone interviews and will be entered in REDCap.[35] A research assistant interviewer will collect complete telephone survey data from CGs at baseline, 3 months and 6 months using a 30-minute survey (Appendix 3). Some baseline CG interviews will be conducted in person at both sites, depending on CG availability prior to CR discharge. The RA will enter de-identified survey data from each survey wave into a HIPAA-compliant REDCap electronic database hosted at NYU. REDCap baseline data will be electronically linked to care manager software so that specific relevant data fields can populate the POISED RN care manager pre-visit data and limit redundancy in questions and CG interview burden. DataCore—a resource launched by the NYU Langone Medical Center (NYULMC), housed within the NYULMC IT Department and formed in collaboration with the Clinical and Translational Science Institute (CTSI), the Biomedical Informatics and Translational Library Programs, and the Department of Population Health—will provide enterprise level support to ensure the integrity of electronic data during its capture, storage, management, extraction, and sharing. DataCore will merge these three data streams using unique identifiers assigned to the study participants and provide regular backups onto a secure server.

Data and Safety Monitoring Plan:

Our study team will monitor all adverse events and accumulated study data through weekly meetings to review enrollment progress and identify any adverse events. We will evaluate any adverse effects related to recruitment, enrollment, interview process and the care management intervention (including the possible issues of severe caregiver depression and unsafe home situations). Adverse events will be reported to the study IRBs and will include any medical event regardless of its relationship to the study intervention. All such events will be recorded but blinded (where possible) except for the IRB who will be unblinded and notified immediately of any serious and unexpected event. In such instances, the IRB will determine appropriate action with respect to reporting and additional steps. For more urgent situations, the study interviewer or the Care Management team may contact any of the physician investigators on the team for urgent medical decisions or contact 911 in the case of an inhome emergency. Any adverse event will be reported to the IRB within 72 hours, which includes Caregiver or Care Recipient hospital admission, death or Care Recipient Emergency Department revisit. As is required by the IRB, the research team will submit an annual report for the data safety monitoring with continuing review.

Statistical Plan

We will compare randomization results to the pre-planned schedule, to ensure randomization integrity. To verify the comparability of the randomized groups, we will compare dyads to identify differences between their baseline characteristics (age, gender, race, education), CR comorbid medical conditions, and the Charlson comorbidity index. We will also look for differences in the number of primary care visits and acute care use during the year prior to enrollment between POISED and the usual care group by using analysis of covariance (ANCOVA) models for continuous variables and the Cochran-Mantel-Hansel statistic for categorical variables. We will control for stratification variables: recruitment site (NYU or IU), English vs Spanish (at NYU site), living arrangement (CG lives with CR or not), and cognitive status (Mini-CogTM score of a 3 or less). A cutoff of 0 or 1 is more strongly associated with functional disability than a cutoff of 3. Subjects requiring the IQ-CODE with scores >3.4 will be included with those with MiniCogTM scores =0 to reflect greater impairment for those who cannot complete the Mini-CogTM. We will examine the distributions of continuous variables and use transformation or nonparametric methods in cases of violation to the normal distribution assumption. We will also examine the frequency distribution of all categorical variables and use exact inference procedures in cases of zero or small cell size. We will use SAS 9.4 (SAS Institute, Carey, North Carolina) for all analyses.

Specific Aim 1: We will use logistic regression models to compare the rates of ED admissions during the 6-month intervention period following the index (recruitment) ED visit. ED readmission within 6 months will be used as a binary outcome in the logistic model and randomization group will be the independent variable while adjusting for all stratifying variables including site, language, living arrangement and CR cognitive status. Baseline characteristics that are shown to be unbalanced in univariate comparisons between the two groups will also be adjusted.

Specific Aim 2: We will use mixed effects models with CG activation scores at 3 months and 6 months as the outcome measure and randomization group as the independent variable while controlling for baseline activation score and stratification variables (site, language, living arrangement and CRs' cognitive status). We will conduct post-hoc comparisons of the activation scores between the POISED group and the usual care group at 3 and 6 months using linear contrast from the mixed effects model following a significant group effect. To explore what changes are responsive to the POISED intervention, we will also use the mixed effects model to examine differences in activation domain scores between the two groups. The mixed effects

model will account for potential correlations between repeated measures from the same individual and deal with missing data appropriately when the probability of missing data is unrelated to the missing observation.

Specific Aim 3: We will use mixed effects models with repeatedly measured PHQ-9, GAD-7 and MOS social support scores collected at 3 and 6 months as dependent variables. The independent variable for the mixed effects model will be the indicator variable for the randomization group while controlling for baseline scores and stratification variables. We will use post-hoc analysis to determine group differences in these measures between the two groups at the 3- or 6-month evaluations. The modeling approach resembles that for Aim 2.

Sensitivity analysis for missing data: The analysis plan outlined above assumes that outcome measures at follow up are missing at random with respect to demographic characteristics and baseline results. We will compare baseline characteristics of subjects with missing outcomes due to death or withdrawal to detect potential violation of the missing-at-random assumption. Further sensitivity analyses will involve various imputation methods or a full parametric likelihood approach that assumes various patterns of missing data86.

Sample Size and Power Consideration: Sample size for the proposed study is estimated for achieving 80% power in reducing acute care use in the POISED group compared with the usual care group in Specific Aim 1. A previous study had reported a 30-day readmission rate of 58% in dementia patients as compared to 38% in those without dementia. Given that our patient sample may include less severe cognitive impairment with less ED use, we assume, conservatively, that the rate of ED visits in the usual care group is 40%. With 320 patients enrolled per group, we will have 82% power to detect an odds ratio of 0.62 for repeat ED visits in the POISED group compared to the usual care group at the 0.05 significance level. This detectable odds ratio is equivalent to reducing the ED visit rate to 29% or lower in the POISED group compared with the 40% assumed for the control group. The use of stratified randomization ensures that patients in the intervention and control groups are similar on the stratification variables, thus reducing the variance of the difference between the two group means and resulting in greater power than simple randomization. Therefore, actual power for our study will be higher than projected here. Since we will be using EMR for acute care data and phone follow-up to supplement out of network use, we anticipate complete data from all study participants for this aim.

For Aims 2 and 3, assuming that 205 (64%) dyads will complete the 6-month evaluation (see Figure 2), we will have 80% power to detect an effect size of 0.28 or greater on the CG activation score, PHS-9, GAD-7 and MOS scores between POISED group and the control group using a two-sample t-test at the 0.05 significance level. The detectable effect size of 0.28 used in our power estimation is reasonable and justified given that previous studies on collaborative care management of dementia patients have shown an effect size of 0.45 SD on a number of caregiver psychosocial outcomes. Our previous studies have found a mean PHQ-9 score of 4.4 (SD=5.6), and a mean GAD-7 score of 3.2 (SD=3.5). Thus our projected effect size will allow us to detect a change as small as 1.6 on the PHQ-9 and 1 on the GAD-7. As described above, the use of stratified randomization will provide greater power than those projected here.

References

1. Alzheimer Association. Alzheimer's disease facts and figures. http://www.alz.org/facts/downloads/facts_figures_2015.pdf. Updated 2015. Accessed January 12, 2016.

2. Hurd MD, Martorell P, Delavande A, Mullen KJ, Langa KM. Monetary costs of dementia in the united states. *N Engl J Med*. 2013;368(14):1326-1334.

3. Ferri CP, Prince M, Brayne C, et al. Global prevalence of dementia: A delphi consensus study. *Lancet*. 2005;366(9503):2112-2117.

4. Hebert LE, Scherr PA, Bienias JL, Bennett DA, Evans DA. Alzheimer disease in the US population: Prevalence estimates using the 2000 census. *Arch Neurol*. 2003;60(8):1119-1122.

5. Chodosh J, Petitti DB, Elliott M, et al. Physician recognition of cognitive impairment: Evaluating the need for improvement. *J Am Geriatr Soc*. 2004;52(7):1051-1059.

6. Chodosh J, Seeman TE, Keeler E, et al. Cognitive decline in high-functioning older persons is associated with an increased risk of hospitalization. *J Am Geriatr Soc*. 2004;52(9):1456-1462.

7. Boustani M, Baker MS, Campbell N, et al. Impact and recognition of cognitive impairment among hospitalized elders. *J Hosp Med*. 2010;5(2):69-75.

8. Chan DC, Kasper JD, Black BS, Rabins PV. Presence of behavioral and psychological symptoms predicts nursing home placement in community-dwelling elders with cognitive impairment in univariate but not multivariate analysis. *J Gerontol A Biol Sci Med Sci*. 2003;58(6):548-554.

9. Smith GE, O'Brien PC, Ivnik RJ, Kokmen E, Tangalos EG. Prospective analysis of risk factors for nursing home placement of dementia patients. *Neurology*. 2001;57(8):1467-1473.

10. LaMantia MA, Stump TE, Messina FC, Miller DK, Callahan CM. Emergency department use among older adults with dementia. *Alzheimer Dis Assoc Disord*. 2015.

11. Han JH, Schnelle JF, Ely EW. The relationship between a chief complaint of "altered mental status" and delirium in older emergency department patients. *Acad Emerg Med*. 2014;21(8):937-940.

12. Kasper JD, Freedman VA, Spillman BC. Disability and care needs of older americans by dementia status: An analysis of the 2011 national health and aging trends study. www.aspe.hhs.gov/daltcp/reports/2014/NHATS-DS.cfm. Updated 2014. Accessed January 10, 2016.

13. Gillespie R, Mullan J, Harrison L. Managing medications: The role of informal caregivers of older adults and people living with dementia. A review of the literature. *J Clin Nurs*. 2014;23(23-24):3296-3308.

14. Lowthian J, Straney LD, Brand CA, et al. Unplanned early return to the emergency department by older patients: The safe elderly emergency department discharge (SEED) project. *Age Ageing*. 2016.

15. Borson S, Scanlan J, Brush M, Vitaliano P, Dokmak A. The mini-cog: A cognitive 'vital signs' measure for dementia screening in multi-lingual elderly. *Int J Geriatr Psychiatry*. 2000;15(11):1021-1027.

16. Tsoi KK, Chan JY, Hirai HW, Wong SY, Kwok TC. Cognitive tests to detect dementia: A systematic review and meta-analysis. *JAMA Intern Med*. 2015;175(9):1450-1458.

17. Borson S, Scanlan JM, Watanabe J, Tu SP, Lessig M. Improving identification of cognitive impairment in primary care. *Int J Geriatr Psychiatry*. 2006;21(4):349-355.

18. Borson S, Scanlan JM, Chen P, Ganguli M. The mini-cog as a screen for dementia: Validation in a population-based sample. *J Am Geriatr Soc*. 2003;51(10):1451-1454.

19. Patel A, Parikh R, Howell EH, Hsich E, Landers SH, Gorodeski EZ. Mini-cog performance: Novel marker of post discharge risk among patients hospitalized for heart failure. *Circ Heart Fail*. 2015;8(1):8-16.

20. Jorm AF, Jacomb PA. The informant questionnaire on cognitive decline in the elderly (IQCODE): Socio-demographic correlates, reliability, validity and some norms. *Psychol Med*. 1989;19(4):1015-1022.

21. Jorm AF. The informant questionnaire on cognitive decline in the elderly (IQCODE): A review. *Int Psychogeriatr*. 2004;16(3):275-293.

22. Sadak, T., Wright, J., & Borson, S. (2016). Managing Your Loved One's Health Development of a New Care Management Measure for Dementia Family Caregivers. *Journal of Applied Gerontology*, 733464816657472. https://doi.org/10.1177/0733464816657472

23. Borson S, Scanlan JM, Sadak T, Lessig M, Vitaliano P. Dementia services mini-screen: A simple method to identify patients and caregivers in need of enhanced dementia care services. *Am J Geriatr Psychiatry*. 2014;22(8):746-755.

24. Wu AW, Lipshutz AK, Pronovost PJ. Effectiveness and efficiency of root cause analysis in medicine. *JAMA*. 2008;299(6):685-687.

25. Latino RJ. *Patient safety: The PROACT root cause analysis approach.* Boca Raton, FL: Taylor and Francis; 2008.

26. Five Whys Technique. http://www.adb.org/publications/five-whys-technique. Updated 2009. Accessed January 25, 2016.

27. Sadak, T., Wright, J., & Borson, S. (2016). Managing Your Loved One's Health Development of a New Care Management Measure for Dementia Family Caregivers. *Journal of Applied Gerontology*, 733464816657472. https://doi.org/10.1177/0733464816657472

28. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. *Journal of General Internal Medicine*. 2001;16(9):606-613.

29. Kroenke K, Spitzer RL. The PHQ-9: A new depression and diagnostic severity measure. *Psychiatric Annals*. 2002;32:509-521.

30. Lowe B, Unutzer J, Callahan CM, Perkins AJ, Kroenke K. Monitoring depression treatment outcomes with the patient health questionnaire-9. *Med Care*. 2004;42(12):1194-1201.

31. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: The GAD-7. *Arch Intern Med*. 2006;166(10):1092-1097.

32. Kroenke K, Spitzer RL, Williams JB, Monahan PO, Lowe B. Anxiety disorders in primary care: Prevalence, impairment, comorbidity, and detection. *Ann Intern Med*. 2007;146(5):317-325.

33. Sherbourne CD, Stewart AL. The MOS social support survey. *Soc Sci Med*. 1991;32(6):705-714.

34. Monahan PO, Boustani MA, Alder C, et al. Practical clinical tool to monitor dementia symptoms: The HABC-monitor. *Clin Interv Aging*. 2012;7:143-157.

35. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-381.

Appendices:

1) **List of variables**
2) **Chronic Management Guide Example**
3) **Research Survey**
4) **Poised Detailed Care Management Strategies**

Appendix 1: Data Variables

Table 1: Measures			
Measure	**Data Source**	**Measure Construction**	**Measures refer to: CG* and / or CR*; Assessment times: 0/BL*, 3, 6, 12 month**
Predisposing Fixed Characteristics			
Basic			
Age	EMR/ Survey	Years	CG, CR; 0 mo. (BL)
Gender	EMR/ Survey	Categorical: Male/Female	CG, CR; 0 mo. (BL)
Race/Ethnicity	EMR/ Survey	Categorical: White, Black, Hispanic, other	CG, CR; 0 mo. (BL)
Education	Survey	Categorical: <H.S., H.S., Some College, College graduate+	CG; 0 mo. (BL)
Prior (1-year) non-acute use	EMR/ Survey	Counts: physician ambulatory visits, in-home supportive services	CR; 0 mo. (BL)
Prior (1-year) acute use	EMR/ Survey	Counts: physician ambulatory visits, ED, hospital visits / bed days	CR; 0 mo. (BL)
ADRD-Specific			
Dementia Type	EMR	Categorical: including AD, Lewy Body disease, Parkinson's Disease, Vascular, Frontotemporal, and mixed	CR; 0, 3, 6 mo.
Caregiver relationship to CR	Survey	Categorical: Spouse, child, other relative, friend/other	CG, CR; 0 mo.
Functional State	Survey	14 items: ADL/IADL' for CG; within HABC-M* for CR	CG, CR; 0, 3, 6 mo.
Marital Status	Survey	Categorical: Single/never married, married, divorced, widowed	CG, CR; 0, 3, 6 mo.
Substance use history	Survey	Current: Yes/No; Past history: Yes/No	CG, CR; 0, 3, 6 mo.
Mental illness history	Survey	Yes/No: Depression, schizophrenia, PTSD, other	CG, CR; 0 mo.
Enabling Time Varying Effect Characteristics			
Basic			
Distance to hospital (ED)	Calculated	Miles	CG, CR; 0, 3, 6 mo.
Distance to usual source of care (USC)	Calculated	Miles	CG, CR; 0, 3, 6 mo.
Difference in distance ED vs. USC	Calculated	Miles (USC) – distance to hospital	CG, CR; 0, 3, 6 mo.
Change in PCP	Survey	Yes/No	CR; 0, 3, 6 mo.
Insurance	EMR	Yes/No	CR; 0, 3, 6 mo.
Current non-acute use	EMR /Survey	Counts: physician ambulatory visits, in-home supportive services	CR; 0, 3, 6, 12 mo.
Current acute use	EMR/ Survey	Counts: physician ambulatory visits, ED, hospital visits / bed days	CR; 0, 3, 6, 12 mo.
ADRD-Specific			
Mode of transportation	Survey	Categorical: personal car, taxi, train, bus, walk	CR; 0, 3, 6 mo.
Caregiver living arrangement	Survey	Categorical: Live with subject, close proximity (miles), other	CG; 0, 3, 6 mo.
Caregiver stress	Survey	Stress thermometer (scale), 5-level visual analogue scale*	CG; 0, 3, 6, 12 mo.
Dementia symptoms	Survey	HABC-M* (measuring severity of CR symptoms)	CR; 0, 3, 6 mo.
Need Characteristics			
Basic			
Acute illness	Survey	Counts: episodes by type (classification by study physicians)	CR; 0, 3, 6 mo.
Falls, other injuries	Survey	Counts: episodes by type (classification by study physicians)	CR; 0, 3, 6 mo.
Non-acute illness	Survey	Counts: episodes by type (classification by study physicians)	CR; 0, 3, 6 mo.
Medication need for refill	Survey	Categorical: Yes/No	CR; 0, 3, 6 mo.
Clinical co-morbid conditions	EMR	Charlson comorbidity index*	CR; 0, 3, 6 mo.
Satisfaction	Survey	Scale: 0-10 (worst possible care to best possible care*	CG; 0, 3, 6 mo.
ADRD-Specific			
Functional State	Survey	14 items: ADL/IADL' for CG; within HABC-M* for CR	CG, CR; 0, 3, 6 mo.
Behaviors	Survey	BEHAVE 5+*	CR; 0, 3, 6, 12 mo.
Caregiver Activation	Survey	MYLOH™ Instrument*	CR; 0, 3, 6, 12 mo.
Social Support	Survey	MOS Abbreviated Social Support (4-item; 5-point Likert scale)[7,8]	CG; 0, 3, 6 mo.
Other root causes	EMR	Application of post-hoc adjudication of root causes for ED use	CR; 0, 3, 6 mo.
****LEGEND: Caregiver= CG; Care Recipient = CR; Baseline = BL***			

References

1. Katz S. Assessing self-maintenance: Activities of daily living, mobility, and instrumental activities of daily living. *J Am Geriatr Soc*. 1983;31(12):721-727.

2. Monahan PO, Boustani MA, Alder C, et al. Practical clinical tool to monitor dementia symptoms: The HABC-monitor. *Clin Interv Aging*. 2012;7:143-157.

3. Borson S, Scanlan JM, Sadak T, Lessig M, Vitaliano P. Dementia services mini-screen: A simple method to identify patients and caregivers in need of enhanced dementia care services. *Am J Geriatr Psychiatry*. 2014;22(8):746-755.

4. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. *J Chronic Dis*. 1987;40(5):373-383.

5. HCAHPS: Hospital consumer assessment of healthcare providers and systems. http://www.hcahpsonline.org/home.aspxd. Accessed January 23, 2016.

6. Sadak, T., Wright, J., & Borson, S. (2016). Managing Your Loved One's Health Development of a New Care Management Measure for Dementia Family Caregivers. *Journal of Applied Gerontology*, 733464816657472. https://doi.org/10.1177/0733464816657472

7. Sherbourne CD, Stewart AL. The MOS social support survey. *Soc Sci Med*. 1991;32(6):705-714.

8. Dour HJ, Wiley JF, Roy-Byrne P, et al. Perceived social support mediates anxiety and depressive symptom changes following primary care intervention. *Depress Anxiety*. 2014;31(5):436-442.

Appendix 2:
POISED intervention Chronic Disease-Specific Care Management Guides: Dementia and Diabetes

CARE MANAGEMENT MATTERS

***The basics*:**
Following a prescribed diet plan, monitoring blood sugar regularly, using medications correctly, keeping a daily log, recognizing when diabetes is getting out of control, and keeping communication open with the medical team to respond to problems – all are important for successful management of diabetes. Team-based care management can help assure that caregivers have the support they need to accomplish these tasks. Care managers can also spot trends that indicate that a problem may require caregiver coaching, or more intensive medical care.

Know how dementia affects diabetes:

- People with dementia may have problems with eating and drinking properly, and this can make diabetes harder to control. Problems can include under-eating, overeating, eating too few different foods, eating things that are not foods, and refusing to eat or drink fluids.
- Dementia may alter activity (exercise) patterns – higher or lower levels of activity may occur and can affect diabetes management.
- People with dementia need help managing medications. When dementia is mild, sometimes it's enough for a family member to watch over a loved one's self care, or help organize a schedule and make sure the log is completed accurately to monitor food, fluids, testing, and medications. Caregivers need to look for warning signs that more help is needed – since most people with *any* level of dementia benefit from more active help from family caregivers. In many cases caregivers will need to take over all aspects of diabetes care, and some will need coaching to assure that the person with dementia allows this transition to happen.

***Understand how diabetes affects dementia**:*
Big fluctuations in blood sugar – either too high or too low – cause people with dementia to have more trouble with confusion and erratic behavior, and reduce their ability to function. Long periods of poor control of blood sugar can lead to long-term, permanent worsening in brain function. Assuring good control of diabetes gives people the best chance to live well with dementia and diabetes.

Make and monitor a plan for everyday home care and caregiver coaching:
MANAGING FOOD AND FLUID INTAKE

- Know the individual's prescribed diet. Identify and problem solve any specific difficulties patients and caregivers have in understanding or following it.
- Record food and fluid intake on a log. This helps avoid blood sugar that is too low (hypoglycemia) or too high (hyperglycemia).
- Record weight on a log, and note trends over time.

TESTING BLOOD SUGAR AND GIVING MEDICATIONS

- Know how to use the blood sugar meter and the blood sugar log ('daily glucose tracker').
    - Know how often to test and record blood sugar levels.

- Know when and how to adjust medication (if home adjustments are prescribed by the doctor).
- Take time to prepare the person with dementia before each test and each time medication is to be given – don't assume he remembers why this is important or what is happening.
- Identify caregivers who need coaching with any of these steps. Some caregivers may have trouble learning what to do, keeping on track, or approaching the person with dementia in a way that ensures cooperation.

Red flags:

- **Blood sugar readings below 80 mg/dl**
- **Sweating and shakiness (early warnings of hypoglycemia)**
- **Weight loss or gain of 5 or more pounds**

People with dementia may not notice or tell you about these symptoms.

Tips for smarter caregiving:

Giving medication:

- People with dementia may forget to take their medication.
- They are also at risk of taking too much medication because they forgot they already did. Medication boxes (MediSets) and blister packs help for medications given by mouth.
- Caregivers should use a log or calendar to check off when medications are given (caregivers get busy).
- All medications and over-the-counter medications should be kept safely out of reach to reduce the chance of mistakes.
- Some people with dementia may resist taking medications or have trouble swallowing. Ask the doctor about crushing the oral medication or disguising in food like pudding that the person will accept.
- Insulin injections: easiest when the routine is the same as before cognitive impairment developed, as long as this is medically recommended.

Exercise:

- Provide a predictable, regular, and pleasurable routine for daily exercise and rest (for the caregiver too!).

Eating and food preparation:

- When feeding becomes a problem, break it down:
    - Is lighting adequate in the dining area?
    - Is it quiet or is light music helpful?
    - Is the type and amount of social interaction conducive to eating? Some people may prefer to eat alone.
    - Is the person distracted by conversation, TV or radio, noise in another room?
    - Is there enough time allowed to chew and swallow?
    - Are foods the proper size?
        - Chop foods small enough to grasp, chew and swallow.
        - Puree foods when whole foods are not possible to eat due to the inability to chew or lack of teeth.
    - People who put food in their mouths and forget to swallow may be cued by gently stroking the sides of their neck.

- Caregivers should be taught the Heimlich maneuver to assist a choking person.
- Foam handles on utensils can facilitate grasping.
- For people who cannot use a spoon, a cup may be used to drink soup.
- Rubberized placemats may help to keep the food plate from slipping
- Are the food items distinguishable on a white or lightly colored plain plate. (People with dementia may not be able to distinguish food items from decorations embedded in the plate). A plain plate with dividers (as in a child's plate) may be helpful by separating foods and providing a "wall" against which foods may be pushed.
- Is the food at a reasonable temperature (not too hot or too cold)?
- People with severe dementia may "forget" how to eat. These people may be able to be coaxed by "following the leader."
- Dental disease, gum inflammation or soreness, mal-fitting dentures may interfere with eating.
- Visual impairment may impede eating. (Check that eye glasses are clean and in place)
- Constipation or bladder fullness may cause diminished eating.
    - Offer fluids every 2 hours; offer the bathroom an hour later.
    - Offer the bathroom ½ hour after eating a meal.
    - Acute refusal may indicate the need to defecate or void. Clues to this are resistance to sitting at the table or tugging at clothes.
- Because of amnesia associated with dementia, people may forget they have just eaten and request more food.
- Provide a standard and predictable routine for eating meals.

- Food preparation is a process that may require too many steps for a person with dementia living alone. An intermittent caregiver can prepare foods that are easy to open and do not require preparation. Consider home-delivered meals that do not require refrigeration or heating.

Working with the doctor:

- Caregivers need to know when to contact the doctor. Schedule a conversation to get those questions answered. Provide caregivers with a card they can post in a prominent place, with red flags, warning signs, and information about when and whom to call.
- Examples:
    - No bowel movement in 3-5 days signals a potential problem with constipation and should be brought to the attention of the doctor. Be sure to provide the food and intake log to the doctor.
    - If the person seems apathetic or sleepy, tell the doctor. Toxicity from too many medications or certain medications may lead to apathy or sedation. Bring the full up-to-date list of medications (including additional herbs and over-the-counter medications) to the doctor.

- Have a plan that all caregivers know about, including part-time and intermittent caregivers.
- Work with the doctor to simplify routines and medication plans.
- For every doctor visit: Bring a written list of caregiver's concerns, the full up-to-date list of medications (prescriptions, over the counter, supplements, and herbal medications) daily glucose tracker, and food and fluid intake and weight logs.

Appendix 3:
POISED Research Evaluation Survey

POISED STUDY
RESEARCH EVALUATION SURVEY

SURVEY OVERVIEW

Notes to IRB:

The POISED Study research evaluation survey is the baseline evaluation survey that will be modified for follow-up surveys. Text will be adjusted to orient the respondent to the follow-up survey time frames (3 months and 6 months). Also, demographic characteristic questions will not be repeated.]

The study research assistant will administer the baseline survey either in person at the Emergency Department visit if is practical and feasible without disrupting patient care as delivered by ED and hospital staff, or at a time by telephone that is agreeable to the caregiver.

The research assistant will administer the follow-up surveys by telephone.

FOR TELEPHONE:

- Hello, my name is [*interviewer name*] from the POISED study. May I speak with [*Insert name of caregiver*]?

Caregiver comes to telephone

- Hello, my name is [*interviewer name*]. I am from the POISED research study. You may remember that you spoke with me
    - when we did [the consent] or [the other survey about 3 months ago *(if this is a follow-up survey)*].
- I am calling you as part of the evaluation of this research study.
- Is it okay if we talk now?

INSTRUCTIONS TO INTERVIEWER:

If 'No', ask about another time that is more convenient.

If the person refuses to participate in the survey interview, thank the person.

If 'Yes', continue…→

- The program looks at ways to improve care for people with memory or thinking problems. The program is also for those family members or friends who provide help to the person with memory problems. We refer to individuals who provide help as caregivers or care

partners.

- Your participation in the program and interview will help us understand how best to help people with memory loss. Your participation will also help us understand how to help caregivers or care partners.

Introduce Survey:

- The interview will take about 30 minutes to complete. We will keep all of your answers confidential. Participating in this telephone interview is completely voluntary.
- If you feel uncomfortable answering specific questions, you can refuse to answer any or all questions. You may stop the interview at any time and continue it later. You may end the interview at any time and not continue.
- At the end of this interview, we will mail you a $40 gift card for your time.
- Your decision to participate does not in any way affect the health care that either you or *[name of Care Recipient]* receives. None of the doctors that you or *[name of Care Recipient]* see will know whether or not you have participated in this survey.
- Do you have any questions about the study or about your participation?"
  IF YES: RESPOND TO ALL QUESTIONS BEFORE PROCEEDING.

Now I'm going to ask you a few questions to make this call as easy as possible.

1a. Are you in a quiet and comfortable location?

☐ Yes

☐ No (wait for respondent)

1b. Am I speaking loudly and clearly enough for you to understand me?

☐ Yes

☐ No (go to 1c)

1c. (INTERVIEWER SPEAKING LOUDER) is this better?

☐ Yes

☐ No (code Hearing Impaired)

[If "No," thank the subject and end the interview explaining that you cannot conduct the interview because of difficulty hearing on the telephone. Immediately Contact the Program Coordinator. If the interviewer thinks the difficulty hearing is because of a bad connection (due to cell phone) offer to call at another time.]

May I start the interview?

☐ No/Refused ➡ End Interview: Thanks very much for listening. Goodbye.

[REASON:
_____]

GENERAL QUESTIONS

First, I would like to start this interview by asking you some brief general questions about yourself.

1. How old are you today? _____ years old

2. What is your gender? ☐ Male ☐ Female

3. What is your race/ethnicity? You may answer yes to more than one.
   ☐ White ☐ Black ☐ Asian
   ☐ Hispanic ☐ Other

4. What is your highest level of education?
   ☐ Less than high school ☐ Completed High school
   ☐ Some college ☐ College graduate+

5. What is your relationship to [*name of Care Recipient*], your Care Recipient?
   ☐ Spouse ☐ Child
   ☐ Other relative ☐ Friend/other

6. How many years have you been his/her caregiver? _____ years

7. What is your marital status?
   ☐ Single/never married ☐ Married
   ☐ Divorced

8. What are your current living arrangements?
   ☐ Live with Care Recipient
   ☐ Live in close proximity How many miles? _____miles
   ☐ Other (please specify: _____)

9. How hard is it for you to pay for the very basics like food, housing, medical care, and heating? Would you say it is…
   ☐ Very hard
   ☐ Somewhat hard
   ☐ Not hard at all

Financial Strain: Study of Women's Health across the Nation (SWAN) and the Coronary Artery Risk Development in Young Adults (CARDIA) studies (see, for example, Hall et al. [2009] and Puterman et al. [2013])

Now I am going to ask you some questions about [*insert name of Care Recipient*], the person you care for.

1. Where does he/she live? (ex. private home, assisted living, nursing home, other?)
   ☐ Apartment/home/condo
   ☐ Assisted living/ Board and Care
   ☐ Nursing home
   ☐ Other (please specify: _____)

2. Has [*name of Care Recipient*] ever received a diagnosis of dementia?
   ☐ Yes ☐ No

3. If Yes,
   About what year did he/she receive that diagnosis? _____
   Or, about how many years ago? _____

4. Has [*insert name of Care Recipient*] had a change in his/her primary care provider in the last year? ☐ Yes ☐ No

5. Does [*insert name of Care Recipient*] have health care insurance? ☐ Yes ☐ No

6. We have to ask for our study whether [*insert name of Care Recipient*] has a history of substance abuse, including alcohol?
   ☐ Yes ☐ No ☐ Don't know/refused

7. Does he/she currently have a substance abuse problem?
   ☐ Yes ☐ No ☐ Don't know/refused

8. Has [*insert name of Care Recipient*] received a diagnosis of any of the following conditions:
   ☐ Depression ☐ PTSD ☐ Schizophrenia
   ☐ Other (please specify: _____)

Now I will ask you a few questions about traveling.

9. We have [*insert name of Care Recipient*] address as [Fill In]. Is this correct?

10. What is the primary mode of transportation you use?
    ☐ Personal car ☐ Taxi
    ☐ Train ☐ Bus
    ☐ Walk ☐ Other (please specify: _____)

11. Where do you go when you have to bring [*insert name of Care Recipient*] to see the doctor, meaning the doctor's office or clinic (usual source of care – USC) ? Do you have the location or address? _____

12. Where do you usually go if you need to travel to the hospital or Emergency Department (ED)? _____

(For Calculating Miles and Difference in distance between ED vs. USC)

Next, I want you to think about the last 12 MONTHS and the care you have provided to [*insert name of Care Recipient*]. It might help to get a calendar.

NOTE: FOR FOLLOW-UP SURVEYS, REPLACE "12 MONTHS" WITH THE CORRESPONDING TIME FRAME SUCH AS 3 MONTHS, 6 MONTHS

1. How many times did [*insert name of Care Recipient*], the person you care for, visit his/her Primary Care Provider or PCP) in the last year? #____ times

2. For each time, please indicate the primary reason for going to the PCP"

   2a. Was the visit for a new symptom or for a change in a symptom that [*insert name of Care Recipient*]'s had previously? ☐ Yes ☐ No — Acute use

   2b. A fall or other injury? ☐ Yes ☐ No

   2c. A symptom that has been present for more than the past month? ☐ Yes ☐ No — Non-acute use

   2d. A medication refill? ☐ Yes ☐ No

   2e. Other (please specify: _____)

3. Have you had any difficulty getting medication refills for [*insert name of Care Recipient*] ☐ Yes ☐ No

4. Over the past [*insert time frame*] has [care recipient name] had any new medical problems or illness? ☐ Yes ☐ No

5. Over the past [*insert time frame*] has [*insert name of Care Recipient*] had any injuries? ☐ Yes ☐ No

6. How many times did he/she use the Emergency Department? #____ times

7. How many times did he/she stay in the hospital overnight or longer in the last year? #____ times

   7a. For each stay in the hospital, I want you to tell me, to the best of your knowledge, the month and number of days he/she was in the hospital?

   i. Stay number 1: Month: _____. #_____days
   ii. Stay number 2: Month: _____. #_____days
   iii. Stay number 3: Month: _____. #_____days
   iv. Stay number 4: Month: _____. #_____days
   v. Stay number 5: Month: _____. #_____days
   vi. Stay number 6: Month: _____. #_____days

8. Over the past [*insert time frame*], has [name of CR] received help from the "In-Home Supportive Services" Program? This program helps pay for services to help keep [name of CR] safely in [his/her] home. Services include personal care and household tasks such as housecleaning, meal preparation, laundry, and grocery shopping. ☐ Yes ☐ No — Non-acute use

   8a. If Yes, how many months? _____

8b. How hours per week on average _____

HCAHPS[1] COMPONENT

Using any number from 0 to 10, where 0 is the worst health care possible and 10 is the best health care possible, what number would you use to rate _____'s health care?

0 1 2 3 4 5 6 7 8 9 10

Now I am going to ask you some questions about [*insert name of Care recipient*]'s memory, mood, behaviors, and day-to-day activity. I will also ask questions about your overall health. When answering these questions please keep in mind the following:

1. Answer each questions based on your first reaction – evidence of actual change is not as important as your gut instinct.
2. There are no formal definitions for the symptoms you are being asked to rate, although, in some cases, examples of the symptom are included. In general, whatever the term means to you in a reasonable and acceptable definition.
3. Rate the frequency of the symptoms over the past two weeks using a scale of:
    a. Not at all (0-1 day)
    b. Several days (2-6 days)
    c. More than half the days (7-11 days)
    d. Nearly every day (12 -14 days)
4. First, how well do you know [*insert name of Care Recipient*]?

☐ Not at all ☐ Somewhat well ☐ Well ☐ Very well

Over the past **two weeks**, how often did [insert name of Care recipient] have problems with the following items:	Not at all (0-1 Day) 0 Points	Several days (2-6 Days) 1 point	More than half the days (7-11 Days) 2 points	Almost daily (12-14 days) 3 points
Judgment or decision-making				
Repeating the same things over and over such as questions or stories				

Forgetting the correct month or year				
Handling complicated financial affairs such as balancing checkbook, income taxes & paying bills				
Remembering appointments				
Thinking or memory				
Learning how to use a tool, appliance, or gadget				
Planning, preparing, or serving meals				
Taking medications in the right dose at the right time				
Walking or physical ambulation				
Bathing				
Shopping for personal items like groceries				
Housework or household chores				
Leaving him/her alone				
His/her safety				
His/her quality of life				
Falling or tripping				
Less interest or pleasure in doing things, hobbies or activities				
Feeling down, depressed, or hopeless				
Being stubborn, agitated, aggressive or resistive to help from others				
Feeling anxious, nervous, tense, fearful or panic				
Believing others are stealing from them or planning to harm them				
Hearing voices, seeing things or talking to people who are not there				
Poor appetite or overeating				
Falling asleep, staying asleep, or sleeping too much				

Acting impulsively, without thinking through the consequences of her/his actions				
Wandering, pacing, or doing things repeatedly				
Over the past **two weeks**, how often did **you** have problems with: (Use **√** to indicate your answer.)	Not at all (0-1 Day) 0 Points	Several days (2-6 Days) 1 point	More than half the days (7-11 Days) 2 points	Almost daily (12-14 days) 3 points
Your quality of life				
Your financial future				
Your mental health				
Your physical health				
	Cognitive subscale:			
	Functional subscale:			
	Behavioral and mood subscale:			
	Caregiver stress subscale:			
	Total score:			

I would like to ask you some questions about how YOU, the care partner/caregiver, are managing with your own day-to-day activities. Do you need assistance with any of the following?

ACTIVITIES OF DAILY LIVING (ADLS)[3]			
	Needs no help	Needs some help	Unable to do at all
A. Bathing	2	1	0
B. Dressing	2	1	0
C. Toileting	2	1	0
D. Transferring, (use explanatory text as necessary: "Transferring means changing positions such as going from bed to standing, standing to sitting,	2	1	0
E. Continence	2	1	0
F. Feeding	2	1	0

INSTRUMENTAL ACTIVITIES OF DAILY LIVING (IADLS)[3]			
	Needs no help	Needs some help	Unable to do at all
G. Using the telephone	2	1	0
H. Getting to places beyond walking distance	2	1	0
I. Grocery shopping	2	1	0
J. Preparing meals	2	1	0
K. Doing housework or handyman work	2	1	0
L. Doing laundry	2	1	0
M. Taking medications	2	1	0
N. Managing money	2	1	0

Now I will ask a few questions about how YOU have been feeling over the last 2 weeks. Possible answers are: Not at all; Several days; More than half the days; or Nearly every day

GAD-7 COMPONENT[4]

GAD-**Over the last 2 weeks, how often have you been bothered by the following problems?**	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious, or on-edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

How often is each of the following kinds of support available to you if you need it? Possible answers are: None of the time; A little of the time; Some of the time; Most of the time; or All of the time.

SOCIAL SUPPORT "SS-5" [5]

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
A. Someone to confide in or talk to about problems.	1	2	3	4	5
B. Someone to get together with for relaxation.	1	2	3	4	5
C. Someone to help you with daily chores if you were sick.	1	2	3	4	5
D. Someone to turn to for suggestions about how to deal with a personal problem.	1	2	3	4	5
E. Someone to love and make you feel wanted.	1	2	3	4	5

Patient **H**ealth **Q**uestionaire-9 (**PHQ-9**)[6]

Over the past 2 weeks how often have you been bothered by any of the following problems. **Possible answers are: Not at all; Several days; More than half the days; or Nearly every day**		Not at all	Several Days	More than half the days	Nearly every day
1.	Little interest of pleasure in doing things	0	1	2	3
2.	Feeling down depressed or hopeless	0	1	2	3
3.	Trouble falling asleep, staying asleep or sleeping too much	0	1	2	3
4.	Feeling tired or having little energy	0	1	2	3
5.	Poor appetite or overeating	0	1	2	3
6.	Feeling bad about yourself – or that you have been a failure or let yourself or your family down	0	1	2	3
7.	Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8.	Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3

9.	Thoughts that you would be better off dead or of hurting yourself in some way**	0	1	2	3
10.	If you selected any of these problems, how difficult have those problems made it for you to do your work, take care of things at home, or get along with other people	☐ Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult			

****Refer to local site Suicide Prevention Protocol**

MYLOH© COMPONENT[7]

Now I am going to ask you some questions about any problems you might have in helping [*name of Care Recipient*]. Many of the questions are very similar to what has already been asked.

Please keep in mind the following definitions *when answering these questions:*

- The terms "***He/She, Him/Her***" refer to your care recipient.
- The term "***Health Care Providers"*** refers to doctors, nurse practitioners, physician assistants, nurses, social workers, pharmacists, medical specialists (ex. cardiologist, psychiatrist), and other healthcare staff.
- The term "***Care Partner***" refers to YOU.
    - ***Primary Care Partner*****:** Live with or nearby the person who needs care. Regularly provide care and assist with daily and medical decisions and care tasks.
    - ***Helper Care Partner*****:** Live with or nearby. Help a primary care partner when needed.
    - ***Long-distance Care Partner*****:** Live further away. Visit when they can and assist with making decisions.

What kind of Care Partner are you? Please answer questions below.

☐	☐	☐
The **primary** person responsible for care	A **helper** who assists with care	A person who assists with care from a **long-distance**

From a score of 1 to 5; "1" being 'Not difficult' and "5" being 'Extremely difficult', please tell me…

How difficult is it for you to pay for all of the basic needs* for the person with dementia?:

1 2 3 4 5

NOT DIFFICULT ⟶ **EXTREMELY DIFFICULT**

*Basic Needs ex. food, medical & other supplies, medications

Next I want to understand what his/her problems are. I will name several possible problems your care recipient <u>might</u> have. Possible answers to the questions are: Agree completely; Agree; Disagree; Disagree completely; or Not my job.

	Agree Completely	Agree	Disagree	Disagree Completely	Not My Job
1. I understand WHAT his/her problems are:					
A. With **Memory** (ex. remembering, planning, making decisions)					
B. With **Mood/Behaviors** (ex. anger, sadness, irritation, poor sleep)					
C. With **Medical Issues** (ex. illnesses, pain, headaches)					
D. With **Self-Care** (ex. eating, dressing, showering, using the toilet)					
2. Right now, I can deal with DAY-TO-DAY problems he/she has:					

A. With **Memory** (ex. remembering, planning, making decisions)					
B. With **Mood/Behaviors** (ex. anger, sadness, irritation, poor sleep)					
C. With **Medical Issues** (ex. illnesses, pain, headaches)					
D. With **Self-Care** (ex. eating, dressing, showering, using the toilet)					
3. I know, or can get information about:					
A. What medications his/her health care provider recommends (prescription and non-prescription)					
B. What dose, **when and how** these medications should be taken (ex.10 mg tablet twice a day)					
C. What conditions these medications are used for (ex. blood pressure, blood sugar, dementia)					
4. I watch to be sure that he/she takes medications correctly and **provide help when needed**					
5. If I have concerns about his/her medications (ex. I worry about the safety or value of what is prescribed) I tell the clinician about them					

	Agree Completely	**Agree**	**Disagree**	**Disagree Completely**	**Not My Job**
6. I can tell when there are NEW or RAPIDLY WORSENING changes in his/her:					
A. Memory (ex. remembering, planning, making decisions)					

B. Mood/Behaviors (ex. anger, sadness, irritation, poor sleep)					
C. Medical Issues (ex. illnesses, pain, headaches)					
D. Self-Care (ex. eating, dressing, showering, using the toilet)					
7. When NEW or RAPIDLY WORSENING changes happen, I know:					
A. What to **watch for** and what to **report** to his/her healthcare provider					
B. What I can **deal with on my own**					
C. When to **contact** his/her **health care provider**					
D. Which health care provider I should contact (ex. doctor, nurse, pharmacist)					
E. When I **need immediate assistance** and I should call 911 or other emergency medical help					
8. In helping with HEALTH CARE DECISIONS (ex. start new medication, go to a hospital have surgery), **I understand:**					
A. What would be important to the person I care for					
B. How to speak up on his/her behalf					
C. The responsibilities of a person who has a Power of Attorney for Medical Decision Making					
9. In regards to CAREGIVING RIGHT NOW:					
A. I **can do everything needed** to ensure that his/her care needs are met					
B. I am **taking care of myself** so that I can **continue to care** for					

him/her (ex. I take a break when needed)					
C. When I **need help** with caregiving, I know how to **get it**					
D. I know **what to do** if I have a personal crisis and **cannot provide care** or help with care as I usually do.					

Based on all the questions you just answered, please tell me the 3 **most important questions** to discuss with a healthcare provider **now**:

INSTRUCTIONS TO PERSON ADMINISTERING SURVEY: (enter descriptor text and the question number after rereading the question to be sure you have it right)

The question you would like to discuss **first**: Question#_____

The question you would like to discuss **second**: Question# _____

The question you would like to discuss **third**: Question# _____

Is there **anything else** we did not ask about that a healthcare provider **could help you with** in caring for your loved one?

BEHAV5+[8]

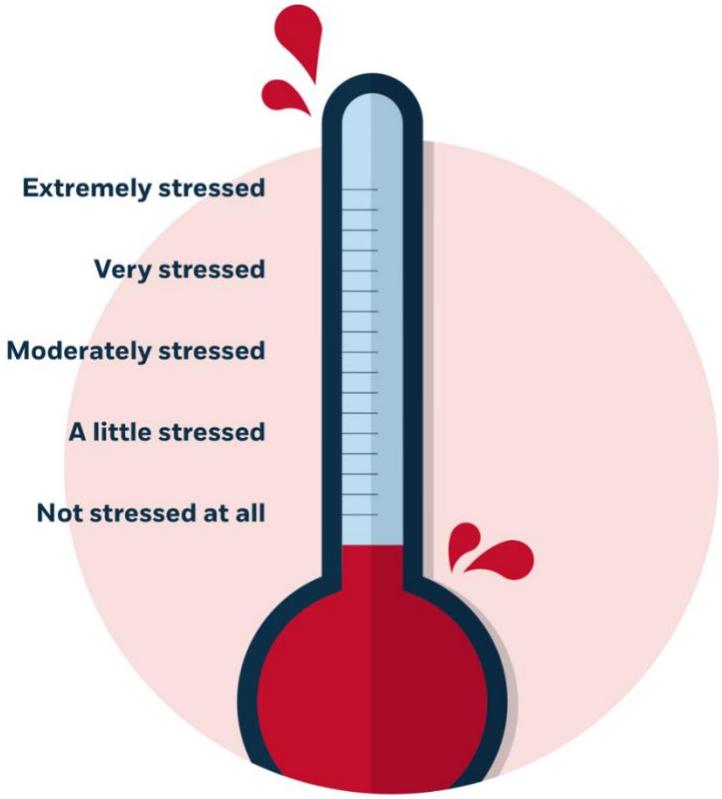
Please check yes for the behaviors that **you have observed** in your **care recipient** in the **past month.**

1. AGITATION/AGGRESSION Does your care recipient get angry or hostile? Resist care from others?	☐ Yes ☐ No
2. HALLUCINATIONS Does your care recipient see and/or hear things that no one else can see or hear?	☐ Yes ☐ No
3. IRRITABILITY/ FREQUENTLY CHANGING MOOD	☐ Yes ☐ No

Does your care recipient act impatient and cranky? Does his or her mood frequently change for no apparent reason?	
4. SUSPICIOUSNESS/PARANOIA Does your care recipient act suspicious without good reason (example: believes that others are stealing from him or her, or planning to harm him or her in some way)?	☐ Yes ☐ No
5. INDIFFERENCE/SOCIAL WITHDRAWAL Does your care recipient seem less interested in his or her usual activities and in the activities and plans of others?	☐ Yes ☐ No
6. SLEEP PROBLEMS Does your care recipient have trouble sleeping at night?	☐ Yes ☐ No

STRESS THERMOMETER COMPONENT[8]

1. Will you please tell me how stressed you are feeling?*
   - ☐ Extremely stressed
   - ☐ Very stressed
   - ☐ Moderately stressed
   - ☐ A little stressed
   - ☐ Not stressed at all
   - ☐ Don't know



STRESS: Feeling tense, nervous, anxious, restless, or unable to sleep because your mind is troubled all the time.

[End of Interview Questions]

In about 3 months, I or another Interviewer for this study will call you to request your participation in another interview. At that time, we will go through the same process that we went through today. Your participation in any future surveys is voluntary and you can decide at that time if you would like to speak with us.

1. May we call you in about 3 months from now?"

☐ Yes, Go Q. 2

☐ No, Skip to "Address Confirmation"

2. Which are the best days and times to reach you about 3 months from now? What do you prefer?

<u>During the week:</u>

☐ Morning ☐ Afternoon ☐ Evening

Telephone: ___ ___ ___ -- ___ ___ ___ -- ___ ___ ___ ___

On Saturdays:

☐ Morning ☐ Afternoon ☐ Evening

Telephone: ___ ___ ___ -- ___ ___ ___ -- ___ ___ ___ ___

ADDRESS CONFIRMATION

For the purpose of sending you a $40 gift card that we are giving to you in appreciation of your time with this interview, I need to verify your mailing address:

Address: _____

Please call our Study Coordinator, [*insert full name*] at [*insert hospital name*] at [*insert telephone number*] if you should have new your contact information so that we can contact you for the next telephone survey. Again, that number is [*insert telephone number*].

If you have any other questions or concerns about the research, please feel free to contact the Principal Investigator, [*insert site PI name*] at [*Insert telephone number*]

If you wish to ask questions about your rights as a research participant or if you wish to voice any problems or concerns you may have about the study to someone other than the researchers, you may contact the [*insert head of IRB*] at [*insert site*]. The telephone number is [*Insert telephone number*]. **Thank you again!**

References:

1. HCAHPS: Hospital consumer assessment of healthcare providers and systems. http://www.hcahpsonline.org/home.aspxd. Accessed January 23, 2016.

2. Monahan PO, Boustani MA, Alder C, et al. Practical clinical tool to monitor dementia symptoms: The HABC-monitor. *Clin Interv Aging*. 2012;7:143-157.

3. Katz S. Assessing self-maintenance: Activities of daily living, mobility, and instrumental activities of daily living. *J Am Geriatr Soc*. 1983;31(12):721-727.

4. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: The GAD-7. *Arch Intern Med*. 2006;166(10):1092-1097.

5. Dour HJ, Wiley JF, Roy-Byrne P, et al. Perceived social support mediates anxiety and depressive symptom changes following primary care intervention. *Depress Anxiety*. 2014;31(5):436-442.

6. Kroenke K, Spitzer RL. The PHQ-9: A new depression and diagnostic severity measure. *Psychiatric Annals*. 2002;32:509-521.

7. Sadak, T., Wright, J., & Borson, S. (2016). Managing Your Loved One's Health Development of a New Care Management Measure for Dementia Family Caregivers. *Journal of Applied Gerontology*.

8. Borson S, Scanlan JM, Sadak T, Lessig M, Vitaliano P. Dementia services mini-screen: A simple method to identify patients and caregivers in need of enhanced dementia care services. *Am J Geriatr Psychiatry*. 2014;22(8):746-755.

Appendix 4:
POISED Detailed Care Management Strategies

POISED includes:

1. Initial Assessment: The POISED care management team is structured to maximize the skill sets of specially-trained nurses functioning as care managers (CMs) and para-professionals in the role of care manager assistants (CMAs) in a collaborative model to maximize effectiveness and decrease cost. The CM and CMA conduct a biopsychosocial/environmental needs assessment by phone within 48 hours of emergency room discharge if not possible during the ED stay. This initial assessment (in person or by phone) includes a briefer demographic and psychosocial interview (compared with the home visit) focused on achieving most urgent problem identification. The program uses standardized assessment tools including "Managing Your Loved Ones Health" (MYLOH™) for chronic disease management[1] and BEHAVE 5+[4] . If the consented CG is not available, we will attempt to complete the CG questions at a later date either by phone or in person. The CM's interview also uses principles of root cause analysis (RCA) (further described below) to better understand the events and potential causes leading to the ED visit. The CM team then focuses on initial problem clarification and reviews the assessment findings, the medical record, medication lists, ED discharge plans and pharmacist consultation. The CM also reviews any diagnostic testing, any brain imaging results, and functional details of the assessment to determine the presence or absence of a likely dementia diagnosis, identifying any reversible and co-morbid conditions and, for complex cases, the need for referral for further evaluation at either NYU's or IU's well-developed dementia assessment centers.

2. First Home Assessment: After review of all findings from prior data and the first telephone encounter, the CM and CMA create an initial plan and identify areas needing further assessment to be conducted at the first home visit (within 2 weeks after enrollment). That visit enables the CM team to conduct some additional cognitive and functional testing while the POISED RN uses the time to address more sensitive issues that the CG may be uncomfortable discussing in the presence of the CR. The results of this initial assessment and home visit are forwarded to the CR's PCP with requested feedback and further direction as needed.

3. Root-Cause Analysis of Emergency Department Visit or Repeat Visit / Hospitalization: Both CM and CMA members of the care management team will be well versed in the strategies of Root Cause Analysis. Starting with the ED visit and working backwards in time, the team will explore and identify problems or branch-point situations that progressed to the need for ED care. Using a logic tree as a cause and effect approach to create a timeline of events leading to ED visit[2] and asking the question, "how could this occur?" or "why" based on the "Five-Whys" strategy[3] they will ask "why" for each successive answer starting with "why did you come to the Emergency Department." Answers will be applied to medical record review looking for other possible triggers and opportunities for intervention. This brainstorming/investigative process is a successfully used quality improvement strategy and is also deployed by patient safety teams investigating adverse events.

4. Self-Management/Caregiver Skills Enhancement: Prior to the second home visit, the CM prepares the various relevant materials to enhance patient self-management or caregiver skills. These materials (the Patient or Caregiver Care Manual) can include: chronic disease specific self-management strategies and medical information focused on identifying "red-flag" signs or symptoms, medication effects and proper use, enhanced information based on RCA investigation relevant to the sentinel ED visit, information on legal and financial planning with referrals made to elder law specialists and legal services programs in the community; specific behavioral interventions techniques to help manage, reduce or avoid care recipient problem behaviors; and/or coping strategies to ensure the caregivers' emotional and physical health remain intact. These materials are provided to dyads via various face-to-face or home counseling sessions. If the dyad's needs are particularly complex, the counseling can take place over more than one face-to-face and/or telephone session.

5. Informal Telephone Support: Dyads will have access to telephone consultation with the care team. Any Family members participating in the patient's care can initiate the telephone contact. Offering access to the care team empowers caregivers to more readily try different interventions.

6. Problem Solving Process: Using data collected from the structured caregiver interview or during face-to-face visits, the care team uses standardized protocols to manage behavioral and psychological symptoms related to dementia. The care team educates the caregiver on implementing these protocols and monitors the success of such implementation via face-to-face or telephone follow-up interactions.

7. Reducing the Anticholinergic Cognitive Burden: Using the Anticholinergic Cognitive Burden Scale (ACBS), developed by the Indiana Aging Brain group, the care team reviews the over-the-counter and prescribed medications taken by the patient and coordinates with the primary care provider (PCP) to identify the presence of any anticholinergic medication in efforts to balance their benefits and harms.

8. Prescribing FDA-Approved Medications: The care team, in coordination with the PCP, discusses the indications, benefits and expectations of using FDA-approved medications for dementia.

9. Managing High Vascular Disease Burden: The care team will review the care recipient vascular burden and provide the PCP with data to reduce burden with pharmacological and non-pharmacological approaches.

10. Monitoring and Support of the Caregiver's Emotional and Physical Health: The care team will use brief assessments to monitor care recipient cognitive, functional, behavioral and psychological symptoms; and caregiver stress using the caregiver Stress Thermometer.[4]

11. Managing Transitional Care: Starting with the ED visit or within 48 hours and after any emergency department or hospital discharge the CM will reconcile discharge instructions, medications, and counsel and support the dyad to carry out any post-discharge care plans.

12. Managing Acute Care Problems: There are times when a care recipient or caregiver will call the care management team with an acute care problem and seek direction. To avoid a potentially unnecessary ED visit, the care team may make a home visit, inform the PCP, and address the problem accordingly.

13. Care Prioritization: Under circumstances where patients have significant needs that exceed the capacity of the clinical program, the care team will utilize established guidelines to prioritize addressing these needs to ensure the most vulnerable patients (those who require a hospital or emergency department visit followed by those who require post-hospital or emergency department transitional care) receive timely care coordination by the care team including a home visit within 72 hours of discharge from a hospital or emergency department.

14. Discharge Criteria: The care team will discharge the patient and caregiver if they meet any of the following criteria: 1) patient expires; 2) patient and/or family/caregiver decline to continue in the program; 3) primary care provider requests patient discharge from the program; 4) patient transitions to another health care system or move outside Marion County; 5) patient's living situation/environment becomes unsafe for patient and/or staff and therefore requires long-term skilled nursing home care; or 6) complete the 6-month study.

1. Sadak T, Korpak A, Borson S. Measuring caregiver activation for health care: Validation of PBH-LCI:D. *Geriatr Nurs*. 2015;36(4):284-292.

2. Latino RJ. *Patient safety: The PROACT root cause analysis approach.* Boca Raton, FL: Taylor and Francis; 2008.

3. Five Whys Technique. http://www.adb.org/publications/five-whys-technique. Updated 2009. Accessed January 25, 2016.

4. Borson S, Scanlan JM, Sadak T, Lessig M, Vitaliano P. Dementia services mini-screen: A simple method to identify patients and caregivers in need of enhanced dementia care services. *Am J Geriatr Psychiatry*. 2014;22(8):746-755.

Appendix 5:
POISED Laminated Information Card

POISED

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