Implementation of MIND at Home Program in Primary Care for People Living with Dementia: A Pilot Study

Principal Investigator:

Elizabeth L. Ciemins, PhD, MPH, MA, Senior Vice President, Research and Analytics, AMGA

Supported by:

The National Institute on Aging

FY_Pilot1_Ciemins

Study Intervention Provided by: N/A

Sponsor of IND/IDE: N/A

NCT #: 05406921

Version 1.6
July 25, 2023

TABLE OF CONTENTS

PRÉCIS

Implementation of MIND at Home Program in Primary Care for Patients Living with Dementia: A Pilot Study

Objectives

The primary objective of this pilot study is to embed and test the feasibility of a novel best practice-based approach, MIND at Home, within primary care to enhance and elevate the role of existing primary care staff to Memory Care Coordinators (MCCs), increase primary care access to interdisciplinary collaborative care, and systematically combine the benefits of clinic-based services with home- or telephone/video-based enhanced assessment to support family-centered care planning and implementation for people living with dementia (PLWD) and their care partners. Our overarching goal is to test and establish feasibility, acceptability, fidelity, and sample size/referral rate data for MIND at Home in primary care (PC) to prepare for a future multi-site embedded pragmatic trial.

The secondary objective is to test the feasibility of collecting and validating data from large health systems through the extraction of data on 100 additional patients who will not be enrolled in the intervention but will participate in the data validation arm.

Design and Outcomes

Using a pragmatic trial design, *this project will embed and test the feasibility of a novel best practice-based approach*, MIND at Home, within PC to enhance and elevate the role of existing PC staff to Memory Care Coordinators (MCCs), increase PC access to interdisciplinary collaborative care, and systematically combines the benefits of clinic-based services with home- or telephone/video-based assessment to support family-centered care planning and implementation for PLWD and their care partners. Weekly virtual collaborative learning sessions that include geriatric psychiatry consultants augment the PC care team's work to support the development and mastery of, and confidence in, dementia assessment and care management skills at the PC sites. Our ***overarching goal*** is to test and establish feasibility, acceptability, fidelity, and sample size/referral rate data for MIND at Home in PC to prepare for a future multi-site embedded pragmatic trial.

- Aim 1: Evaluate the feasibility and validity of eligible PLWD identification, referral, and enrollment in a best practice-based dementia care coordination program (MIND at Home) at 3 primary care clinics.
- Aim 2: Evaluate the feasibility, acceptability, and fidelity of implementing MIND at Home in 3 primary care clinics in 2 geographically and demographically diverse integrated health systems.
- Aim 3: Evaluate the feasibility of ascertainment of patient-level outcomes over time using electronic health record (EHR) data.

Embedding a collaborative, best-practice based approach such as MIND at Home into PC is a potentially powerful strategy to organize care, improve quality, reduce costs, and maximize population-level benefit for PLWD. This proposal tests the feasibility of implementing MIND at Home into PC in a racially, ethnically, and geographically diverse PLWD population to prepare for a multisite ePCT to evaluate effectiveness, and eventually to support broader dissemination and uptake in PC.

Interventions and Duration

This study will test a single intervention. **M**aximizing **Ind**ependence at Home–**MIND at Home (MIND)** is a comprehensive care coordination program born from geriatric psychiatry. This model takes an interdisciplinary, collaborative care approach to care by systematically assessing and addressing a wide range of dementia-care related needs of both PLWD and their care partners that place both at increased

risk for poor outcomes.

The five key program components include: (1) identification of dementia-related needs for the PLWD and care partner, using standardized procedures and definitions, including an in-home or telephone/video assessment by the MCC using the Johns Hopkins Dementia Care Needs Assessment (JHDCNA) (13 domains, 61 items; see Appendix B); (2) family-centered need-based care planning involving the MCC in collaboration with the PC team, following standard protocol, to address unmet needs and match priorities/preferences of the PLWD and family targeting both medical and non-medical determinants of health relevant for all stages of dementia (including social and environmental needs); (3) implementation of care plans linked with proven practice derived care strategies/interventions (e.g., education, coaching, symptom/need assessment, referrals, care coordination/navigation) by the MCC using standardized proven methods and need-based protocols; (4) care monitoring and plan revision, which include regular contact at least every 30 days; and (5) standardized initial program orientation for MCCs and all PC team members and weekly virtual collaborative learning sessions that include a structured case discussion (de-identified) and a short didactic on a specific care topic. Sessions are attended by geriatric psychiatry to support the PC care team's work and advance dementia assessment and care management capacity at PC sites.

PLWD and their care partners will be enrolled for a total of 3 months.

Sample Size and Population

Using a pragmatic trial design, 150 community-residing PC PLWD will be enrolled in the program, each for a 3-month period. Data on an additional 100 PLWD will be pulled for validation purposes.

STUDY TEAM ROSTER

Principal Investigator: **Elizabeth L. Ciemins**

AMGA
One Prince Street
Alexandria, VA 22314
406-281-3275
eciemins@amga.org
Main responsibilities/Key roles: Dr. Ciemins, VP, AMGA Research and Analytics, will provide overall project oversight, including managing and working closely with the 2 subcontracts and 1 consortium partnership. She will oversee all project staff. She will work with NIA on data safety monitoring and adverse event reporting. She will provide expertise in implementation science to guide intervention implementation activities.

Co-Investigator: **Quincy Samus**

Johns Hopkins School of Medicine
5200 Eastern Ave
Mason F. Lord Building, East Tower #326
Baltimore, MD 21224
(410) 550-6493
qmiles@jhmi.edu
Main responsibilities/Key role: Johns Hopkins University Medical Center will serve as a consultant/co-investigator providing oversight for the implementation of the intervention, MIND at Home. Dr. Samus will provide oversight for the Memory Care Coordinators (MCCs) at the participating primary care practices. She will provide orientation materials and will host 2 half-day sessions with all MCCs to answer any questions. She will oversee all orientation activities of the MCCs. Together with Dr. Johnston, Dr. Samus will serve as liaison to the weekly didactic learning and case discussions for all team members, including the MCCs, at the study sites.

Co-Investigator: **Deirdre Johnson**

Johns Hopkins University Hospital
600 North Wolfe Street Meyer Building, Suite 235
410.955-6158
djohnst4@jhmi.edu
Main responsibilities/Key role: Johns Hopkins University Medical Center will serve as a consultant/co-investigator providing oversight for the implementation of the intervention, MIND at Home. Dr. Johnston, together with Dr. Samus will serve as liaison to the weekly didactic learning and case discussions for all team members, including the MCC, at all study sites.

Biostatistician: **Jeff Mohl**

AMGA
One Prince Street
Alexandria, VA 22314
406-425-1097
jmohl@amga.org
Main responsibilities/Key role: Dr. Mohl will oversee all statistical analysis and provide oversight of data collected from the study sites. He will monitor quality and integrity of the data and all analyses. He will work closely with the PI, who will provide final approval for all analyses and reports.

PARTICIPATING STUDY SITES

Site #1 Co-Investigator: Christina L.H. Taylor

McFarland Clinic
1215 Duff Avenue, P.O. Box 3014
Ames, IA 0010-3014
Phone (515) 239-4452
ctaylor@mcfarlandclinic.com
Main responsibilities/Key role: Dr. Taylor is chief medical officer at McFarland. She will oversee all aspects of implementation activities at the two McFarland clinic sites. She will liaison with AMGA/JHU and the two site coordinators to ensure adherence to IRB-related activities, providers are engaged, integrity of data-collection, and budget oversight. She will also provide clinical expertise in how to adapt the model for delivery within the family medicine program at McFarland Clinic.

Site #1 Co-Investigator: Mia Yang

Wake Forest University Health Sciences
Medical Center Boulevard
Winston-Salem, NC 27157
Phone: 336-716-8153
miyang@wakehealth.edu
Main responsibilities/Key role: Dr. Yang is Assistant Professor and Director of the Wake Forest House Call Program in the Wake Forest Sticht Center on Aging and Alzheimer's Disease Prevention, Department of Internal Medicine and the section on Gerontology & Geriatric Medicine. Dr. Yang will oversee all aspects of implementation activities at the Atrium Health Wake Forest Baptist Clinic in Winston-Salem, NC. She will liaison with AMGA/JHU and the site coordinator to ensure adherence to IRB-related activities, providers are engaged, integrity of data-collection, and budget oversight. Dr. Yang will also provide clinical expertise in how to adapt the model for delivery within primary care at Atrium Health Wake Forest Baptist.

1 STUDY OBJECTIVES

1.1 Primary Objective

The primary objective of this pilot study is to embed and test the feasibility of a novel best practice-based approach, MIND at Home, within primary care (PC) to enhance and elevate the role of existing primary care staff to Memory Care Coordinators (MCCs), increase primary care access to interdisciplinary collaborative care, and systematically combine the benefits of clinic-based services with home- or telephone/video-based assessment to support family-centered care planning and implementation for people living with dementia (PLWD) and their care partners. Our overarching goal is to test establish feasibility, acceptability, fidelity, and sample size/referral rate data for MIND at Home in PC to prepare for a future multi-site embedded pragmatic trial.

1.2 Secondary Objective

The secondary objective is to test the feasibility of collecting and validating data from large health systems through the extraction of data on 100 additional patients who will not be enrolled in the study but will serve as a data validation arm.

2 BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

PLWD represent some of the highest-need and highest-cost individuals living in the community and PC plays a pivotal in the detection, diagnosis, and delivery of services for this vulnerable population. Despite the availability of a range of evidence-based dementia management and symptom approaches, few American PLWD receive adequate care; embedding effective evidence-based interventions and dementia best practices into PC settings is needed, but not yet widely done. PC is the focus of a new CMS-driven alternative payment model (Primary Care First), designed to improve quality, enhance patient experience of care, and reduce expenditures by increasing patient access to advanced primary care services.

2.2 Study Rationale

Recent health policy, research, and payment model developments focusing on PC as the nexus of care, coupled with availability of affordable evidence-based care management approaches for dementia, present a profound and timely opportunity to embed effective supports into PC settings to drive value-based care and transform the way care is delivered for PLWD. **M**aximizing **Ind**ependence at Home–**MIND at Home (MIND)** is a comprehensive care coordination program born from geriatric psychiatry. This model takes an interdisciplinary, collaborative care approach to care by systematically assessing and addressing a wide range of dementia-care related needs of both PLWD and their care partners that place both at increased risk for poor outcomes. With strong evidence demonstrating its impact on reduction of unmet needs, delay in transition from home to institutionalized settings, improved quality of life, and cost savings through reductions of hospitalization and skilled nursing use, we propose to embed and implement MIND into PC for the first time. Use of MIND in the context of PC is a strong approach that brings a home- or telephone/video-based component to what is often exclusively clinic-based care delivery. It includes a structured assessment to facilitate dementia care planning that holistically addresses patient and caregiver needs and provides valuable initial and ongoing education designed to build PC team dementia management capacity through regular interdisciplinary collaboratives with dementia experts. The MIND model of care directly aligns with stakeholder priorities: PLWDs' wish to remain in their homes as long as possible (evidence suggests PLWD have higher quality of life at home versus in long term care facilities);[1] care partners' desire to avoid burnout while providing the best care possible for their loved ones; primary care providers' incentives to serve their patients by keeping them healthy with the highest quality of life possible; health systems' financial need to avoid unnecessary hospitalizations and ED visits

in an environment of value-based care; payors' motivation to contain costs; and health officials' impetus to improve population health and reduce health care inequities.

The proposed pilot study builds on five prior studies that developed or evaluated the MIND at Home dementia care coordination model in community settings, including two RCTs (MIND-Pilot: n=303; 2007-2012; an NIA RCT (MIND-RCT; n=302; 2014-2020), and a quasi-experimental CMS Health Care Innovation Award Round 2 demonstration project (MIND-HCIA; n=342; 2014-2018).[2-5] MIND is designed to help PLWD be healthy at home, addressing dementia-related needs to provide better care, better quality, at lower cost. In addition, MIND is currently being implemented in two operational pilots (Superior HealthPlan Medicaid Texas, 2018-2021 and Johns Hopkins (JH) Home Health Care Group private pay in Maryland). Findings to date are:

- ***Unmet care needs are common, both non-medical and medical.*** Studies[6,7] consistently show that unmet needs are very common for both PLWD and care partners, and most are non-medical. The most recent pooled analysis (n=646) shows common unmet PLWD needs on the JHDCNA are for home and personal safety (98%), medical care (84%), daily activities/meaningful activities (74%), behavioral management (67%), and legal/advance care planning (58%). Common caregiver needs were memory disorder education and care skills (98%), legal issues (74%), mental health (44%), and informal support (43%).[6] More unmet care needs are related to socio-demographics (e.g., Black race, age), lower quality of life, depression, and care partner burden.[7,8]
- ***Delay in transition from home and nursing home placement.*** MIND-Pilot showed delayed all-cause transition from home (median 288 extra days, or ~9.5 months, over a median follow-up period of 2 years) compared to the augmented usual care group.[2] In an analysis of the pilot RCT data restricted only to PLWD (total n=265; MIND n=99, control n=166) MIND participants delayed time to LTC transition (e.g., nursing home, assisted living) or death (mean 470 days vs. 506 days, mean difference= 36 days) over 18 months. Adjusted hazard of LTC placement decreased by 38% (HR= 0.62, 95%CI 0.39-0.98, p=0.042).
- ***Reductions in use of acute and institutional care and total spending.*** MIND Pilot and MIND-HCIA showed health care utilization patterns and spending redistribution away from acute/institutional care, towards home-, community- and physician-based services.[9,10] A sub analyses in MIND-HCIA showed a reduction in total Medicaid spending and slower growth in Medicaid inpatient spending and LTC spending compared to propensity matched controls.[9] A pre-post Poisson regression analyses of a pooled sample of MIND intervention recipients (MIND HCIA+MIND RCT; n=442) showed mean number of hospital admissions decreased by 27% (1-0.73) within one year after baseline (95% CI: 6%, 44%, p=0.01). Rates of ≥1 hospitalization declined 36.8% to 32.5%, a crude rate pre/post reduction of 11.6% (unadjusted).
- ***Improvement in care quality, behavior, and high program satisfaction***. MIND is associated with decreases in unmet care needs on the JHDCNA, improved quality of life, and reduced time spent with the PLWD (objective caregiver burden)(unadjusted) compared to augmented usual care in RCT.[2,3] In the MIND HCIA, MIND recipients had fewer overall unmet dementia-related needs (PLWD: β=-19.95, SE 0.7, p<0.0001) and in all subdomains (all p<0.0007), fewer behavioral issues (NPI) (β = -5.16, SE 1.4, p=0.0003), reduced caregiver burden (ZBI short) (β = -1.69, SE 0.6, p=0.0054), and reduced caregiver distress (NPI-Distress) (β = -1.63, SE 0.8), p=0.0347) from baseline to 18 months (within subject, pre-post adjusted mixed models). Program satisfaction data (n=390) show that recipients had high service in all domains.
- ***MIND at Home is potentially cost-effective.*** In MIND-HCIA, cost for delivery of MIND were estimated. A difference-in-differences analysis of Medicaid spending estimated return-on-investment (ROI) for a subgroup of participants with claims data (120 dually eligible MIND participants vs. 360 matched controls).[9] The average cost to deliver MIND per enrollee per month was $110, or $1,320 per annum. Medicaid expenditures of dual eligibles grew 1.12 percentage points per quarter more slowly than matched controls. Savings came from slower growth in

inpatient and LTC use. The five-year Medicaid savings were estimated at $7,052 per beneficiary, a 1.12-fold ROI.

3 STUDY DESIGN

3.1 Overview of study design and procedures

Using a pragmatic trial design, 150 community-residing PC PLWD will be enrolled and receive MIND coordination services for 3 months to test program recruitment and implementation feasibility in PC practice settings. (An additional 100 patients will serve as a data validation arm to demonstrate the feasibility of collecting and validating data from large health systems and will not be enrolled in the intervention.) Enrollees will be recruited through EHR diagnosis and PC referrals. They will undergo a program intake screen (in-clinic or by phone) with a member of the PC team or the memory care coordinator (MCC) to establish program interest and identify the care partner. Interested and eligible enrollees will receive an office- plus home- or telephone/video-based dementia care assessment by the MCC with input from the PC care team. Assessment will be followed by collaborative family-centered care planning, and care plan implementation by an interdisciplinary PC-based team, supported by regular cased-based learning sessions. The primary (hospital transfers, i.e., admissions, ED visits, observation stays) and secondary outcomes (polypharmacy, antipsychotics, acetylcholinesterase, and memantine) will be obtained from regularly collected EHR data.

3.2 Study population and eligibility

Community residing adults, ≥18 years, living with dementia and who are actively receiving primary care services at one of the three study primary care practices within two participating health care organizations (HCOs) will be targeted. Active patients are defined by the HCO but typically include patients who have received any type of health care service from the HCO in the past three years. PLWD will be defined using algorithms based on CMS' Chronic Care Warehouse definition of Alzheimer's Disease, Related Dementias, Related Disorders, and Senile Dementia.[11] This definition includes those who have an eligible ICD-9/ICD-10, CPT4, or HCPCS code on any eligible claim (i.e., inpatient, outpatient, SNF, or home health visit or stay) in the past three years, a diagnosis on a patient problem list, or a prescription for a dementia-related medication (see Section 4.1 for list). Eligible PLWD must also have a reliable care partner who speaks English (or a language spoken by the MCC) and who is willing to participate in all study home, telephone, or video visits and related activities. PLWD in crises (e.g., show signs of abuse, neglect, extreme risk of danger to self or others), will be referred to receive appropriate services, but will be excluded from the study.

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

PLWD will be identified in the EHR of their respective HCOs and will be approached in two ways. PLWD who present with their care partners for an outpatient office visit will be invited to participate in the program. After establishing eligibility, dyads can choose to enroll by scheduling an initial home visit or phone/video intake with the MCC. Potential participants will be provided a program information sheet, see Appendix C. Enrollment will begin with an initial needs assessment (JHDCNA) during a home or telephone/video visit. Sites will also identify PLWD in the EHR who meet program eligibility criteria but are not scheduled for a visit. PLWD may be identified and referred from other providers to the study primary care clinics. Care partners/PLWD will be contacted by telephone and invited to enroll in the program using a script, based on local context and cultural adaptation of an existing script developed by the JHU team. To ensure equity, racial minorities and other underserved populations will be prioritized and approached using culturally sensitive processes to ensure a representative sample of participants. Recruitment will be supported with existing MIND outreach and engagement resources. MCCs will seek

to enroll a minimum of seven PLWD every other week for a maximum caseload of 42, to accommodate other non-dementia patients who may be part of the MCC total caseload.

4.1 Inclusion Criteria

Participants must meet all the inclusion criteria to participate in this study:

- Community residing adults, ≥18 years
- PLWD defined in one of two ways:
    - A diagnosis using algorithms based on CMS' Chronic Care Warehouse definition of Alzheimer's Disease, Related Dementias, Related Disorders, and Senile Dementia.[11] This definition includes those who have an eligible ICD-9/ICD-10, CPT4, or HCPCS code on any eligible claim (i.e., inpatient, outpatient, SNF, or home health visit or stay) in the past three years or a diagnosis on the patient problem list; OR
    - A dementia medication including donepezil, donepezil/memantine combination, galantamine, rivastigmine, aducanumab, or memantine on the patient medication list or a pharmacy claim in the past three years.
- Actively receiving primary care services at one of three primary care practices within two participating health care organizations selected as study sites.
- Have a reliable care partner who speaks English (or a language spoken by the Memory Care Coordinator).
- Willing to participate in all study home or telephone/video visits and related activities for the entire length of the study (3 months).

4.2 Exclusion Criteria

All candidates meeting any of the exclusion criteria at baseline will be excluded from study participation:

- PLWD in crisis, e.g., show signs of abuse, neglect, extreme risk of danger to self or others), will be connected to appropriate services, but will be excluded from the study.

4.3 Study Enrollment Procedures

PLWD will be identified in the EHR of their respective HCOs and approached in two ways. PLWD who present with their care partners for an outpatient office visit will be invited to participate in the program and provided a program information sheet (see Appendix C). After establishing eligibility, dyads can choose to enroll by scheduling an initial home or telephone/video visit with the MCC. Enrollment will begin with an initial needs assessment (the JHDCNA, Appendix B) during a home or telephone/video visit. Telephone intake will be supplemented with a home visit at a later date or photos of the living situation to identify safety issues or ways to improve the PLWD's care. Sites will also identify PLWD in the EHR who meet program eligibility criteria but are not scheduled for a visit. To ensure equity, racial minorities and other underserved populations will be prioritized and approached using culturally sensitive processes to ensure a representative sample of participants. Care partners/PLWD will be contacted by telephone to enroll in the program using a script, based on local context and cultural adaptation of an existing script (see Appendix D). Recruitment will be supported with existing MIND outreach and engagement resources. To assess feasibility and validity of eligible patient identification, referral, and enrollment, MCCs will electronically record the number of patients flagged as eligible, referred, enrolled, and retained or who refused, were unreachable, or lost to follow-up. Referral, recruitment, patient acceptance, and attrition rates will be calculated to assess the feasibility of use of the algorithm and of the

recruitment protocol. MCCs will enroll a minimum of seven PLWD every other week for a maximum caseload of 42, to accommodate other non-dementia patients who may be part of the MCC total caseload.

As this is a minimal risk, best-practice based quality improvement intervention, a waiver of consent will be requested for this study for both the intervention patients and the data validation arm cohort. Further justification is described in section 11.2.

Patients will not be randomized for this pilot study.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

We will embed and implement an evidence-based dementia care coordination model, MIND at Home, at three primary care practice sites. The five key **Program Components** include: (1) identification of dementia-related needs for the PLWD and care partner, using standardized procedures and definitions, including an in-home or telephone/video assessment supplemented by photos of the home by the MCC using the JHDCNA (13 domains, 61 items); (2) family-centered need-based care planning involving MCC in collaboration with the PC team, following standard protocol provided the MCC and staff, to address unmet needs and match priorities/preferences of the PLWD and family targeting both medical and non-medical determinants of health relevant for all stages of dementia (including social and environmental needs); (3) implementation of care plans linked with proven practice derived care strategies/interventions (e.g., education, coaching, symptom/need assessment, referrals, care coordination/navigation) by the MCC using standardized proven methods and need-based protocols; (4) care monitoring and plan revision, which include regular contact at least every 30 days; and (5) standardized initial program orientation for all PC team members and MCCs and weekly virtual collaborative learning sessions that include a structured case discussion (de-identified) and a short didactic on a specific care topic. Sessions are attended by geriatric psychiatry to support the PC care team's work and advance dementia assessment and care management capacity at PC sites.

MIND Program Bundle: Existing materials will be utilized for this pilot that include, but are not limited to: staff orientation and onboarding materials (e.g., web-based certifications, scope of practice (SOP) manual, role definitions, and job descriptions, etc.); intervention protocol (MIND at Home Intervention Handbook©, MIND Intervention Field Reference Guide© (Appendix A), Care Plan Builder Template,© Telecollaborative Toolkit© and the JHDCNA [Appendix B]); and enrollee support, engagement and resources (outreach and program promotion materials, Caregiver Resource Toolkit). Select tools are included as Appendix A and B.

Program delivery: Enrolled patients will receive office- plus home- or telephone/video-based initial care needs assessment using the JHDCNA including (but not limited to) safe medication administration and adherence; nutrition and hydration; home safety issues (e.g., environmental hazards, wander- and fall-risk management); daily routine and meaningful activities; advanced care planning; and 18 items addressing care partner needs. Telephone needs assessments will be supplemented with photos/videos of the home environment. Following the needs assessment, the MCC will develop a care plan in collaboration with the PLWD's PCP and other team members. MCCs will then review the care plan with the PLWD/care partner, prioritize needs, and provide a written copy to the PLWD/care partner that identifies specific need items and individualized recommendations for linked care strategies/interventions. The MCC, supported by the PCP and an interdisciplinary team, will then work with the PLWD and care partner to prioritize and address identified needs. PLWD may select the interventions/treatments they or their PCP deem appropriate (absolute adherence to recommendations is not required). Enrollees will have a minimum of three contacts over three months (e.g., mix of phone/video and in-home visits) but contact

intensity will be driven by individual needs and preferences. Participating dyads will have regular access to their MCC through phone, video conference, text, email, and the EHR patient portal. In addition to the written care plan, participating care partners will also receive the MIND Caregiver Resource Toolkit, a hardcopy binder with select tools and individualized resources.

Team orientation and support: MCCs**,** who have already been identified by each HCO, will initially complete an eight-module, interactive online MIND certification course (15 CME/CEU), during which they will learn skills specific to the care of PLWD as well as program processes. Delivery of the intervention involves orientation to the MIND program tools (discussed above). The online orientation will be followed by two virtual, half-day practice- and scenario-based learning sessions with the JHU lead investigator (Dr. Samus) and the JHU geriatric psychiatrist (Dr. Johnston), during which the MCCs can ask questions about the information in the orientation modules and the practice elements of assessment and care planning protocols. During orientation and in close collaboration with the MCC and PC care team, the JHU team will help adapt the program resources and tools to the local setting/team to accommodate the diverse needs and cultures of the populations being served. Throughout the pilot study period, the MCC and Study Site Leaders will meet every other week with the AMGA/JHU research team, as well as PRN with the JHU MIND team (geriatric psychiatrist, Senior MCC, lead investigator). The MCCs will be expected, and PC care team will be strongly encouraged, to attend weekly virtual collaborative case conferences and clinical sessions with the JHU MIND faculty clinical support team (1 CME/CEU/session). These activities are designed to promote co-learning and mentorship, review new cases, and discuss ongoing complex cases.

5.2 Handling of Study Interventions

The delivery of this behavioral intervention is described in the previous section.

5.3 Concomitant Interventions – N/A

5.4 Adherence Assessment

Implementation feasibility will be assessed by collecting a standard set of process measures and fidelity metrics. For all participant dyads, process measures will be collected by the MCC and submitted monthly to the AMGA research analyst including number, duration, type, and general content of encounters per dyad to assess the feasibility of implementation within PC practices. All process measures will be monitored and stratified by using socio-demographic data on participants (rurality, race/ethnicity) to assess differential rates of adherence, attrition/retention. Fidelity will be assessed by tracking completion of core intervention components (# needs assessment completed, # care plans completed, # completed 3 months, # with MCC encounter at least once every 3 months), and attendance at weekly virtual learning sessions by team member types (>50% of sessions). Collection of this information is facilitated by documents created for MIND on program implementation fidelity. See Appendix A. Fidelity measures will be captured and monitored using a work process template/spreadsheet completed by MCCs for each assigned dyad for each encounter. The template serves as an operations checklist the MCC completes at each home or telephone/video visit/contact that includes each component of the visit, the care plan with needs being addressed, actions taken, and follow up plans. A de-identified version of the management template will be shared with the JHU Investigators (Drs. Samus & Johnston) biweekly for review and feedback. De-identified program implementation data will be sent by the study site to the AMGA research analyst weekly. The MCC will contact the care partner to assess whether the care plan recommendations have been implemented.

6 STUDY PROCEDURES

All outcomes' data will be collected from the participating HCOs' respective EHRs using existing data regularly collected to provide standard patient care and to monitor quality. Participants enrolled in the

intervention will be ‘flagged’ in the EHR as pilot participants and monitored longitudinally.

AMGA regularly collects data from HCOs on a monthly or quarterly basis for all quality improvement, research, and best practices learning collaborative programs, and has a long history of creating detailed data specifications and reporting templates to which member organizations respond and complete. Participating sites have confirmed their ability to do this for this pilot. Monthly data will be submitted to AMGA at the end of study months three, seven, and 10 (see milestones and timeline). Seven total months of EHR data will be collected from each participant: three months prior to enrollment, three months during the intervention, and one month post program discharge.

6.1 Summary of primary and secondary outcome measures by data collection interval relative to patient enrollment

Outcome Measure	*Study Month -3*	*Study Month -2*	*Study Month -1*	*Baseline/ Enrollment Study Month 0*	*Study Month 1*	*Study Month 2*	*Study Month 3*	*Post Study Month 4*
Hospital Transfers (hospitalizations, ED visits, observation stays)	***X***	***X***	***X***		***X***	***X***	***X***	***X***
Number of Medications	***X***	***X***	***X***		***X***	***X***	***X***	***X***
Number of Anti-psychotics Rx	***X***	***X***	***X***		***X***	***X***	***X***	***X***
Number of acetylcholinesterase inhibitors Rx	***X***	***X***	***X***		***X***	***X***	***X***	***X***
Number of memantine Rx	***X***	***X***	***X***		***X***	***X***	***X***	***X***
Sex				***X***				
Age				***X***				
Race				***X***				
Ethnicity				***X***				
Rural Residence				***X***				
Comorbidities				***X***				

6.2 Description of Evaluations

At enrollment, basic patient information will be collected including sex, age, race, and ethnicity.

Monthly data on hospital transfers (hospitalizations, emergency department visits, observation stays without admission), number of medications, number of anti-psychotic medications, and acetylcholinesterase inhibitors and memantine medications will be collected on each enrolled patient over a 7-month period (and submitted to AMGA per schedule described above). The pre-intervention data will be collected retrospectively. Exhibit 6.1shows the baseline (at enrollment) and monthly data collection per patient and includes 3 months of data prior to enrollment, 3 months of data during enrollment, and 1 month of data post-enrollment. All data will be collected from site EHRs using data collected as part of routine clinical care.

6.2.1 Screening Evaluation

We have requested a waiver of informed consent.

Screening by Clinic Staff

PLWD will be identified in the EHR of their respective HCOs, by clinic staff, as *ever* having a diagnosis of ADRD or prescription for a dementia-related medication, on an administrative claim, patient problem list (Dx), or patient medication list (Rx) for the duration of time the patient has data in the EHR. Patients with an existing diagnosis of mild cognitive impairment may be assessed for ADRD during the visit by their provider. Patients must be living at home and in the care of an informal care partner. Patients eligible for the study based on EHR data will be flagged prior to their visit. Once the provider has confirmed eligibility by confirming diagnosis or medication and living situation, eligible PLWDs and their care partners will be invited to participate in the program. For PLWD without a scheduled visit, care partners/PLWD will be contacted by telephone to enroll in the program using a script, based on local context and cultural adaptation of an existing script. (See Appendix D.)

After establishing eligibility, enrollment will be initiated by scheduling an initial home, telephone, or video visit with the MCC. Enrollment will begin with a needs assessment (JHDCNA) during the intake visit.

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

PLWD and their care partners will be enrolled by the Memory Care Coordinator who will record baseline demographic data of the PLWD available in the EHR, i.e., sex, age, race, ethnicity, and will schedule their initial home, telephone, or video visit. Data will be recorded on a case report form, separate from the EHR. See Appendix B. In addition to baseline demographic data, enrollment date, name of PLWD and care partner, care partner contact information will be collected and recorded.

Baseline Assessments

There are no planned baseline assessments aside from the collection of the demographic data listed above for the pilot study.

Randomization

Patients will not be randomized for this pilot study.

6.2.3 Follow-up Visits

Enrollees will have a minimum of three contacts with the MCC over three months (e.g., mix of phone and in-home visits). Contact intensity will be driven by individual needs and preferences.

There are no required office visits during the intervention.

6.2.4 Completion/Final Evaluation

At the final home, telephone, or video visit during Study Month 3, the MCC will complete a final evaluation of the participant including an assessment of adherence to the care plan.

6.2.5 Program Satisfaction Surveys

6.2.5.1 Clinic Staff Surveys

After program completion, brief surveys developed in prior MIND studies will be sent (email or mail) to PC clinic staff to assess experience (satisfaction, perceived benefit, challenges, ways to improve program). The surveys will be used to assess the program and are voluntary. The surveys are included in the request for waiver of informed consent for the clinic staff. We will be surveying clinic staff on program satisfaction as part of the intervention, to solicit feedback and make improvements. We will take their responses into account when measuring feasibility of implementing the intervention into primary care.

The surveys will be anonymous. They will not include the name or identifier of the person taking the survey. They will capture who is being assessed, or the participant for the clinic staff surveys. The surveys will therefore "stand alone" and will not be linkable to the EHR clinical data. The surveys are a regular quality part of the MIND program. We will use the results to inform Aim 2, feasibility of implementing this program into primary care.

6.2.5.2 Participant Surveys

After program completion, brief surveys developed in prior MIND studies will be sent (email or mail) to participants/care partners to assess experience (satisfaction, perceived benefit, challenges, ways to improve program). Participant Surveys are included in the Appendix. The surveys will be used to assess the program and are voluntary. The surveys are included in the request for waiver of informed consent for the study participants. We will be surveying them on program satisfaction as part of the intervention, to solicit feedback and make improvements. We will take their responses into account when measuring feasibility of implementing the intervention into primary care.

The surveys will be anonymous. They will not include the name or identifier of the person taking the survey. They will capture who is being assessed, the MCC for the participant surveys. The surveys will therefore "stand alone" and will not be linkable to the EHR clinical data. The surveys are a regular quality part of the MIND program. We will use the results to inform Aim 2, feasibility of implementing this program into primary care.

7 **SAFETY ASSESSMENTS**

Since the intervention is a coordinated care program, risk of study-related adverse events is expected to be minimal. Expected serious adverse events include hospitalizations and deaths but these are in line with what would be expected for this elderly population. We will not be carrying out medical interventions or treatments as part of the pilot study. In some cases, participants may be referred to their primary care provider or other health professional regarding pharmacologic therapy or other therapies. Final decisions about treatment will be made by these physicians or other qualified health providers. The MCC may recommend care strategies that may incur additional costs. Neither the PLWD nor the care partner will be obligated to seek or accept these services. There are potential risks of discomfort about answering personal questions during the evaluation. There are potential risks to confidentiality should the findings of the assessment become known to others.

7.1 Minimization of Risks

To minimize discomfort or frustration that may occur during the needs assessment, participants may decline to answer any questions, take frequent breaks, or stop the assessment. The results of the dementia evaluation will be kept confidential and shared only as needed with members of the study team and with the primary care provider as part of the patient's care. Permission for the MCC to make referrals to various agencies or services is necessary for study participation. However, referrals made by the MCC will be in collaboration (agreed upon) with the PLWD/care partner and will follow best practices, including care options or strategies that are available in the community. These recommendations should provide beneficial outcomes in the aggregate. At any time, the PLWD/Care Partner may choose to refuse a service or discontinue their participation in the pilot study. The quality of their medical care will not be adversely affected if they decide to refuse a service and/or withdraw from the study. (See Program Information Sheet, Appendix C.)

Confidentiality of data will be ensured in several ways. Anonymous data collection forms will be used, with unique study identifying numbers and will be maintained in a secure location, and we will maintain a source document chart for each participant that will contain contact information, clinical information, and notes. Source documents will be password-protected and shared with the study team using a secure drop box link. Data entry will be performed concurrent with fieldwork via appropriate data entry forms that will be created with embedded validation criteria. The database will be kept locally at the study sites on secure servers which offer routine off-site back up.

7.2 Plans for Reporting Unanticipated Problems or Study Deviations

The entire study team will be trained on immediately reporting any adverse events, alerts (e.g., hazardous or emergency situations), or study deviations to the PI. See Chart A below for types of possible alerts that may be encountered and types of actions to be taken. See the DSMP below. If any serious possible or potentially study-related adverse events arise, the PI will notify the IRB, the DSMB Chair, and IMPACT SO, and others as stated in the data safety monitoring plan (DSMP), within 48 hours of learning of the events and will provide a safety report describing the adverse event and actions taken by the study. See the DSMP below. Deaths will be reported within 24 hours, per the DSMP. Additionally, the PI will keep a log of adverse events in compliance with IRB policies and per direction from the DSMB and whether the event is unrelated, possibly related, or probably related to the study or intervention. Study deviations will be reported when discovered along with any corrective actions taken by the study to the IRB, DSMB Chair, IMPACT SO, and others as stated in the DSMP. Routine adverse events (such as non-intervention related events such as death) will be reported within 24 hours and summarized and shared with appropriate individuals per the DSMP. At the start of the study, participants and care partners will be instructed to report serious adverse events to the MCC who in turn will notify the PI, who will notify the appropriate persons per the DSMP. Serious adverse events, discovered either by the clinical team in routine activities or ones which the family report, will be presented to the PI, the Is, and study team who together with the available data will make a determination as to whether the event is unrelated, possibly related, or probably related to the study intervention. Because this is a guideline-driven psychosocial intervention which seeks to provide coordinated care to meet the care needs of individuals with dementia living in the community, we do not anticipate adverse events beyond the background rate for this elderly population.

7.3 Chart A. Specific Alerts and Actions Taken

ALERT	ACTION TAKEN
Medical emergency:	

-Chest pains - Excessive bleeding - Fall and cannot get up - Difficulty breathing	If MCC or clinic staff encounters this situation over the telephone, we identify whether another individual is in the home, the person is put on hold, and we call 911 immediately and stay on phone until external help arrives. If situation occurs within home, then MCC calls 911 immediately, and stays with participant until help arrives. PI is informed within 24 hours of the event. Clinical study staff member (Dr. Deirdre Johnston) then contacts individual as a follow-up within two days. MCC completes alert form and provides to study coordinator and PI.
Suicidal ideation, threats to hurt self or others	If MCC encounters a situation in which the person (PLWD or CP) threatens to hurt self imminently/immediately, then MCC stays with person (on phone or in home), calls 911 and stays with individual until help arrives. If the person (PLWD or CP) is determined to not be an immediate threat to self, then the person is actively encouraged to contact physician or contact is made for the person if they allow that to occur. A verbal contract or agreement is obtained with the person that they will not hurt themselves. The MCC also informs the person that a member of the research team will be contacting him/her shortly to follow-up. Immediately at the conclusion of the interview, the PI is notified of the situation. The clinical study staff member (Dr. Deirdre Johnston) will contact the person as soon as possible to obtain further information and encourage immediate action to be taken (e.g., physician referral). Clinical study staff and PI further consult about case within 24 hours of event with medical team to determine what further actions should be taken. MCC completes alert form and provides to study coordinator and PI.
Evidence of abuse	Evidence of physical abuse is as follows: 1) CP or PLWD states to MCC that abuse occurs; or 2) MCC observes physical evidence (black eye, black and blue marks on arms/legs). MCC informs participant or CP that a senior member of the research team will contact him/her later that day. MCC informs PI immediately upon completion of interview or intervention session. Clinical study staff member contacts participant to obtain further information. Participant is strongly encouraged to call his/her physician and/or Adult Protective Services (phone number will be provided). Based on the situation, the designated clinical study staff may notify Adult Protective Services and/or clinical study team members for consultation. MCC completes alert form and provides to study coordinator and PI.
Unlocked gun in home	If this is discovered on-site, the MCC notifies study coordinator within 24 hours of learning of gun in home. Study coordinator (or

	designate) contacts person immediately to obtain further information and work on plan for removal, dismantling or storage of gun in locked cabinet. Study coordinator (or designate) provides education as to the potential danger of having a gun in home with a person with dementia. If participant keeps a loaded gun in the home, he/she is informed that we cannot go into the home until it is removed, dismantled, or locked in an inaccessible location. If alert is identified prior to enrollment visit, the person is not enrolled into the study until gun has been removed or dismantled or stored in locked area. If discovery of gun occurs after person has been enrolled, he/she is informed that they will be discontinued from study until gun has been removed, dismantled, or stored locked. MCC completes alert form and provides to study coordinator and PI.
Extreme Home Hazards -Exposed electrical -External door missing or cannot be locked -Ceiling, floors caved in -No temperature control (no air or heat – must be extreme) -Major infestation	MCC notifies study coordinator within 24 hours. If alert is identified prior to enrollment, the individual is not enrolled in study until home hazard is addressed. If situation is discovered after person is enrolled in study, the MCC works on resolving the situation with the family caregiver but does not make home visits until the environment is safe. MCC completes alert form and provides to study coordinator and PI.

7.4 Adverse Events and Serious Adverse Events

7.4.1 Definitions

AE Definition: AE is any untoward or unfavorable medical occurrence in a human study participant, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

SAE Definition: SAEs consist of any adverse event that results in death; is life threatening or places the participant at immediate risk of death from the event as it occurred; requires or prolongs hospitalization; causes persistent or significant disability or incapacity; results in congenital anomalies or birth defects; is another condition which investigators judge to represent significant hazards.

Unanticipated Problem (UP) Definition: any incident, experience, or outcome that meets all of the following criteria:

- unexpected, in terms of nature, severity, or frequency, given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol; and (b) the characteristics of the study population;
- related or possibly related to participation in the research; and
- suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.4.2 AE/SAEs for this study

AEs for this study. We are not anticipating any adverse medical occurrences related to participation in this research. The intervention is an enhanced usual care approach and does not introduce any components that would put subjects at risk for medical AEs.

SAEs for this study. Study team investigators are not anticipating serious medical events related to participation in the research. However, we do anticipate SAEs to occur based on this being an older population. The intervention is an enhanced usual care approach and does not introduce any components that would put subjects at risk for medical SAEs.

7.4.3 Classification of Severity and Study Relatedness

All data and safety monitoring reporting will classify SAEs and AEs as to their severity, expectedness, and potential relatedness to the study intervention as per the definitions below:

Severity

- **Mild:** Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.
- **Moderate**: Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities, but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning
- **Severe**: Events interrupt the participant's normal daily activities and generally require systemic drug therapy or other treatment; they are usually incapacitating

Expectedness

- **Unexpected** - nature or severity of the event is not consistent with information about the condition under study or intervention in the protocol, consent form, product brochure, or investigator brochure.
- **Expected** - event is known to be associated with the intervention or condition under study.

Unexpected events will be subject to expedited reporting requirements as described in the NIA Guidance on Clinical Trials.

Relatedness

- **Definitely Related**: The adverse event is clearly related to the investigational agent/procedure – i.e., an event that follows a reasonable temporal sequence from administration of the study intervention, follows a known or expected response pattern to the suspected intervention, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure and that could not be reasonably explained by the known characteristics of the subject's clinical state.
- **Possibly Related**: An adverse event that follows a reasonable temporal sequence from administration of the study intervention follows a known or expected response pattern to the suspected intervention, but that could readily have been produced by several other factors.
- **Not Related**: The adverse event is clearly not related to the investigational agent/procedure - i.e., another cause of the event is most plausible; and/or a clinically plausible temporal sequence is inconsistent with the onset of the event and the study intervention and/or a causal relationship is considered biologically implausible.

7.4.4 Reporting Procedures

Process for identifying AEs, SAEs, and UPs: Members of the research team who have not already received training in how to recognize and report an adverse event will be trained immediately once the pilot is awarded. The process of recognizing, collecting, and reporting these data will also be explained to all team members with access to the PLWD and their care partners during the study. Reports will be made using the NIA-approved adverse event reporting form. Site investigators will review study data regularly to ensure no adverse events have occurred.

Reporting schedule:

If a serious adverse event occurs, clinic staff and investigators will be instructed to report the event to the PI who will notify the IRB and the NIA per the schedule below. The PI will provide a safety report describing the adverse event and any actions taken. The PI will keep a log of all adverse events (minor and serious) in compliance with IRB and NIH policies including whether the event is unrelated, possibly related, or probably related to the study or intervention. This log will be provided to all necessary parties as indicated below.

- All **adverse events that are serious** (SAE) **and unexpected** (i.e., have not been previously reported for the study's intervention) will be reported to the IMPACT Collaboratory Regulatory and Data Team Leader (Dr. Julie Lima), NIA IMPACT Collaboratory Program Officer (PO) (Dr. Partha Bhattacharyya), and the IMPACT Collaboratory DSMB Chair or Safety Officer within 48 hours of the study's knowledge of the SAE.
    - Only those adverse events that are serious (SAE), unexpected, ***and related to the intervention*** must also be reported to Advarra IRB. Unexpected and ***unrelated*** SAEs will be reported to Advarra IRB on a case-by-case basis if requested by the IMPACT Collaboratory DSMB Chair, Safety Officer, or NIA IMPACT Collaboratory PO.

- All deaths will be reported to IMPACT Collaboratory Regulatory and Data Team Leader (Dr. Julie Lima), NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharyya), and the IMPACT Collaboratory DSMB Chair or Safety Officer within 24 hours of the knowledge of death.
    - Advarra IRB does not require the specific reporting of death outside of the SAE reporting requirement above, but they will be notified on a case-by-case basis if requested by the IMPACT Collaboratory Chair, Safety Officer or NIA IMPACT Collaboratory PO.

- All **unanticipated problems** (**UPs)** will be reported to the IMPACT Collaboratory Regulatory and Data Team Leader (Dr. Julie Lima), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharyya), and the IMPACT Collaboratory DSMB Chair or Safety Officer within 48 hours of the study's knowledge of the event.

- The summaries of all previously reported unexpected and related SAEs, deaths, and UPs, *as well as* all other SAEs and AEs will be reported to IMPACT Collaboratory Regulatory and Data Team Lead (Dr. Julie Lima), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharyya), and the IMPACT Collaboratory DSMB Chair or Safety Officer at a minimum every 6 months, or at a frequency requested by the IMPACT Collaboratory DSMB Chair or NIA IMPACT Collaboratory PO.

Summary table of reporting structure, individuals, and timing.

Reported To	SAE and unexpected A	Deaths B	Unanticipated problems C	Summaries A, B, & C
Dr. Julie Lima[1]	X	X	X	X
Dr. Partha Bhattacharyya[2]	X	X	X	X
DSMB Chair	X	X	X	X
IMPACT Safety Officer	X	X	X	X
Advarra IRB	X[3]	X[3]	X	X
Timing	Within 48 hours	Within 24 hours	Within 48 hours	Every 6 months

[1] IMPACT Regulatory and Data Team Lead
[2] IMPACT Collaboratory PO
[3] Only if also related to intervention

7.5 Safety Monitoring

Per the NIA Guidelines on Data and Safety Monitoring, we have an NIA-appointed Data and Safety Monitoring Board and IMPACT Safety Officer (SO). The PI will be responsible for ensuring participants' safety on a daily basis. In addition, the NIA IMPACT Collaboratory DSMB and Safety Officer will oversee all data and safety monitoring activities for this study. The number of DSMB members will be determined by NIA, and one will be designated the Chairperson. DSMB members and the Safety Officer will be appointed by the NIA Director. This DSMB and SO will act in an advisory capacity to the NIA Director and the PI to monitor participant safety, to evaluate the progress of the study, and to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses.

7.6 Frequency of Data and Safety Monitoring

The study PI will teleconference into the DSMB meeting to present their safety reports at the intervals described below.

For the study, the frequency of DSM will proceed as follows: 1. Prior to the start of participant enrollment and data collection, the study PI will submit a DSMP for approval by the DSMB and/or the NIA PO; 2. Six months after the initiation of participant enrollment and/or data collection, the study PI will submit a DSM report to the DSMB or Safety Officer. This interim report will be reviewed by the DSMB or Safety Officer to determine whether there are any human subjects or data safety concerns; and 3. At the end of the study, the PI must submit a final DSM report to the DSMB and Safety Officer.

7.7 Content of Data and Safety Monitoring Report

The content of the data and safety monitoring report will include:

- Name of the organization conducting the research
- Title of the research project
- Name of the principal investigator on the protocol
- Number of the research project assigned by the Advarra IRB
- Study status

    - Participants screened, enrolled, completed, and discontinued
    - Participant risk vs. benefit
    - Performance of study sites
- Safety information
    - Detailed description of any adverse or serious adverse events
    - Actions taken or planned to address identified issues/problems
- Study quality
    - Data quality and timeliness of data collection
    - Fidelity of intervention based on measures of completeness of intervention components

For any reportable incidents, the local site study team, including the MCC, will unmask the studysubject as required to share with the DSMB.

7.8 Conflict of Interest for DSMB Members

Each DSMB member and the Safety Officer will sign a **Conflict of Interest Statement** which includes current affiliations, if any, with pharmaceutical and biotechnology companies (e.g., stockholder, consultant), and any other relationship that could be perceived as a conflict of interest related to the study and / or associated with commercial interests pertinent to study objectives.

7.9 Protection of Confidentiality

Data will be presented in a blinded manner during the open sessions of the DSMB. At DSMB meetings or in reports, data and discussion are confidential. Participant identities will not be known to the DSMB members.

8 INTERVENTION DISCONTINUATION

The intervention may be voluntarily discontinued by a subject at any time. In addition, if a subject is permanently transferred from their home to a long-term care facility, they will no longer be eligible to continue the study. There are no other reasons to discontinue a subject from the intervention as long as they continue to live at home, have an informal care partner, and are willing to participate.

We will continue to collect data on subjects who withdraw voluntarily from participation in the study. All data collection is passive, pulled from the EHR where the subject receives their regular primary care.

Subjects who discontinue before the study has completed will be replaced, if possible, as long as this does not extend the length of the study.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

We expect to include a total of 250 patients in the pilot study. Of these, 100 patients will serve as a data validation arm to demonstrate the feasibility of collecting and validating data from large health systems and will not be enrolled in the intervention. The pilot study is intended to test the feasibility of integrating the intervention (MIND at Home) into primary care, as well as the processes and procedures of identifying and recruiting subjects and collecting data. Therefore, we do not have a statistical hypothesis because the pilot study is not powered to demonstrate statistically significant results.

9.2 Sample Size and Randomization

The pilot study is not powered to detect significant changes in our selected outcome measures. However, we estimated power, nonetheless. Preliminary studies of the MIND at Home program report a reduction from 1 to 0.73 in number of hospital admissions per year, or a 27% decrease. Our primary outcome is hospital transfers (which includes admissions but also ER visits and observation stays without admissions), but we expect that the relative effect size on this outcome will be similar to hospital admissions alone. Because our observation periods are 3 months (as opposed to 1 year), our assumed base rate is 0.50. To make our power estimates slightly conservative, we will assume an effect size of 25%. Given these factors, the estimated power is 37.5% to detect the effect (Z-test with square root adjustment for low base rates). This low power is primarily caused by the short duration of the intervention per patient in the pilot, making outcome observations (transfers) very rare. In the full trial we will use a 12-month intervention period.

For the full trial, sample size estimates will be based on the primary outcome (hospital transfer rate over 12 months). We intend to implement a cluster-controlled cohort design with a baseline period, which requires specialized power calculations (Hemming et al., 2020). Calculations will assume a Poisson distribution of hospitalization rates, equal cluster sizes, and an equal number of clusters in the treatment and control arms. Because validated estimates of correlations are not available, we will use conservative assumptions for intra-cluster correlation (0.05) and individual autocorrelation (0.2). Baseline hospital transfers are estimated to occur at a rate of 1 transfer per year. Assuming this rate, the study will be powered to detect a 0.2 absolute reduction (20% relative reduction) at greater than an 80% power level. This will require at least 11 clusters in each arm of two study arms, with each practice recruiting approximately 50 patients. Analysis of the full study will make use of mixed-model ANCOVA, controlling for both patient level and cluster level confounding variables.

9.3 Interim analyses and Stopping Rules – N/A

No interim analysis is planned for this study. AEs and SAEs will be monitored throughout the study, but no safety or efficacy issues are anticipated as the intervention has been well studied and efficacy has been established. The novel approach of this pilot is the integration of the intervention into the primary care setting.

9.4 Outcomes

While this pilot study is not powered to detect statistically significant changes in outcomes, we will analyze the outcomes as a feasibility test.

9.4.1 Primary outcome

The primary outcome is hospital transfers (hospitalizations, emergency department visits, observation stays without admission), and will be collected on each enrolled patient over a 7-month period. Per the table above, data will be collected monthly for the 3 months prior to enrollment, the 3 months during enrollment, and one month post enrollment.

9.4.2 Secondary outcomes

The secondary outcomes are number of total medications, number of anti-psychotics, acetylcholinesterase inhibitors, and memantine medications and will be collected on each enrolled patient over a 7-month period. Per the table above, data will be collected monthly for the 3 months prior to enrollment, the 3 months during enrollment, and one month post enrollment.

9.5 Data Analyses

A total of 150 PLWD and their care partners receiving care at one of three primary care practices at two health care organizations will be enrolled in the intervention to maximize the likelihood that this pilot study will support the feasibility, generalizability, and scalability to a full-scale ePCT. Data on an additional 100 patients will be extracted for data validation. Data collected during the pilot study will help inform the full ePCT by testing implementation and data collection procedures. Because patients will be enrolled on a rolling basis, we will establish the measurement periods individually for each patient, e.g., for the primary outcome of hospital transfers, we will measure the number of monthly hospitalizations over a 7-month period: three months prior to enrollment, three months during, and one month post discharge from the program. This will allow us to compare the baseline rate (rate of hospitalizations per 1,000 person-days prior to enrollment) with the hospitalization rate in the three months while the patient is enrolled. We will also collect data from the month following program discharge to assess whether hospitalization rates are maintained. We will follow a similar strategy for the secondary outcome of total number of active medications per month. Only exploratory analysis will be performed on the pilot data due to lack of a comparison/control population and low sample size. Descriptive statistics of the study population characteristics and outcomes will be calculated, including stratification at both the cluster and demographic level to identify potential disparities. Outcomes will be compared between the pre- and post-intervention time periods to estimate the effect size of the intervention and will be evaluated using repeated measures ANOVA, though the sample size of the pilot study may not permit definitive results. The R programming language will be used to carry out analysis. Survey results will be reported using descriptive statistics (means and standard deviations for continuous variables and frequency percent for discrete variables) to summarize individual survey items along with histograms for distributions of variables and bar charts/other charts to present the data. To plan for the full trial, we will conduct exploratory analysis to determine measurement reliability and the rate of missingness of patient level (baseline outcome rates, age, sex, race/ethnicity, and comorbidities) and cluster level covariates.

Data on fidelity of the intervention as well as process measures to assess feasibility are described in Section 5.4 Adherence Assessment and will be reported in the overall presentation of results.

Program satisfaction surveys will be analyzed descriptively and reported in aggregate.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Data will be collected from the EHRs of participating HCOs using existing data regularly collected to provide standard patient care and monitor quality, and through post program satisfaction survey data.

Enrollment Feasibility (Aim 1). Algorithms based on CMS' Chronic Care Warehouse definition of AD/ADRD[11] will be deployed in each respective clinic EHR to identify eligible PLWD and standardize referral and enrollment protocols. To assess feasibility and validity of **eligible patient identification, referral, and enrollment,** MCCs will electronically record the number of patients flagged as eligible, referred, enrolled, and retained or who refused, were unreachable, or lost to follow-up. Referral, recruitment, patient acceptance, and attrition rates will be calculated to assess the feasibility of use of the algorithm and of the recruitment protocol **(Aim 1).** Attention will be paid to potential differential referral, enrollment implementation for PLWD of minority race/ethnicity and other underserved populations, e.g., rural residents. All data collected on participants will be collected electronically, using password-protected files and saved on password-protected computers.

Program implementation feasibility (Aim 2). Implementation feasibility will be assessed by collecting a standard set of process measures and fidelity metrics. For all participant dyads, process measures will be collected by the MCC and submitted monthly to the AMGA research analyst including number, duration, type, and general content of encounters per dyad will be calculated to assess the feasibility of implementation. All process measures will be monitored and stratified by minority participants (rurality, race/ethnicity) to assess differential rates of adherence, attrition/retention. Fidelity will be assessed by tracking completion of core intervention components (# needs assessment completed, # care plans completed, # completed 3 months, # with MCC encounter at least every 3 months), and attendance at weekly virtual learning sessions by team member types (>50% of sessions). Collection of this information is facilitated by documents created for MIND on program implementation fidelity. (See Appendix A.) Fidelity measures will be captured and monitored using a work process template/spreadsheet completed by MCCs for each assigned dyad for each encounter. The template serves as an operations checklist the MCC completes at each home visit/contact that includes each component of the home, telephone, or video visit, the care plan with needs being addressed, actions taken, and follow up plans. All data collected on participants will be collected electronically, encrypted during upload, download, and transfer, using password-protected files, and saved on password-protected computers.

A de-identified version of the management template will be shared with the co-investigators (Drs. Samus & Johnston) biweekly (i.e., every other week) for review and feedback. De-identified program implementation data will be sent by the study site to the AMGA research analyst monthly. Acceptability will be assessed from multiple stakeholder perspectives. In the final 2 months of the pilot, brief surveys developed in prior MIND studies will be sent (email or mail) to dyads (post program) to assess experience (satisfaction, perceived benefit, challenges, ways to improve program). The participant survey is included in the Appendix.

Patient-level outcomes (Aim 3). All outcomes' data will be collected from the participating HCOs' respective EHRs using existing data regularly collected to provide standard patient care and to monitor quality. Participants enrolled in the intervention will be 'flagged' in the EHR as pilot participants and monitored longitudinally.

Monthly data will be submitted to AMGA at the end of study months three, seven, and 10 (see milestones and timeline). (A test dataset will be sent after month one for review and feedback.) Seven total months of EHR data will be collected from each participant: three months prior to enrollment, three months during the intervention, and one month post program discharge. The **primary outcome** is rate of hospital transfers (per 1,000 person-days), including hospital admissions, emergency department visits, and observation stays (non-admissions). The **secondary outcome** is total number of active medications for enrolled PLWD. Accuracy of ascertainment will be tested through chart review. All data collected on participants will be collected electronically, using password-protected files and saved on password-protected computers. Data will be transferred to AMGA using a secure Dropbox folder that is encrypted when data are uploaded and downloaded and during transfer.

10.2 Data Management

Clinic study sites are responsible for data collection and management as described above. MCCs will collect data on study feasibility, validity of patient identification, and intervention fidelity. Information technology staff at participating organizations will be responsible for extracting data on participants from their EHRs and working closely with the AMGA research analyst during the file transfer process to ensure confidentiality and protection of participant data.

AMGA staff will be responsible for working closely with clinic site investigators and clinic staff in the collection of study data. Once data are transferred through a secure Dropbox link, AMGA staff will be responsible for maintaining and protecting the confidentiality of all study data. AMGA staff will keep the

password-protected files on secure servers on password-protected computers. Only the AMGA research analyst, biostatistician, and study PI will have access to study data.

Study feasibility, validity, and fidelity data will be collected using Excel spreadsheets that are password protected. EHR data will be abstracted by the study sites using their usual methods of extracting data for quality purposes. Data will be sent to AMGA as csv files.

10.3 Quality Assurance

10.3.1 Training

All study staff at each study site will take the online NIH Good Clinical Practice training. A link to the free NIH training has been provided to each study site. The study site investigators will report to the PI when all staff have been trained and will provide certificates of completion.

10.3.2 Quality Control

AMGA research staff will conduct quality control on all data collected for research purposes. This entails running frequencies for all variables, looking for invalid entries, and identifying values that exceed those that are physiologically possible. Values are also evaluated for reasonableness in relation to published or previously reviewed data. Data and analytic code are reviewed by a minimum of two AMGA research staff throughout data collection and analysis, and documentation is generated for any errors and corrective action. In the case of suspected data errors, AMGA staff will contact data providers directly to validate data quality.

10.3.3 Metrics

For outcome measures of hospitalizations and medications, quality control metrics will include mean, medians, maximum and minimum values, standard deviations, and inter-quartile range. These values can be compared across study sites, across data storage locations (e.g., primary data reporting forms and analytic databases), and across time to identify potentially erroneous data reports.

10.3.4 Protocol Deviations

This protocol will be strictly followed. The study investigators will look for deviations from the protocol. Because of the regular review of documents both by the AMGA and JHU investigators and staff, deviations will be captured early. All investigators and staff have reviewed the protocol and will be on instructed to report all deviations to the study PI, who will document all deviations and review with the other study investigators, the DSMB, and the IRB as appropriate.

10.3.5 Monitoring

As described above, a de-identified version of the management template will be shared with the JHU Investigators (Drs. Samus & Johnston) every other week for the first 3 months for review and feedback. De-identified program implementation data will be sent by the study site to the AMGA research analyst monthly. This will allow investigators to monitor sites to assure protocol compliance and data quality.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and any subsequent modifications will be reviewed and approved by Advarra, the IRB responsible for oversight of the study.

11.2 Request for Waiver of Informed Consent

We are studying a program that will augment best practices in clinical care for people living with dementia (PLWD) and their care partners (a.k.a., dyads). The program will be presented to the dyads who can choose to participate or not. Dyads will be informed that participation is voluntary and that they may withdraw from the program at any time, without prejudice, and that the quality of their medical care will not be adversely affected if they decline to participate in this program. The dyads will be provided a Program Information Sheet (Appendix A) to review. They will be given the opportunity to discuss with other family members before agreeing to participate.

We are providing an information sheet about the MIND program itself and participation is voluntary, but we are requesting a waiver of informed consent for research purposes for all components of the study, not only for those that take the MIND program but for all individuals for whom we will obtain data. This includes the patients included in the data validation arm, due to the impractability of obtaining their consent and the minimal risk of accessing their data for this study. This also includes the survey for intervention participants and for clinic staff.

We meet all 5 required criteria for informed consent for all of these populations.

11.2.1.1 This research involves no more than minimal risk to subjects.

This is a minimal risk, best-practice based quality improvement intervention. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Minimal risk here means that the probability and magnitude of the harm or discomfort anticipated in the research is not greater than those ordinarily encountered in daily life or during routine care for dementia. This applies to intervention subjects and clinic staff, but even more so for the data validation arm, who will have absolutely no interaction with the health system.

The intervention protocol is derived from decades of dementia care clinical expertise, published recommended practice, observational and clinical studies, the MIND at Home pilot RCT and several other previously conducted MIND at Home studies. The intervention includes resource referrals and access to trained geriatric, gerontology, and dementia behavioral experts, as well as an interdisciplinary primary care team that will oversee the care plan for the PLWD. Any event that might arise will be immediately addressed by this robust team of professional experts along with the supportive services, navigation, coordination, education, dementia skills, emotional support, and problem solving that will be available during the intervention.

11.2.1.2 This research could not be practicably carried out without the waiver.

Required informed consent would undermine the pragmatic nature of this trial and would impede the generalizability of the findings. We are rolling out this program within a health care setting as it would be rolled out in regular practice with the aim of understanding how well it is accepted by participants and implemented in a real-world setting. As in regular practice, potential participants will have the choice to accept or decline to participate. We are requesting a waiver for the knowledge of the research component as requiring informed consent for research purposes would undermine the real-world application/rollout of the program. Results would potentially be biased as we would not be able to determine whether enrollment numbers reflect real-world uptake. This would potentially limit our findings to a subsample of the population that we think will benefit and that we are trying to study. The systematic bias that would be introduced would reduce the scientific validity of the study and we would not have the ability to determine the effect of the intervention on the general population.

In addition, not all PLWD have a legally authorized representative (LAR) and if they do, it is not necessarily the person who would be accompanying them to their health care visit or their care partner. Therefore, we cannot assume that care partners would be able to provide consent on behalf of study eligible individuals. Some LARs may be not in the geographic area and health systems may not have information on the LAR, nor how to contact them. Also, state laws vary on who can consent for research. With a study timeframe of only 12 months to recruit 150 socioeconomically and racially diverse PLWD and their care partners, who are already difficult to recruit into research programs, adding additional time to track down LARs is impracticable, which could take weeks to months. ADRD, which is how we will define PLWD, is under-detected which reduces the potential pool of eligible patients at these 2 sites and pilot funding levels and staffing resources are minimal for the activities and target sample size for recruitment. In addition, those without an LAR may disproportionally represent minoritized patients, biasing the study sample. If we do encounter this issue, we would not have time to request modifications to the consent protocol, which takes 3-4 weeks for IRB review and approval. This is a minimal risk study that does not differ from the care coordination currently encountered at specialty memory clinics. We will provide patients and care partners a clear explanation of the program and have a process in place to monitor AEs. The reason we cannot request a waiver of documentation instead is that we cannot ensure that the care partner is the LAR if the patient is believed to lack capacity.

For the data validation arm, it would be impracticable to contact them as they are not currently seeking care, they have only sought care sometime in the past. It would be impracticable to contact 100 patients, ensure capacity, locate the LAR if they do not have capacity and then explain how their data are being used for the study. This may be impossible for some but would be impracticable for all to do this in a timely fashion to be able to proceed with this limited-funded pilot study.

11.2.1.3 The research involves using identifiable information and could not be practicably carried out without using data in an identifiable format.

The clinical outcomes for this research are not collected directly from the patient. Instead, they comprise EHR data that are collected as part of routine, clinical care and include utilization (hospital transfers) and medication data. Use of these data for this research is analogous to use for quality improvement and other administrative purposes. Data need to be identified so that they can be linked to patients who enroll in the program. Data are routinely used this way for pragmatic clinical trials. The data validation arm is to further validate the feasibility of extracting data for the study and to examine data quality.

11.2.1.4 The waiver will not adversely affect the participants' rights and welfare.

Participants are not required to participate in this program. Dyads will be informed that participation is voluntary and that they may withdraw from the program at any time, without prejudice, and that the quality of their medical care will not be adversely affected if they decline to participate in this program. Evidence suggests that this program is effective and therefore participants are likely to be better off by participating in the program than not. As with all research, steps will be taken to protect the privacy and confidentiality of the data, including maintaining a linking document with medical record numbers and study identification numbers separate from all other study data. This document, and all study data, will be kept on password-protected computers on secure servers that are designed to protect patient health information.

11.2.1.5 Participants will be provided additional pertinent information after participation.

Following completion of the study, clinic directors will be provided with de-identified results of the study that they may choose to disseminate as they see fit. They may include the study results in a clinic newsletter or other patient-facing communication medium to let the clinic patient population, including program participants and all clinic staff, know that the study happened and the results.

11.3 Request for Full HIPAA Waiver of Authorization

We are requesting a full HIPAA waiver of authorization for the study sites to release patient data to AMGA for this study for the following reasons.

11.3.1.1 Use of data involves no more than minimal risk to the privacy of study participants

We have established a plan to protect health information identifiers from improper use or disclosure based on our extensive experience handling patient-level data. The study sites will create a Study Key that will be the only document linking patient identifying information to the patients. The Study Key will list Study IDs for all patients that will be used anywhere the patient data are used or stored. Once the IT department has pulled the data, they will use the Study Key to de-identify the file from all patient identifiers.

In terms of requested variables, we do not require dates, just that an event occurred during a specific time frame. For example, we need to know counts of hospitalizations per month, but not the exact date of the hospitalization. We have applied several different strategies in the past just as providing utilization at the week level. In addition, we do not need 'data of birth' just age as of a specific date. Therefore, even though no patient identifiers will be included in the data file, including name, address, MRN, SSN, we will also ensure that there are no additional variables that could be traced back to the patient.

We have a plan to destroy any documents that include identifiers, i.e., the Study Key document, and any other study-related documents that might pose a risk. We will have the study sites permanently delete these files one-year after study completion to allow for time to publish the study findings and respond to journal reviewers.

Finally, we have written assurances that the PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule.

11.3.1.2 Research could not practicably be conducted without the waiver or alteration

For the same reasons we cannot practicably conduct the research without a waiver of informed consent, we cannot practicably conduct the research without a waiver of HIPAA authorization. Please see previous section for a list of reasons.

11.3.1.3 Research could not practicably be conducted without access to and use of PHI.

The planned outcomes of this research require access to and use of PHI. We need to be able to link the patients who receive the intervention with their data. Therefore, we need to be able to identify the

patients so that an EHR data pull can be completed on our primary and secondary clinical outcomes, i.e., hospital transfers, and medication use.

11.4 Participant Confidentiality

The study PI will confirm that all study investigators have been trained on the protection of human subjects in research as well as the protection of health information. Other potential risks will be minimized by using procedures that are consistent with sound research design, that do not expose subjects to unnecessary risks, and that are based on established research and clinical protocols. The site study teams are located within health care organizations that have established HIPAA, protection of human subjects, and clinical practice compliance standards as a component of operations.

Regarding patient confidentiality of sensitive personal health information, all data stored and transmitted by AMGA and its members is compliant with the Health Insurance Portability and Accountability (HIPAA) and HITECH Acts. All data submitted to AMGA from the study sites will first be de-identified to prevent disclosure of confidential protected health information. The study sites will maintain a key to identify participants so that outcomes data can be collected. Although de-identified, access to data from the sites will still be restricted to a small group of authorized users within AMGA Analytics, LLC, who have all had certified training on HIPAA and the Federal Policy for Protection of Human Subjects. All AMGA and site systems, network infrastructure, policies, and operating procedures appropriately secure Protected Health Information (PHI) and Personal Identifiable Information (PII) as required by law.

AMGA maintains data integrity by incorporating a series of network monitoring and information security practices. Our security infrastructure consists of layers of defenses comprised of access lists, firewalls, network-based intrusion prevention systems, and multiple end-point security tools. Logs created by the network security devices are reviewed regularly and are maintained for a minimum of 7 years. Alerts triggered by the monitoring systems are reviewed by the Chief Security Officer and, as appropriate, escalated to the Chief Technology Officer. All staff who work with sensitive data use laptops with full-disk encryption. A cross functional team at AMGA conducts regular risk assessment as part of the AMGA Risk Management plan to ensure appropriate action and mitigation of potential security threats. If a Contractor or Vendor is performing work on an AMGA system using a computer not owned or managed by AMGA, the Contractor or Vendor agrees to AMGA's technical controls and must maintain these controls throughout the term of the agreement with AMGA.

11.5 Study Discontinuation

The study may be discontinued at any time by the IRB, the NIA, the OHRP, the FDA, or other government agencies as part of their duties to ensure that research participants are protected.

12 ETHICAL CONSIDERATIONS

This study will follow the seven main principles that guide the conduct of ethical research. (1) The research question has social and clinical value that justifies any risk presented to participants. Society will gain useful knowledge that will be shared from this study. (2) The study has scientific validity in that a research question has been asked and will be able to be answered. (3) The study has a favorable risk-benefit ratio in that the benefits of participating outweigh any risks. (4) The study protocol has been reviewed by an independent body with no vested interest in this particular study. (5) Informed consent has been considered and addressed. (6) Individuals will be treated will respect from the time they are approached for possible participation throughout their participation and after their participation ends. (7) The study provides fair subject selection in that participants will be selected to minimize risk and enhance benefits with the primary basis of recruitment being the scientific goals of the study.

13 COMMITTEES

The DSMB will provide oversite for this research in terms of the data and safety of participants. The role of the DSMB is described above.

A Steering Committee will be formed that will include all study investigators, the study biostatistician, the study coordinator, and the site investigators from each of the two study sties. Members of this committee will meet monthly to discuss study progress as well as determine plans for publication of findings.

14 PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this pilot study will be governed by the policies and procedures developed by the Steering Committee as well as by the IMPACT Collaboratory. Any presentation, abstract, or manuscript will be made available for review by the IMPACT Collaboratory prior to submission.

15 REFERENCES

1. Olsen C, Pedersen I, Bergland A, et al. Differences in quality of life in home-dwelling persons and nursing home residents with dementia - a cross-sectional study. *BMC Geriatr.* 2016;16:137.
2. Samus QM, Johnston D, Black BS, et al. A multidimensional home-based care coordination intervention for elders with memory disorders: the maximizing independence at home (MIND) pilot randomized trial. *Am J Geriatr Psychiatry.* 2014;22(4):398-414.
3. Tanner JA, Black BS, Johnston D, et al. A randomized controlled trial of a community-based dementia care coordination intervention: effects of MIND at Home on caregiver outcomes. *Am J Geriatr Psychiatry.* 2015;23(4):391-402.
4. Samus QM, Black BS, Reuland M, et al. MIND at Home-Streamlined: Study protocol for a randomized trial of home-based care coordination for persons with dementia and their caregivers. *Contemp Clin Trials.* 2018;71:103-112.
5. Samus QM, Davis K, Willink A, et al. Comprehensive home-based care coordination for vulnerable elders with dementia: Maximizing Independence at Home-Plus-Study protocol. *Int J Care Coord.* 2017;20(4):123-134.
6. Black BS, Johnston D, Leoutsakos J, et al. Unmet needs in community-living persons with dementia are common, often non-medical and related to patient and caregiver characteristics. *Int Psychogeriatr.* 2019;31(11):1643-1654.
7. Black BS, Johnston D, Rabins PV, Morrison A, Lyketsos C, Samus QM. Unmet needs of community-residing persons with dementia and their informal caregivers: findings from the maximizing independence at home study. *J Am Geriatr Soc.* 2013;61(12):2087-2095.
8. Hughes TB, Black BS, Albert M, et al. Correlates of objective and subjective measures of caregiver burden among dementia caregivers: influence of unmet patient and caregiver dementia-related care needs. *Int Psychogeriatr.* 2014;26(11):1875-1883.
9. Willink A, Davis K, Johnston DM, et al. Cost-Effective Care Coordination for People With Dementia at Home. *Innov Aging.* 2020;4(2):igz051.
10. Amjad H, Roth DL, Samus QM, Yasar S, Wolff JL. Potentially Unsafe Activities and Living Conditions of Older Adults with Dementia. *J Am Geriatr Soc.* 2016;64(6):1223-1232.
11. Taylor DH, Jr., Fillenbaum GG, Ezell ME. The accuracy of medicare claims data in identifying Alzheimer's disease. *J Clin Epidemiol.* 2002;55(9):929-937.

16 APPENDICES

A. MIND at Home Field Reference Guide

B. The Johns Hopkins Dementia Care Needs Assessment Screening Tool

C. Program Information Sheet

D. MIND Phone Script Draft

E. PLWD/CG Program Satisfaction Survey