**Cover page for clinicaltrials.gov**

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| Protocol title: | Improving How People Living with Dementia Are Selected for Care Coordination: A Pragmatic Clinical Trial Embedded in an Accountable Care Organization |
| NCT number: | NCT05651308 |
| Protocol date: | November 2, 2023 |

# Clinical Interventional Study Protocol Template

**PREFACE**

*The Clinical Intervention Study Protocol Template is a suggested format for clinical trials sponsored by the National Institute on Aging (NIA). Investigators are encouraged to use this format, as appropriate, when developing protocols for their studies. Large multi-site observational studies will also benefit from this protocol template.*

*Note that instructions and explanatory text are indicated by italics and should be replaced in your protocol with appropriate text. Section headings and template text formatted in regular type should be included in your protocol document as provided in the template.*

*The goal of this template is to provide a general format applicable to all single- and multicenter clinical intervention trials (e.g., drug, surgery, behavioral, nutritional, device, etc).*

*As you can see the version number and date are on the bottom of each page. When making changes to an approved and "final" protocol, please provide a summary of the changes, with the date, at the front of the protocol.*

List of changes to the protocol

| Protocol number | Date of Protocol | Revision made, if any |
|---|---|---|
| 1 | May 11, 2022 | Original approved protocol |
| 2 | September 9, 2022 | Adding an exclusion for people enrolled in home hospice |
| 3 | October 26, 2022 | Stratifying randomization by care management team |
| 4 | November 2, 2023 | Changing 24-hour reporting requirement from all deaths to unexpected deaths and updating reporting logistics |

# FULL PROTOCOL TITLE

Improving How People Living with Dementia Are Selected for Care Coordination:
A Pragmatic Clinical Trial Embedded in an Accountable Care Organization

## Study Chairman or Principal Investigator:

Lisa M. Kern, MD, MPH, Associate Professor of Medicine, Weill Cornell Medicine

## Supported by:

## The National Institute on Aging

NIA IMPACT Collaboratory

FY22_Demo2_Kern

## Study Intervention Provided by:

Not applicable

## Sponsor of IND/IDE:

Not applicable

*(Any modification to the protocol should be annotated on the coversheet or in an appendix. The annotation should note the exact words that are changed, the location in the protocol, the date the modification was approved, and the date it became effective.)*

**Version 4**
**November 2, 2023**

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## PRÉCIS

### Study Title

Improving How People Living with Dementia Are Selected for Care Coordination: A Pragmatic Clinical Trial Embedded in an Accountable Care Organization

### Objectives

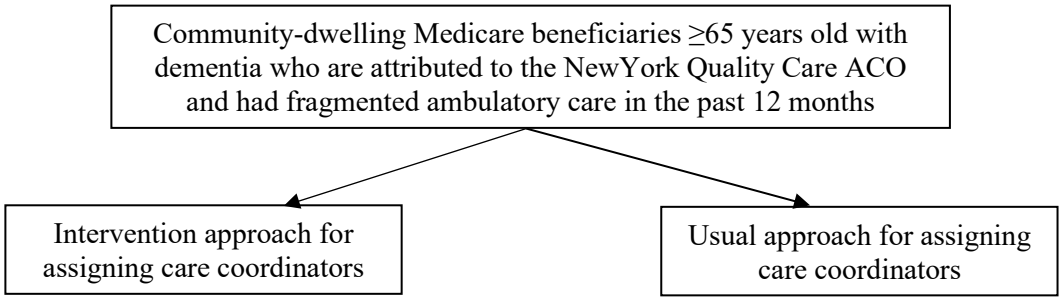
The primary objective is to determine the comparative effectiveness of two different approaches for allocating care coordinators to people living with dementia (PLWD) in the context of a Medicare Accountable Care Organization (ACO) (i.e., based on care partners' reported need for care coordination vs. usual care, which is typically after hospital discharge) on the combined outcome of emergency department (ED) visit or hospital admission over 12 months of follow-up, as measured in claims.

The secondary objective is to measure implementation outcomes for the trial to inform future dissemination: acceptability (percent of participants who engage with the care coordinators), appropriateness (types and frequencies of different care coordination services provided), fidelity (percent of eligible individuals who receive care coordination services based on perceived need), and efficiency (total number of care coordinator hours), as measured with data from electronic health records.

### Design and Outcomes

The proposed study is a pragmatic clinical trial embedded in a Medicare ACO with prospective randomization to determine the comparative effectiveness of two different approaches for allocating care coordinators to PLWD. It will include Medicare beneficiaries who have had fragmented ambulatory care (that is, care spread across multiple providers without a dominant provider), because individuals with fragmented ambulatory care are at risk for gaps in communication across providers, which care coordinators can address.

Figure 1. Overview of study design




Participants will be followed for the primary combined outcome of emergency department visit or hospitalization over 12 months.

**Interventions and Duration**

Overview: This study will leverage the existing infrastructure of the NewYork Quality Care (NYQC) ACO, which already works with care coordinators. Care coordinators are members of the medical team (typically with previous training in nursing, social work, or another related field) whose job it is to facilitate communication among all the participants involved in an individual's care. ACOs typically have thousands of patients assigned, or attributed, to them by Medicare and only a few care coordinators. Thus, care coordinators are a scarce resource, and it is not known how best to allocate them. This study will not change what care coordinators do; rather, it will test the comparative effectiveness of two different strategies for allocating care coordinators to PLWD.

Usual care: Usual care assigns attributed patients to care coordinators in response to: 1) a discharge from an NYQC hospital (approximately 80% of cases), 2) a discharge from a non-NYQC hospital (approximately 15% of cases), or 3) a referral from an NYQC physician asking for care coordination for a specific patient (approximately 5% of cases).

Intervention: The intervention group will assign care coordinators to PLWD based on perceived need for assistance with care coordination, as follows. The PLWD who are randomized to the intervention arm will each receive an initial call from a care coordinator, which we will refer to as the "screening" call. If the patient has severe dementia and is not able to participate in a phone call (as judged by the care coordinator), the care coordinator will reach out to the healthcare proxy documented in the EHR. The care coordinator will administer a previously validated 7-minute telephone survey on perceptions of care coordination. If the patient or proxy responds to the survey in a way that indicates a perceived problem with care coordination in the past 6 months (i.e., a "positive" response to ≥1 of 8 questions, as defined previously), then we will consider this a "positive screening." The care coordinator will then ask open-ended questions to understand the specific problem with care coordination and proceed to address it. (As in the usual care group, referrals from NYQC physicians asking for care coordination for a specific patient will also be allowed for the intervention group.)

Timeline: The first 3 months after randomization will be considered the period of time for qualifying events (e.g. a hospitalization in the usual care group or a positive survey in the intervention group). PLWD who are assigned to care coordinators (in both groups) will receive care coordination services for a minimum of 30 days. After 30 days, the 12-month follow-up period (for the occurrence of and ED visit or hospitalization) will begin.

**Sample Size and Population**

We will include Medicare beneficiaries ≥65 years old who: 1) are attributed to NYQC by Medicare, 2) have dementia (using the previously validated Bynum-Standard 1-year definition for ICD-10 codes), 3) reside in the community, and 4) had fragmented ambulatory care in the previous 12 months (defined as a reversed Bice-Boxerman Index ≥50$^{th}$ percentile). At the time of the grant application, 688 individuals met these criteria. We will recalculate eligibility at the start of the trial, since attribution changes over time, but we expect the total number of eligible individuals to be similar.

**STUDY TEAM ROSTER**

*List individuals who play key roles in the development and execution of the study, especially those who may need to be contacted by the sites during the course of the study. Include address, telephone, fax and e-mail address of each individual listed and include a brief summary of each individual's main responsibilities.*

**Principal Investigator:**

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E: lmk2003@med.cornell.edu
Role: PI (As PI, Dr. Kern will oversee all aspects of the research, including coordination of the research team (including the subcontract to NewYork Quality Care), study design, data collection, data analysis, interpretation of results, manuscript preparation, dissemination of results, and coordination with the IMPACT Collaboratory.)

**Co-Investigators:**

**Name:** Samprit Banerjee, PhD
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Role: Biostatistician (As the Biostatistician, Dr. Banerjee will contribute his methodological expertise to this project, advising on study design, overseeing randomization, and overseeing statistical analysis. He will also assist with revising manuscripts for critical scientific content.)

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Role: Geriatrician **(**Dr. Phongtankuel will contribute to this project his expertise in the clinical care of patients with dementia, contributing to study design, interpretation of results, revisions of manuscripts, and dissemination. He will also be available to the PI and the care coordinators as a clinical resource.**)**

Catherine Riffin, PhD
Weill Cornell Medicine
420 East 70th Street, 3rd Floor
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Role: Social scientist (Dr. Riffin will contribute her expertise in family care partners for individuals with dementia, contributing to study design, interpretation of results, revisions of manuscripts, and dissemination. She will be available to the PI and the care coordinators for any questions that may arise with the proxy respondents.)

**PARTICIPATING STUDY SITES**

*List the name and address of each study site investigator, including telephone numbers and e-mail address. Use the same format as used for the Study Team roster.*

**Site PI:** **Name:** Paul Casale, MD, MPH
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Role: Co-I, Executive Director of NYQC (Dr. Casale will contribute to this project his expertise on how advancing care coordination aligns with the goals of accountable care organizations. He will contribute to interpretation of study results. Dr. Casale will also oversee the activities of the NewYork Quality Care staff.)

Note on the relationship between Weill Cornell Medicine and NewYork Quality Care:
NewYork Quality Care is an accountable care organization that brings together NewYork-Presbyterian Hospital, Weill Cornell Medicine, and ColumbiaDoctors. Weill Cornell Medicine is thus a part of NewYork Quality Care. NewYork Quality Care does not have its own IRB and instead relies on the IRBs of its component organizations. We are providing a letter from NewYork Quality Care, saying that for this project they cede IRB oversight to Weill Cornell Medicine and thus cede to the Advarra IRB.

# 1 STUDY OBJECTIVES

## 1.1 Primary Objective

The primary objective is to determine whether a novel approach to allocating care coordinators to PLWD (i.e., based on care partners' perceived need for care coordination) results in fewer ED visits and hospitalizations over 12 months, compared to usual care, which allocates care coordinators to PLWD after hospital discharge.

## 1.2 Secondary Objectives

The secondary objective is to determine the acceptability (percent of participants who engage with the care coordinators), appropriateness (types and frequencies of different care coordination services provided), fidelity (percent of eligible individuals who receive care coordination services based on perceived need), and efficiency (total number of care coordinator hours) of this novel approach to allocating care coordinators to PLWD based on care partners' perceived need for care coordination.

# 2 BACKGROUND AND RATIONALE

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

In response to a survey in 2021 about how their organizations approach care for PLWD, members of the NEJM Catalyst Insights Council (>500 clinicians, clinical leaders, and executives directly involved in care delivery) reported that "fragmentation of care delivery" is the #1 barrier to improving dementia care.[1] Fragmentation of care delivery refers to ambulatory care that is spread across numerous ambulatory providers without a dominant provider.[2,3] Seeing multiple providers may be clinically appropriate, but it increases the risk of gaps in communication across providers caring for the same patient.[4] Fragmented ambulatory care is ubiquitous in the U.S., with 25% percent of Medicare beneficiaries ≥65 years old seeing ≥11 ambulatory providers each year.[5-7] Although PLWD may not be the only people who experience fragmentation of care, they may be particularly vulnerable to its adverse effects; that is, they may not have the physiologic reserves to withstand the drug-drug interactions, repeat tests, and unnecessary procedures that are associated with fragmented care.[8] How best to address fragmented ambulatory care for PLWD is not known.

Care coordination is one solution to fragmented ambulatory care, and care coordination has been found to be an efficacious intervention for PLWD.[9] However, there are not enough care coordination resources for all the people who might benefit from their help.[10] "Care coordinators" are members of the medical team whose job it is to facilitate communication among all the participants involved in a patient's care.[11,12] They usually have previous training in nursing or social work,[13,14] and they are already employed by providers across the country, including accountable care organizations (ACOs).[11] An ACO is a formal organization that brings together physicians, hospitals, and other clinical entities for the purpose of providing care to a population of patients.[15] ACOs contract with payers, such as Medicare.[15] ACOs typically have thousands of attributed patients (including PLWD) and only a small number of care coordinators. For example, an ACO with 9,000 attributed patients may only have 3 care coordinators, who can care for

approximately 350 patients each, for a total of 1,050 patients (12%).[10] Determining how best to allocate care coordinators is critical for patient outcomes and the success of the ACO. However, there have been no studies of the comparative effectiveness of different approaches.

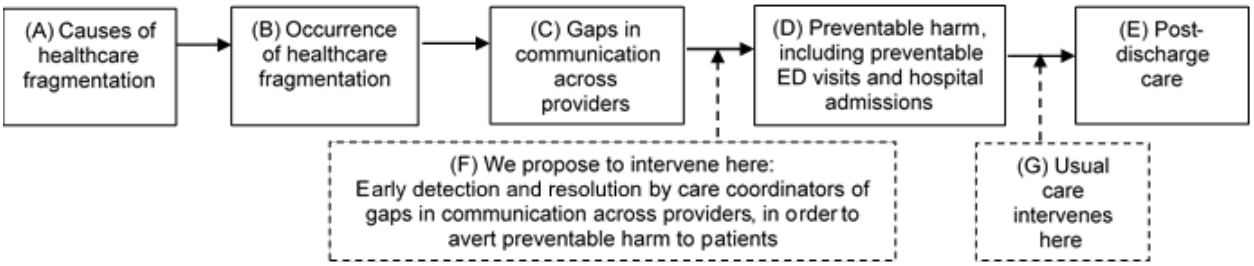
## 2.2 Study Rationale

The usual approach for selecting the patients who will receive assistance from care coordinators is to select patients who are the "sickest" (based on type or severity of illness) or who experience a transition in care, such as a hospital discharge.[16,17] This approach is reasonable, but it assumes that all patients meeting those criteria have problems with care coordination, which they may not. The usual approach also has the disadvantage of often waiting until after a hospitalization, at which point the patient, care partner, and care coordinator need to manage not only the illness that prompted the hospital admission but also any complications from the admission itself.

An alternate approach would identify patients and care partners who experience problems with care coordination and then assign care coordinators to them. This approach would involve identifying patients with highly fragmented care (who are at high risk of having poor care coordination) and then asking them or their care partners their perceptions of the extent to which care is coordinated. Patients and care partners have a unique vantage point from which to detect gaps in care coordination, as they are the first to know if the patient seeks care from multiple health systems.[18] They are also often the first to know if something with care does not seem right, such as being asked to repeat a test.[18] In a national 2020 survey by AARP, 31% of care partners for PLWD reported difficulty coordinating care among their care recipient's providers, which was up from 23% in 2015.[19] Self-reported concerns with care coordination have recently been validated against objective measures of quality of care.[20]

This study is based on a conceptual model that has arisen from Dr. Kern's previous work (Figure 2).[4] The model describes the relationships among fragmentation, communication, and harm and identifies different time points at which interventions could occur. The intervention we are proposing in this application would detect and address gaps in communication before they cause harm (Box F). By contrast, usual care would intervene after a hospital admission (Box G). This is not to say that all hospital admissions are preventable or related to fragmented care; they are not. However, our preliminary data suggest that more fragmented care for Medicare beneficiaries over 12 months independently increases the risk of an incident ED visit[(under review)] or incident hospital admission[21] in the subsequent 1-3 months, compared to less fragmented care. The magnitude of this association is a 31% increase in the risk of an ED visit (95% confidence interval [CI] 29%, 34%) and, separately, an 18% increase in the risk of a hospital admission (95% CI 12%, 24%). If this risk can be modified with better communication, the potential for averted ED visits and hospital admissions is substantial.

Figure 2. Conceptual model describing the relationships among fragmentation, communication, and harm




Of note, in a nationwide survey, Black Medicare beneficiaries were significantly more likely than White Medicare beneficiaries to report experiencing an adverse event that they thought could have been prevented with better communication among their healthcare providers.[22] Addressing concerns about care coordination has the potential to avert preventable events that may disproportionately affect racial minorities.

## 3 STUDY DESIGN

We will conduct a pragmatic clinical trial embedded in an ACO (ePCT) with prospective randomization. The trial consists of a parallel design with two groups of equal size. Masking is not feasible.

The trial will determine the comparative effectiveness of two different approaches for allocating care coordinators to PLWD. The primary outcome is the combined outcome of ED visit or hospitalization over 12 months of follow-up. The secondary outcome consists of implementation measures (acceptability, appropriateness, fidelity, and efficiency), which will be used to inform future dissemination.

The setting for the study is the NewYork Quality Care (NYQC) ACO, the ACO that brings together NewYork-Presbyterian Hospital, Weill Cornell Medicine, and ColumbiaDoctors.[23,24] Individuals in the study have already been assigned to NYQC by Medicare and will be contacted by care coordinators who already work with NYQC. Interactions between care coordinators and individuals in the study (PLWD or their proxies) will be done by telephone or by video, both of which are part of standard care.

The study population will consist of Medicare beneficiaries ≥65 years old who: 1) are attributed to NYQC by Medicare, 2) have dementia (using the previously validated Bynum-Standard 1-year definition for ICD-10 codes),[25,26] 3) reside in the community, and 4) had fragmented ambulatory care in the previous 12 months (defined as a reversed Bice-Boxerman Index ≥50$^{th}$ percentile).[27,28] At the time of the grant application, 688 individuals met these criteria. We will recalculate eligibility at the start of the trial, since attribution changes over time, but we expect the total number of eligible individuals to be similar. This population will be randomized to the two arms of the trial (344 per arm).

At the start of the study, we will have the list of participants and will randomize them into two groups. (We will be requesting a waiver of informed consent and a waiver of HIPAA authorization, as described below in section 4.3, so there will be no recruitment per se.)

The first 3 months after randomization will serve as the period during which individuals will have "qualifying events" for receipt of care coordination services. In the usual care group, a qualifying event is discharge from a hospitalization. In the intervention group, a qualifying event is a "positive screening call" (indicating a perceived problem with care coordination), as described in Section 5.2 below. Direct referrals from physicians to care coordinators for assistance with particular patients will be allowed in both groups.

Individuals with qualifying events in both groups will receive care coordination services, which will be consistent with the professional standards of the American Case Management Association and the Case Management Society of America.[29,30] Usual care includes describing care coordination to the patient or proxy and inviting them to engage in care coordination; approximately 70-80% of people agree to engage. Each interaction with a patient or proxy (including declining care coordination) is documented in the electronic health record (EHR). Usual care coordination is broad and encompasses post-discharge medication reconciliation, inquiries about any symptoms post-discharge, a review of upcoming appointments, assistance with obtaining transportation, review of paid home care services, and any other needs that may arise, with the primary goal of preventing rehospitalization. Patients and proxies are given the care coordinator's contact information and are invited to reach out with any questions or concerns. Care coordination in the intervention group will start narrowly, with the care coordinator seeking to understand the positive screening result (exactly what the patient or proxy thinks is not working well and why). The care coordinator will then seek to address the issue, documenting the process in the EHR. The care coordinators will be free to engage in broader care coordination activities (e.g., general medication reconciliation, reviewing upcoming appointments, arranging transportation, etc.) at their discretion.

The length and frequency of interactions between the patient or proxy and the care coordinator varies depending on the patient's needs and the care coordinator's discretion. Patients are followed for a minimum of 30 days and a maximum of 1 year, which is a typical duration for care coordination.[31] Care coordination starts at the time of the qualifying event. Follow-up for ED visits and hospitalizations begins after the first 30 days of care coordination.

# 4 SELECTION AND ENROLLMENT OF PARTICIPANTS

*Key components of the success of a clinical study are the selection and enrollment of participants who are reasonably representative of the populations or characteristics under investigation to allow for sufficient generalizability. This section should define and describe the study population.*

## 4.1 Inclusion Criteria

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

- Medicare beneficiaries ≥65 years old who are attributed to NYQC by Medicare,[24]
- Who have dementia, using the previously validated Bynum-Standard 1-year definition with ICD-10 codes from Medicare claims for the previous 12 months,[25,26] and

- Who had fragmented ambulatory care, based on Medicare claims in the previous 12 months, defined as a reversed Bice-Boxerman Index (BBI) score ≥50th percentile.[27,28]

$$reversed\ BBI = 1 - BBI = 1 - \frac{\left(\sum_{i=1}^{p} n_i^2\right) - n}{n\ (n-1)}$$

where n = total number of ambulatory visits in the 12-month period
$n_i$ = number of ambulatory visits to provider *i*
p = total number of ambulatory providers

## 4.2 Exclusion Criteria

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

- Those whose addresses are the same as the addresses of nursing homes and other long-term care facilities, as those individuals have distinct care coordination needs. This is routinely captured by the NYQC ACO.
- Those who are enrolled in home hospice, as captured in Medicare claims. The rationale for excluding these individuals is that they are not at the same risk of having an ED visit or hospitalization as other community-dwelling individuals. By virtue of being enrolled in home hospice, they have essentially agreed not to receive services in those more acute settings.

## 4.3 Study Enrollment Procedures

For this trial, we are collaborating with the NYQC ACO. The Centers for Medicare & Medicaid Services (CMS) requires that ACOs inform Medicare beneficiaries if their doctor chooses to participate in an ACO.[32] This notification can come in the form of a letter, written information provided when the patient sees the doctor, a sign posted in the doctor's office, or a verbal conversation between patient and doctor.[32] NYQC chooses to notify patients by putting up posters in their providers' practices. Medicare beneficiaries do not have to seek care within the ACO; they are free to seek care elsewhere. NYQC receives from CMS the names of the patients that have been assigned, or attributed, to NYQC. Attribution is done by CMS and is based on prior healthcare utilization.

We are requesting a waiver of informed consent. We believe that the study meets the 5 Common Rule criteria for a waiver,[33] as follows.

(i) Minimal risk: The research involves no more than minimal risk to the subjects, because receipt of care coordination services is part of standard clinical care. Completing the survey is also minimal risk, as the survey does not inquire about sensitive topics. Review of data in the electronic health record and analysis of claims data are also minimal risk activities.

(ii) Practicability: The research could not practicably be carried out without the waiver. This is because, during usual care, patients are not aware of care coordinator resources unless they are assigned a care coordinator through a physician referral or after a recent discharge. If we were to try to obtain informed

consent, we would need to explain care coordination, which may then raise concerns about care coordination among the participants and proxies. This would be especially problematic in the control group, which by the design of the study cannot directly request the assistance of care coordinators. This would then create problems for the feasibility and validity of the trial.

(iii) Identifiable information: The research could not practicably be carried out without the use of identifiable information. The trial relies on identifying community-dwelling Medicare beneficiaries 65 years and older with dementia who are attributed to NewYork Quality Care. We then need to reach out to those individuals who qualify for care coordination in each group, provide care coordination services, review their electronic health record data for implementation outcomes, and follow them over time for the occurrence of emergency department visits and hospital admissions as captured in claims. This study is not possible without the use of identifiers.

(iv) Rights and welfare: The waiver will not adversely affect the participants' rights. There is uncertainty about the optimal way to allocate care coordinators; this study is a comparative effectiveness trial of two approaches. Which approach is superior is currently unknown. In addition, even if a waiver is granted, eligible participants in both groups will have the option to agree to or decline care coordination services.

(v) Distribution of pertinent information after the trial: NYQC will have the opportunity to distribute the results of the trial to its attributed population. This may take the form of posters or flyers distributed in doctors' offices, a form of communication which NYQC has used previously.

We are also requesting a full waiver of HIPAA authorization for this study. We are requesting this for use of protected health information from the EHR and for use of Medicare claims for research purposes (both recruitment and outcome assessment) in compliance with the HIPAA Privacy Law. We believe that the study meets the criteria for a full HIPAA waiver, as follows:

(i) Use or disclosure involves no more than minimal risk to the privacy of individuals: We have an adequate plan in place to protect health information identifiers from improper use or disclosure. We will destroy identifiers at the earliest opportunity, absent a health or research justification or legal requirement to retain them. We also have adequate written assurances that the protected health information 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.

(ii) Research could not practicably be conducted without the waiver: The research could not practicably be carried out without the waiver because, during usual care, patients are not aware of care coordinator resources unless they are assigned a care coordinator through a physician referral or after a recent discharge. If we

were to try to obtain authorization, we would need to explain care coordination, which may then raise concerns about care coordination among the participants and proxies. This would be especially problematic in the control group, which by the design of the study cannot directly request the assistance of care coordinators. This would then create problems for the feasibility and validity of the trial.

(iii) Research could not practicably be conducted without access to and use of PHI: The research could not practicably be carried out without the use of identifiable information. The trial relies on identifying community-dwelling Medicare beneficiaries 65 years and older with dementia who are attributed to NewYork Quality Care. We then need to reach out to those individuals who qualify for care coordination in each group, provide care coordination services, review their electronic health record data for implementation outcomes, and follow them over time for the occurrence of emergency department visits and hospital admissions as captured in claims. This study is not possible without the use of identifiers.

If this waiver is granted, then there will be no recruitment or enrollment per se, because we will include 100% of eligible individuals. Even with a waiver of informed consent, participants in both the intervention and control groups will be able to decline care coordination services if they do not want them. Currently, with usual care, about 70-80% of Medicare beneficiaries who are approached by the NYQC care coordinator agree to engage in care coordination. Each interaction with a patient or proxy (including declining care coordination) is documented in the EHR.

Of note, under usual care, care coordinators interact with PLWD and informally assess their capacity to participate in answering questions related to their healthcare. If care coordinators believe that the PLWD cannot accurately answer questions related to their healthcare, they contact the healthcare proxy listed in the electronic health record. We will apply this approach to the intervention group as well. We considered expanding "care partners" to non-healthcare-proxies, but since this is not consistent with usual care, we will not. Thus, we will not consider proxies to be separate participants in the trial; they will answer questions on behalf of the PLWD. We are not asking any information about the proxies themselves. Care coordinators routinely document in the EHR whether they spoke to the patient or proxy.

If a patient has severe dementia and does not have a healthcare proxy documented in the EHR, the patient will not be excluded (because they are still the responsibility of the ACO); in that case, the care coordinator will review the EHR to assess the extent of care coordination and rectify any apparent gaps in communication.

Randomization will be overseen by Dr. Samprit Banerjee (biostatistician). He will advise the data analyst at NYQC on how to employ random number generators to randomly allocate the study population into two equal size groups. Masking is not feasible for this study, so NYQC will be aware of which patients are allocated to which group. This is necessary, because they will need to conduct screening surveys for everyone in the intervention group. (See section 5.2 for a more detailed discussion of masking.)

# 5 STUDY INTERVENTIONS

## 5.1 Interventions, Administration, and Duration

The intervention in this trial is the method for allocating PLWD to care coordinators. The content of the care coordination services will be essentially the same in both groups, with slight differences in the start of care coordination (whether focused on the problem that led to a positive survey screen or whether focused on post-discharge management). Overall, though, care coordination services will be highly flexible and tailored to meet each patient's needs, as is standard. See section 5.2 for more information.

## 5.2 Handling of Study Interventions

As above, the intervention consists of a novel method for assigning care coordinators to PLWD based on perceived need. Perceived need will be measured with a previously validated 7-minute telephone survey. This survey consists of 22 questions, has been previously administered to more than 7,000 adults ≥65 years old (with funding from Dr. Kern's R01 HL135199), and is published.[34] This published paper, which includes the survey instrument as an appendix, is being provided to the IRB with this protocol. The survey includes 8 questions regarding perceptions of care coordination; the other questions relate to self-reported ambulatory utilization and self-reported preventable adverse events. The 8 questions on perceptions of care coordination include 6 questions from the previously validated Care Coordination Measure for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Medicare survey, which was previously tested on more than 300,000 Medicare beneficiaries[35] These 8 questions ask (using different wording) whether the respondent has experienced difficulty with care coordination over the past 6 months, and the responses are ultimately combined into a single indicator for the presence or absence of a self-reported problem with or "gap" in care coordination. Of the 7,568 respondents in the original administration (average age 77 years), 38% reported a gap in care coordination.[34]

Care coordinators will administer this survey by telephone to participants (patients or proxies) in the intervention group. The care coordinators will document the survey responses in customized data entry form in REDCap, a secure web-based data management platform.[36] If the patient or proxy responds to the survey in a way that indicates a perceived problem with care coordination in the past 6 months (i.e., a "positive" response to ≥1 of 8 questions, as defined previously),[34] then we will consider this a "positive screening." Care coordinators will be trained in advance to recognize "positive" responses and respond to them in real time, asking open ended questions to understand why the respondent felt that that there was a problem with care coordination. For patients and proxies whose screening calls were "negative" (not revealing a perceived problem with care coordination), the care coordinators will give them their contact information and invite them to reach out with any questions or concerns. NYQC considers administration of this survey to be part of clinical care.

We will have a data analyst review the survey responses to measure (as part of the implementation measure for fidelity) whether surveys were correctly categorized as positive or negative.

For the control group, an administrator at NYQC is responsible for querying daily the

Epic EHR to identify discharges from NYQC hospitals and for querying daily a New York City health information exchange called NYCLIX to identify hospital discharges from non-NYQC hospitals. [37,38] (An emergency department visit that results in discharge to home without hospital admission does not qualify.) The administrator assigns each discharged patient to a care coordinator, who then reaches out to the patient by phone.

Care coordination services for both groups will be provided consistent with the professional standards of the American Case Management Association and the Case Management Society of America.[29,30] Most components of care coordination are flexible and can be varied by staff. For example, the care coordinators will have some discretion over what types of care coordination tasks to engage in. Facilitating provider-provider communication will be emphasized in the intervention group, but care coordinators can also help with other tasks, such as reviewing upcoming appointments or arranging transportation. One of our implementation outcomes will consist of measuring the frequencies of different types of care coordination activities in the two groups. This is a highly pragmatic approach.

Masking is not feasible for this study, so NYQC will be aware of which patients are allocated to which group. This is necessary, because the care coordinators will conduct screening surveys for everyone in the intervention group. The care coordinators will know that this is part of a research study. The same care coordinators may be assigned to individuals in the intervention group and in the control group. However, we do not expect contamination to be an issue, because an administrator at NYQC (the same one who monitors hospitalizations) will assign intervention patients to the care coordinators for administration of the survey. The administrator will supervise the care coordinators to ensure that they approach patients as intended (either for post-discharge planning or for assessment through the survey).

Interactions between care coordinators and individuals in the study (PLWD or their proxies) will be done by telephone or by video, both of which are part of standard care. Note that all participants will be included, regardless of language spoken. For non-English speaking patients, the care coordinators use a professional interpreter service, which they conference in through an 800 number. The current service they use is LanguageLine Solutions, which provides on-demand, live interpreters in more than 200 languages (https://www.languageline.com/s/). Because this is a usual care process, we are not planning to have any translations reviewed by Advarra.

Additional considerations: The research team carefully considered how to handle several complexities that are interrelated. (1) Consistent with standard practice in which patients are followed for a maximum of 1 year, patients in the usual care group may continue to have events that qualify them for care coordination beyond the 3-month timeframe that we have specified for the "qualifying event window." That is, patients in the usual care group will continue to be assigned care coordinators when they are hospitalized and discharged. (2) Patients randomized to the intervention group may be hospitalized during the first 3-month qualifying-event-window and after that window as well. (3) Patients randomized to the intervention group may be referred by their physicians for care coordination, just as that occurs for about 5% of the usual care participants. To address these complexities, we have developed the following approach. If a physician refers a

patient who is assigned to the intervention group to care coordination, we will honor that referral and provide care coordination. If a patient in the intervention group has a hospital admission at any time (during the first 3-month qualifying window or during follow-up), we will administer the perceptions of care coordination survey after discharge and provide care coordination if the survey indicates a need. We believe this is more ethical than not providing care coordination at all to discharged patients in the intervention group; assignment of care coordinators would still be made based on reported problems with care coordination and not given automatically. Thus, during the 3-month window for qualifying events, all participants in the intervention group will receive the survey; after that, the survey will be given to those intervention participants who are discharged from the hospital.

## 5.3 Concomitant Interventions

### 5.3.1 Allowed Interventions

Not applicable

### 5.3.2 Required Interventions

Not applicable

### 5.3.3 Prohibited Interventions

Not applicable

## 5.4 Adherence Assessment

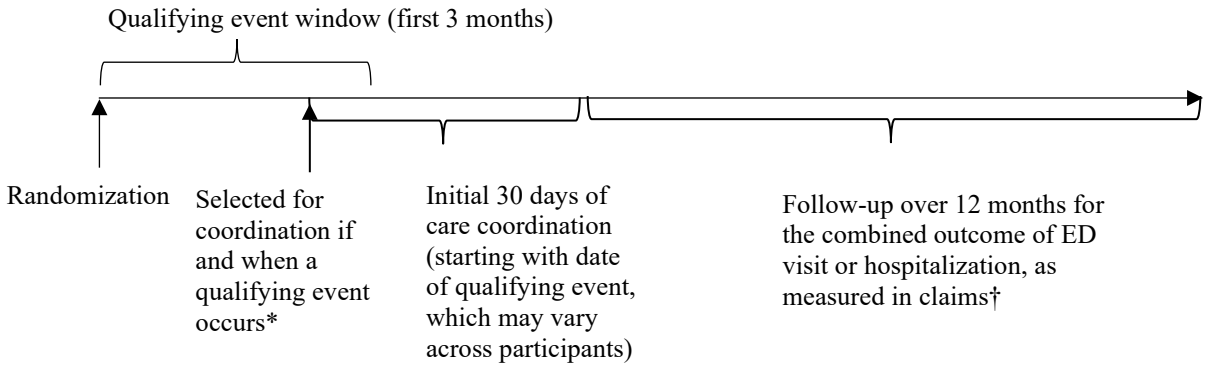
We will measure different versions of adherence when we collect implementation outcomes for the secondary objective of the study. These implementation outcomes will be collected by a research assistant, who will review the EHRs for participants in both study groups. The research assistant will extract data from the EHRs manually, using a structured form in REDCap. The following implementation outcomes will be collected: acceptability (percent of participants who engage with the care coordinators in both groups), appropriateness (types and frequencies of different care coordination services provided in both groups), fidelity (percent of eligible individuals who receive care coordination services based on perceived need in the intervention group), and efficiency (total number of care coordinator hours in both groups). These implementation outcomes are drawn from the Consolidated Framework of Implementation Research (CFIR) and related work by Proctor et al.[39-41]

# 6 STUDY PROCEDURES

## 6.1 Schedule of Evaluations

This trial does not have a schedule of evaluations per se. Instead, we show a timeline of events for all participants in the trial (Figure 3).

Figure 3. Timeline of events for each participant (not to scale)




*See section 3 for the definition of qualifying event, which varies based on the arm of the trial
†Care coordination may extend beyond 30 days for participants in either trial arm, at the discretion of the care coordinator, but the follow-up period still starts after the initial 30 days of care coordination. For those participants who do not have a qualifying event, their follow-up period for ED visits or hospitalizations will start 4 months after randomization (simulating the 3-month qualifying period + 1 month during which they did not receive care coordination). See also section 5.1 for more information.

The study will use three data sources: the survey on perceptions of care coordination, the EHR, and Medicare claims. The survey data will be used to determine eligibility for care coordination in the intervention group. The EHR will be used to collect demographic and clinical characteristics of patients (age, race, sex, co-morbidities), as well as the implementation outcomes. Medicare claims will be used to measure fragmentation as an eligibility criterion and the primary outcome of ED visit or hospital admission over 12 months. The survey will be administered by care coordinators, the EHR data collection will be done by a research assistant, and the Medicare claims will be analyzed by data analysts.

Note that all participants will contribute data to the study whether they are selected for care coordination or not. This is because we are comparing two methods for allocating care coordinators, and we are interested in ED and hospitalization outcomes for both those selected and those not selected.

## 6.2. Description of Evaluations

### 6.2.1 Screening Evaluation

Consenting Procedure

We are requesting a waiver of informed consent and a waiver of HIPAA authorization (see section 4.3).

Screening

This is not applicable, because the study will include all community-dwelling Medicare beneficiaries with dementia who have been attributed to NYQC and had

fragmented care in the past 12 months. All of these criteria will be measured using claims, not interactions with patients or proxies.

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

The enrollment date for all participants will be the date of randomization.

Baseline Assessments

The research assistant will manually review the EHR for participants' demographic characteristics (age, race, sex, co-morbidities).

Randomization

See section 6.1 for a timeline of randomization, intervention, and follow-up.

6.2.3 Follow-up Visits

Follow-up visits per se are not applicable to this trial. The length and frequency of interactions between the care coordinator and patient or proxy will vary with the patient's needs and care coordinator's discretion.

6.2.4 Completion/Final Evaluation

A completion or final evaluation visit is not applicable to this trial. The length and frequency of interactions between the care coordinator and patient or proxy will vary with the patient's needs and care coordinator's discretion. The ED and hospitalization outcomes will be measured in claims.

# *7* SAFETY ASSESSMENTS

## 7.1 Specification of Safety Parameters

This is not a drug trial, so we will not be assessing safety with laboratory values. See below for how we will monitor safety in this trial.

## 7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

This is not a drug trial, so we will not be assessing safety with laboratory values. See below for how we will monitor safety in this trial.

## 7.3 Adverse Events and Serious Adverse Events

**Adverse Event (AE):** Any untoward or unfavorable medical occurrence in a clinical research study participant, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

> **AEs for this study:** AEs may include a mild increase in anxiety or stress on the part of the patient or patient's healthcare proxy. This may be expected from a discussion about the challenges of navigating healthcare, but is expected to be short-lived, due to the provision of resources to address the problem.

**Serious Adverse Event (SAE):** 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
- Causes persistent or significant disability or incapacity
- Is another condition which investigators judge to represent significant hazards

**SAEs for this study:** Because the study population consists of PLWD, the possibility of emergency department visits and hospitalizations may be reasonably expected. The occurrence of these events will be measured by the study as outcomes, and it is hypothesized that the intervention group will have fewer of these events than the control group. Because the study population consists of PLWD, the possibility of death is also an expected occurrence, though it is not expected to be related to the intervention. We will monitor for this event as well, although it is not a study outcome per se.

7.3.1 Reporting Procedures

**Process for identifying AEs and SAEs:**

If the care coordinators perceive that a patient or healthcare proxy has increased anxiety, the care coordinator will report this to the PI, who will consult with the research team's geriatrician. The geriatrician can discuss the case with the care coordinator and also with the patient's physicians.

The research team will analyze Medicare claims monthly to monitor for the outcomes of emergency department visits and hospitalizations. These are expected events that will be tracked and reported to the PI.

Any deaths that are detected through review of electronic health records by the care coordinators or research assistant will be reported to the PI.

Any unanticipated problems encountered by team members will be reported to the PI.

**Severity of Event**

All AEs will be assessed for severity by the PI using the following scale:

• Mild – Events require minimal or no treatment and do not interfere with the participant's daily activities.

• Moderate – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.

• Severe – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious."

**Relationship To Study Intervention**

All adverse events (AEs) will have their relationship to study intervention assessed by the PI who will evaluate the situation based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

• Definitely Related – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event occurs in a plausible time relationship to study intervention administration and cannot be explained by other factors.

• Possibly Related – There is some evidence to suggest a causal relationship. However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related," as appropriate.

• Not Related – The AE is completely independent of study intervention administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by a qualified medical professional.

7.3.2 Follow-up for Adverse Events

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during interactions between care coordinators and study participants and their proxies. The occurrence of an AE or SAE may also come to the attention of study personnel upon review of medical records.

All AEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, qualified medical professional's assessment of severity, relationship to study, and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed.

**Reporting schedule:**

- 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 and NIA IMPACT Collaboratory PO for dissemination to the IMPACT Collaboratory DSMB Chair (or the project's Safety Officer) within 48 hours of the study's knowledge of 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 (or the project's Safety Officer) or NIA IMPACT Collaboratory PO.
- All unexpected deaths will be reported to IMPACT Collaboratory Regulatory and Data Team and NIA IMPACT Collaboratory PO for dissemination to the IMPACT Collaboratory DSMB Chair (or the project's Safety Officer) within 24 hours of study's 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 (or the project's Safety Officer) or NIA IMPACT Collaboratory PO.

- All **unanticipated problems** (**UPs)** will be reported to the IMPACT Collaboratory Regulatory and Data Team and NIA IMPACT Collaboratory PO for dissemination to the Advarra IRB and the IMPACT Collaboratory DSMB Chair (or the project's 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 for dissemination to Advarra IRB, NIA IMPACT Collaboratory PO, and the IMPACT Collaboratory DSMB Chair (or the project's Safety Officer) 6 months after the start of enrollment and at the end of enrollment or data collection (whichever comes later), or at a frequency requested by the IMPACT Collaboratory DSMB Chair (or the project's Safety Officer) or NIA IMPACT Collaboratory PO.

### 7.4 Safety Monitoring

The NIA Guidelines on Data and Safety Monitoring generally require that a NIA-appointed Data and Safety Monitoring Board or Safety Officer monitor clinical trials. This trial will have oversight from the Data and Safety Monitoring Board appointed by the NIA IMPACT Collaboratory.

## 8 INTERVENTION DISCONTINUATION

No interim analysis is planned, as the planned trial is fairly short, with 12 months of follow-up for the combined outcome of an emergency department visit or hospital admission. Interim analyses of emergency department visits and hospital admissions will not likely be sufficiently powered to be meaningful.

However, findings that might trigger a safety review are the number of unexpected deaths in the trial. Such findings are presented to the study statistician or to the Data and Safety Monitoring Board (DSMB) statistician to review the events by group to determine whether there are statistical as well as clinical concerns. The statistician reports his findings to a closed session of the DSMB or to the Safety Officer and/or NIA. The findings are used to determine what steps will be taken.

## 9 STATISTICAL CONSIDERATIONS

### 9.1 General Design Issues

The trial is based on the hypothesis that assigning care coordinators to PLWD whose care partners' perceive a problem with care coordination will result in fewer ED visits and hospitalizations than assigning care coordinators to PLWD at the time of hospital

discharge. To avoid circularity, we will separate exposures and outcomes in time. That is, we will have a 3-month exposure period, during which a hospitalization that prompts care coordination will only be counted for the exposure and not as an outcome.

The 3-month time period was chosen, based on preliminary data suggesting that more fragmented care over 12 months independently increases the risk of an incident ED visit[(under review)] or incident hospital admission[21] in the subsequent 1-3 months, compared to less fragmented care.

A parallel design was chosen because it is a robust design that allows for concurrent comparisons. The outcome of ED visit or hospitalization will be measured using Medicare claims data, which are the gold standard, because they capture events across health systems and are thus broader than EHRs.

## 9.2 Sample Size and Randomization

The primary outcome is the number of events (emergency department visits or hospitalizations) / person-time alive. Preliminary data (for the control group) show an average event rate per person of 1.99 events over 334 live days (0.92 years). Using Poisson regression, with a sample size of 688 PLWD and assuming 20% attrition and $\alpha = 0.05$, we have >90% power to find an event rate ratio of 0.74 (i.e., a reduced event rate of 1.47 or lower in the intervention group vs. 1.99 in the control group), which is a meaningful difference. Data will be analyzed using an intention-to-treat approach. We will use descriptive statistics to report our secondary implementation outcomes; these are designed to inform future iterations and dissemination of this intervention, rather than test hypotheses per se.

### 9.2.1 Treatment Assignment Procedures

Randomization will be overseen by Dr. Samprit Banerjee (biostatistician). He will work with the data analyst at NYQC to enumerate the study population and conduct stratified randomization by care management team. That is, the study population will first be stratified into groups based on care management team. Within each group the study population will be randomized to the two trial arms, so that the trial arms will be of equal size. One rationale for randomizing by care management team is that the demographic characteristics of patients vary with care management team (for example, dual eligible beneficiaries are currently more likely to be assigned to one care management team than another). A second rationale for randomizing by care management team is that the clinical styles of care management teams may vary. By stratifying randomization by care management team, we will minimize any unmeasured confounding that variation by care management team might have otherwise introduced. Randomization will be done with random number generators.

Masking is not feasible for this study, so NYQC will be aware of which patients are allocated to which group. This is necessary, because they will need to conduct screening surveys for everyone in the intervention group.

## 9.3 Interim analyses and Stopping Rules

No interim analysis is planned, as the planned trial is fairly short, with 12 months of follow-up for the combined outcome of an emergency department visit or hospital admission. Interim analyses of emergency department visits and hospital admissions will not likely be sufficiently powered to be meaningful.

However, findings that might trigger a safety review are the number of unexpected deaths in the trial. Such findings are presented to the study statistician or to the Data and Safety Monitoring Board (DSMB) statistician to review the events by group to determine whether there are statistical as well as clinical concerns. The statistician reports his findings to a closed session of the DSMB or to the Safety Officer and/or NIA. The findings are used to determine what steps will be taken.

## 9.4 Outcomes

### 9.4.1 Primary outcome

We will measure the occurrence of ED visits and hospital admissions using Medicare claims.

### 9.4.2 Secondary outcomes

Secondary outcomes will consist of four implementation outcomes drawn from the Consolidated Framework of Implementation Research (CFIR) and related work by Proctor et al.[39-41] Acceptability will be operationalized as the percent of study participants who are retained in each group over time (that is, continue to engage with the care coordinators when contacted). Appropriateness will be operationalized as: a) the types of problems with care coordination uncovered in response to the survey in the intervention group, and b) the frequency of different types of care coordinator activities in each group (i.e., facilitating provider-provider communication, facilitating transportation, etc.). Fidelity will be measured by tracking the percent of eligible individuals who receive care coordination services. Implementation Cost (or Efficiency) will be measured as the total number of care coordinator hours spent in each group. Implementation outcomes will be measured through manual review of the EHR, using a structured abstraction tool.

## 9.5 Data Analyses

We will compare the characteristics of the PLWD in each study group, using chi-squared tests for dichotomous variables and t-tests for continuous variables, to confirm that the study groups are balanced ($p > 0.05$). We will use Poisson regression to compare study groups for the outcome of the number of events (ED visits or hospital admissions) per person-time alive, adjusting for care management team (as it was used to stratify randomization[42]) and any co-variates that were imbalanced between the study groups at baseline. We will conduct analyses using an intention-to-treat approach, considering all individuals as members of the group to which they were randomized. We will use descriptive statistics to report implementation outcomes.

We will take biological sex and race/ethnicity into consideration in both the design and valid analysis of the trial. We will employ inclusive eligibility criteria, including individuals in the study regardless of sex or race/ethnicity. We will allocate study participants of both sexes and all races/ethnicities to the intervention and control groups by the unbiased process of randomization. We will conduct unbiased assessment of the occurrence of outcomes in all study participants. We will also use unbiased methods of statistical analysis and inference for the study population overall. In addition, we will conduct analyses to determine if the effect of the intervention varies with subgroups by sex and, separately, by race/ethnicity. For Aim 1 (which has the combined outcome of emergency department visits or hospital admissions), we will conduct exploratory moderator analyses with sex and race as potential moderators of treatment effect by introducing moderator x treatment interactions into our regression models. For Aim 2 (which captures implementation outcomes), we will conduct exploratory analyses stratifying implementation outcomes (such as the types and frequencies of care coordination activities provided) by sex and, separately by race/ethnicity.

# 10 DATA COLLECTION AND QUALITY ASSURANCE

## 10.1 Data Collection Forms

Care coordinators will collect survey responses, which will be entered into a REDCap form. The research assistant will extract data from the EHR, regarding participant demographics and clinical characteristics, as well as the data for the implementation outcomes. The PI will use separate forms to report data on any AEs and SAEs.

## 10.2 Data Management

A data analyst at Weill Cornell Medicine will be responsible for data management and analysis of the survey data on perceptions of care coordination. A data analyst at NYQC will be responsible for data management and data analysis of Medicare claims.

## 10.3 Quality Assurance

### 10.3.1 Training

The PI will coordinate the activities of the members of the research team. The PI will provide any training needed for this study, though the team members are already experienced in the roles they will play.

### 10.3.2 Quality Control Committee

Not applicable

### 10.3.3 Metrics

Not applicable

10.3.4 Protocol Deviations

The PI will meet weekly with the care coordinators, research assistant, and geriatrician to follow the progress of the study. The PI will be responsible for detecting and reporting any protocol deviations.

10.3.5 Monitoring

See 10.3.4. above.

# 11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

## 11.1 Institutional Review Board (IRB) Review

This protocol and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study.

## 11.2 Informed Consent Forms

We are requesting a waiver of informed consent and a waiver of HIPAA authorization, as described in section 4.3.

## 11.3 Participant Confidentiality

To minimize the likelihood of a breach in confidentiality, we will use several methods to keep data secure. Care coordinators will enter survey data into customized forms that we will build using Research Data Electronic Capture (REDCap), a secure web-based data management platform. REDCap was developed by Vanderbilt University, supported in part by the National Institutes of Health. Weill Cornell Medicine provides its investigators with access to REDCap. All other interactions between care coordinators and study participants will be documented in the Epic electronic health record, which has its own security features. Identifiable Medicare claims will be maintained by NewYork Quality Care. Access to study data will be restricted to authorized staff, the IRB, and the Office of Human Research Protections (OHRP). No publications or presentations arising from this research will include personally identifiable information.

## 11.4 Study Discontinuation

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

# 12 ETHICAL CONSIDERATIONS

This study is guided by the ethical principles of the Belmont Report, which was written by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This study is also guided by the Common Rule (U.S. Protection of Human Subjects).

## 13 COMMITTEES

Not applicable

## 14 PUBLICATION OF RESEARCH FINDINGS

Any presentation, abstract, or manuscript will be made available for review by the sponsor and the NIA prior to submission.

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## 16 SUPPLEMENTS/APPENDICES

Article by Kern et al., describing survey instrument to be used in this study (with survey instrument included as an Appendix), same as reference #34 above