Video-Assisted Palliative Care Intervention for Patients With Advanced Dementia at Home
Dr. Nathan Goldstein
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Icahn School of Medicine at Mount Sinai
Mount Sinai Beth Israel
Mount Sinai Brooklyn
The Mount Sinai Hospital
Mount Sinai Queens
New York Eye and Ear Infirmary
of Mount Sinai
Mount Sinai St. Luke's
Mount Sinai West

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Initial Application
IRB-19-01975
Nathan Goldstein

Table of Contents

1. Summary - Title

Protocol Title

Palliative Care for Patients with Dementia

Principal Investigator Nathan Goldstein

When the application is complete, it will be sent to the PI for submission

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Primary Department Geriatrics and Palliative Medicine

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Application Initiated By Harriet Mather

Lay Summary

We propose a single-blinded, randomized-controlled, clinical trial to evaluate the impact of an innovative model of home-based palliative care on outcomes for patients with advanced dementia and their caregivers. 250 subjects (125 patients, 125 caregivers) will be enrolled from across the Mount Sinai Health System and randomized to receive the home-based palliative care program or usual care. Intervention patients will be cared for by a pyramid of palliative care focused providers, the core of which comprises specially trained community health workers, social workers, and registered nurses. These providers are supported by a palliative care advanced practice nurse and physician. All visits will be done by video or telephone from 3/19/20 due to the ongoing risk of transmission of COVID-19. Usual care patients will have the results of their baseline interview shared with their Mount Sinai provider. Additionally, caregivers in the usual care arm will receive training from a health coach on a health issue identified as important to them (e.g., smoking cessation, healthy eating). This is a kind of attention control. of this intervention on meaningful outcomes for patients, caregivers, and the health system. Outcomes are symptom control and quality of life in persons with dementia; caregiver burden; caregiver satisfaction with care; patient days in the hospital and ED visits. In exploratory analyses we will also determine if the intervention decreases costs of healthcare. Outcomes will be ascertained through interviews with caregivers, chart abstraction from the medical record, and the Mount Sinai Data Warehouse.

IF Number IF2478054

2. Summary - Setup

Funding Has Been Requested / Obtained	Yes
Application Type	Request to Rely on Mount Sinai IRB
Research Involves	Prospective Study ONLY
Consenting Participants	Yes
Requesting Waiver or Alteration of Informed Consent for Any Procedures	No
Humanitarian Use Device (HUD) Used Exclusively in the Course of Medical Practice	No
Use of an Investigational Device to Evaluate Its Safety or Effectiveness	No
Banking Specimens for Future Research	No
Cancer Related Research that Requires Approval from the Protocol Review and Monitoring Committee (PRMC).	No

Is this Cancer Related Research? Cancer Related Research is defined as research that has cancer endpoints or has a cancer population as part of or all of its targeted population. This includes protocols studying patients with cancer or those at risk for cancer.

Clinical Trial	No

**** A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).***
**** Used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.***

Drugs / Biologics	No

**** Drugs / Biologics That Are Not a Part of Standard Practice***
**** Controlled Substances***
**** Drugs / Biologics Supplied by the Research Sponsor or Purchased with Study Funds***

Ionizing Radiation for imaging or therapy, including X-Ray, Fluoroscopy, CT, Nuclear Medicine, PET andor Radiation Therapy:

*** Purely for standard of care:**	No
*** In frequency or intensity that exceeds what is necessary for standard of care:**	No

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Hazardous Materials	No

**** Recombinant DNA***
**** Viral Vectors***

- ***Plasmids***
- ***Bacterial Artificial Chromosomes***
- ***Toxic Chemicals, Potentially Toxic Medications, Carcinogens***
- ***Autologous Cell Lines***

Request Use of Clinical Research Unit Resources	No

3. Summary - Background

Objectives

The objective of this study is to determine whether a new home based palliative care program for patients with advanced dementia: 1) Improves overall symptom control and quality of life in patients with dementia; 2) Reduces caregiver burden, increases caregiver satisfaction, reduces caregiver depression; and 3) Reduces healthcare utilization (number of hospital admissions, days in hospital, emergency department visits) and increases days at home.

Background

Comprehensive case management programs for people with dementia and their caregivers have traditionally been clinic-based. In recent years, programs have been developed for care delivery in the home for patients with dementia, but these models focus on patient monitoring, care coordination, and caregiver support through the use of clinical and/or non-clinical coordinators. Each of the programs has had some elements of a palliative care approach, but none have been intentionally designed to provide comprehensive home-based palliative care using a team as novel as we are proposing. Our model is tailored to the needs of patients with advanced dementia and focuses on the core palliative care concepts of symptom control, caregiver support, better aligning treatments to goals and preferences, and assuring appropriate care plans to keep patients at home if this is consistent with their preferences. In addition, there is a national shortage of physicians and nurse practitioners with specialty-level training in the fields of palliative care and geriatrics. Our model is particularly innovative in that it will create a cadre of community health workers (CHWs), social workers (SWs), and registered nurses (RNs) to work with dementia patients and their caregivers. The integration of the lower-cost, more community-based CHWs within a comprehensive palliative care team builds on their effectiveness in chronic disease management while simultaneously helping to solve issues of workforce shortage.

Primary and Secondary Study Endpoints

1. Patient symptoms and quality of life (co-primary endpoints). Measured using Symptom Management at the End-of-Life in Dementia (SM-EOLD) and Quality of Life in Alzheimer's Disease (QOL-AD) respectively. Measured at baseline, 3 months, 6 months.

2. Caregiver burden, satisfaction with care, and depression. Measured using Zarit Burden Inventory, FAMCARE-10, and Patient Health Questionnaire 9 (PHQ-9) respectively. Measured at baseline, 3 months, 6 months. We will also study the effect of the intervention on caregiver self-efficacy, using the revised scale for caregiving self-efficacy.

3. Healthcare utilization: from the data warehouse as well as using the Resource Use Instrument (RUI) collected through interviews with patients. Healthcare cost: measured through the Mount Sinai Data Warehouse.

Study duration is 6 months.

Protocol Was Already Approved by the Icahn School of Medicine at Mount Sinai (ISMMS) Institutional Review Board (IRB) Under a Different Principal Investigator	No
Protocol Was Previously Submitted to an External(non-ISMMS) IRB	No

4. Research Personnel

Name/Department	Role/Status	CC	Access	Obtaining Consent	Phone	Email
Nathan Goldstein / Geriatrics and Palliative Medicine	PI / 1		SIGNAUTH		212-241-1446	
Harriet Mather / Geriatrics and Palliative Medicine	Study Coordinator /		SIGNAUTH	Yes		
Christian Espino / Geriatrics and Palliative Medicine	Study Coordinator /		SIGNAUTH	Yes		
Magdalena Grzebyk / Geriatrics and Palliative Medicine	Research Assistant /		READONLY	Yes		
Mohammed Husain / Geriatrics and Palliative Medicine	Research Assistant /		EDIT			
Meng Zhang / Medicine	Co-Investigator /		READONLY		212-241-4141	
Brenda Green / Social Work Service	Research Nurse /		READONLY			
Latoya Sealy / Geriatrics and Palliative Medicine	Research Nurse /		READONLY			
Marie Persaud / Geriatrics and Palliative Medicine	Study Coordinator /		READONLY	Yes		
Linda DeCherrie / Geriatrics and Palliative Medicine	Co-Investigator /		READONLY		na	
R Morrison / Geriatrics and Palliative Medicine	Co-Investigator /		READONLY		(212) 241-1446	
Amy Kelley / Geriatrics and Palliative Medicine	Co-Investigator /		READONLY		212-241-2631	
Lihua Li / Population Health Science and Policy	Co-Investigator /		READONLY		2126599663	
Barbara Vickrey / Neurology	Co-Investigator /		READONLY			
Katherine Ornstein / Geriatrics and Palliative Medicine	Co-Investigator / 1		READONLY		917-518-2250	
Carolyn Zhu / Geriatrics and Palliative Medicine	Co-Investigator /		READONLY		718-584-9000 x3810	
Xiaobo Zhong / Population Health Science and Policy	Co-Investigator /		READONLY			

5. Sites

Site Name	Icahn School of Medicine at Mount Sinai
Other External Site Name	
Contact Details	
Approved	
Approval Document	
Funded By Mount Sinai	
Other IRB	

Site Name	Mount Sinai Beth Israel
Other External Site Name	
Contact Details	
Approved	0
Approval Document	
Funded By Mount Sinai	1
Reviewed By	Mount Sinai IRB
Other IRB	

Site Name	The Mount Sinai Hospital
Other External Site Name	
Contact Details	
Approved	
Approval Document	
Funded By Mount Sinai	
Other IRB	

Site Name	Mount Sinai St. Luke's
Other External Site Name	
Contact Details	
Approved	0
Approval Document	
Funded By Mount Sinai	1
Reviewed By	Mount Sinai IRB
Other IRB	

Site Name	Mount Sinai West
Other External Site Name	
Contact Details	
Approved	0
Approval Document	
Funded By Mount Sinai	1
Reviewed By	Mount Sinai IRB
Other IRB	

6. Subjects - Enrollment

Site Name	Icahn School of Medicine at Mount Sinai
Subjects To Be Enrolled	
60	
Site Name	Mount Sinai Beth Israel
Subjects To Be Enrolled	
40	
Site Name	The Mount Sinai Hospital
Subjects To Be Enrolled	
90	
Site Name	Mount Sinai St. Luke's
Subjects To Be Enrolled	
40	
Site Name	Mount Sinai West
Subjects To Be Enrolled	
20	
Total Number of Subjects to be Enrolled Across All Listed Sites Above (Auto Populated)	250

7. Subjects - Setting and Resources

Setting of Human Research	Faculty Practice Associates, Emergency Department, Internal Medicine Associates, Other

Specify Other Setting of Human Research

Patient home - we enroll subjects in their home as well as conducting follow up interviews in their home. This has been specified elsewhere in the previously approved protocol. This is because without home enrollments, many of the subjects would not be able to access the study.

Note - from 3/19/2020, we will no longer plan to conduct home enrollments, due to the risk of transmission to patients from COVID-19. Instead, we will transition to using an electronic consent protocol. Baseline and follow up interviews will be conducted telephonically in all cases.

Total Number of Subjects Needed To Complete Study 250

Feasibility of Meeting Recruitment Goals

Our enrollment target is 4 dyads per month (50 dyads per year). Through preliminary analysis, we have identified around 1700 patients per quarter who have a diagnosis of dementia, and around 60% of these are in the advanced stages. To meet our enrollment target, we would have to enroll 5% of these patients. We are therefore confident of reaching our target.

Facilities To Be Used for Conducting Research

The Department of Geriatrics and Palliative Medicine is consistently ranked as one of the top programs in the nation. The Department provides expert care for the most frail and complex patients; conducts research in aging with an emphasis on medical decision-making and palliative medicine; and teaches geriatrics and palliative medicine to medical students, house staff, attending physicians, and other health professionals. The principal investigator is Dr. Nathan Goldstein, a geriatrician and palliative care physician who has experience in administering large clinical trials, as is demonstrated by his multi-center trial that enrolled more than 550 patients across 6 sites. Dr. Sean Morrison is a geriatrician and palliative care physician whose research has focused on enhancing decision making for patients with dementia and developing health system interventions to improve outcomes. Dr. Amy Kelley is a geriatrician, palliative care physician, and a health services researcher who will lead the use of models to identify eligible patients based on diagnostic codes from the electronic health record. Dr. Linda DeCherrie is a geriatrician and the Director of Mount Sinai Visiting Doctors as well as Clinical Director of Mount Sinai Hospital at Home. She has expertise in the delivery of clinical models that provide care to complex older adults living in the community.

Multi-Center Study No

Community-Based Participant Research Study No

PI must attest to the following.

**** Process is adequately described to ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.***

8. Subjects - Populations

Inclusion Criteria

Patients must have: advanced dementia (any form of dementia, including Alzheimer's, vascular, mixed), based on Global Deterioration Score (GDS) > or equal to 6; impairment in at least one ADL (which is inherent in this level of GDS); a physician who is primarily responsible for their dementia-related care whose clinical outpatient site is associated with one of the four Mount Sinai sites in Manhattan; an informal/ unpaid caregiver willing to enroll; a residence in Manhattan where they are currently living (not in a long-term care facility); capacity to consent or a legal representative available to provide consent; conversant in English or Spanish, or their legal representative must be conversant in English or Spanish. We will only enroll adults over the age of 18 - dementia does not occur in patients below the age of 18 and our team is not trained to manage the needs of pediatric patients. Most of our subjects either live with their caregiver or have a home health aide who administers the care. In either case, we will only enroll subjects where they have consistent access to the internet and a device on which they can download video visit software. We will follow the rules outlined by the Office for Civil Rights which guide the type of software that can be used during the COVID-19 pandemic.

Caregivers: the caregiver will be the relative or unpaid nonrelative who provided the most hours of help with activities of daily living or instrumental activities of daily living in the prior week; they must be over the age of 18; conversant in English or Spanish

Exclusion Criteria

Exclusion criteria are: patient receiving hospice care or enrolled in another study of a patient/caregiver intervention.

There are no specific exclusion criteria for caregivers where they meet the inclusion criteria above.

Enrollment Restrictions Based Upon Gender, Pregnancy, Childbearing Potential, or Race	No
Age Range(s)	18 to 64 Years, 65 Years and Over
Targeted Population(s)	Adults - Patients , Impaired Mental Capacity, Decisionally Impaired

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Other Aspects that Could Increase Subjects Vulnerability

The clinical team caring for the patients in this study have extensive experience of caring for patients with advanced dementia, and are well aware that procedures carried out in routine clinical care may incur greater burden and distress for individuals with moderate-severe dementia. The procedures involved in this study for the patients do not differ from those which would be provided by any in-home clinical service designed to improve the clinical care of patients with dementia.

Safeguards to protect Subjects rights and welfare

We have undertaken numerous steps to protect patients' rights and safeguard their welfare, in light of their likely impaired capacity.

1. The patient's healthcare provider will introduce the study and determine interest before we approach the patient and caregiver.

2. We will ask the patient's healthcare provider to complete a capacity assessment. Where the patient lacks capacity to consent to study involvement (which we anticipate in most cases) we will follow standard protocol for consent in patients lacking capacity (i.e., their LAR will provide authorization)

3. We will clearly state the dyad's right to refuse participation and to withdraw at any time during the study period without affecting their routine clinical care.

4. The intervention will be provided by a team of highly trained professionals, who have extensive experience in caring for patients with moderate-severe dementia and their caregivers.

5. The procedures undertaken in the patient's home (which may include: clinical examination, recording of vital observations, blood draws, X rays, ultrasound) will be dictated only by the clinical needs identified using standardized assessments. The clinical team will record all encounters with the patient or caregiver in the secure

electronic medical record. Note - as of 3/19/2020 we will no longer be doing home visits as part of the intervention due to the risk of transmission of COVID-19 to a high risk population, with the exception of clinical emergencies that cannot be managed using telemedicine as previously documented.

6. Medications will be prescribed and de-prescribed according to need to treat clinical problems on the basis of clinicians' experience and in accordance with relevant guidelines. In all cases, medications will be prescribed by licensed providers, either the palliative care MD or the palliative care advanced practice nurse. Risks and benefits will be discussed in all cases of prescribing or de-prescribing a medication with the patient where they have capacity, or with their LAR when the patient lacks capacity. Additionally, the provider will communicate all medication changes to the patient's nominated physician.

7. All appropriate measures will be taken to ensure the secure transmission, storage and use of protected health information.

NOTE: The clinical intervention will provide an additional layer of support for patients with dementia and their caregivers and is designed to extend high quality palliative care to patients and their caregivers who, through functional and behavioral impairment, would not otherwise be able to access such services. Additionally, for patients in the control arm, the baseline interview will provide valuable information about the patient and caregiver needs which will be relayed to the patient's physician, potentially improving their care. In other words - what we are testing is a new, additional layer of support for individuals with profound needs, and adding more care to their care team - the drugs/ interventions/protocols that we are using are already well established best practice guidelines for the care of patients with advanced dementia.

9. Subjects - Participation

Duration of an Individual Subjects Participation in the Study

6 months

Duration Anticipated to Enroll All Study Subjects

2 years

Estimated Date for the Investigators to Complete This Study	Within 3-5 years

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Procedures for Subjects to Request Withdrawal

At the time of enrollment, we will emphasize subjects' right to withdraw. If a subject/ their LAR wishes to withdraw, they will make contact with either the research staff or the Principal Investigator. When this happens, the research coordinator will complete a study termination form to indicate subject withdrawal from the study. We will record why the subject wished to withdraw (with their or LAR agreement) as this will provide additional data around the acceptability of the intervention. Where subjects/ LAR wish to withdraw from the study, we will request permission to collect information from their routine medical care (for patients only), as documented on the consent form.

Procedures for Investigator to Withdraw Subjects

1. Death of patient (caregiver will be withdrawn)
2. No available caregiver
3. Transition to long term care (patients and caregivers)
4. Transition to skilled nursing facility for longer than 30 days (patients and caregivers)
5. Inpatient hospitalization for longer than 30 days (patients and caregivers)
6. Relocation of patient outside of Manhattan
7. Safety of clinical team cannot be assured
8. Study stopped
9. Principal Investigator deems it to be in the subject's best interest
10. The subject withdraws permission to use their PHI for research

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Participants Will Be Recruited	Yes
Recruitment Method(s)	Clinical Practice, Records (e.g. Medical, Employment, School), Information Letter/ Pamphlets, Physician Referral

How Participants Will Be Identified

1. Patients will be identified either by physician referral or through a data warehouse query and subsequent chart screen.

Data warehouse query

Every quarter, we will obtain a cohort of patients from the Mount Sinai Data Warehouse who have a diagnosis of dementia (this is obtained either from their problem list or as a billing encounter). The problem list is contained within the patient's EMR and collated centrally by the data warehouse. The billing codes are diagnosis codes generated at the time of the clinical encounter by the treating provider and collated centrally.

We will then screen the charts to see whether these patients have evidence of moderate to severe dementia as one of the following:

(i) Physician note of behavioral or psychological symptoms of dementia (i.e., agitation, anxiety, depression, irritability, apathy, elation, disinhibition, delusions, hallucinations, sleep disturbance)
(ii) Psychotropic medication (antidepressant, anxiolytic, antipsychotics)
(iii) Documented MMSE < 20
(iv) Other evidence of advanced dementia: any from: needs assistance with dressing, bathing, toileting; urinary or fecal incontinence; weight loss; dysphagia/ aspiration; immobility; loss of ability to communicate.

The data collection sheets for the data warehouse and chart screening are contained in this application.

We will email these patients' physicians to introduce the study, confirm eligibility (moderate to severe dementia, available caregiver, resident in Manhattan outside of long term care, not receiving hospice). We will then ask the physician to introduce the study to the patient and their caregiver, in the way they see fit, and if the patient and caregiver are interested in the study, we will contact the patient and caregiver to discuss.

Physician referral

We will outreach to physicians at targeted practices (Geriatrics, Primary Care, Internal Medicine) to inform them of the study and request that they refer dyads who may be interested. For these patients, we will confirm eligibility with the physician (moderate to severe dementia, available caregiver, residence in Manhattan outside of long term care, not receiving hospice) before meeting with the dyad.

Finally, we will distribute information to clinic physicians by hand.

2. Caregivers will be identified by the patient or their LAR at the time of introducing the study. It is highly likely that the patient's LAR and caregiver are the same.

Who Will Initially Approach Potential Participants	Member of Primary Care Team, Treating Physician, Clinic Personnel

How Research Will Be Introduced to Participants

In all cases, we will ask the patient's treating provider to introduce the study to the patient or their legally authorized representative and if they are interested, the study team will contact them by telephone.

How Participants Will Be Screened

Prior to contacting the dyad, the study team will ensure they meet inclusion criteria. Specifically, they will confirm with the physician that they have moderate-severe dementia, a caregiver who may be willing to enroll, are resident in Manhattan, outside of long term care and not receiving hospice.

When the research coordinator introduces the study to the dyad by telephone they will once again ensure they meet these criteria.

The RC will additionally confirm ahead of sending consent forms to the patient whether they have capacity (this will be documented by the patient's treating physician).

10. Subjects - Risk and Benefits

Risks to Subjects

The clinical intervention is intended to improve outcomes for subjects, including symptoms, quality of life, caregiver burden, depression, satisfaction, and self-efficacy. In particular, the intervention seeks to align healthcare received by patients with their preferences. However, there are some risks associated with participation, outlined below.

1. Medications (patient subjects only)
There are risks to patients related to the prescription of medications, particularly those that may be prescribed for pain (including opioids) and behavioral and psychiatric symptoms (antipsychotics). These medications will only prescribed in accordance with clinical guidance, after careful consideration of the risks and benefits of their use. In particular, we will only use antipsychotics for the management of behavioral symptoms where reversible causes have been considered and treated as appropriate, and the patient is at extreme risk or in severe distress. In all cases where a new medication is commenced we will inform the patient's treating physician and counsel the caregiver about the medication.

Please note that we are enrolling patients with advanced dementia who are by definition at high risk of both worsening delirium and function, hospitalization, death and other serious events. As such these outcomes are expected and will not be considered SAEs.

2. Breach of confidentiality (patients and caregiver subjects)
Information about any encounter with a patient or caregiver by the clinical team during the course of the study will be recorded in the electronic medical record (EPIC), a HIPAA secure platform used for storage and transmission of healthcare information across the clinical network. Any video visits that are used in the course of clinical care will use software compliant with Office for Civil Rights framework. While there is a theoretical risk of breach of confidentiality, this is no more than would be encountered in routine clinical care. There is a theoretical risk of loss of protected health information for subjects in both intervention and control arm that is recorded for the purpose of research. However, this risk is minimized through precautions detailed in the "Data" section of this proposal.

3. Risks of interviews
Talking about illness may arouse difficult emotions in patients, their proxies, and caregivers. However, research coordinators are trained to recognize these emotions, and to respond with sensitivity. Where subjects show signs of significant distress, the research coordinator will discuss the case with the Principal Investigator, who will decide on whether it is necessary to inform the subject's healthcare team. This course of action will only be taken with the subject's consent, unless there is significant risk of harm to the subjects or others, in which case consent to share the information arising from the interview is not a requirement (but should be sought).

Description of Procedures Taken to Lessen the Probability or Magnitude of Risks

Patients in the intervention arm will be cared for by a highly trained team of providers, with experience in caring for patients with dementia and their caregivers. Our intention is to have written communication with the PCP at the time the patient comes on to the program to establish roles within this co-management model of care. As part of this communication, we would include the statement: "Where there is a need to prescribe medications, we will seek your agreement prior to prescribing. However, if we do not receive a response within 48 hours, or the clinical situation demands a more urgent response, we will not await your agreement before prescribing medications. In all cases, we will inform you of our action." This written statement is also included in the Attachments tab.

The research team are highly experienced and all research coordinators will be trained on sensitive interviewing and research protocols.

Any expression of significant mental health issues exposed in a survey response will be discussed with the PI or study manager. We will set thresholds for escalation to the PI based on scores on Zarit Burden Inventory and PHQ-9, any expressions of distress, and any concerns by the study team. The PI or study manager would then contact the caregiver to encourage them to seek additional support from their primary physician and/or the intervention team as appropriate.

Provisions for Research Related Harm / Injury

It is not anticipated that patients or caregivers will come to harm during this study, as the intervention does not differ substantially from routine clinical care that is based on clinical guidelines. The clinical team has vast experience and competence in managing side effects and adverse events related to medication use in these patients. Where adverse events related to medication use cannot be managed in the home, the patients will be admitted to hospital at Mount Sinai. Generally, this medical care will be billed to the research subject and/or his/her health care insurance in the ordinary manner and the research subject will be responsible for all treatment costs not covered by insurance, including deductibles, co-payments and coinsurance. This does not prevent the research subject from seeking payment for injury related to malpractice or negligence. As outlined above, interviews can arouse emotions in patients and caregivers. We have outlined the provisions for this eventuality above.

Expected Direct Benefit to Subjects

The study is anticipated to have a number of benefits for subjects (patients and caregivers) in both intervention and control arms.

1. Intervention subjects

Patients and caregivers in the intervention arm will benefit from receiving an additional in-home care program delivered through video visits and telephone by highly trained and skilled professionals, and designed to address their needs. It is hoped that the intervention will bring about reduction in patients' symptom burden and improvement in quality of life, and reduce burdensome hospitalizations. Additionally, it is hoped that the intervention will lead to reduction in caregiver burden, and improvement in overall caregiver satisfaction. Subjects will receive the benefit of participating in a research study, which is a cited as a highly valued opportunity for patients with end-stage illness and their caregivers.

2. Control subjects

While control subjects will not receive clinical care, research coordinators will undertake interviews with patients (or proxies) and caregivers at baseline. The results of these interviews will be relayed to the patient's nominated physician. These will serve to highlight previously unrecognized problems. Additionally, caregivers in the control arm will be offered coaching from a health coach on health improvement (e.g., dietary education, smoking cessation). The health coach will be certified in providing health education.

Benefit to Society

There is an urgent imperative to develop in-home models of palliative care to address the significant needs of patients with advanced dementia and their caregivers. In the context of COVID-19 these are being delivered increasingly through the use of telemedicine. Such models of care must be scalable and deliverable in the context of limited numbers of specialist trained providers. This study, and the program of research it advances, will be of great benefit to the wider population of patients with dementia and their caregivers through the development and evaluation of an innovative new care model mapped to their needs.

Provisions to Protect the Privacy Interests of Subjects

1. Recruitment

Patients will be recruited through a member of their Mount Sinai healthcare team. The research team will contact the patient and their caregiver only after they have demonstrated interest in the study.

2. Enrollment

The consent forms will be emailed to the patient's proxy (in the event that they lack capacity to consent) and the baseline interview for both the patient/ informant and caregiver will be conducted via telephone. The research team will ensure the subject has understood all the information in the consent forms.

3. Privacy protections during the study

At the time of enrollment all subjects will be informed that information arising in the course of clinical care will be recorded in the patient's electronic medical record, which can be viewed by the clinical team and other providers within the Mount Sinai Health System as necessary to provide clinical care. Clinical information will not be shared with providers not involved in the patient or caregiver's care without their prior consent. Information arising from interviews will only be shared with the subject's provider with their consent, unless in the case that they are considered to be at risk to themselves or otherwise mandated by law.

Economic Impact on Subjects

We do not anticipate that subjects will incur any economic costs through participation in the research study. Subjects will not be charged for their care or participation in this study.

11. Subjects - Adults Without Capacity

There is Anticipated Direct Benefit to the Subjects	Yes
Assent is Required of	All Subjects Capable of Being Consulted

Select Which of the Following Best Describes the Risk to Subjects
**** Intervention: the risk to the subjects is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject.***
**** Monitoring Procedure: more than minimal risk to subjects is presented by a monitoring procedure that is likely to contribute to the subject's well-being.***

Risk to Subjects	Intervention

PI must attest that all of the following are true.
**** The risk is justified by the anticipated benefit to the subjects.***
**** The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.***
**** The proposed plan for the assessment of the capacity to consent is adequate (and the PI states he/she will comply with institutional policy GPP-312).***
**** The assessment of the capacity to consent will be performed by a qualified attending physician with appropriate training, licensing and certification, with special attention paid to qualifications re: assessing incapacity due to mental illness, mental retardation or developmental disability.***
**** The proposed plan for the assessment of capacity includes the assessment of the cause and extent of the incapacity and likelihood that the subject will regain capacity.***
**** The PI has indicated that he/she will document this determination with the above details of the assessment appropriately (eg. In the medical record when applicable and in research record).***
**** The consent document includes a signature line for a legally authorized representative.***

12. Procedures - Narrative

Description of the Study Design

The study is a randomized controlled trial design. Participating dyads will be randomized to receive either the intervention (home based palliative care) or usual care, in a 1:1 randomization, parallel design.

The patient/ caregiver dyad will not be blinded. However, the research coordinator (outcome assessor) conducting the follow-up interviews will be unaware of assignment, hence calling this a single-blind trial.

Description of Procedures Being Performed

Intervention dyads

For intervention dyads, the CHW, RN, and SW team conduct in-depth intake assessments that may include assessment of the following: disease stage (RN); physical, psychological and behavioral symptoms (RN); cognitive, functional and nutritional status (RN); medication reconciliation (RN); durable medical equipment needs (RN); dyad understanding of disease, goals of care, and advance directives (RN+SW); caregiver support network (SW); caregiver burden and unmet needs (SW); legal, financial and insurance needs (SW); spiritual concerns (SW). The CHWs accompany the RN and SW on initial visits to develop an understanding of the family and cultural context and their need for connections to community resources. The care team creates a comprehensive care plan to address the needs identified at the intake assessment. The care plan is implemented with the support of the CHWs, SW and RN and evaluated regularly. From 3/19/20 and due to the COVID-19 pandemic, all initial video visits and subsequent assessments will be conducted using video visit software. However, in the exceptional case that the the patient has a clinical emergency that, according to the MD/NP cannot be managed using telemedicine and/or transfer to the hospital (e.g., uncontrolled agitation in a patient whose goals of care are to remain at home) we will consider the option of a home visit, after a thorough assessment and documentation in the clinical record of the risks and benefits, and guided by Institutional procedures for home visits in the context of the COVID-19 emergency which include strict adherence to infection control procedures. Note, to provide for this unlikely event, all team members have been trained in the use of personal protective equipment.

As a co-management model, the team works collaboratively with the PCP and existing in-home services such as home health aides or visiting nurse services with the goal to provide an added layer of support, rather than replace existing care.

Frequency of contacts with the team will be individualized according to the dyad's needs. Some assessments will include multiple team members simultaneously while others will be done individually. Intervention dyads receive access to 24-hour telemedicine support, using the pre-existing infrastructure within our Department. We will also use Mount Sinai's 24/7 community paramedic program whereby physicians can dispatch Mount Sinai paramedics to provide in-home treatments without automatic transport to the emergency department. Community paramedicine are operating under guidelines to reduce the risk of COVID-19 transmission.

At the end of their time on the program, the dyad continues care with their usual providers, or is referred onward to other services as appropriate (e.g., Mount Sinai Visiting Doctors, hospice).

Control dyads

Dyads randomized to control will continue to receive care with their usual care providers. In addition, a copy of their baseline assessment will be uploaded into the EMR with the subject's consent, and the provider notified of this by email, with explicit notification of any areas for concern (i.e., uncontrolled symptoms). In addition, the caregiver-subject within control dyads will receive a health coach who will identify a physical health goal with the caregiver (e.g. weight reduction, smoking cessation) and work, through monthly visits, towards this goal. This control arm will assure balance between the groups in terms of "attention received" in a way that will not impact study outcomes.

All dyads - data collection

For dyads in both arms, there will be an interview undertaken at baseline, 3 months, and 6 months. This will be undertaken either in person (at the dyad's home or a Mount Sinai facility) or over the telephone. At all times confidentiality will be assured. These interviews will last around 30 minutes.

Any concerns that arise during interview will be shared with the patient's treating provider (either the palliative care team or for control patients, their PCP).

Description of the Source Records that Will Be Used to Collect Data About Subjects

1. EMR - we will abstract data from the patient's EMR at baseline, 3 months, and 6 months and after every hospitalization.

2. Mount Sinai Data Warehouse. We will request data on utilization and costs of care from the data warehouse on enrolled subjects.

3. Claims databases. We will request claims data for enrolled patients (using the same variables as the data warehouse) to study the impact of the intervention on utilization and costs.

Description of Data that Will Be Collected Including Long-Term Follow-Up

1. Patient/ proxy and caregiver reported data - through interviews.

Data to be collected will include: (i) patient demographics; (ii) symptoms; (iii) quality of life; (iv) resource use; (v) physical function; (vi) agitation; (vii) care preferences; (viii) financial burden.

We will obtain information from the patient's caregiver (as a subject) about: (i) caregiver demographics; (ii) caregiver health; (iii) caregiver function; (iv) caregiver burden; (v) caregiver depression; (vi) caregiver satisfaction; (vii) caregiver self-efficacy.

2. Data warehouse/ claims database (ClaimsStar)

We will abstract data from the data warehouse and the claims database on utilization, diagnoses, and costs of care.

Research Requires HIV Testing No

13. Procedures - Genetic Testing

Genetic Testing Will Be Performed No

Guidance and Policies > Future Use Data Sharing and Genetic Research

14. Procedures - Details

Surveys or Interviews Yes

Type of Instruments Being Used Standardized, Created By Research Team

Names of Standardized Instruments

1. Symptom management at the end of life in dementia
2. Quality of Life in Alzheimers Disease
3. Zarit Burden Inventory (caregiver subject)
4. Patient Health Questionnaire-9 (caregiver subject)
5. FAMCARE-10 (caregiver subject)
6. Resource Use Instrument
7. KATZ ADL (caregiver and patient)
8. KATZ comorbidity questionnaire (caregiver subject)
9. Cohen Mansfield Agitation Inventory
10. Revised scale for caregiving self-efficacy (caregiver subject)
11. Neuropsychiatric Inventory Questionnaire

Description of Instruments Created By Research Team

1. Patient demographics
2. Caregiver demographics
3. Record of advance care planning documentation and preferences for care
4. Financial burden questionnaire

Audio / Photo / Video Recording No

Deception No

Results of the Study Will Be Shared with Subjects or Others Yes

How the Results Will Be Shared

1. Peer review publication
2. Presentation at conferences

When the Results Will Be Shared

After the conclusion of the study and completion of analysis

15. Procedures - Instruments

Instruments Created By Research Team

Type	Study team created instruments
Name	
Upload	Study instruments.docx

16. Procedures - Compensation

Compensation for Participation	No

17. Consent - Obtaining Consent

Consent Process	Adult Consent, Legally Authorized Representative (LAR) Permission

Where and When Consent Will Be Obtained

Consent will be obtained at enrollment. Consent forms will be emailed to the patient or their proxy and the caregiver subject. The RC will ensure that the subject has understood all elements of the consent form and had adequate time to read them prior to enrollment.

Waiting Period for Obtaining Consent

Patients and caregiver will be given a study information leaflet prior to the study team obtaining consent. This will be emailed to the patient or their legally authorized representative and their caregiver.

In all cases, the study team will ensure the LAR has had sufficient time to read the study information, ask any questions, and will provide the possibility of contacting the study team at a later date if they require further time to consider participation.

SOP HRP-090 Informed Consent Process for Research Is Being Used	Yes

PPHS Worksheets, Checklists and SOPs

Process to Document Consent in Writing	Will Use Standard Template
Non-English Speaking Participants Will Be Enrolled	Yes

What Languages Other Than English Will Be Used

Spanish

What Process Will Be Used	Long Form

The consent document must be translated into the language of the potential subject, and approved by the IRB, before you can go through the consent process with the non-English speaking person. If, after the project is approved, a short form consent process is needed, please see the PPHS policy and submit a modification.

18. Consent - Legally Authorized Representative

Process to Determine Whether an Individual is Capable of Consent

Capacity to consent will be determined by a qualified attending physician with the necessary license, training, and certification who is familiar with the patient's clinical situation (in most cases, this will be the physician who provides authorization for the study team to introduce the study to the dyad).

The capacity assessment will focus on the subject's understanding of the purpose of the study, the experimental nature, risks and intended benefits, the right to withdraw, and alternatives to participation. The assessment of capacity will include a determination of the cause and extent of the incapacity and the likelihood that the subject will regain capacity. The determination of capacity procedure and results will be documented in the electronic medical record, and a copy kept for the research study.

For patients lacking capacity to consent to participation (likely the majority) we will require consent from the patient's legally authorized representative (LAR).

In the unlikely event that the patient has capacity to consent to participation at baseline, it is likely that they will subsequently lose capacity to consent during the study period. Therefore, even where patients have capacity, as an additional safeguard we will seek additionally seek the consent of the LAR at baseline, such that if the patient subsequently loses capacity, we can transition to LAR consent.

We have understood and will follow the procedures outlined in the following policies and documents: A3-113 and A3-113.9 and HRP-422.

Prioritized List of Individuals from whom Permission will be Obtained

In accordance with SOP HRP013, we will define the prioritized list of individuals who can act as the patient's legally authorized representative as a court appointed guardian who is specifically given authorization to consent to participation in research. In the absence of a court appointed guardian who is specifically given authorization to consent to participation in research, any of the following individuals:

1. A court appointed guardian who is specifically given authorization to consent to health care
2. A previously designated health care proxy
3. Spouse (if not legally separated) or domestic partner
4. Children > 18 years of age
5. Parents
6. Siblings > 18 years of age

This is in accordance with New York State Law (New York Family Health Care Decisions Act, Mental Hygiene Law) and Mount Sinai Policies.

Process for Assent of the Subjects

Where patients lack capacity to consent, we will seek assent to study participation where they are capable of being consulted.

We will seek patient assent for all procedures/ interactions with the clinical team members (as would happen in the normal course of clinical care) where capable of being consulted. Dissent will always be respected.

For research conducted in New York State, review “SOP HRP-013 Legally Authorized Representatives, Children, and Guardians” to be aware of which individuals in the state meet the DHHS and FDA definition of “legally authorized representative."

For research conducted outside of New York State, obtain consultation from Mount Sinai legal counsel as to the definition of “legally authorized representative” in the jurisdiction(s) where you are performing your research. After receiving consultation with Legal, provide an explanation in this section about which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this Human Research.

19. Consent - Documents

Consent Documents

Type	Patient without capacity
Name	
Upload	Adult without capacity 5.22 COVID_clean.docx
Type	Patient with capacity
Name	
Upload	Adult with capacity COVID amended - clean 5.22.docx
Type	Caregiver
Name	
Upload	Caregiver consent clean 5.22 for COVID.docx

Consent Templates

20. Data - Collection

Health Related Information Will Be Viewed, Recorded, or Generated	Yes

Description of Health Information That Will Be Viewed, Recorded, or Generated

Data warehouse query (screening purposes):

1. Patient name
2. Patient MRN
3. All encounters within the Mount Sinai system in quarter of request and 12 months prior:
a. Encounter ID
b. Dates of encounter (admit and discharge)
c. Encounter type (e.g., outpatient, inpatient)
d. Discharge disposition
e. Discharge location to
f. ICD10 code and diagnosis description
g. ICU admission
h. Encounter site
i. Provider
j. Payer
k. Wheelchair order
l. Hospital bed order

4. Patient zipcode
5. Patient date of birth

From this information, we will generate a list of patients with a diagnosis of dementia. We will then review the charts of these patients to determine potential eligibility.

Chart review (screening purposes):

1. Name, MRN, date of birth
2. Physician note of behavioral or psychological symptoms of dementia (yes/no)
3. Psychotropic medication (yes/no; type)
4. Documented MMSE < 20 in past 6 months (yes/no).
5. Evidence of any of the following: needs assistance with dressing, bathing, toileting; urinary or fecal incontinence; weight loss; dysphagia/ aspiration; immobility; loss of ability to communicate (yes/no; checkbox for each)

Interviews (enrolled subjects):

Patients:

Demographics (study team)
Symptoms (SM-EOLD) - standardized
Quality of life (QOL-AD) - standardized
Function (KATZ ADL and IADL) - standardized
Resource use (RUI) - standardized
Care preferences - study team
Cohen Mansfield Agitation Inventory - standardized
Financial burden - study team
Neuropsychiatric Inventory Questionnaire - standardized

Caregivers:

Caregiver demographics (study team)
Caregiver burden (Zarit Burden Inventory) - standardized
Caregiver depression (PHQ-9) - standardized
Caregiver satisfaction with care (FAMCARE-10) - standardized
Caregiver self efficacy (revised scale for caregiving self-efficacy) - standardized
Caregiver comorbidities (KATZ) - standardized

Chart reviews at baseline and follow up (enrolled subjects)

1. Medications (name, dose)
2. Hospitalizations and ED visits in past 12 months (yes/ no/ number)
3. Advance care planning documentation
4. Receipt of any of the following: (i) IV fluids (ii) IV antibiotics (iii) PEG (iv) Intubation (v) CPR

Data warehouse (enrolled subjects):

All encounters in the Sinai health system from enrollment until study termination:

1. Patient name
2. Patient MRN
3. All encounters within the Mount Sinai system in quarter of request and 12 months prior:
a. Encounter ID
b. Dates of encounter (admit and discharge)
c. Encounter type (e.g., outpatient, inpatient)
d. Discharge disposition
e. Discharge location to
f. ICD10 code and diagnosis description
g. ICU admission
h. Encounter site
i. Provider
j. Payer
k. Wheelchair order
l. Hospital bed order

4. Patient zipcode
5. Patient date of birth
6. Costs associated with care

Non-Health Related Information Will Be Viewed or Recorded	Yes

Description of Non-Health Information That Will Be Viewed or Recorded

1. Patient and LAR address, telephone number, email address
2. Caregiver address, telephone number, email address

HIV / AIDS Related Information Will Be Viewed or Recorded	Yes
Informed Consent Will Be Obtained to Access Identifiable HIV / AIDS Information	Yes
Data That Will Be Viewed, Recorded, or Generated Contains ANY of the Following Directly Identifiable Information	Yes
Will Be Viewed	Name, Medical Record Number, Address by street location, Telephone number, Health Plan Beneficiary Number, Account Number, Geographical Subdivisions Smaller Than a State, All Elements of Dates for Dates Directly Related to an Individual (i.e., Birth Date, Admission Date, Discharge Date), Email Address
Will Be Recorded	Name, Medical Record Number, Address by street location, Telephone number, Health Plan Beneficiary Number, Account Number, Geographical Subdivisions Smaller Than a State, All Elements of Dates for Dates Directly Related to an Individual (i.e., Birth Date, Admission Date, Discharge Date), Email Address

Data Collection Sheet	Datasheet for data warehouse and screening.xlsx

A Data Collection Sheet is required if you are either performing a retrospective review, or your study meets the category of exempt 4 research, or your study meets the category of expedited 5 research. Please upload it here.

Data Collection Source(s)	Participant, Medical Chart (Paper or Electronic), Data Warehouse

21. Data - HIPAA

Obtaining HIPAA Authorization	Yes

How PHI Will Be Protected from Improper Use or Disclosure

All data will be recorded stored in a restricted folder on Mount Sinai's secure server. Each person who will work with the data has a unique username and password to log onto the server, and then only these individuals will have access to a folder on the server for the Department of Geriatrics and Palliative Medicine. No data will be stored on local hard drives or movable media (i.e. no data will be stored on flash drives, etc). Any printouts that have PHI (which will be extremely rare) will be stored in locked cabinets in locked offices. All printouts will be destroyed/ shredded as soon as they are no longer needed.

PHI Will Be Destroyed at the Earliest Opportunity Consistent with the Research	Yes

When and How PHI Will Be Destroyed

We will remove all PHI at the earliest time possible be deleting these variables from the dataset. Any PHI that is printed will be shredded as soon as possible.

PHI Will Be Shared	No

PI must attest to the following.
**** I assure that the protected health information (PHI) will not be disclosed to any other person or entity not listed on this form except where required by law or for the authorized oversight of this research project. If at any time I want to reuse this PHI for other purposes or disclose it to other individuals or entities I will seek approval from the IRB.***

22. Data - HIV/AIDS

Name	Harriet Mather
Clinical / Adminstrative Role	Study coordinator

Name	Nathan Goldstein
Clinical / Adminstrative Role	Principal Investigator

23. Data - Storage

Location Where Data Will Be Stored

Data, obtained from the subject interviews and the clinical record, will be stored in on Sinai's secure server in a restricted-access folder. Access to the database will be restricted to the Principal Investigator, Co-Investigators, study coordinator and data analysts. The database will be maintained on the Mount Sinai Medical School's server which is firewall protected. We are not proposing to analyze the content of the video visits, and thus the video consults will not be recorded, saved, or stored.

All aspects of the intervention will be in the treating record as the intervention is provision of clinical care to patients and their caregivers and it is important that the information is documented within the electronic medical record as it would be for any clinical care. The results of the interviews with patients at baseline will be shared with patients' providers through the EMR.

How will the data be stored?	Other

Specify How Data Will Be Stored

Data on patients, caregivers, and legally authorized representatives will be stored with identifiers intact. It is necessary to keep these identifiers intact as the data may be subdivided into separate databases for portions of the analyses and these identifiers will be needed to link it back with other portions of the data. All data will be stored on Sinai's secure server that is accessible only through password protected individual logins. Once all of the data analyses are done, the identifiers will be removed from the dataset such that at some point in the research it will become an anonymous dataset stripped of identifiers.

Research Personnel Responsible for:	Nathan Goldstein
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Harriet Mather
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Christian Espino
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Magdalena Grzebyk
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Mohammed Husain
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	

Research Personnel Responsible for:	Meng Zhang
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Brenda Green
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Latoya Sealy
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Marie Persaud
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Linda DeCherrie
Accessing Data	
Receipt or Transmission of Data	
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	R Morrison
Accessing Data	
Receipt or Transmission of Data	
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Amy Kelley
Accessing Data	
Receipt or Transmission of Data	
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Lihua Li
Accessing Data	
Receipt or Transmission of Data	
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Barbara Vickrey
Accessing Data	
Receipt or Transmission of Data	

Holding Code That Can Be Linked to Identity of Participants

Research Personnel Responsible for: Katherine Ornstein

Accessing Data

Receipt or Transmission of Data

Holding Code That Can Be Linked to Identity of Participants

Research Personnel Responsible for: Carolyn Zhu

Accessing Data

Receipt or Transmission of Data

Holding Code That Can Be Linked to Identity of Participants

Research Personnel Responsible for: Xiaobo Zhong

Accessing Data

Receipt or Transmission of Data

Holding Code That Can Be Linked to Identity of Participants

Duration Data Will Be Stored

We will maintain our records for three years after closing out the Human Research

Steps That Will Be Taken to Secure the Data During Storage, Use, and Transmission

All data will be recorded and stored on Sinai's secure servers in a restricted access folder. Interview data will be recorded using a REDCaP platform on the secure server. All users will have a unique user ID and password to log onto the Sinai server and then only the individuals on this trial will have access to the folder which contains the data files and

PHI associated with them. As soon as possible, all identifiable information is removed from the databases and related files so that PHI is removed from the dataset as soon as possible. No data will be stored on local drives or removable media of any type.

Power Analysis/Data Analysis Plan (Including Any Statistical Procedures)

Please see the data analysis plan in the accompanying proposal.

24. Data - Safety Monitoring

More Than the Minimum Data Safety Monitoring Will Be Done	Yes

Principal Monitor

Additional Monitors

Specific Items That Will Be Monitored for Safety

All SAEs, regardless of treatment group or relationship to research, will be reported to the IRB within 24 hours in a full written report. Note that these patients have advanced illness and are receiving palliative care. As such deaths will be recorded and regularly reported to the IRB but deaths are not in and of themselves considered SAEs due to the nature of the patient population. We will review each death and evaluate the relationship of that death to any medications prescribed or recommended by the study team. If the team believes there is a causal relationship between the prescription of the medication and the subject's death, this will be reported to the IRB as a serious adverse event.

Frequency of Data Review

All adverse events that are both serious and unexpected will be reported to the IRB, NIA PO, and the independent study monitor within 48 hours of the study's knowledge of the SAE. All adverse events will be reported as per the IRB's policies.

The PI and program manager will also report data on enrollment, data collection, adverse events, serious adverse events and unanticipated problems every quarter to the independent safety monitor.
The PI will report all adverse events and serious adverse events every 6 months to the program officer at the NIA.
The PI and program manager will meet every week for the duration of the study.
Note that in the first month of the study, Dr. Goldstein and the project manager will review all adverse events/ serious adverse events with the independent safety monitor to ensure they agree with the determinations as to which ones are study related.

Rules for Alteration of Study Design

This is a pilot randomized controlled trial and there are no provisions for alterations in study design.

Selection Procedures to Minimize Toxicity

Not applicable.

Grading System to Evaluate Adverse Events

We will consider adverse events according to the grading system to include: unanticipated events, adverse events, and serious adverse events.

Procedures to Assure Data Accuracy

All data will be checked on a quarterly basis by the program manager to ensure the data is being entered with a high degree of accuracy.

Suspension Reported to

If the study is suspended for any reason, we will report this to the IRB and the program officer at the NIA.

Anticipated Circumstances of Subject Withdrawal

While we do not anticipate subjects wishing to withdraw, we do have procedures in place should subjects wish to withdraw and these are detailed in the consent form and will be emphasized by the research coordinator at the time of enrollment. Subjects will be withdrawn if they die, they transition to long term care, they have a hospital stay exceeding 30 days, or they relocate outside of Manhattan.

Primary or Secondary Safety Endpoints

We are not performing any interim analyses.

Data Monitoring Committee Description	Goldstein - DSMP - Pall Care Home Dementia - R 56 - March 30 2020.pdf
DMC Charter Available	No
Will the Research Include Data Coordinating Center Activities?	No

25. Funding

Funding Source Name	National Institutes Of Health/DHHS
Contact	
Funding Category	Federal/State
	Meditrack (https://contracts.tractmanager.com/Contracts/Login.aspx)
Grant or Contract Title	Palliative Care at Home for Patients with Dementia and their Caregivers
Grant or Contract Number	19-1232
Funding Status	Funded
Project Initiated By	Investigator
Grant / Contract Principal Investigator (PI)	Nathan Goldstein
Department	Geriatrics and Palliative Medicine
Department	Geriatrics and Palliative Medicine
Phone	212-241-1446
Email	nathan.goldstein@mssm.edu
Protocol and Funding Proposal Match	Yes
Identify Substantive Differences Between Protocol and Funding Proposal	

Funding Source Name	Fan Fox And Leslie R. Samuels Foundation
Contact	
Funding Category	Foundation
	Meditrack (https://contracts.tractmanager.com/Contracts/Login.aspx)
Grant or Contract Title	Palliative Care at Home for Patients with Dementia
Grant or Contract Number	19-0935-00001-01-PD
Funding Status	Funded
Project Initiated By	Investigator
Grant / Contract Principal Investigator (PI)	Nathan Goldstein
Department	Geriatrics and Palliative Medicine
Department	Geriatrics and Palliative Medicine
Phone	212-241-1446
Email	nathan.goldstein@mssm.edu
Protocol and Funding Proposal Match	Yes
Identify Substantive Differences Between Protocol and Funding Proposal	

26. Attachments

Type	Name	Version	Status	Filename	Uploaded Date
Consent Documents	Adult consent - with capacity.docx	1	approved	Adult with capacity COVID amended - clean 5.22.docx	05/22/2020
Funding Proposal / Grant Application	Completed Application Downlaoded 3 15 19.pdf	1	approved	Completed Application Downlaoded 3 15 19.pdf	06/02/2019
Other - Participant Educational Materials	Patient/caregiver letter for mailing	1	approved	Patient mailing letter_ng_clean.docx	03/06/2020
Consent Documents	Adult consent patient - lacking capacity.docx	1	approved	Adult without capacity 5.22 COVID_clean.docx	05/22/2020
Consent Documents	Adult consent caregiver.docx	1	approved	Caregiver consent clean 5.22 for COVID.docx	05/22/2020
Data Collection Sheet	Datasheet for data warehouse and screening.xlsx	1	approved	Datasheet for data warehouse and screening.xlsx	06/02/2019
Instruments	Study instruments.docx	1	approved	Study instruments.docx	06/02/2019
Consent - Phone Script	Telephone script - not consent - patient or LAR	1	approved	Telephone script_patient or LAR.docx	06/02/2019
Consent - Phone Script	Telephone script - not consent - caregiver	1	approved	Telephone script_caregiver.docx	06/02/2019
Funding Proposal / Grant Application	Goldstein - R56 for R01 AG067045-01.pdf	1	approved	Goldstein - R56 for R01 AG067045-01.pdf	03/06/2020
Other - Other IRB Correspondance	Comparative review form	1	approved	HRP-215 - FORM - 19-01975.doc	04/08/2020
Consent - Consent Document	Adult with capacity	1	approved	Adult with capacity CoC tracked.docx	04/10/2020
Data Monitoring Committee Description	Goldstein - DSMP - Pall Care Home Dementia - R 56 - March 30 2020.pdf	1	approved	Goldstein - DSMP - Pall Care Home Dementia - R 56 - March 30 2020.pdf	05/22/2020
Other - Other IRB Correspondance	Continuation form for study	1	approved	Continuing review 19-01975_v2.doc	05/28/2020