Video-Assisted Palliative Care Intervention for Patients With Advanced Dementia at Home
Dr. Nathan Goldstein
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THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR AN INCAPACITATED ADULT
TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai,
Mount Sinai Beth Israel, Mount Sinai St. Luke's, Mount Sinai West

Form Version Date: 3/27/2022

STUDY INFORMATION:

Study Title: Palliative Care at Home for Patients with Dementia

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SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A "research study" is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help the participants or others. Participation is entirely voluntary. It is completely up to you* whether or not you give permission for the patient-research subject to take part. You can also change your mind at any time and it will not affect your ability, or the patient-research subject's ability, to get medical care within the Mount Sinai Health System.

The purpose of this research study is **to see whether a new in-home palliative care program improves quality of life for patients with dementia and their caregivers.** Palliative care is specialized medical care for people living with serious illness, including dementia. It focuses of providing relief from the symptoms and stress of illness. The goal is to improve quality of life for both the patient and their loved ones. Palliative care is currently provided in the hospital, and in clinics, but isn't routinely available to patients in their home. We have developed an in-home palliative care program for patients with dementia and their caregivers and are seeking to study whether it improves quality of life for patients with dementia and their caregivers. In this study, patient-participants and caregiver-participants (as a dyad) will be randomized to receive the in-home care program or to continue with usual care. The study treatment received will be random, like flipping a coin. There is an equal chance of receiving the in-home care program or continuing with usual care.

If you choose to give permission for the research subject to participate, he/she will be asked to

*Throughout this document "you" refers to the person authorized to provide permission for the research subject

- Complete an interview at enrollment, 3 months after enrollment, 6 months after enrollment (this will be done by an informant, which could be you, where the patient-research subject is not able to complete an interview)
- Be available to have the in-home palliative care team visit the patient-research subject in their home.
- There are no costs associated with participation

The main risks to the patient-research subject if you choose to give permission for him/her to participate are risks related to side effects from medications, but all medications are prescribed in accordance with standard care and with oversight by the care program's MD– this study is not testing any new medications. The patient-research subject may benefit from participation in this research. If they are randomized to receive the in-home palliative care team, they may benefit from that additional care in the home. Due to COVID-19 we are doing a blended model for visits, they will be in person and/or over video or telephone visits. If they are randomized to continue with usual care alone, we will share a copy of their baseline interview with their main provider so that any concerns that arise can be addressed by their provider.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to give permission for the patient-research subject to participate. Any new information that develops during this research study that might make you change your mind about the subject participating will be given to you promptly.

The patient-research subject may qualify to take part in this research study because they have dementia and have a provider within the Mount Sinai Health System.

Funds for conducting this research are provided by the Fan Fox and Leslie R. Samuels Foundation, Inc., the National Institutes of Health, and the Icahn School of Medicine at Mount Sinai.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify the research subject. At most, the Web site will include a summary of the results. You can search this Web site at any time.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

The patient-research subject's participation in this research study is expected to last 6 months.

The total number of people expected to take part in this research study across all sites is 250 (125 patients-research subjects, 125 caregiver-research subjects).

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to give permission for the patient-research subject to participate in this research study, the following information describes what may be involved.

Shortly after signing consent, a member of the research team will interview the patient-research subject, or an informant who knows the patient-research subject well, to gather data about the patient-research subject's symptoms, quality of life, and experiences of care. The interview will take around 30 minutes. The interview can be done either over the phone or at another location of the informant's choosing, where privacy is assured.

After the interview has taken place, the patient-research subject will then be randomized, together with the caregiver-research subject, to receive either the in-home palliative care program, or to continue with usual care. The study treatment the patient-research subject gets will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what experimental study treatment the patient research subject gets. The patient-research subject will have an equal chance of being given each experimental treatment.

If the patient-research subject is randomized to receive the care program, around 1-2 members of the care team will do a home visit around one week after enrollment, to introduce the program to the patient research subject and their caregiver and assess the patient-research subject and their caregiver's needs. The care team will then develop a care plan based around these needs, and work with the patient-research subject, caregiver, and other healthcare providers towards meeting their care goals and addressing their needs. The frequency of visits will then be determined by the patient-research subject's needs. The in-home palliative care team includes community health workers, registered nurses, a social worker, an advanced practice nurse, with supervision from an MD. Additionally, there will be a 24-hour advice line staffed by a Mount Sinai physician to provide advice and support outside of office hours.

The care team may do the following, dependent on what is needed under the scope of standard of care: (i) Assess the patient-research subject's symptoms, (ii) Order tests (for example a blood draw or an Xray), (iii) Alter medications – in communication with the patient-research subject's primary doctor, (iv)

Request additional equipment in the home, (v) Discuss and record the patient-research subject's preferences for healthcare, (vi) Provide ongoing support and education to caregivers. The study will not be testing any new medications and only uses medications that are already established. The study will last for 6 months.

If the patient-research subject is selected to continue with usual care without the in-home palliative care program, they will continue with usual care with their current healthcare providers. This may include services such as case management if these are clinically indicated and requested by the research subject's MD. In addition, the results of the initial interview with the research team will be shared with their provider. Caregiver-research subjects of patients in the usual care arm will receive a health coach who will identify a physical health goal with the caregiver-research subject (e.g., weight reduction, smoking cessation) and work, through monthly visits, towards this goal.

Whether the patient-research subject receives the in-home palliative care program or continues with usual care, at 3 months, and 6 months after enrollment, the patient-research subject or an informant will be interviewed by a member of the research team to ask about the patient-research subject's symptoms, quality of life and experience of care.

USE OF THE RESEARCH SUBJECT'S DATA AND/OR SPECIMENS:

The private information and/or samples collected as part of this research will never be used or shared for future research, even if the identifiable information is removed.

RESPONSIBILITIES FOR PARTICIPATION IN THIS RESEARCH:

If you decide to give permission for the research subject to take part in this research study you will be responsible for the following things: ensuring that there is an informant available for interview by the research team at 3 months, and 6 months.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

The research subject will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you or the research subject.

POSSIBLE BENEFITS:

It is important to know that the patient-research subject may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits if the patient-research subject is

randomized to receive the in-home palliative care program may include having access to in-home assessments from the healthcare team (by video only from 3.19.2020), including visits by community health workers, social workers, registered nurses, with the oversight of the advanced practice nurse and the MD. If the patient-research subject is randomized to receive their usual care, without the additional care program, their baseline assessment will be shared with their nominated provider to provide information about current care needs which can be addressed as appropriate. Caregiver research subjects who are randomized to usual care will receive the services of a health coach who will identify a physical health goal with the caregiver (e.g., weight reduction, smoking cessation) and work, through monthly visits (via video), towards this goal.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

These are as follows:

- Side effects from medications: while there is always a risk of side effects from medications, all medications used by the in-home palliative care team are already established in care and will be prescribed and monitored under the guidance of an MD. This study is not testing medication, but instead testing a new way of delivering healthcare.
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- Economic risks. All visits by the healthcare providers in the in-home palliative care team are free of charge. However, any additional costs, including medications, investigations and other services received through the care program will be billed to the patient-research subject and/or his/her health insurance in the ordinary manner and he/she will be responsible for all treatment costs not covered by the insurance, including deductibles, co-payments and co-insurance.
- Group Risks - Although we will not give researchers the patient-research subject's name, we will give them basic information such as the patient-research subject's race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as the patient-research subject. However, they could also be used to support harmful stereotypes or even promote discrimination.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to allow the patient-research subject to take part in this research study without any penalty. The choice is totally up to you. Other options such as case management services will be available to the patient-research subject outside of the study in the usual manner (through their MD).

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If the patient-research subject is injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to the patient-research subject or the patient research subject's insurance in the ordinary manner and the patient-research subject will be responsible for all treatment costs not covered by the patient-research subject's insurance, including deductibles, co-payments and coinsurance. This does not prevent the patient-research subject from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information**.**

ENDING PARTICIPATION IN THE RESEARCH STUDY:

The patient-research subject may stop taking part in this research study at any time without any penalty. This will not affect the patient-research subject's ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which the patient-research subject is otherwise entitled.

If you decide to stop the patient-research subject from continuing to be in the research study, please contact the Principal Investigator or the research staff.

If you decide to stop the patient-research subject from continuing to be in the research study, they will no longer be able to receive the in-home palliative care program.

If you decide you don't want the patient-research subject's samples and/or data to be used for research anymore, you can contact the researcher and ask to have the patient-research subject's samples and/or data removed from future use. If any samples or data have already been shared without the patient-research subject's identity, it won't be possible to retrieve them because no one will know who the patient-research subject is. Samples and data that have already been used will not be affected by your decision. Any samples and/or data that are still linked to the patient-research subject's identity by a code the researcher has will be withdrawn so that no future sharing of the patient-research subject's samples and/or data will take place. If the patient-research subject's samples have already been deposited in an external repository, the study team will request that the patient-research subject's samples be removed.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop the patient research subject's involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in the patient-research subject's best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent. More possible reasons for removal from the study include relocation outside of Manhattan, stay in a skilled nursing facility for longer than 60 days, admission to nursing home, admission to hospice care, safety of clinical team cannot be assured, caregiver withdraws.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed the patient-research subject, please contact the office of the research team at phone number 212-241-0699.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk the research subject's physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As the patient-research subject takes part in this research project it will be necessary for the research team and others to use and share some of the patient-research subject's private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect the patient-research subject's name, address, telephone/fax numbers, dates directly related to the individual (birth, admission, discharge, date of death, etc.), e-mail/internet protocol (IP) addresses medical records number, health plan numbers, account numbers. The researchers will also get information from the patient-research subject's medical record available through the Mount Sinai Health System electronic medical record.

During the study the researchers will gather information by:

- Interviews with the patient-research subject or an informant who knows the patient-research subject
- Review of the patient-research subject's medical records
- Reviewing HIV-related information, which includes any information indicating that the patient research subject has had an HIV related test, or have HIV infection, HIV related illness or AIDS, or any information which could indicate that the research subject has been potentially exposed to HIV.

Why is the research subject's protected health information being used?

The patient-research subject's personal contact information is important to be able to contact the patient-research subject during the study. The patient-research subject's health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who the research subject is, unless you give separate permission to do so.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share the patient-research subject's information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see the patient-research subject's information. If the patient-research subject receives any payments for taking part in this study, the Mount Sinai Finance Department may need the patient-research

subject's name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive the research subject's protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose the patient-research subject's protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- The United States Department of Health and Human Services and the Office of Human Research Protection.

In almost all disclosures outside of Mount Sinai, the patient-research subject will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to the patient-research subject without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep the patient research subject's name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose the research subject's protected health information? Your authorization for use of the patient-research subject's protected health information for this specific study does not expire.

During the patient-research subject's participation in this study, you will have access to the patient research subject's medical record and any study information that is part of that record. The investigator

is not required to release to you research information that is not part of the patient-research subject's medical record.

Do you need to give us permission to obtain, use or share the research subject's health information?
NO! If you decide not to let us obtain, use or share the patient-research subject's health information you should not sign this form, and the patient-research subject will not be allowed to volunteer in the research study. If you do not sign, it will not affect the patient-research subject's treatment, payment or enrollment in any health plans or affect the patient-research subject's eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of the patient-research subject's protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the patient-research subject's protected information that was already collected if that information is necessary to complete the study. The patient-research subject's health information may still be used or shared after you withdraw your authorization if the patient-research subject should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use the patient-research subject's protected health information for research that means the patient-research subject will also be withdrawn from the research study, but standard medical care and any other benefits to which the patient-research subject is entitled will not be affected. You can also tell us you want to withdraw the patient-research subject from the research study at any time without canceling the Authorization to use the patient-research subject's data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses the patient-research subject's protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if the patient-research subject's information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive the research subject's information to continue to protect the patient-research subject's confidentiality.

If as part of this research project the patient-research subject's medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns the patient-research subject. If this

research does not involve any review of medical records or questions about the patient-research subject's medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use the participant's HIV-related information without authorization. If the patient-research subject experiences discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting the research subject's rights.

Certificate of Confidentiality:

To further protect the research subject's privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that the research subject's identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying them in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above. The research staff will not share any of the research subject's research information or bio specimens with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about the research subject or their involvement in this research. This means that you and your family must also actively protect the research subject's privacy. If an insurer or employer learns about the research subject's research participation, and you agree that they can have the research subject's research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

SIGNATURE BLOCK FOR ADULT UNABLE TO CONSENT:
Your signature below documents your permission for the subject named below to take part in this research and to the use and disclosure of the research subject's protected health information. A signed and dated copy will be given to you.

_____
Printed Name of Subject

_____	_____	_____	_____
Signature of Authorized Representative	Printed Name of Authorized Representative	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date	Time

Assent
✈ Obtained
✈ Not obtained because the capability of the subject is so limited that he or she cannot reasonably be consulted.

*Throughout this document "you" refers to the person authorized to provide permission for the research subject

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of Witness	Printed Name of Witness	Date	Time
_____	_____	_____	_____