VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Loneliness and Health Outcomes in the High Need Population
Version Date:	6/13/2022
PI:	Balucan, Francis

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

Loneliness and isolation are recognized entity that contributes to worsening depression and health care utilization, and mortality. The study aims to

a. Describe how shared medical visits, which are group visits with other patients that allow both a medical provider and social worker to only address medical needs but also address social, emotional, spiritual, social needs in one setting with other patients that have multiple medical conditions, can improve your perception of loneliness, and improve your sense of community with other patients.

The potential benefits from the study for you would include, your decreased perception of loneliness, depression, sense of community with other patients and increased patient empowerment. The potential risks of the study may include your emotional distress from the questionnaires or from conversations with other patients.

You would be randomly assigned to a group for this study.

If you are assigned to the first group, you will have a commitment of 2 clinic encounters, 9 months apart in the clinic, or via telehealth. You will be screened by our licensed social worker in our clinic or via telehealth using validated questionnaires for loneliness.

If you are assigned to the second group, you would commit to three encounters, scheduled on September 2022, December 2022, and March 2023 with our licensed clinical social worker and physician/APP. You will be screened by our licensed social worker in our clinic or via telehealth using validated questionnaires for the first visit. Afterwards, you would be part of shared medical visits are

Study Title: Loneliness and Health Outcomes in the High Need Population
Version Date: 6/13/2022
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group encounters of up to 120 minutes (about 2 hours) for up to 15 patients with multiple medical conditions. These are facilitated by both physician/APP and licensed social worker and on topics about Managing Multiple Medications, Stress and Sleep, and Palliative Care Palliative Care.

Our licensed social worker would also give a group check-in questionnaire. In these questionnaires, you will be asked about your distress during the session, and a goal worksheet for us to gather your expectation during these sessions. At the end of every visit, you will be asked the net promoter score, which is the likelihood that you would recommend shared medical visits to your colleagues or friends. As this is also a medical visit, if you have any specific questions, or if you have an acute medical condition, you can be seen by our physician or APP in the clinic.

You have no restrictions or limitations by participating in the study. Lastly, as this is also a medical visit, you will be billed through insurance as a regular medical visit.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because…
Loneliness is a risk factor for poor health behaviors, physical health problems and psychiatric conditions. Shared medical visits may be a form of a support group intervention to increase clinician patient contact time and provide patients with support and prevention of chronic conditions increasing patient empowerment.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

No side effects or risks are expected if you take part in the study. You may experience emotional distress in answering questionnaires or talking with patients in a group setting. Additionally, as everyone

Study Title: Loneliness and Health Outcomes in the High Need Population
Version Date: 6/13/2022
PI: Balucan, Francis

attending the shared visit has multiple medical conditions or has been in the hospital multiple times, it is possible that some personal health information such as your diagnosis may be disclosed.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study: Increase recognition of loneliness, depression, and social determinants of health for the high need population.

Procedures to be followed:

The purpose of this study is to describe how many patients who have multiple medical problems and are hospitalized frequently have loneliness, and how shared medical visits can improve that. Loneliness is defined by having fewer relationships with friends and colleagues than what is desired, as well as the intimacy in relationships that one wishes has not been realized. This is studied using the "De Jong Giervald Loneliness" scale that measures loneliness.

You may be randomized to a group that will be doing a shared medical visit, which are group encounters of up to 120 minutes (about 2 hours) for up to 15 patients with multiple medical conditions. These are facilitated by both physician/APP and licensed social worker and on topics about Managing Multiple Medications, Stress and Sleep, and Palliative Care Palliative Care. Our social worker will also be giving a group check-in questionnaire and a goal worksheet questionnaire for us to understand the level of distress you may be experiencing during that day. Additionally, at the end of visit, we will administer the net promoter score, which is a single survey question asking you to rate the likelihood that they would recommend the shared medical visit to a colleague or a friend.

We will also be reviewing the electronic medical record to determine how many times you have been hospitalized or visited the emergency room in the year.

Payments for your time spent taking part in this study or expenses:

You will be given a $40 gift card for every completed encounter, regardless of if you are in either group of the study. Additionally, if transportation to Vanderbilt is a barrier to participation, we can arrange for a taxi to ensure participation.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however; you will not be paid if you are a resident of a country restricted by the U.S. government 's comprehensive territorial sanctions or if you

Study Title: Loneliness and Health Outcomes in the High Need Population
Version Date: 6/13/2022
PI: Balucan, Francis

are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Christy Claiborne, LCSW at 615-900-6195 or Dr. FRANCIS BALUCAN at 615-900-6255. If you cannot reach the research staff, please page the study doctor at 615-831-8644

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

What will happen if you decide to stop being in this study?

Study Title: Loneliness and Health Outcomes in the High Need Population
Version Date: 6/13/2022
PI: Balucan, Francis

If you decide to stop being part of the study, you should tell your study doctor. Deciding not to be part of the study will not change your regular medical care in any way.

Confidentiality:
Information and screenings will be stored electronically in a secure database in RedCap. Only investigators who are part of this study will have access to the data. After analysis of data, any identifiers will be destroyed at earliest opportunity replaced by a study code stored separately from study database. Protected health information would not be reused or disclosed to any other person or entity as required by law for oversight of research study. Database will be maintained for up to 5 years to allow for validation of study.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit because of the tests done on your samples. These tests may help us, or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
We will provide them with a paper or electronic copy of a synopsis written in lay language and invite patients to a PowerPoint presentation summarizing the study rationale, design, findings, and implications and present it in several sessions open to study participants and family/friends. We will also provide participants and community partners with the option to receive copies of selected academic publications and media coverage and references to all publications and coverage.

Authorization to Use/Disclose Protected Health Information

Study Title: Loneliness and Health Outcomes in the High Need Population
Version Date: 6/13/2022
PI: Balucan, Francis

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Study Title:	Loneliness and Health Outcomes in the High Need Population
Version Date:	6/13/2022
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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

Time: _____