Loneliness in the High Need Population

Please complete the survey below.

Thank you!

1) Date

_____

2) Last Name

_____

3) First Name

_____

4) Date of Birth

_____

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 describe the prevalence of Loneliness among the high need population

The potential benefits from the study include your understanding of the prevalence of loneliness, and depression, in patients who have multiple medical comorbidities and have recurrent hospitalizations. The potential risks of the study include your emotional distress from the questionnaires.

You would expect to have a commitment of two encounters with our licensed clinical social worker. You would be screened initially through telehealth or in our clinic by our Licensed Social Worker. These encounters would involve the De Jong Giervald Loneliness Scale, a valid reliable measurement for overall emotional and social loneliness. At the end of the study, we will review the electronic medical record of how many times you have been hospitalized or visited the emergency room.

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. We intend to understand the prevalence of loneliness using the validated De Jong Giervald Loneliness Scale and their association with measures of depression, alcohol use and health care utilization in the high need population.

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.

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. Loneliness is shown 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.

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.

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?

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:

Results of the study will be shared with all participants, We will provide them with a paper or electronic copy of a synopsis written in lay language, and also 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

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.

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.

Last Name: [last_name_aim1]

First Name: [first_name_aim1]

Date: [survey-date-started:instrument]

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5) signature

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