Stay Connected: Testing an Intervention to Combat COVID-19 Related Social Isolation Among Seattle-area Older Adults

NCT04966910

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UNIVERSITY OF WASHINGTON
CONSENT FORM
STAY CONNECTED: Test Phase – Older Adults

Researchers:

Patricia Areán, PhD	Professor, Principal Investigator	Psychiatry & Behavioral Sciences	(206) 221-8692
Patrick Raue, PhD	Professor, Principal Investigator	Psychiatry & Behavioral Sciences	
Study Line	**For appointments and questions**		**(206) 616-2129**

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

PURPOSE OF THE STUDY

The purpose of this study is to learn whether or not interventions designed to combat social isolation in older adults living in senior living communities or members of senior centers are effective in reducing negative impacts of social isolation.

STUDY PROCEDURES

As a participant in this study, you will receive one of two interventions designed to combat social isolation in older adults. You will be randomly assigned – just like flipping a coin - to which intervention you will receive, either Stay Connected or usual care supplemented by a resource guide focused on resources to combat social isolation. Neither you nor the study staff have the ability to chose which intervention you receive.

Regardless of which intervention you receive, you will receive 9 weeks of support from a staff member at the senior living community where you live or the senior center that you are affiliated with. If you receive the Stay Connected intervention, you will be asked to participate in weekly calls lasting about 30 minutes for 9 weeks with a staff member. If you receive the resource guide intervention, you will receive services similar to usual services at your residence or senior center supplemented by a resource guide focused on resources to combat social isolation.

Because this is a research study, the study team will ask you questions about your mood, quality of life, and social interaction prior to starting the study. We'll ask you the same questions before you start the intervention, when you are 4 weeks into the intervention, and then when you are done after 9 weeks. We anticipate these questions will take about 20 minutes to answer and you can answer them online or by phone. We will pay you $15 for each time that you answer these questions; if you answer them each of the 3 times that we reach out, you'll receive $45, which can be sent to you as either a check or an Amazon gift code. We anticipate that you'll receive that payment within four weeks of completing the questions each time that you complete the questions.

Overall, we anticipate that participating in the study, including receiving support from staff members at your residence or senior center and the research assessments, will take about 6 hours over about 10 weeks.

RISKS, STRESS, OR DISCOMFORT

Some of the questions that we ask may be uncomfortable to answer since we are asking some personal questions about your mood, quality of life, and social interactions. You may refuse to answer any question at any time and still continue with the study. The questionnaires may result in fatigue; however, you may take breaks if you choose.

There is a slight risk of loss of confidentiality. A breach of confidentiality may result in psychological or social harm (embarrassment, guilt, stress). To ensure participant confidentiality, the information about you will be numbered and linked to your name only on a master list that is password protected and will be kept until the study ends and data analysis is complete. We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

BENEFITS OF THE STUDY

There will be no direct benefit to you from participating in the study. However, the information that you provide in this study may inform future development of programs that could benefit older adults experiencing social isolation.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. However, your personal information may be given out if required by law. We will ask you if you have had any thoughts that you would be better off dead, or of hurting yourself in some way. If we learn that you intend to harm yourself or others, we must report that to the authorities. We may also inform staff at the senior living community where you live or the senior center you attend if we are concerned about your safety.

The State of Washington mandates that we must report physical abuse of a child, elder or dependent adult; the abandonment; isolation, neglect, or financial abuse of an elder; and/or instances in which a in which a person indicates that they have plans to harm themselves or others.

As stated above, the information you provide may be used to inform future work on program development to address social isolation. However, we will not use your personal information in any reports about this study, such as journal articles or presentations.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institute of Mental Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;

- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is April 30, 2022. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

USE OF INFORMATION

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

FUNDING SOURCE

This study is funded by the National Institute of Mental Health.

OTHER INFORMATION

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

There are no costs to you to participate in the study. In return for your time and effort, we will provide you with a $15 for completing each set of questions for a total of $45. We can either send you a check or Amazon gift codes; our study team will ask you which you would prefer. We will send you $15 each of the three times that you complete questions and expect that you'll receive payment within 4 weeks of completing the questions.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact the principal investigator, Dr. Patricia Areán, at 206-221-8692 or the study team at 206-616-2129 right away.

If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098, call collect at (206) 221-5940, or email hsdinfo@uw.edu.

This form is reviewed online by the older adults or on the phone with a member of the study team. After reviewing, they will be prompted to answer the following questions:
Do you have any questions about participating in the study? YES/NO

If YES, please call 206-616-2129 or email creativ@uw.edu. If we do not hear from you soon, a member of the study team will give you a call or email you to answer your questions.

Because this is a research study, it is important that you know what is going to happen. Please answer these questions:

Being in the research study is voluntary. TRUE/FALSE

True: That's right! Being in this study is completely voluntary and you can stop at any time.
False: Good try! Actually, being in this study is voluntary and you can stop at any time.

No one other than the people working on the study will see my answers to the questions, unless I may be in an unsafe situation. TRUE/FALSE

True: That's right! We will keep all of your answers private. The only time that we would need to tell someone else is if we are concerned about your safety.
False: Nice try! We actually do keep all of your answers private. The only time that we would need to tell someone else is if we are concerned about your safety.

Thanks for answering our questions. Now is the time to let us know whether or not you would like to participate in the study. Please check one of the boxes below.

☐ Yes, I agree to take part in this study.
☐ No, I do not want to take part in this study.

The participant's selection of one of these boxes serves as documentation of consent or lack of consent. If the consent is completed on the phone, the study team member obtaining consent will select the appropriate box in REDCap. The study team member's name and date are captured in REDCap.