Technology and Family Thriving Study

ClinicalTrials.gov ID: NCT05150990

Consent Form – Older Adult
Approved by IRB 10.10.23

IRB Protocol Number: 38-23-0548
Approved by UCSB Human Subject Committee on 10/10/2023
for use through 10/09/2024

Participant ID #:_____

Community: _____

CONSENT TO PARTICIPATE IN A RESEARCH STUDY
RESIDENT'S CONSENT
UNIVERSITY OF CALIFORNIA, SANTA BARBARA

Title of the Study: The THRIVE study: Using technology to improve the quality of life of older adults in senior living communities and their adult children

Lead Investigators: Dr. Tamara Afifi, Department of Communication, UCSB, tafifi@comm.ucsb.edu
Kyle Rand, CEO of Rendever, Boston, MA, kyle@rendever.com
Dr. Nancy Collins, Psychological & Brain Sciences, UCSB, ncollins@psych.ucsb.edu

Study sponsor: National Institutes of Health (NIH), National Institute on Aging

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PURPOSE

The purpose of the study is to examine how new technologies like Virtual Reality (VR) and Zoom (chatting through a video screen on a computer) can help you connect with your family and help you thrive. Our previous research has shown that technology can help improve emotional well-being, relationships with family, and quality of life. To participate in this study, you must be a resident at one of the senior living communities participating in this project. You must also have an adult child who can participant with you from a distance (from their own home).

PROCEDURES

After filling out a consent form and some brief background information about your health, you will complete a survey that asks about your daily activities, quality of life, and relationships with your family. You will then use either VR or Zoom with your adult child once a week for four weeks. Your adult child will participate in the study with you from their own home. If you are using VR, we will put a small headset on you and you will see images and pictures. Your son or daughter will be using the technology with you from their own home and will see the same images and pictures. If you are using Zoom, you will be able to see and talk to your son or daughter on a computer screen. Each technology session will last approximately 30 minutes and will be followed by a brief survey to determine how you feel. At the end of the four weeks, you will complete a survey to ask about your experiences in the study and your current thoughts and feelings. Finally, we will follow-up with you 1 month and 3 months after the study is over to see how you are doing. These surveys will ask about your experiences with the technology, relationship with your child, quality of life, and psychological well-being. The entire study will take about 7 to 9 hours total over the course of 4 months. With your permission, we will also be audiotaping and videotaping the technology sessions. These recordings will be coded for various emotions, communication behavior, and physical engagement. You can still participate in the study even if you decide that you do not want us to audio/videotape these sessions.

RISKS AND DISCOMFORTS

There is some risk that you could feel sad when completing surveys that ask about your health and emotional well-being. If you are ever in distress, we can stop the survey and take a break. You can also skip any questions that you do not want to answer. There is also some risk that you could feel mildly ill or dizzy while using the technology, and you might feel sad when talking about things from the past. If you are ever in distress, we can take the VR headset off or stop the Zoom session and take a break. If you are using VR, you can also watch the same images on an iPad instead. However, the use of the technology should be a fun and exciting experience. The technology we are using is being used in many senior communities around the country, with extremely positive responses from residents. To insure your physical safety, you will be seated at all time while using the technology. In addition, research team members will comply with all Covid-related safety protocols required by UCSB and your senior living community.

BENEFITS

By participating in this study, you may experience improvements in well-being and social connection with your adult child. You may also benefit from learning about the study findings and contributing to scientific research on healthy aging. However, there is no guarantee that you will benefit from being in this research. We hope that results from this study will help us understand how new technologies can benefit older adults and their family members. Being in this study may also help us develop new activities that residents can do with their adult children who might not be able to see each other as often as they would like.

INVESTIGATOR DISCLOSURE OF FINANCIAL CONFLICT OF INTERESTS

This study is funded by a grant from the National Institutes of Health (NIH), awarded to UCSB and Rendever. Kyle Rand, the CEO of Rendever, is a principal investigator on this project. He helped invent the VR platform being used in this study and might benefit financially if marketed.

CONFIDENTIALITY

Your participation in this research is confidential. We will keep the information you tell us private. Your child will not have access to the information you provide on any of the surveys (and you will not have access to their information). Researchers on this project (at UCSB and at Rendever) will have access to identifying information on your surveys, but this information will be removed after the study is completed. All research records will be stored on secure servers and in locked cabinets that can only be accessed by the research team. To allow us to match your surveys together, we will assign you a code number on each survey. The list matching names to code numbers will be password protected and will be destroyed when the study is completed. The information resulting from your participation will be retained indefinitely and may be shared with other researchers in the future for research purposes not detailed within this consent form. If research records are shared with other researchers, your name and any other identifying information will be completely removed.

If you agree to be audio and videotaped for this study, these recordings will be identifiable. You will be asked to complete a separate consent form where you can decide whether, and how, these recording can be used in the future.

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. The following people/groups may inspect and copy records pertaining to this research: • The Office of Human Research Protections in the U. S. Department of Health and Human Services • The UCSB Institutional Review Board (a committee that reviews and approves research studies) and • The National Institutes of Health and the National Institute on Aging, the funding agency for this study, and its authorized representatives. Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

COMPENSATION FOR PARTICIPATION

To thank you for your time and effort, you and your child will each receive $150. You will be given $100 shorty after you finish the technology sessions and then $50 at the end of the follow-up surveys.

RIGHT TO REFUSE OR WITHDRAW

Your participation is voluntary. You are free to decline to answer any specific questions. You may refuse to participate and still receive the care you would receive if you were not in the study. You may change your mind about being in the study and quit after the study has started. If you quit before the study has ended, you will receive $20 per technology session and follow-up survey. If you participate until the end of the study but simply miss 1 session, you will receive the full amount ($150). You also have the right to not be videotaped and audiotaped during the technology sessions.

CONTACT INFORMATION FOR QUESTIONS OR CONCERNS

You have the right to ask any questions you may have about this research. If you have any questions or concerns about this research project or if you think you may have been injured as a result of your participation, please contact Dr. Tamara Afifi in the Department of Communication at UCSB (**tafifi@comm.ucsb.edu** or 805-679-1812). If you have any questions regarding your rights and participation as a research subject, please contact the Human Subjects Committee at (805) 893-3807 or hsc@research.ucsb.edu. Or write to the University of California, Human Subjects Committee, Office of Research, Santa Barbara, CA 93106-2050

CONSENT:

PARTICIPATION IN RESEARCH IS VOLUNTARY. YOUR SIGNATURE BELOW WILL INDICATE THAT YOU ARE VOLUNTARILY CHOOSING TO PARTICIPATE IN THIS RESEARCH STUDY. YOU WILL BE GIVEN A SIGNED AND DATED COPY OF THIS FORM TO KEEP.

If you agree to take part in this research study and to the information outlined above, please sign your name and date below.

_____	_____
Participant Signature	Date
_____	_____
Signature of Researcher Obtaining Consent	Date

Is it okay to videotape and audiotape the technology sessions?	NO	YES
Would you like a copy of the research results?	NO	YES