Technology and Family Thriving Study

ClinicalTrials.gov ID: NCT05150990

Consent Form – Adult Child
Approved by IRB 10.10.23

THRIVE Study – Electronic Consent Forms ADULT CHILD (10.10.23)

(This form is completed by the Adult Child electronically via Qualtrics – this is a copy of the Qualtrics document)

THRIVE Study Consent and Health Forms

Welcome to the **THRIVE Study**! We are so happy that you and your parent decided to participate. Before we begin the study, we have two **Consent Forms** for you to read and sign. Please read these forms carefully - they have important information about the study and about your rights as a research participant.

Following the consent forms, we will gather some demographic information and have three brief **health forms** for you to complete (assessing physical, emotional, and social well-being) so that we are aware of any health conditions that might need to be considered when participating in the study. The measures will take about 10 minutes.

Please let us know if you have any questions about these forms or about the study. Thank you in advance for your time and cooperation.

What is your **Participant ID number**? (This is the unique code that the research team gave you in an email. If you cannot find or remember that number, please call or email Dr. Jennifer Stamps at 904-476-1350 or jennifer@rendever.com, to fill this in before you continue.)

_____

Which senior living community are you and your parent associated with?

- ○ Autumn Glen
- ○ Bayberry
- ○ Carriage House at Lee's Farm
- ○ Laurelwood
- ○ Stone Hill
- ○ Stonebridge
- ○ Other _____

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

Form #1: Consent for Research Participation

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

PURPOSE

The purpose of this study is to examine how new technologies like Virtual Reality (VR) and Zoom (video chat on a computer) can help improve older adults' quality of life, emotional well-being, and family relationships. The ultimate goal is to help older adults who might be experiencing memory decline thrive in senior living communities by connecting them with family members who live at a distance. In previous research, we have shown that technology can improve the quality of life of older adults in senior living communities and their family members. The technology platforms we use are designed for older adults. They are safe to use for older adults with a range of cognitive and physical challenges, from those with no memory decline to those with moderate dementia. To participate in this study, your parent must be a resident at one of the senior living communities involved in this project. You must also be able to participate with your parent in the study from a distance (from your own home or office).

PROCEDURES

You will use either VR or Zoom with your parent once a week for four weeks. You will participate from your own home or office, and your parent will participate from their senior living community. We will mail you all the necessary equipment and show you how to use it. Before your first session, you will complete an online consent form and a few brief health measures. The week before you start the technology sessions, you will complete a survey (20-30 min) that asks about your background, well-being, and your relationship with your parent. You will also receive an orientation to the technology. Next, you and your parent will participate in the technology sessions together, once a week for 4 weeks. Each session will last approximately 30 minutes. You and your parent will be talking to each other during the session and the research team will guide you through the session. Following each session, you will complete a brief (10 to 15 min) online survey that asks about the session and your experiences that week. A few days after your final session, you will complete a survey that asks about the project more broadly (20-30 min), and then a similar survey 1 month and 3 months later. These surveys will ask about your experiences with the technology, relationship with your parent, quality of life, and psychological well-being. We will ask your parent similar questions, reading aloud the questions to him/her if needed. In preparation for

using the technology, we might ask you to upload some family photos and favorite addresses from the past to a secure online portal. The entire study will take about 7 to 9 hours total over the course of 4 months. With your and your parent's permission, we will also be audiotaping each session and videotaping your parent's sessions. These recording will be coded for various emotions, communication behaviors, and physical engagement. You can still participate in the study if you decide that you do not want us to audio/videotape the sessions. Once the study is over, you will mail any equipment back to us in a pre-paid shipping box.

RISKS AND DISCOMFORTS

There is some risk that you could feel sad when completing surveys that ask about your emotional well-being and relationship with your parent. If you are ever in distress, you can stop the survey at any time and take a break. You can also skip any questions that you do not want to answer. There is some risk that you or your parent could feel mildly ill, dizzy, or agitated while using the technology. For example, there is a chance that your eyes might get slightly irritated from the VR goggles or Zoom screen. You or your parent might also get sad from talking about things from the past. If your parent gets upset or sad, we will stop using the equipment and comfort them if needed. If you experience distress, you should tell the researcher about it immediately and we can address it. However, the use of the equipment 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 and your parent will be seated at all times while using the technology. Research team members will comply with all Covid-related safety protocols required by UCSB and your parent's senior living community.

BENEFITS

By participating in this study, you may experience improvements in well-being and social connection with your parent. 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. Results from this study may benefit society by improving our understanding of how to help older adults thrive in senior living communities. Results may also guide the development of new technologies to improve social connections among older adults and their family members.

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 parent 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 in this study 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 parent will each receive $150. You will receive $100 shortly after you complete the technology sessions and then $50 at the end of the study.

RIGHT TO REFUSE OR WITHDRAW

Your participation is voluntary. You are free to decline to answer any specific questions. You or your parent may refuse to participate and will still receive the care you would receive if you were not in the study. You or your parent 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 for each technology session and follow-up survey you completed. 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 audio or video recorded 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 ELECTRONIC 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 the information outlined above, please sign your name below. (Electronic)

Please type your full name below.

_____

Please indicate the date (e.g., mm/dd/yyyy)

_____

Is it okay to videotape and audiotape the technology sessions?

- ○ No
- ○ Yes

Would you like a copy of the research results?

- ○ No
- ○ Yes

If YES, please type your e-mail address here:

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Form #2: Consent for Video and Audio Tape Release and Use

Thank you for agreeing to participate in the THRIVE Study. You consented to allow us to record the technology sessions for this study and be analyzed by the research team. As part of this project, we would like your permission to keep your video and audio recordings for future research purposes. Please indicate below the use of the videos/audios to which are you willing to consent. This is completely voluntary and up to you. In any use of the videos/audios, your name will not be used but your image/voice will be.

For each statement below, please indicate by selecting “yes” or “no” if you would like your recordings used.

	YES	NO
The recordings can be used for scientific presentations.	○	○
The recordings can be used in classrooms to students.	○	○
The recordings can be used in public presentations to non-scientific groups.	○	○
The recordings can be used on television and radio.	○	○
The recordings can be shared with other researchers.	○	○
The recordings can be used by Rendever (the VR company) for marketing purposes.	○	○

Retention of recordings: With your permission, we will retain the audio and video recordings indefinitely (forever). If you do not want us to retain them indefinitely, we will erase them at the conclusion of the study (after the audio/videotapes are transcribed and coded).

	YES	NO
May we keep the recordings indefinitely (forever)?	○	○

If you agree to the information outlined above, please sign your name below. (Electronic)

Please type your full name below.

_____

Please indicate the date (e.g., mm/dd/yyyy)

_____