

Technology and Family Thriving Study

ClinicalTrials.gov ID:
NCT05150990

Consent Form – Legal Representative
Approved by IRB 10.10.23

THRIVE Study – Electronic Consent Forms **LEGAL REP (10.10.23)**

(This form is completed by the Legally Authorized Representative electronically via Qualtrics – this is a copy of the Qualtrics document)

THRIVE Study Consent Forms for Legal Representative

As the legal representative for the older adult who will be participating in the THRIVE Study, we appreciate your cooperation in completing these consent forms for their participation. Please be assured that the older adult has been fully informed of all study procedures and safeguards and has expressed their desire to participate in the study with their adult child. The study will begin (and continue) only with the full and active consent of the older adult.

There are two **Consent Forms** for you to read and sign. The first consent form describes the study purpose, procedures, risks, and safeguards. If you consent to audio and video taping, the second consent form requests further permissions for specific uses of the audio and video taped data. Please read these forms carefully - they have important information about the study and about the older adult's rights as a research participant.

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

What is your **Family 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 _____

Form #1: Consent for Research Participation for Legal Representative

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

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, the older adult must be a resident at one of the senior living communities involved in this project. In addition, the older adult must have an adult child who agrees to participate with them in the study from a distance (from their own home or office).

PROCEDURES

Once a week for four weeks, the older adult will use either Virtual Reality or Zoom with their adult child. The older adult will participate from their senior living community and the adult child will participate from their own home or office. All necessary equipment will be mailed to the adult child. Before the first technology session, the older adult and adult child will complete an online consent form and a few brief health measures. Next they will complete a background survey (20-30 min) that asks about quality of life and family relationships. The older adult will complete these surveys on paper with the assistance of a research associate. If needed, the research associate will read aloud the questions to the older adult. The adult child will complete all surveys online. Next, the older adult and adult child will participate in the technology sessions once a week for 4 weeks. Each session will last approximately 30 minutes. The older adult and adult child will be talking to each other throughout the session and the research team will guide them through everything. Following each session, the older adult and adult child will complete a brief (10 to 15 min) survey that asks about the session and their experiences that week. A few days after the final session, the older adult and adult child 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

their experiences with the technology, their relationship, quality of life, and psychological well-being. In preparation for using the technology, we might ask the adult child 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 everyone's permission, we will also be audiotaping the technology sessions and videotaping the older adult's sessions. These recordings will be coded for various emotions, communication behaviors, and physical engagement. Families can still participate in the study if they decide that they do not want us to audio/videotape the sessions. Once the study is over, family members will mail any equipment back to us in a pre-paid shipping box.

RISKS AND DISCOMFORTS

There is some risk that the older adult could feel sad when completing surveys that ask about their health and emotional well-being. If they are ever in distress, we will stop the survey and comfort them if needed. We can also skip any questions that the older adult does not want to answer. There is also some risk that the older adult could feel mildly ill, dizzy, or agitated while using the technology. For example, their eyes might get slightly irritated from the VR goggles or Zoom screen. Or, the older adult might get sad from talking about things from the past. If the older adult gets upset or sad, we will stop using the equipment and comfort them if needed. 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 their physical safety, the older adult will be seated at all times while using the technology. In addition, research team members will comply with all Covid-related safety protocols required by UCSB and the older adult's senior living community.

BENEFITS

By participating in this study, the older adult may experience improvements in well-being and social connection with their adult child. They may also benefit from learning about the study findings and contributing to scientific research on healthy aging. However, there is no guarantee that they 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

Participation in this research is confidential. We will keep the information that participants tell us private. The older adult and their adult child will not have access to each other's survey responses. Researchers on this project (at UCSB and at Rendever) will have access to identifying information on the 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 the surveys together, we will assign a code number on each survey. The list matching names to code numbers will be password protected and destroyed when the study is completed. The information resulting from 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, names and any other identifying information will be completely removed.

If you give permission for the older adult to be audio and videotaped, these recordings will be identifiable. You will be asked to complete a separate consent form where you can decide whether, and how, these recordings can be used in the future.

We will keep participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of the older adult's 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 the older adult. Reasonable efforts will be made to keep the personal information in the 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 the older adult. At most, the website will include a summary of the results. You can search this website at any time.

COMPENSATION FOR PARTICIPATION

To thank them for their time and effort, the older adult will each receive \$150. They will receive \$100 shortly after they complete the technology sessions and then \$50 at the end of the study.

RIGHT TO REFUSE OR WITHDRAW

Participation is voluntary. Participants are free to decline to answer any specific questions. The older adult may refuse to participate and will still receive the care they would receive if they were not in the study. The older adult may change their mind about being in the study and quit after the study has started. If they quit before the study has ended, they will receive \$20 for each technology session and follow-up survey they completed. If they participate until the end of the study but simply miss 1 session, they will receive the full amount (\$150). They also have the right to not be audiotaped or videotaped 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 the older adult may have been injured as a result of their 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 the older adult's 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: BY PROVIDING YOUR ELECTRONIC SIGNATURE BELOW, YOU GIVE PERMISSION FOR THE OLDER ADULT TO PARTICIPATE IN THIS RESEARCH STUDY. YOU WILL BE GIVEN A SIGNED AND DATED COPY OF THIS FORM TO KEEP.

If you give permission for the older adult to participate in this research study, please sign your name below.(Electronic)



A rectangular placeholder box for an electronic signature. It contains the text "SIGN HERE" in a large, bold, gray font, with a small "X" icon to its left. At the bottom right of the box is a small red "clear" button.

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:

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

Thank you for providing consent for the older adult to participate in the THRIVE Study. You consented to allow us to record the technology sessions for this study, which will be analyzed by the research team. As part of this project, we would like your permission to keep the 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 and the older adult (who will be providing their own, independent consent). In any use of the videos/audios, participants' names will not be used but their image/voice will be.

For each statement below, please indicate by selecting "yes" or "no" if you give permission for the recordings to be used.

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

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)? | <input type="radio"/> | <input type="radio"/> |

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)

This concludes your consent process as the Legal Representative for the older adult.

Thank you for taking the time to complete these forms. If you have any questions about the study, please do not hesitate to contact the research team.