KESSLER FOUNDATION

INSTITUTIONAL REVIEW BOARD
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Notice of Approval
IRB Protocol Number: E-996-17

Principal Investigator(s): Peii Chen, PhD

Title: "Development of a Virtual Reality Spatial Retraining Therapy to Improve Neglect in Stroke Survivors"

Sponsor *(if applicable)*: ***NIDILRR***

Type of Review: Full [ ] **Expedited [X]** Limited [ ]

Type of Approval: Initial [ ] Continuation [ ] **Amendment [X]**

Approval Date: **March 11, 2022** **Expiration Date:** **N/A**

1. **ADVERSE EVENTS:** Federal regulations require that any unanticipated complications or unexpected event(s) that occur in conjunction with this study must be reported promptly to the IRB Office. Serious Adverse Events must be reported to the IRB within 48 hours; unexpected adverse events of moderate or greater severity must be reported to the IRB within 5 business days (for details see Policy No. 5010 – March 15, 2004).

2. **RENEWAL**: You are no longer required to apply to the IRB for an annual renewal. However, it is your responsibility to submit Amendments, reportable adverse events, reportable instances of suicidal ideation, and/or closure when applicable. The IRB will send you an annual email on the anniversary of this approval inquiring about the status of this protocol.

3. **CONSENT FORM:** Attached is your IRB-approved **consent form and recruitment flyer** that has been stamped on each page. This is the only valid Consent Form that can be presented to subjects enrolled in your study or candidates interested in participating. Please retain the original and use it to make photocopies to be signed by the research subjects. (All subjects must receive a copy of the consent form; the original signed copy must be kept in a secure place by the Principal Investigator.)

4. **SUBJECTS:** Number of participants approved for this study: **85**. If you wish to increase the number of subjects in this protocol, you must first obtain approval for an amendment from the IRB.

5. Any change in the protocol must be submitted as an amendment application for review and approval by the IRB. If additional procedures are being added to the protocol and you would like to apply the new procedures to subjects who have already been consented, you will need to re-consent these subjects using the revised consent form.

6. This approval applies only to the above-referenced project. It is important to secure prior approval of the IRB for any changes in your approved protocol that would affect the involvement of human subjects.

7. **AMENDMENT**: Addition of recruitment flyer and modifications to the consent form for clarity.

Richard Greene, M.D., Ph.D., Chair, IRB

March 16, 2022
Date

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Stroke Survivors: Pilot Trial

TITLE OF STUDY: Development of a Virtual Reality Spatial Retraining Therapy to Improve Neglect in Stroke Survivors

RESEARCH STUDY #: E-996-17

I, _____, am being asked to consent to participate in a research study led by Dr. Peii Chen. Other persons who work with her as study staff may be asked to help her. I understand that taking part in this study is completely voluntary; I do not have to be part of this study unless I choose to be. I am free to leave the study at any time if I change my mind. All research studies carried out at Kessler Foundation are covered by the rules of both the Federal Government and Kessler Foundation.

The Information provided may contain words I do not understand. I will ask the study doctor or the study staff to explain any words or procedures I do not understand.

The table below contains a brief summary of key information about this research study. Additional information can be found throughout this document.

Study Summary	
Why is this research being done?	The purpose of this research study is to evaluate the preliminary efficacy of a computer-based treatment using virtual reality technology and reveal opportunities for implementing immersive virtual reality training through tele-rehabilitation in treating spatial neglect and other cognitive deficits at home. The goal of this study is to help stroke survivors, who have a disorder called spatial neglect, regain spatial functions that are important in locating objects, personal belongings, paying attention to traffic when crossing streets, and making body movements toward the side of space affected by stroke. I am being asked to participate in this study because I am a stroke survivor who has spatial neglect.
How long does the study last?	The study will take me up to 23 visits (9 assessment sessions and 15 treatment sessions), which will be scheduled across 7-9 weeks. It will take 1-2 hours for each visit.
What will happen during this research study?	While I am part of this study, during each assessment visit I will be asked to undergo assessment for spatial neglect, including paper-based tests and observational assessment. During each treatment visit, I will be asked to complete therapy activities created in virtual reality.
What risks are	I have been told that the study described above may involve the risks and/or

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associated with participating in this study?	discomforts of nausea and dizziness while using the virtual reality system. If I experience these symptoms, I will stop using the virtual reality system. There also may be risks and discomforts that cannot be foreseen.
What are the benefits of participating in this research study?	I will receive no direct benefit from taking part in this study, but the information obtained from this study may help the researchers to develop new rehabilitation techniques to better treat spatial neglect.
What other options are available to me if I choose not to participate in this study?	Participation in this study is completely voluntary. If I choose not to participate in this study, there will be no effect on my medical care, employment status, or access to benefits to which I am otherwise entitled.

The following sections offer more detail about the study.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research study is to evaluate the preliminary efficacy of a computerized treatment system software using VR technology and reveal opportunities for implementing immersive virtual reality training through tele-rehabilitation in treating spatial neglect and other cognitive deficits at home. The ultimate goal is to help stroke survivors whose functional abilities are affected by spatial neglect. Spatial neglect is a disorder of spatial attention and awareness where stroke survivors have trouble locating objects, finding personal belongings and avoiding obstacles on the side of the body that was affected by the stroke. The VR treatment software is designed to hopefully help stroke survivors improve their spatial attention and awareness, and to facilitate spatial neglect treatment for the clinicians working with the stroke patients. I am being asked to participate in this study because I am a stroke survivor.

WHAT WILL HAPPEN DURING THIS RESEARCH STUDY?

While I am a part of this study, I will be asked to do the following:

- I will undergo assessments for spatial function. These will include paper-based tests (for example, crossing out items on a touch screen iPad using a stylus (Apple pencil) and/or an observational assessment (for example, I will be asked to put on a jacket). I will have 3 assessment sessions across 8-9 days before starting a VR session. Upon completion of the last VR session (see the next bullet point), I will complete one more assessment session, and then up to three more over the next two weeks.
- I may be asked to wear an eye tracking device that will track my eye movements.
- I will be asked to undergo VR treatment sessions over the course of 15 visits across 5 weeks. During the VR session, I will be asked to wear a headset and perform light physical activities (for example, rotating head from left to right and raising an arm). I will be audio- and video- recorded during the study, so that the researchers may collect all the information they need correctly. I will indicate below my willingness to be recorded for purposes of this research study.

[ ] **Yes**, I agree to allow audio and/or video recording of my study sessions.

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Participant Signature: _____

[ ] **No**, I do not agree to allow audio and/or video recording of my study sessions.

Participant Signature: _____

- I will be using an incomplete, working version of the VR system during this study. The system and all of its components and ad documentation are confidential. I will not copy, describe, discuss, or provide to anyone outside of the Kessler Foundation the activities I performed using the VR system. Also, I will not describe or discuss with anyone other than Kessler Foundation researchers my experience using the VR system.

_____ Participant's Initials

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Up to 45 people will take part in this study. Testing and training will be performed by study staff and may be conducted at Kessler Foundation and/or at my residence.

WHO QUALIFIES TO PARTICIPATE IN THIS STUDY?

To be included in the study, I must meet all of the following requirements.

- 18 years or older
- Read and speak English fluently
- First unilateral stroke
- Presence of spatial neglect

WHAT MIGHT MAKE ME INELIGIBLE FOR THIS STUDY?

If any of the items listed below are true for me, I will tell the researcher. To ensure my privacy, I do not have to say which item or items apply to me. If I choose to tell the investigator which items are true for me, the information will not be shared with anyone.

- Presence of cognitive impairment
- Progressive neurological disorder, for example, Alzheimer's disease, Parkinson's disease, multiple sclerosis
- Significant psychiatric history, for example, schizophrenia, bipolar disorder, or obsessive-compulsive disorder
- History of vestibular disorders, for example, vertigo (a sensation of spinning and loss of balance)

WHAT RISKS ARE ASSOCIATED WITH PARTICIPATING IN THIS STUDY?

The study described above may involve the following risks and/or discomforts: nausea and dizziness while using the VR system. If I experience these symptoms, I will stop using the VR system. There also may be risks and discomforts that cannot be foreseen

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WHAT WILL HAPPEN IF THE RESEARCHERS LEARN NEW INFORMATION ABOUT THE STUDY?

During the course of the study, I will be told about any new findings that might affect my willingness to remain in the study.

WHAT WILL BE DONE TO PROTECT INFORMATION ABOUT ME?

Every effort will be made to maintain the privacy of my study records.

Protected Health Information

The researchers would like to use information about my health as well as information that identifies me. This information is referred to as "Protected Health Information" and is given special protections under The Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996. The researchers must obtain my approval to use Protected Health Information.

If I participate in this research study, information that will be used and/or released may include the following:

- Information from my medical records, such as my diagnoses, medications or other treatments I am receiving, laboratory test results, images (such as x-rays or other scans), reported symptoms, ability to function, and other observations made by health professionals as part of my medical care.
- Questionnaires about how I am feeling physically or emotionally
- Results of tests of my physical or mental function
- Other observations made by researchers during the course of the research study

Protected Health Information such as my name, address, date of birth, etc., that is stored electronically is kept in the REDCap system that includes all the protections of my health information required by HIPAA, including requiring users of my information to be pre-approved by the study director and a mechanism that will remove any information that identifies me in research data that is shared with other institutions. Access to study data will be limited to the members of the study team and will require study team members to submit 2 different access codes to use this data. REDCap/SIMS also tracks access to, and changes made to any study records. Kessler Foundation does not permit Protected Health Information to be kept electronically in documents that do not hide information that can identify me. Hard copy documents that contain my name, phone number, address, date of birth, etc., are kept in locked cabinets that only members of the research team can access.

Sharing Protected Health Information

My health information may be shared with people and researchers at this institution and associates of the sponsor(s), university, clinic or hospital who help with the research. The researchers may share this information with other people or organizations who are in charge of the research, others who are helping the research study to be done, those who pay for the research, or those who make sure that

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the research is done properly.

The study team may share a copy of this approval form and records that identify me with the following people or organizations:

- The Institutional Review Board - a committee that reviews research studies for the protection of the people who participate in research.
- Auditors from Kessler Foundation or government agencies responsible for the conduct of research to make sure the researchers are following regulations, policies, and study plans.
- Members of the study team, including Peii Chen, PhD; Denise Krch, PhD

I have the right to look at my study information at the study doctor's office and to ask (in writing) for corrections of any of my information that is wrong.

If the findings from the study are published, I will not be identified by name. My identity will remain private unless its release is required by law.

Removing Approval

I can change my mind at any time and remove my approval to allow my information to be used in the research. If this happens, I must remove my approval in writing. Beginning on the date I remove my approval, no new information will be used for research. However, researchers may continue to use the information that was provided before I withdrew my approval.

If after signing this form, I want to remove my approval, I can contact the person(s) below. He/she will make sure the written request to remove my approval is processed correctly.

Peii (Peggy) Chen, Ph.D., Principal Investigator
Senior Research Scientist, Kessler Foundation
1199 Pleasant Valley Way, West Orange, New Jersey 07652
Email: pchen@kesslerfoundation.org Phone: 973-324-3574

Approval Expiration

This approval has no expiration date. However, as stated above, I can change my mind and remove my approval at any time.

Questions should be directed to the research staff person who is reviewing this form with me. I can also call the Kessler Foundation Privacy Board – *John DeLuca, Ph.D., ABPP at (973) 324-3572.*

WHERE ELSE CAN I FIND INFORMATION ABOUT THIS STUDY?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This web site will not include information that can identify me. At most, the Web site will include a summary of the results. I can search this Web site at any time using the NCT # NCT04793516 to search for this study.

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WILL IT COST ANYTHING TO PARTICIPATE IN THIS STUDY?

There will be no cost to me for my taking part in this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

I will receive up to $125 for completing this study (completing all the assessment and treatment sessions). This $125 payment will be broken up into three payment as follows; $25 for completing the three baseline assessment sessions (first three sessions), $50 for completing all the VR treatment sessions , and $50 for completing the outcome assessment sessions. I will also be reimbursed for travel, at the ongoing rate plus tolls.

NOTE: If I receive $600 or more in a calendar year from Kessler Foundation for participation in research, I will have to provide my social security number to Kessler Foundation before I can be paid due to United States tax laws. I have the option to provide my social security number to the research team now, or wait until it is required for payment and provide it at that time. As described above, many actions will be taken to ensure that the confidentiality of my social security number is protected

WHAT WILL HAPPEN IF I AM INJURED IN THIS STUDY?

Medical treatment will be arranged for me by the Principal Investigator for any physical injuries suffered as a direct result of my taking part in this study. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical treatment. All claims for out of pocket medical expenses for my medical treatment should be made to the Principal Investigator. I understand there will be no cost to me for the treatment. No financial payment will be provided to me other than my out of pocket medical expenses for physical injuries that happened as a direct result of my taking part in this study.

CAN I CHANGE MY MIND ABOUT PARTICIPATING IN THIS STUDY?

I understand that taking part in this study is my choice, and I may refuse to take part, or may stop taking part in the study at any time without penalty or loss of benefits to which I am otherwise entitled. I also understand the investigator has the right to withdraw me from the study at any time.

WHO CAN I CONTACT FOR MORE INFORMATION?

If I have any questions about my treatment or the research procedures, I can contact:

Peii (Peggy) Chen, Ph.D., Principal Investigator
Research Scientist, Kessler Foundation
Email: pchen@kesslerfoundation.org Phone: 973-324-3574

If I have concerns only regarding my **rights as someone taking part in a research study**, I may contact Donna Servidio, IRB Manager, at 1-800-648-0296, extension 6972.

I will receive a copy of this consent form if I agree to take part in this research study.

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WILL INFORMATION ABOUT ME BE USED FOR OTHER RESEARCH STUDIES IN THE FUTURE?

The information collected in this research study may be useful in future research studies.

In some future studies, the researchers may want to use my information in a way that identifies me. This means that the researchers would have access to my name, contact information, medical record number, or other identifying information, and would know that I am the person who provided the information or samples. If, in the future, researchers wish to use information that can identify me, they will be required to obtain my specific permission, in writing, for the use of my information or samples.

In other cases, researchers may want to use my information in a way that does NOT identify me. In this situation, the researchers do not have access to my name (or other identifying information) and would not know that I am the person who provided the information. In this section, I am being asked whether it is acceptable to me for researchers to use information that do not identify me without asking for my specific permission at the time of the future research study.

[ ] **Yes**, I agree to allow information collected in this study that do not identify me to be used in future research without my specific permission.

Participant Signature: _____

[ ] **No**, I do not agree to allow information collected in this study that do not identify me to be used in future research without my specific permission.

Participant Signature: _____

SIGNATURE OF PARTICIPANT

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study.

Participant Name:_____Signature:_____

Date:_____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL

To the best of my knowledge, the participant, _____, (or his /her parent/legal guardian) has understood the entire content of the above consent form, and comprehends the study and its risks as well. The participant's questions and those of his/her parent/legal guardian have been accurately answered to his/her/their complete satisfaction.

Investigator Name:_____Signature:_____

Date:_____

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SIGNATURE OF WITNESS

I was present when the researcher(s) described the study to the participant (or his/her parent or legal guardian) and I am a witness to the fact that the participant (or his/her parent or legal guardian) consented to participation in this study.

Witness Name:_____

Signature: _____

Date:_____

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Do you have spatial neglect after stroke?

Would you like to participate in a new therapy using virtual reality technology?

Spatial neglect is a condition that affects one's awareness of their surroundings.

Kessler Foundation has developed a new therapy using virtual reality technology to help people who have spatial neglect. We are looking for volunteers to try the new therapy.

Participants must be 18 years or older, have had a stroke and are affected by spatial neglect.

Participants will receive up to $125.

Study lasts up to 9 weeks at your home.

The principal investigator for this study is Dr. Peii Chen.

For more information, contact: Emma Kaplan
ekaplan@kesslerfoundation.org 973-243-6880

1199 Pleasant Valley Way, West Orange NJ 07052

The study is supported by the Healthcare Foundation of NJ and the Wallerstein Foundation for Geriatric Life Improvement.

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