Title: Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability

VCU IRB Protocol Number: HM20011840

NCT03421964

This consent was submitted to the IRB for approval on 5/25/2021 (as noted on the left bottom section of the document) and it was approved by the IRB on 5/27/2021 for use by the study team (as noted on the right side of the document).

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title: Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability

VCU IRB Protocol Number: HM20011840

Sponsor: National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)

Investigator: Nancy Hsu, Psy.D. and Ron Seel, Ph.D.

Please ask the study staff to explain any words that you don't understand. You will get a copy of this paper to keep. You can think about this as much as you want, then let us know what you want to do. You can also talk it over with your family and friends, and then let us know what you want to do.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

What is the purpose of this study?

To learn more about how a treatment program helps people after brain injury: Do patients feel better and function better after going through the program? What kinds of people get better after going through the treatment program? People in the Department of Physical Medicine and Rehabilitation at the Virginia Commonwealth University Health System (VCUHS) are doing this study.

What happens if I agree to be in this study?

You would let us

- Get information from your medical records like how severe your injury was.
- Ask you questions and have you fill out some surveys. There are questions about your day-to-day functioning, stress, depression, anxiety, and alcohol and drug use.
- Set up meeting times to complete the surveys before and immediately after treatment, as well as at 3, 4, and 9 months after the treatment.
- Set up 7 times to meet with you for the treatment sessions. Some people will have 3 more sessions. These 7 sessions will occur weekly, and the 3 additional sessions will occur between 3 and 4 months after the initial 7 sessions. Sessions focus on education, skill-building and psychological support. Topics include: understanding the effects of brain injury, engagement in recovery, setting goals, problem-solving, managing anger and other emotions, and communication. Homework includes reading materials on the topics discussed in the session. Some sessions may be audio recorded to make sure the therapist is presenting the information in the same way for each participant. You can choose whether or not the session is recorded.
- Call you to remind you about meeting times.

As part of this study, you will be placed in one of two groups by the study staff. The first group will take part in the treatment program. The second group will take part in the treatment program and will then complete 3 additional sessions. You will have an equal chance of being in either group. Regardless of your group assignment, your participation in this study will last approximately 9 months.

Are there any risks or discomforts by taking part in this study?

- We will only be asking you to answer questions. You might feel uncomfortable or sad when answering questions and talking about feelings and changes since the injury. But, you don't have to answer any questions that you don't want to.
- There is the potential risk of a breach of confidentiality or privacy (including health information). We try to minimize those risks by: using an ID number, not your name, on all study materials; using password-protected files; storing information in locked file cabinets; limiting access to data to only study personnel; and completing interviews with you in a private location (private offices with doors closed).

- If you are pregnant, there are no additional anticipated risks to you or your fetus.
- The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

Are there any benefits to taking part in this research?

- We will offer you written information about brain injury. We will also talk to you about available services or programs that may be helpful to you.
- Your everyday functioning and/or behavior may or may not get better with the treatment.
- We may learn more about how people function after brain injury.
- This study may help us improve the treatment of people after brain injury

Will it cost me anything to take part in this study?

There is no cost to you to take part in this research. The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) pays for this study. They are part of the United States Department of Health and Human Services.

Will I be paid for taking part in this study?

If you complete the study, you will receive a total of $140. You will receive a payment each time you complete the surveys. You will complete the surveys 5 times during the study.

- $25 for completing the intake session and post-treatment session surveys.
- $30 at each of the remaining 3 survey time points (3, 4, and 9 months after the post-treatment session).
- You will get paid even if you don't finish all the surveys during each session.
- If you are traveling more than 60 miles roundtrip, funds will be provided to offset travel costs (IRS mileage rate of 19 cents per mile driven).

Do I choose whether to be in the study or not?

Yes, you get to choose whether you want to be in the study. You don't have to be in the study if you don't want to be.

- Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled.
- If you do participate, you may freely withdraw from the study at any time. Your decision to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.
- If you do choose to be in the study, you can still refuse to answer any questions or surveys that you don't want to answer.

The study staff can take you out of the study if the sponsor stops the study.

What will happen if I don't take part in the study?

If you don't take part, it will not change your medical or rehabilitation care, or any other benefits you receive. If you want to get help for your brain injury, but don't want to be in the study, talk to the study staff. The study staff can tell you about ways to get help.

How will information about me be protected?

- VCU has established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.
- Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. If you say you are planning to hurt yourself or someone else, the law tells us to let people in authority know so they can help you.

- We may audio record some sessions. The audio recording will not identify you by name but only by a number and will be kept in a locked filing cabinet. One of the study staff will listen to the recording to make sure that everyone receives the same treatment. After the study staff listens to the recording, it will be destroyed.
- Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.
- In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.
- Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:
  - The study Sponsor
  - Representatives of VCU
  - Officials of the Department of Health and Human Services
- In general, we will not give you any individual results from the study. Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.
- A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

How will my health information be used and shared during this study?
As part of this research study, we will ask you to share identifiable health information with us and permit us to access existing information from your healthcare records. New health information may also be created from study-related questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research? The following types of information may be used for the conduct of this research:

☒ Complete health record	☒ Diagnosis & treatment codes	☒ Discharge summary
☒ Nursing flow sheets	☒ Emergency Department record	☒ Progress notes
☒ Information about drug or alcohol abuse	☒ Information about mental health	

Who will use or share protected health information about me? VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

Principal Investigator and Research Staff	Study Sponsor
Health Care Providers at VCU Health	Data Coordinators
Institutional Review Boards	Others as Required by Law
Government/Health Agencies	

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire? This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of privacy rights: You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you will no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at: Nancy Hsu, VCU Box 980542, Richmond, VA 23298-0542.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator named below is the best person to contact if you have any questions, complaints, or concerns about your participation in this research:

Nancy Hsu
Virginia Commonwealth University, Department of Physical Medicine and Rehabilitation
1200 E. Broad Street, Room 3-109, Box 980542, Richmond, Virginia 23298-0542
804-828-3705 or toll free at 866-296-6904

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000 Box 980568, Richmond, VA 23298-0568
804-827-2157; https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Your sessions may be audiotaped for quality control and training purposes.
____ (initial): I agree to be audiotaped
____ (initial): I do not agree to be audiotaped.

_____

Participant name printed Participant signature Date

_____

Name of Legally Authorized Representative (if appropriate) Relationship to Participant

_____

Legally Authorized Representative Signature (if appropriate) Date

_____

Name of Person Conducting Consent Discussion (printed) Date

_____

Signature of Person Conducting Informed Consent Discussion Date

_____

Investigator Signature (if different from above) Date