Official Study Title: ENGAGE Pilot Study: Promoting Participation and Health After Stroke

ClinicalTrials.gov ID: NCT04019275

Document Date: February 16, 2021

University of Pittsburgh
School of Health and Rehabilitation Sciences
Department of Occupational Therapy

100 Technology Drive
Bridgeside Point I, Suite 350
Pittsburgh, PA 15219
412-383-6620
Fax 412-383-6613
otpitt@shrs.pitt.edu
www.shrs.pitt.edu/ot

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: ENGAGE: Promoting Participation and Health for People After Stroke

PRINCIPAL INVESTIGATOR: Elizabeth R. Skidmore, PhD, OTR/L, Professor
Occupational Therapy
University of Pittsburgh
5012 Forbes Tower, Pittsburgh, PA 15260
Telephone: (412) 383-0112

CO-INVESTIGATORS : (412) 383-0112
Rachelle Brick, MS, OTR/L, Occupational Therapy
Madilyn Douglas, BS, Occupational Therapy
Jessica Kersey, MOT, OTR/L, Occupational Therapy
Courtney Schneider, BS, Occupational Therapy
Minmei Shih, PhD, Occupational Therapy
Rebecca Soliwoda, BS, Occupational Therapy
Kelsey Voltz, MOT, OTR/L, Occupational Therapy

RESEARCH STAFF: (412) 383-1055
Laura Waterstram, MOT, OTR/L
Occupational Therapy

SOURCE OF SUPPORT: National Institutes of Health CTSA Consortium

Resuming participation in important community activities after stroke improves health and function. Researchers at the University of Pittsburgh, Washington University, and University of Illinois at Chicago are conducting a **research study** to test a new rehabilitation program designed to help people resume community activities after stroke. You are being asked to take part in this research study because you experienced a stroke. We will ask 65 to 80 people to participate in this research study.

If you decide to take part in this research study, first you will be asked to **complete 4 tests that measure your moving, thinking, and speaking abilities,** and **ask questions about your feelings and your community activities**. These tests will tell us if you are eligible for this study, and together they will take about 1 hour.

If you are eligible, you will complete **additional tests of your thinking abilities, and answer questions about your health, your sense of belonging, and your daily activities.** These tests will take **1.5 hours** at a community center or your home. We will also ask to **wear a monitor on your leg for 7 days** to measure the amount of time you spend sitting or lying.

After the tests, we will ask you to participate in a group program led by an **occupational therapist and a person who has experienced a stroke**. The group will meet for about **2 hours** in

a community center 2 times per week for 6 weeks for **a total of 12 sessions**. The group will also **attend a community outing** together. The group program will provide training on ways to increase participation in community activities that are important to you, and may have you practice these activities. Sessions will be videotaped.

We will ask you to **repeat all tests at the end of the group program** during a 1 hour session at the community center or at your home. We will also ask you to **wear the monitor on your leg for 7 more days.**

Neither you, nor your insurance provider, will be charged for any of the procedures performed for the purpose of this research study. If you complete the study, you will be paid $50. If you complete part of the study, you will be paid $25 for each completed testing session.

All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 28% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 72% of the expected payment.

There are possible risks and discomforts with this research study that are no greater than risks you experience in everyday life. There is a chance that you may become frustrated, upset, or tired during the testing and the group sessions. If this happens, you will be allowed to take a break or stop the testing. There is also a slight chance that information about you may be seen by someone who is not part of the research team. Research records, including the videotapes, will be stored in a locked file cabinet or in password-protected computer databases, and you will not be identified by name in any publication of the research results unless you sign a separate consent form (release) giving your permission.

There is also a possibility that you may experience a fall or injury during the testing and the group sessions. A trained rehabilitation professional will be present during the testing and the group sessions.

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

We cannot promise any benefits to you if you take part in this study.

We cannot promise complete confidentiality (privacy). In addition to the people listed on the first page of this consent form and their research staff, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information to monitor the appropriate conduct of this research study.

In unusual cases, the research team may be required to release your identifiable information collected in this research study in response to an order from a court of law. If the research team learns that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

The research team may use and disclose your identifiable information collected in this research study for a minimum of 7 years. Your de-identified information obtained during this research study may be shared with other researchers in the future.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Center for Medical Rehabilitation Research within the National Institute of Health, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law if the research team learns that you or someone with whom you are involved is in serious danger or potential harm.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, including progress notes and results from study testing sessions that will be placed in your medical records at UPMC.

Your participation in this research study is completely voluntary. Whether or not you provide your consent to participate in this research study, your decision will have no effect on your current or future relationship with the University of Pittsburgh.

You may withdraw your consent for participation in this research study at any time. Any identifiable research information obtained for this research study prior to your withdrawal may be used and disclosed by the research team for the purposes described above. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date