Consent Form (includes HIPAA Authorization)

Title of Research Study: teleABLE: Adapting a Behavioral Activation-Based Intervention to Reduce Post-Stroke Sedentary Behavior Using Telehealth (Formative Phase)

Investigator Team Contact Information:
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Emily Kringle PhD, OTR/L University of Minnesota School of Kinesiology Phone Number: 612-624-8994 Email Address: ekringle@umn.edu	Study Staff Karli Jahnke, MOT, OTR/L (Research Coordinator) Phone Number: 612-626-4046 Email Address: jahnk160@umn.edu Jessica Walsh, MOT, OTR/L (Research Occupational Therapist) Phone Number: 612-626-3790 Email Address: jwalsh@umn.edu

Supported By: This research is supported by the National Institutes of Health.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you received a stroke diagnosis for the first time within the last 12 months.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Sedentary lifestyles are common among the 7 million Americans who have survived a stroke, which places these individuals at a greater risk of poor health outcomes. Even after recovering from the primary effects of a stroke, many people find it difficult to fully re-engage in non-sedentary activities.

Dr. Emily Kringle previously designed an occupational therapy intervention called Activating Behavior for Lasting Engagement (ABLE). The ABLE intervention was delivered in-person to stroke survivors to help them reduce sedentary behaviors.

The purpose of this research is to adapt the ABLE intervention protocol so that it can be completed remotely using videoconferencing. We hope that what we learn from this initial study will help us optimize the remote ABLE protocol (teleABLE) for use in a future randomized trial.

How long will the research last?

We expect that you will be in this research study for about 8 weeks. You will be asked to complete one interview (lasting about 30 minutes), two assessment sessions (2 hours per session), 11 intervention sessions lasting 30 minutes per session, and one longer 60-minute intervention session.

What will I need to do to participate?

You will be asked to attend 12 remote study sessions over Zoom videoconferencing, using a personal device such as a computer, tablet, or smartphone. You will also be asked to wear an activity monitor for eight days twice during the study (a total of 16 days).

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

Potential risks involved with this research include:

- Risk of injury associated with engaging in daily activities
- Risk of distress or fatigue from completing study assessments or interventions
- Risk of loss of confidentiality of study data

Study activities will be conducted in a way that minimizes risks whenever possible.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a reduction in your sedentary behavior, and health-related improvements to your quality of life. What we learn from this research may also help other stroke survivors in the future.

What happens if I do not want to be in this research?

You do not have to participate in this research. The study investigator can provide you with information on alternatives to being in the study, such as community fitness classes.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect up to 15 people will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

If you agree to be in this research, you will first be asked to complete a remote baseline testing session to complete the initial questionnaires and assessments. This testing session will be completed remotely using Zoom videoconferencing. After that, you will be asked to attend 12 remote study intervention sessions over Zoom videoconferencing, using a personal device such as a computer, tablet, or smartphone. After the fifth intervention session, you will be asked to complete a remote interview. After the intervention sessions are complete, you will be asked to complete a remote post-intervention assessment session to complete additional questionnaires, assessments, and interview.

The activities that will be completed during these study visits are described below.

Eligibility and Consent: You were already asked to complete a screening questionnaire over the phone to determine if you meet the requirements for study participation. Because you are eligible to participate in this study, the study staff will review this informed consent document with you. You can ask as many questions as you want, and take as much time as you need before you decide whether to participate in the research. If you choose to be in the study, you will electronically sign this informed consent document. No study activities will take place until you have signed the consent form.

Questionnaires and Assessments: You will be asked to complete various questionnaires and surveys. These assessments may include questions about the topics below.

- Your quality of life
- Activities that you participate in or avoid
- How you approach problem-solving
- Medical history
- Stroke care
- Cognitive function and physical mobility
- Interpersonal relationships

Activity Card Sort: For this assessment you will view photos of everyday activities. You will be asked to

categorize the activities according to how often you currently do them, or how often you have done them in the past, and rate how confident you feel about completing some activities.

activPAL Monitoring: The activPAL micro3 device is a small monitor used to measure sedentary behavior using an accelerometer (to detect movement) and an inclinometer (to detect standing/sitting/reclined/lying postures). The study team will show you how to attach the activPAL to your thigh using a gentle medical-grade tape. You will be asked to wear the activPAL for 8 days beginning during week 1 and again for 8 days during week 8, and record your sleeping and non-wear time using a diary worksheet. We expect it will take you about five minutes each day to complete the diary worksheet. The diary, activPAL device, and activPAL technical manual will be mailed to you before your first study visit. Pictures of the activPAL are below for reference:

Blood Pressure (Supervised): Before your Week 1 study visit, you will be mailed an upper-arm blood pressure monitor along with the other study materials. The study staff will teach you how to use the blood pressure monitor during the assessment sessions. You will be asked not to consume any caffeine, nicotine, alcohol, and food for 1 hour before the assessment session. The study staff will document your blood pressure readying and any blood pressure medications you are taking.

Blood Pressure (Unsupervised): On the days that you are wearing the activPAL monitor, you will be asked to use the blood pressure monitor to take one blood pressure ready when you first get up in the morning. The blood pressure reading and any blood pressure medications you are taking will be recorded in your study diary.

Sit-to-Stand Tests: You will be asked to complete two activities to measure your lower extremity and lower body strength. For the 5-Times Sit-to-Stand Test, the study team will record how long it takes you to stand up and sit down 5 times, as quickly as possible. For the 30-second Sit-to-Stand Test, the study team will record how many times you are able to stand up and sit down within 30 seconds, as quickly as possible. The Sit-to-Stand Tests are expected to take about 10 minutes total.

teleABLE Intervention: You will meet with an occupational therapist over videoconferencing twice a week for six weeks. Intervention sessions are expected to last about 30 minutes each, with the exception of Session 2, which may last up to 60 minutes.

During the first two interventions (Week 2) you will talk about what sedentary behavior looks like, and discuss what types of non-sedentary activities you might like doing. During the remaining interventions (Week 3 – Week 7), you will work with the therapist to make a plan for doing enjoyable non-sedentary activities using a problem-solving framework. You will be asked to carry out the activities between

sessions and discuss how they went during the following sessions.

You will be mailed a study workbook to use during and between the intervention sessions.

Interview 1: Interview 1 will take place within 14 days of intervention session 5. The study team will ask you about your experience using videoconferencing for the teleABLE interventions. Audio of the interview will be recorded and then transcribed by a confidential transcription service. We expect this interview will last about 30-60 minutes.

Interview 2: Interview 2 will take place after you have completed all of the teleABLE intervention sessions. The study team will ask you about your experience in the study, including what you thought about the study interventions and assessments. Audio of the interview will be recorded and then transcribed by a confidential transcription service.

Study Schedule

	Week 0	Week 1	Week 2		Week 3		Week 4		Week 5		Week 6		Week 7		Week 8
Session		Baseline	1	2	3	4	5	6	7	8	9	10	11	12	Post-Intervention
Eligibility and Consent	X														
Questionnaires / Assessments		X													X
Activity Card Sort				X											X
activPAL Monitoring		X (8 days)													X (8 days)
Blood Pressure (Supervised)		X													X
Blood Pressure (Unsupervised)		X (7 days)													X (7 days)
Sit-to-Stand Tests		X													
teleABLE Intervention			X	X	X	X	X	X	X	X	X	X	X	X	
Interview 1										X[1]					
Interview 2															X

1. Interview 1 will be conducted within 14 days after Session 5.

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

Can I be removed from the research?

It's possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed. Possible reasons why you may be asked to leave the study are:

- You are not able to follow the study safety plans
- You are re-hospitalized for any medical reason

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

Risks associated with study participation are listed below.

Assessment and intervention-related risks

You may become distressed or fatigued while completing the study questionnaires, interviews, and interventions. If any of the study procedures make you feel uncomfortable, let the study team know. You do not have to answer any questions that you do not want to answer. You are allowed to take breaks during any study session. Assessment visits may also be split up over multiple shorter sessions, as needed.

You may feel inconvenienced by study visits and telephone calls. We will minimize any inconveniences by scheduling visits according to your time preferences, and using your preferred method of contact for visit scheduling and reminders.

One of the study assessments measures depressive symptoms. If this assessment indicates that you may be severely depressed, we will let you know. You will be able to discuss these results with the study team, and be provided with additional mental health resources as needed.

Injury risks

It is possible that you may be injured while you are engaging in the daily activities that you plan during the study intervention sessions. Study interventions will be supervised by the study investigator, who is a licensed occupational therapist. Injury risks will be minimized by proactively identifying possible safety concerns and developing a safety plan that will be followed when performing daily activities for the study.

Device-related risks

The adhesive used to attach the activPAL device may cause discomfort or mild skin irritation. If your skin becomes irritated while wearing the activPAL, you should let the study team know. The study team will work with you to find alternative ways to continue using the activPAL for activity monitoring (moving device to the other leg, attaching without adhesives, etc).

Privacy and confidentiality risks

There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you. All of the research assessments and interventions will be paid for by the study.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☐ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study

requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☐ My genetic testing records _____ (initial)

☐ My mental health diagnosis/treatment records ____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- The National Institutes of Health (NIH);

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

- Research Transcriptions, the company involved with transcribing audio recordings of research interviews;

- Greenphire, the company involved in processing payments to research participants.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related

medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include your name or any other direct identifiers such as your contact information. The Web site may include a summary of the results of this research. You can search this Web site at any time.

Will I receive research test results?

Most tests done in research studies are only for research and have no clear meaning for health care. If the research gives results that do have meaning for your health, the investigators will contact you to let you know what they have found.

After you have completed the study assessments, you will also be given the option to schedule a 15-

minute meeting with the study investigator to review your individual study results.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to a total of $100 for your time and effort. You will be paid $25 after you have completed each of the following study activities:

- Week 1 assessments
- Interview 1
- Week 8 assessments
- Interview 2

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive a cardholder agreement. Be sure to read all of this information for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, and MasterCard, will be given your name, date of birth, address and social security number. They will use this information as part of the payment process. Greenphire will only need your social security number if the payment exceeds $599. Greenphire and MasterCard will not receive any information about your health status or the study in which you are participating.

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (Standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out. If you choose to receive any communications via texts or emails, you will be asked to sign a separate form.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

You will also be allowed to keep the blood pressure monitor that you receive to use during the study.

Signature Block:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent