PROTOCOL COVER PAGE

Protocol Title	teleABLE: Adapting a Behavioral Activation-Based Intervention to Reduce Post-Stroke Sedentary Behavior Using Telehealth (Formative Phase)
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Scientific Assessment	Nationally-based, federal funding organizations
IND/IDE # (if applicable)	N/A
IND/IDE Holder	N/A
Investigational Drug Services # (if applicable)	N/A
Version Number/Date:	V5.07.21.2023

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	04.17.2023	Added personnel (Jessica Walsh), assessments (blood pressure, sit-to-stand assessments, technology questionnaire)	Yes
2	06.30.2023	Updated local recruitment methods	No
3	07.10.2023	Updated study inclusion and exclusion criteria	No
4	7.21.2023	Updated local recruitment methods and recruitment materials, removed personnel (Casey Dahl)	No

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ABBREVIATIONS/DEFINITIONS

- ABLE/teleABLE: Activating Behavior for Lasting Engagement (name of intervention under study)
- ACS3: Activity Card Sort
- BIPOC: Black, Indigenous, People of Color
- CITI: Collaborative Institutional Training Initiative
- CKRI: Courage Kenny Rehabilitation Institute
- CTSI: Clinical and Translational Science Institute
- DoD: Department of Defense
- DWELL: Disability and WELLness Laboratory
- HIPAA: Health Information Portability and Accountability Act
- ICAN: Identify Choose Add/Adapt Notice
- ID: Identification
- IRB: Institutional Review Board
- ISP: Information Security and Privacy
- LGBTQ: Lesbian Gay Bisexual Transgender Queer
- M: Mean
- MoCA: Montreal Cognitive Assessment
- NIH: National Institutes of Health
- PI: Principal Investigator
- REDCap: Research Electronic Data Capture
- SD: Standard Deviation

1.0 Objectives

1.1 Purpose: This project is a first step in trial planning for a future pilot randomized controlled trial which examines a remotely delivered intervention designed to reduce post-stroke sedentary behavior. The purpose of this project is to adapt the Activating Behavior for Lasting Engagement (ABLE) intervention protocol for remote delivery using videoconferencing, and to optimize trial study procedures in preparation for a future pilot randomized controlled trial. Our two goals in the present project are: 1) iteratively adapt the ABLE intervention to enable safe remote intervention delivery using videoconferencing (teleABLE), and 2) optimize acceptability of the teleABLE intervention and assessment procedures.

The PI has made draft adaptations to the ABLE intervention protocol in preparation for adapting ABLE to teleABLE. We will recruit 10 ambulatory, community-dwelling people with stroke who sustained their first-ever stroke ≤12 months prior to study enrollment and have access to a personal device that is compatible with videoconferencing (e.g. tablet, smartphone, computer). A sequential descriptive case series will be used to iteratively update the intervention protocol based on feedback from participants and therapists. Participants will complete assessments at 2 timepoints (baseline, 2-months), participate in 12 intervention sessions over 6 weeks, and complete 2 interviews. Findings from this study will result in a refined intervention and assessment protocol that will be deployed in a future randomized controlled trial examining the feasibility and effects of the teleABLE intervention.

Aim 1: Adapt the ABLE intervention protocol to enable safe remote intervention delivery using videoconferencing.

Hypothesis 1a: People with stroke and therapists will identify training content and intervention delivery strategies that support engagement in the teleABLE intervention (intervention interview, therapist documentation).

Hypothesis 1b: People with stroke and therapists will identify strategies that support safety during remotely delivered post-stroke intervention (intervention interview, study exist interview).

Aim 2: Optimize proposed trial study procedures (teleABLE intervention, assessment procedures) to enhance acceptability of trial design.

Hypothesis 2a: People with stroke will indicate satisfaction with teleABLE procedures (Client Satisfaction Questionnaire-8 mean item score ≥3).

Hypothesis 2b: People with stroke will recommend adaptations to intervention delivery and assessment sessions that optimize the study protocol (study exit interview).

2.0 Background

2.1 Significance of Research Question/Purpose: Sedentary lifestyles are prevalent among the 7 million Americans who have survived stroke, placing them at elevated risk for poor health outcomes [1, 2]. Approximately 81% of stroke survivors have at least one comorbid chronic condition, which elevated their risk for primary stroke and contributes to their ongoing risk for recurrent stroke [3]. These conditions – heart disease, hypertension, diabetes, depression, and chronic obstructive pulmonary disorder – persist and their management is compromised by sedentary behavior [4-8]. Reducing sedentary behavior is particularly important for promoting health in the context of stroke-related disability [9]. Even if impairments fully resolve, stroke survivors do not automatically re-engage in non-sedentary activities as impairments diminish [10]. Further, residual impairments, social influences (protective support persons), and environmental factors (transportation, accessibility) create barriers to engagement in personally meaningful non-sedentary daily activities [11-15].

2.2 Preliminary Data: The PI led the development and feasibility testing of the ABLE intervention targeting post-stroke sedentary behavior [16, 17]. Feasibility testing in 20 people with chronic stroke demonstrated that ABLE delivered in-person was safe, well tolerated, and able to be delivered by multiple therapists with high fidelity to the treatment protocol [17]. These promising results form the basis for the present research.

2.3 Existing Literature: Interventions targeting post-stroke sedentary behavior are scant. Interventions that promoted adults' adherence to physical activity were less effective for reducing sedentary behavior than those specifically designed to reduce sedentary behavior [18]. Our systematic review of interventions that measured sedentary behavior or daily physical activity engagement as an outcome revealed only two interventions that specifically aimed to modify post-stroke sedentary behavior [19]. The first (unnamed) employed motivational interviewing and action planning [20], while the second (STUFFS) used action planning in combination with feedback via an activity monitoring device [21]. To our knowledge, ABLE is the third intervention that specifically aims to reduce post-stroke sedentary behavior. The first two interventions facilitated physical activities (standing, walking, stepping, sit-to-stand exercise) during times when participants were at risk for sitting. A pilot randomized controlled trial of the motivational interviewing intervention demonstrated no between-group differences in sedentary behavior change relative to an attention control group which received diet advice. This intervention used a low dose (4 sessions delivered over 7 weeks) to achieve a 39.2 minutes per day within-group reduction in prolonged sitting [20]. It is likely that stroke survivors, who are adjusting to disability, require more structure, repetition, and intensity to achieve goals than adults without newly acquired disability. A single group feasibility study examined the STUFFS intervention during subacute stroke and demonstrated within-group reduction in sedentary time of 54.2 minutes per day, which diminished to 26.8

minutes per day at 8-week follow-up [21]. These findings are similar to results from the preliminary ABLE study.

The proposed adaptations to ABLE will build on existing literature. First, ABLE will be delivered earlier in the rehabilitation process than previously delivered. Sedentary lifestyles are established during the first year after stroke and persist through the chronic phase of stroke [22-24]. Delivering ABLE during this first year will capitalize on a period during which stroke survivors adopt new routines and seek strategies to reduce recurrent stroke risk [25, 26]. Second, ABLE will be delivered via telehealth (videoconference). Because participants complete scheduled activities between sessions, intervention sessions are primarily conversation-based. Thus, ABLE is readily adaptable to telehealth delivery (teleABLE), which will expand reach and access. Further, the COVID-19 pandemic accelerated support for implementation of telerehabilitation models [27, 28]. Simultaneously, this highlighted the need for evidence of safe and effective telerehabilitation interventions in stroke [29-33].

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome: The primary outcome of this research is participant satisfaction as measured by:

- Client Satisfaction Questionnaire-8 at week 8.

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s): The secondary outcomes of this research focus on feasibility metrics and within-person change in behavioral outcomes.

- Safety measured by documentation of treatment-related serious (e.g. injurious) and non-serious (e.g. fall without injury) adverse events that occur during the intervention period (weeks 2 through 7).
- Enacted behavioral treatment dose measured by documentation of intervention session attendance (weeks 2 through 7).
- Participation restrictions measured using the Activity Card Sort 3 (week 8).
- Health-related quality of life measured using the EuroQoL-5 Dimension-5 Level (week 8).
- Sedentary minutes measured using the activPAL micro3 monitor following an 8-day wear protocol (week 8).

4.0 Study Intervention(s)/Investigational Agent(s)

4.1 Description: The structural and active elements of the teleABLE intervention are described in Table 1. teleABLE is adapted from the ABLE intervention. ABLE is a tailored intervention that enables stroke survivors to overcome barriers to

engagement in their own personally meaningful non-sedentary activities. Grounded in behavioral activation, ABLE was developed with the underlying assumptions that: 1) stroke survivors consciously or subconsciously do not return to personally meaningful activities perceived as having potential to result in discomfort or failure (experiential avoidance), and 2) successful participation in personally meaningful non-sedentary activities is motivating to engage in non-sedentary activities. Additionally, sedentary behavior interventions in similarly at-risk populations demonstrated the efficacy of activity scheduling and activity monitoring which align with the behavioral activation framework [34-36].

Table 1. teleABLE intervention elements.

Structural Elements	*Clinician:*	Occupational therapist
	Environment:	Videoconferencing (e.g., Zoom)
	Dose:	2x/week for 6 weeks (12 sessions)
	Materials:	teleABLE workbook
Active Elements	*Activity Scheduling:*	Plan established to complete a specific activity at a specific time.
	Activity Monitoring:	Identification of activity that occurred during waking hours.
	Self-Assessment:	Explicit identification of positive and negative outcomes of activity engagement
	Problem Solving:	Participant-generated solutions to challenges identified.

The intervention process is described in Table 2. Sessions 1 and 2 are focused on providing education regarding sedentary behavior, building awareness of personal sedentary behavior patterns, and identifying non-sedentary activities that are personally meaningful. The remaining sessions include an iterative process during which stroke survivors iteratively apply a 4-step strategy (ICAN Plan) that activates engagement in these non-sedentary daily activities. Participants **I**dentify a time when they are at risk for sitting, **C**hoose an instrumental or daily activity to complete during that time, and create a specific plan to **A**dapt the activity by identifying solutions to anticipated barriers, and safety concerns. Participants are instructed to carry out the plan between sessions and **N**otice aspects of the plan that worked well or that may require a modified plan. Participants also notice how they felt during and after completing the activity. Within the Adapt step, participants are directly prompted to consider the safety of the activity and to develop a plan to assure safety. Therapists will follow the teleABLE Safety Algorithm (included with submission) to support participant dignity and safety. The ICAN process is documented on worksheets provided in the teleABLE workbook. This process guides participants through monitoring, scheduling, problem solving, and self-assessing activity engagement. This strategy enables teleABLE to be individualized to overcome participants' specific impairment and environmental barriers to engagement in preferred non-sedentary activities.

Table 2. teleABLE intervention process

Week	Session	Content	Homework
1	1	Overview: • What is sedentary behavior? • Modifying sedentary behavior patterns	• Self-monitor 1 day
	2	• Reflection: activPAL data, self-monitoring • Brainstorm non-sedentary activities • Introduce ICAN Plan	• Carry out ICAN Plan • Self-monitor 1 day
2 to 6	3 to 12	Iterative process: • Self-Assessment of ICAN Plan, • Modify existing ICAN Plan, or • Develop new ICAN Plan	• Carry out ICAN Plan • Self-monitor 1 day

The teleABLE intervention will be delivered remotely using the University of Minnesota Health Care Component Zoom account which is HIPAA-compliant and will be accessed via their own personal device. Sessions will be delivered by a research assistant who is trained and supervised by the PI (a nationally certified and state-licensed occupational therapist). Participants will complete 2 sessions per week over 6 weeks (12 total sessions). Sessions 1 and 3 to 12 are expected to last approximately 30 minutes each. Session 2 may last up to 60 minutes. A teleABLE workbook and technology manual will be mailed to participants prior to the first intervention session.

4.2 Drug/Device Handling: N/A

4.3 Biosafety: N/A

4.4 Stem Cells: N/A

4.5 Fetal Tissue: N/A

5.0 Procedures Involved

5.1 Study Design: This study uses a sequential case series design to refine the intervention and study protocol based on feedback from participants and the treating therapists. Participants will complete assessments at Baseline (week 1) and 2-months (week 8), participate in 12 intervention sessions over 6 weeks (weeks 2 through 7), and complete 2 interviews (mid-intervention and week 8). Participants will also wear an activPAL activity monitor for 8 days at baseline and 2-months to assess sedentary behavior.

5.2 Study Procedures: Participants will be recruited through Courage Kenny Rehabilitation Institute, community-based recruitment, and Fairview Health System (see section 11.1 to 11.3). Interested potential participants will complete a screening questionnaire over the telephone (see section 8.3). Those deemed eligible will meet with study staff to review the informed consent document and have an opportunity to ask questions before deciding whether they want to consent to participate in the study. Participants who choose to provide consent

will complete eConsent (see section 21.1). After providing consent, the participant will be scheduled to complete the baseline testing session. The schedule of measures is depicted in Table 3. All study procedures, including assessments and intervention sessions, will be conducted remotely using videoconferencing (HIPAA-compliant University of Minnesota Health Care Component Zoom). The study staff administering each questionnaire will display the questions and response options on the Zoom screen. In addition, study staff may read the questions aloud if the participant prefers. The participant will provide a verbal response for all measures. All procedures will be conducted for research purposes.

Table 3: Schedule of Measures

	W1	W2	W3	W4	W5	W6	W7	W8
Technology Questionnaire (5 min)	X							
EuroQoL-5D-5L (5 min)	X							X
Activity Card Sort (30 min)		X						X
Acceptance and Action Questionnaire-II (5 min)	X							X
Survey of Activities and Fear of Falling in the Elderly (5 min)	X							X
Social Problem Solving Inventory-Revised Short Form (10 min)	X							X
General Self Efficacy Scale (5 min)	X							X
Neuro-QOL Item Bank Short Forms (10 min)	X							X
5-Times Sit-to-Stand Test (5 minutes)	X							
30-Second Sit-to-Stand Test (5 minutes)	X							
Client Satisfaction Questionnaire-8 (5 minutes)								X
Demographic Interview (5 min)	X							
Stroke History Interview (5 min)	X							
Self-Administered Comorbidity Index (5 min)	X							
Montreal Cognitive Assessment (5 min)	X							
Dyadic Adjustment Scale-7 (3 min)	X							
Inclusion of Others in Self Scale (3 min)	X							
Supervised blood pressure (10 minutes during assessments)	X							X

Unsupervised blood pressure (3 min/day for 7 days)	X		X
activPAL 8-day monitoring (10 min instruction, 2 min/day)	X		X
Interview 1 (30 min)		X	
Interview 2 (30 min)			X

NOTE: W=Week; Study intervention is delivered during weeks 2 through 7.

Measures:

- **Technology Questionnaire:** This is a 12-item questionnaire that was designed based on our team's findings from a prior Zoom-based intervention for people with stroke (Kringle et al., in press). Participants indicate their confidence using their device and the software, indicate their current approach to each step required to join a Zoom call, and indicate their preferences for learning new technologies. The information gleaned from this questionnaire is used by the study team to support study participants throughout remote interactions that occur throughout the study.
- **EuroQoL-5D-5L:** This is a valid and reliable measure of health related quality of life among people with stroke and other at-risk populations. Participants rank their function on 5 items (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) using a 5-point Likert-type scale. Participants also rate how good or bad their overall health is at the time of assessment using a 0 to 100 scale [37, 38].
- **Activity Card Sort:** This is a valid and reliable measure of activity restriction among adults with stroke and disability. We will use the electronic version of this tool during which participants view photos of 100 everyday activities and categorize activities into those they a) never did, b) do less, c) gave up, d) do now, or e) want to start since the time of their stroke. For activities that the participant indicates that they do less, gave up, or want to start, they are asked to respond to the question: "Given where we're at with COVID and the effects of your stroke, how confident would you be if you did that activity today, from 1 (not at all confident) to 10 (extremely confident)?" Participants are asked to provide a rationale for their confidence level [39].
- **Acceptance and Action Questionnaire-II:** This is a valid and reliable measure of experiential avoidance among adults. Participants rank 7 statements regarding their emotions and worry on a 7-point Likert-type scale. Scores are summed, with high scores indicating high experiential avoidance [40].
- **Survey of Activities and Fear of Falling in the Elderly:** This is a valid and reliable questionnaire that assesses participation in 11 daily activities, and the degree to which fear related to falling is the reason for restricted participation. For each activity, participants identify: a) if they currently do the activity (yes/no), b) fear that they might fall while doing the activity using a 4-point Likert-type scale, c) reasons besides falling for avoiding or not doing the

activity, and d) amount of performance of the activity relative to 5 years ago. Scores are reported as participation restriction, mean fear scores, and can be used to classify participants based on fear of falling and activity restriction [41, 42].

- **Social Problem-Solving Inventory-Revised Short Form:** This is a brief measure of problem-solving approaches that has been validated against longer versions of the Social Problem-Solving Inventory. Participants will respond to 25 statements describing their approach to solving daily problems on a 0 (not at all true of me) to 4 (extremely true of me) Likert-type scale. A composite problem-solving score is derived by reverse scoring negative problem-solving domains (negative problem orientation, impulsive/careless style, avoidance style) and summing all scores. High scores (out of a possible 40) represent greater problem-solving abilities [43].
- **General Self Efficacy Scale:** This is a valid and reliable measure of self-efficacy for navigating daily life situations. Participants rate 10 statements using a 1 (not at all true) to 4 (extremely true) Likert-type scale. Scores are summed, and high scores indicate high self-efficacy [44].
- **Client Satisfaction Questionnaire-8:** This is a valid and reliable measure of client satisfaction with the treatment received. Participants rate 8 statements on a 1 to 4-point Likert-type scale. High scores indicate high satisfaction [45].
- **Demographic Interview:** These characteristics will be obtained during participant interview. We will obtain the following: sex, gender identity, age, race/ethnicity, education, employment status, occupation, presence/absence of support person, living situation (e.g., alone, with or without support person)
- **Stroke History Interview:** These characteristics will be obtained during participant interview. Participants will report the date, type (ischemic vs. hemorrhagic), and side of their stroke, the types of healthcare services that they received after their stroke, and whether their current activity level is higher, lower, or the same relative to pre-stroke levels.
- **Self-Administered Comorbidity Questionnaire:** This is a valid and reliable measure of comorbidities. Participants will indicate the presence or absence of 14 common chronic conditions (yes/no). For each condition present, participants will indicate if they are currently receiving treatment for the condition (yes/no), and if the condition limits their daily life activities (yes/no). One point is assigned to each affirmative response. The severity score is computed by summing all responses (possible scores 0 to 42). High scores indicate high comorbidity severity [46].
- **Neuro-QoL Item Bank Short Forms:** Upper Extremity Function (Fine Motor, ADL), Lower Extremity Function (Mobility), Cognition Function, Communication, Depression, and Anxiety will be assessed via self-report questionnaire. Each domain is measured using a short form where

participants rank their function on 5 to 8 items using a 5-point Likert-Type scale. Scores are summed and converted to T-scores which are interpreted relative to the general population (M=50, SD=10). The Neuro-QOL short forms are valid and reliable measures of the identified constructs in people with stroke [47].

- **5-Times Sit-to-Stand Test:** During this performance-based test of lower extremity strength, participants will be instructed to begin from a seated position in a chair without wheels. They will then be instructed to stand up and sit down 5 times as quickly as possible. The length of time that it takes to complete 5 sit-to-stands will be recorded. This is a valid and reliable measure of lower extremity strength among people with stroke [48].
- **30-Second Sit-to-Stand Test:** During this performance-based test of lower extremity strength, participants will be instructed to begin from a seated position in a chair without wheels. They will then be instructed to stand up and sit down as many times as they can within 30 seconds. The count of full sit-to-stand cycles will be recorded. This is a valid and reliable measure of lower body strength among community-dwelling older adults [49].
- **Montreal Cognitive Assessment (MoCA):** The 5-minute MoCA protocol is a valid and reliable screening tool for assessment of vascular cognitive impairment that was developed to be administered via teleconferencing. This is a performance-based measure where participants complete 5-word learning, verbal fluency, orientation to time and place, and 5-word recall tasks. Each item is scored by the assessor and summed (possible range 0 to 30, low scores indicate greater impairments) [50].
- **Dyadic Adjustment Scale-7:** This is a valid and reliable measure of interpersonal relationships that has been used to assess caregiver-care recipient relationships in stroke. This questionnaire contains 7 items rated on a 6-level ordinal scale describing the extent of agreement or disagreement, frequency of interactions, and happiness in relationships [51-53].
- **Inclusion of Other in Self Scale:** This is a valid and reliable 2-item measure that describes the closeness of interpersonal relationships. Participants select one of 7 images which best represent their relationship with their support person and, separately, their community [54].
- **Supervised Blood Pressure:** Blood pressure measurements will be taken during the remote assessment session following best practices recommended by the American Heart Association and procedures in previously published trials [55, 56]. Prior to the session, participants will receive an Omron Series 5 Upper Arm blood pressure monitor in the study package that will be mailed. Participants will be instructed to abstain from caffeine, nicotine, alcohol, and food for 1 hour prior to the assessment session. During the session, the assessor will verify abstentions. If the abstentions were not followed prior to the session, the assessor will ask the participant to abstain from caffeine,

nicotine, alcohol, and food for the next hour and proceed with the remaining assessments. They will then complete the supervised blood pressure measure after at least one hour has passed. Participants will be instructed in proper use the Omron Upper Arm blood pressure monitor. They will complete a 5-minute rest, followed by 3 blood pressure measurements with a 1-minute rest between each measure. In addition to documenting the systolic and diastolic blood pressure readings, the arm that was used to take the reading (left/right), most recent time any blood pressure medication was taken, and type and dose of blood pressure medication will be documented.

- **Unsupervised Blood Pressure:** During the same time period during which participants are wearing the activPAL monitor, they will be asked to document their morning blood pressure reading following a procedure based on the American Heart Association guidelines for self-measured blood pressure monitoring [55]. Participants will use the Omron Upper Arm blood pressure monitor that they received in the mail. During the Baseline (week 1) assessment session, they will be instructed in proper use of the monitor. Participants will be asked to take 1 blood pressure reading when they first get up in the morning. They will document each reading, the time of the reading, and if blood pressure medication was taken, the time, dose, and type of medication in the Daily Diary.
- **activPAL 8-day monitoring:** The activPAL micro3 (Pal Technologies, Glasgow) will be used to measure sedentary behavior. The activPAL micro3 contains a triaxial accelerometer and inclinometer which detects and records posture throughout the day (sitting/reclined/lying, standing). A validation study in people with and without stroke revealed 100% accuracy for postural detection relative to video observations [57]. We will follow a 24-hour, 8-day wear protocol that we previously deployed in preliminary studies examining post-stroke sedentary behavior [17, 58]. The device will be activated via microUSB cable, using activPAL3 Software. The device will then be waterproofed following recommendations from the manufacturer and mailed to the participant with all required materials for application. During the virtual baseline testing session, each participant will be instructed in how to adhere the device to the anterior aspect of his/her non-stroke thigh using a gentle medical-grade tape [59, 60]. With the device, participants will also receive educational information regarding the device, self-monitoring to assess for skin irritation, and steps to take should skin irritation be identified (remove the device, contact the PI). Participants will also record sleeping and non-wear time using a daily diary provided by the research team. After the monitoring period is completed, participants will return the device and daily diary to the laboratory using a pre-addressed and postage paid mailer provided by the research team. No identifying information is recorded within the device. Upon receipt of the device, raw activity monitor data will be uploaded to the study

Box folder using activPAL3 Pal Analysis Software (v.8, Pal Technologies, Glasgow) and processed using a diary-informed protocol [58, 61].

- **Interview 1:** This interview will be conducted within 14 days after session 5 and focus on the participants' perspectives on: 1) learning to use videoconferencing in the context of the teleABLE intervention, 2) accessing videoconferencing, and 3) ways that the therapist and/or support person support their use of videoconferencing during the study. The interview will be conducted by a research assistant supervised by the PI. We anticipate that the interview will last 30 to 60 minutes. Interviews will be audio recorded using the Zoom record function. The resulting audio file will be stored in the study's UMN BOX folder. Interviews will be transcribed by a company called Research Transcriptions (previously SameDayTranscriptions). Research Transcriptions provides confidential transcription services, using HIPAA-compliant procedures. Interviews will be transcribed in batches based on data accumulation. Deidentified transcripts will be stored in the study's UMN BOX folder.
- **Interview 2:** This interview will be conducted during the post-intervention assessment session after study measures are completed and will focus on participants' perspectives on the intervention, study recruitment, assessment, and intervention procedures that may enhance retention in future trials. Interviews will be audio recorded using the Zoom record function. The resulting audio file will be stored in the study's UMN BOX folder. Interviews will be transcribed by a company called Research Transcriptions (previously SameDayTranscriptions). Research Transcriptions provides confidential transcription services, using HIPAA-compliant procedures. Interviews will be transcribed in batches based on data accumulation. Deidentified transcripts will be stored in the study's UMN BOX folder.

5.3 Study Duration: Individual participants' study participation will occur over 8 weeks. Assessment sessions will occur during weeks 1 and 8 (2 hours per session). During the 8-day monitor wear that occurs during weeks 1 and 8, participants may spend up to 5 minutes daily completing the activPAL diary worksheet. Intervention sessions 1 and 3 through 12 will last 30 minutes each. Intervention session 2 will last 60 minutes. Interview 1, which occurs during week 5, will last 30 minutes.

We anticipate the participants will be recruited and complete all study procedures over 10 months. Data analysis will require an additional 4 months after all data are collected.

5.4 Use of radiation*:* N/A

5.5 Use of Center for Magnetic Resonance Research*:* N/A

6.0 Data and Specimen Banking

6.1 Storage and Access: Data collected for research purposes will be identified by a unique study ID code and stored in REDCap (questionnaires), Excel (activPAL data), and transcribed word processing files (audiorecorded interviews). These data will be stored separately from the linking form in REDCap, which is the only location where the participants' names will be stored with their study ID codes. All fields on the linking form will be marked as identifier fields in REDCap, and the REDCap database will be set to only allow deidentified fields to be exported. Audiorecorded data (interviews, intervention sessions), activPAL data, and REDCap data exports will be stored in the University Box Secure Storage. Only approved researchers who require access to the data to conduct assessments, intervention, or analyses will be granted access to the data. Data will be maintained in this manner until analyses are completed. The study linking form will be destroyed after all data are collected, verified, and analyzed.

6.2 Data: Data stored for future use are:

• Deidentified questionnaire-based data describing: health-related quality of life (EuroQoL-5D-5L), activity restrictions (Activity Card Sort), experiential avoidance (Acceptance and Action Questionnaire-II), activity avoidance (Survey of Activities and Fear of Falling in the Elderly), problem-solving approaches (Social Problem-Solving Inventory-Revised Short Form), self-efficacy (General Self Efficacy Scale), demographic data (sex, gender identity, age, race/ethnicity, education, employment status, occupation, presence/absence of support person, living situation), stroke characteristics (date, type, side of stroke, types of healthcare services received after stroke, activity level relative to pre-stroke), comorbidities (Self-Administered Comorbidity Index), functioning (Neuro-QOL Lower Extremity Function, Upper Extremity Function, Cognition Function, Communication, Depression, Anxiety), cognition (Montreal Cognitive Assessment), interpersonal relationship (Dyadic Adjustment Scale-7, Inclusion of Others in Self Scale).

• Deidentified activPAL monitoring data stored as .csv and .pal files

• Deidentified transcripts of interviews 1 and 2

• Audiorecorded intervention sessions

6.3 Release/Sharing: Although there are no current plans for data sharing, requests for data sharing will be directed to the PI and deidentified data will be provided upon reasonable request through appropriate channels (i.e., Data Use Agreement).

7.0 Sharing of Results with Participants

7.1 **Individual participant results** may be shared with participants at 2 points during the study. (1) During baseline testing, the Neuro-QOL Depression Short Form is administered, which is a validated measure of depressive symptom load in the stroke population [62]. A raw score of ≥26 on this measure indicates that the

participant is experiencing severe depressive symptoms. If the participant meets or exceeds this score of 26 on this measure, the study team will verbally discuss the results with the participant, provide the participant with a packet (via electronic mail) which contains mental health crisis support information and an education sheet on mental health after stroke published by the American Congress of Rehabilitation Medicine, and encourage the participant to discuss these symptoms with their primary care physician. (2) At the post-intervention assessment timepoint, each participant will be offered the option to schedule a 15-minute meeting with the PI to view and discuss their individual results on the primary clinical outcomes (health-related quality of life, activity restrictions, activPAL sedentary time, activPAL step count).

Study results: Aggregate study results will be shared with participants in the form of a study newsletter shared after the results have been analyzed and accepted for publication in a peer-reviewed journal. This newsletter will contain a plain language summary of the findings and a link to the peer-reviewed publication.

7.2 Sharing of genetic testing:

7.2.1 Disclosure of results: N/A: This study does not involve genetic testing

7.2.2 If returning results to participants:

N/A: This study does not involve genetic testing

- Aggregate or individual results: N/A: This study does not involve genetic testing
- Laboratory results: N/A: This study does not involve genetic testing
- Plan for return of results to participants: N/A: This study does not involve genetic testing
- Types of results to be returned to participants: N/A: This study does not involve genetic testing

7.2.3 Future analysis of genotypes: N/A: This study does not involve genetic testing

8.0 Study Population

8.1 Inclusion Criteria:

• Age: 18 years or older

• Diagnosis: Stroke diagnosis ≤12 months prior to study enrollment

• ≥6 hours of sedentary behavior on a typical weekday (Sedentary Behavior Questionnaire) [63]

• Ambulatory with or without assistive device (assessed by Functional Independence Measure, mobility score ≥5) [64]

• Able to access an electronic device (smartphone, tablet, or computer) that is compatible with a videoconferencing application

• Able to identify a support person with whom they have face-to-face interaction at least one time per week

• Able and willing to participate fully in the study and provide informed consent

8.2 Exclusion Criteria:

- Currently receiving care in an inpatient rehabilitation, transitional care unit, or skilled nursing facility
- Severe cognitive or communication impairments (inability to respond accurately to complete study telephone screening or complete informed consent)
- Comorbid neurodegenerative disorder (e.g. Parkinson's disease, multiple sclerosis, amyotrophic lateral sclerosis, myasthenia gravis, dementia, Alzheimer's disease, Huntington's disease, glioblastoma)
- Comorbid cancer, currently undergoing chemotherapy or radiation treatment
- Comorbid major depressive disorder (Patient Health Questionnaire-2, score ≥2) [65]
- Received inpatient treatment or hospitalized for psychiatric condition and/or alcohol or substance abuse within the past 12 months
- Diagnosis of a terminal illness and/or currently receiving hospice care
- Currently pregnant or expecting to become pregnant in the next 8 weeks.
- History of skin sensitivity that precludes the use of medical tape necessary for adherence to activity monitor measure
- Inability to speak, read, or understand English
- Concurrent participation in any other rehabilitation intervention research study (including cognitive and/or physical rehabilitation studies)
- Investigator discretion for safety or adherence reasons

8.3 Screening: Volunteers who express interest in study participation will complete a telephone screening telephone call to determine eligibility. The PI or a research assistant trained and supervised by the PI (a licensed occupational therapist with over 10 years of experience in post-stroke assessment and intervention) will follow a screening script that (1) describes the study, and (2) confirms the volunteer's interest in completing study screening. If the volunteer expresses interest, we will obtain verbal consent to conduct telephone screening. Documentation of (1) verbal consent for screening, and (2) responses to study screening questions will be recorded electronically in REDCap. Volunteers will be

asked questions to determine eligibility based on the eligibility criteria listed in 8.1 and 8.2.

9.0 Vulnerable Populations

University requirements for inclusion of vulnerable populations may be stricter than what may be acceptable for sponsors or for lead investigators at other institutions.

9.1 Vulnerable Populations:

Identify which of the following populations will be allowed to participate in this study. You may not include members of the populations below as participants in your research unless you indicate this in your inclusion criteria above. Inclusion of an individual from one of these groups will require the investigator to develop additional safeguards (Section 9.2) proportional to the degree of vulnerability and proportional to the degree of risk and benefit.

Population / Group	Identify whether any of the following populations will be focus of the research (targeted), included, but not necessarily the focus or excluded from participation in the study.
Children	Excluded
Pregnant women/fetuses/neonates	Excluded
Prisoners	Excluded.
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	Excluded
Non-English speakers	Excluded
Those unable to read (illiterate)	Excluded
Employees of the researcher	Excluded
Students of the researcher	Excluded
Undervalued or disenfranchised social group	included but not the focus.

Active members of the military (service members), DoD personnel (including civilian employees)	included but not the focus.
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	included but not the focus
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	Excluded
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	included but not the focus
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	included but not the focus.

9.2 Additional Safeguards, if any, to ensure inclusion is appropriate:

We will recruit participants with mild stroke who spend ≥6 hours/day sitting and who demonstrate the cognitive and communication ability to provide informed consent. Although not the direct focus of recruitment, this population contains and, to more closely reflect the stroke population, we are not excluding volunteers who are (1) undervalued or disenfranchised in society [e.g. BIPOC, disability community, LGBTQ], (2) active members of the military and/or DoD personnel, (3) individuals who are disadvantaged in the distribution of social goods and services such as income, housing, or healthcare, (4) individuals with fear of negative consequences for not participating in the research [e.g. undocumented immigrants], and (5) another circumstance/dynamic that could increase vulnerability to coercion or exploitation [i.e., insurance no longer covering post-stroke rehabilitative services due to plateau in progress or cap in coverage, unable to afford cost of rehabilitative services].

We have in place the following safeguards to ensure that potential research participants fully understand the research and are free to decline joining the study: (1) During telephone recruitment study description, screening, and informed consent meetings, we will emphasize that the study intervention, though delivered by an occupational therapist, is not traditional rehabilitative services, (2) We will provide the informed consent document via either electronic or hard copy prior to the consent meeting to provide volunteers and their support persons ample time to review the document and identify questions, (3) We will encourage volunteers who screen eligible to invite a support person to the informed consent meeting where the full details of study involvement are provided and questions will be invited and answered, (4) During the consent meeting, we will emphasize the voluntary nature of the research including information on how to withdraw from the study at any point, provide information on alternative community programs (e.g., community fitness classes) that may facilitate post-stroke physical activity, and provide ample time for questions and discussion. We will also offer time for the volunteer to discuss the research with whomever they choose (e.g., support person, physician) without the researcher present, (5) Prior to signing the consent document, the volunteer will be required to complete teach-back describing the purpose of the study, what they will be asked to do, study risks, and how to withdraw should they choose to do so, (6) We will not screen for or ask about immigration status, illegal or stigmatizing behaviors, or military status at any point during the study. Therefore, the participant's status is unlikely to be known to the research team. We do not anticipate vulnerability for any of these groups to be increased by participating in this study.

9.3 If research includes potential for direct benefit to participants, provide rationale for any exclusions indicated in the table above:

The following populations are excluded from this study:

- Children: The behavioral intervention is designed for an adult population and is, therefore not developmentally appropriate for pediatric stroke survivors (i.e., cerebral palsy).
- Pregnant women/fetuses/neonates: Sedentary behavior, daily activity patterns, and barriers to non-sedentary behavior in pregnant women differ from the general population [66]. Including pregnant women would prevent accurate interpretation of the data in such a small pilot study.
- Prisoners: The behavioral intervention is designed for a community-based free living population, which is not reflected in a prisoner population.
- Adults lacking capacity to consent and/or adults with diminished capacity to consent: Adherence to the behavioral intervention requires cognitive ability to follow through and make safe judgements when enacting plans between sessions. People with post-stroke cognitive impairments may

require a more closely supervised or in person approach to post-stroke sedentary behavior intervention than this intervention provides.

- Non-English speakers: The participant workbook is only available in English and the study team does not contain individuals who are fluent in other languages. Therefore, because of the discussion-based nature of the intervention, we are unable to feasibly include non-English-speakers at this time.
- Those unable to read (illiterate): The behavioral intervention requires reading participant workbook materials and writing down plans to refer to between sessions.
- Employees of the researcher: Students of the researcher are excluded to minimize the risk for power dynamics in the employee-employer relationship that may bias feedback on the intervention approach and outcomes measures.
- Students of the researcher: Students of the researcher are excluded to minimize the risk for power in the student-professor relationship to bias feedback on the intervention approach and outcomes measures.
- Individual or group that is approached for participation in research during a stressful situation: This intervention is designed to be delivered during the sub-acute and post-acute phase of stroke. Therefore, volunteers will not be approached for participation in this research during a stressful situation.
- Individual or group with a serious health condition for which there are no satisfactory standard treatments: People with serious health conditions for which there are no satisfactory standard treatments are excluded under our comorbidities-related exclusion criteria, because these conditions differentially impact the clinical study outcomes (health-related quality of life, activity restrictions, sedentary behavior).

10.0 Local Number of Participants

10.1 Local Number of Participants to be Consented:

Lowest number that will allow data analysis: 5 participants

Maximum that might agree to participate: 15 participants.

We are aiming to recruit 5 to 10 participants who will complete the entire study. We have expanded this maximum number to 15 to allow for study withdrawals.

11.0 Local Recruitment Methods

11.1 Recruitment Process:

Courage Kenny Rehabilitation Institute (CKRI): CKRI therapists and care coordinators will be asked to share the study flyer with past or current patients who meet inclusion/exclusion criteria. Prospective participants who are

interested in exploring enrollment will be instructed by CKRI therapists to contact the DWELL Research Laboratory via either telephone or email using the information contained on the flyer. All email contact during recruitment is limited to providing more information about the study and possibly scheduling a time for the telephone screening call. CKRI therapists will also ask patients who indicate interest for permission to share their first and last name and telephone number with the DWELL Research Laboratory staff. If the patient provides permission, CKRI therapists will email the patient's information to the DWELL study team.

Community recruitment: We will also post information about the study on the DWELL Laboratory Website (https://dwell.umn.edu), StudyFinder, invite community-based stroke support groups to share study flyers with their members, and distribute study flyers at DWELL Lab community engagement events (e.g., Driven to Discover Research space at the Minnesota State Fair and county fairs).

Fairview Health System: We will mail study invitation letters to Fairview patients using the Fairview Research Administration's processes. Within the study invitation letter, patients who are interested will be instructed to contact the DWELL Research Laboratory via either telephone or email using the information contained in the letter. We will also post a digital advertisement on screens located in Fairview clinics. This advertisement will direct interested participants to contact the study team using StudyFinder.

11.2 Identification of Potential Participants:

Courage Kenny Rehabilitation Institute (CKRI): CKRI therapists and care coordinators have legitimate access to stroke diagnosis information of potential participants during routine clinical care. The CKRI therapist and/or care coordinator will make the initial contact with the patient and provide the study flyer. The potential participant will make the first contact with the DWELL Laboratory research team. If the potential participant provides the CKRI therapist to share their contact information with the study team as described in section 11.1, the DWELL research team will reach out to the patient.

Community recruitment: Participants may self-refer if they become aware of the study through recruitment materials or word of mouth referrals. Individuals who self-refer will contact the study team using the information provided on study materials. Potential volunteers who receive a study flyer through their stroke support group, DWELL Lab community engagement events, or learn about the study on the DWELL Laboratory website, StudyFinder, or social media will self-identify whether they meet the diagnosis criteria (stroke within the past 12 months) by reaching out to the study team.

Fairview Health System: We will work with the Best Practice Integrated Informatics Core (BPIC) of the Clinical and Translational Science Institute (CTSI) to

request access to the data we require for recruitment. The data will be provided to us in the AHC-IE Data Shelter, which is a virtual Windows server that provides researchers a secure environment in which to work with clinical data. All viewing and manipulation of the data will take place within the Data Shelter. Inbound and outbound Internet traffic, installation privileges and network drives are disabled within the shelter to prevent unauthorized access and to ensure data is not extracted from the shelter. Data is stored on encrypted drives and backed up daily to off-site locations. Only personnel named on our IRB protocol will be given permission to login to the Shelter to view and analyze the requested patient data. Furthermore, per the policies of the AHC-IE, only authorized users who have completed HIPAA training and completed the AHC-IE Attestation Form regarding confidentiality and safeguarding of AHC-IE data will be granted access. DWELL Lab staff who are responsible for this process will complete the Fairview Health System non-employee research staff (NERS) process which will allow staff to further screen charts of patients identified via the recruitment list provided by BPIC to finalize the recruitment list. Only those remaining on this list will receive letters mailed from Fairview Research Administration. In addition, Fairview clinical staff may share study flyers with potential participants with whom they have a treating relationship. If a potential participant is identified, the clinical staff will share the study flyer and instruct the potential participant to contact the study team using the contact information provided on the flyer.

11.3 Recruitment Materials:

Study flyers: We will share electronic and hard copy study flyers with CKRI therapists, care coordinators, and providers who interact with potential volunteers. Study flyers will also be shared with local stroke support groups.

Study invitation letters: Fairview Research Administration will mail letters to patients identified through the BPIC electronic health record query.

Recruitment script: This will be followed when participants contact the DWELL Laboratory to learn more information about the study.

Digital advertisement: This will be displayed on digital screens in the Fairview Health System

11.4 Payment:

Volunteers will receive up to a total of $100 via the Greenphire ClinCard over the duration of their participation in this study. This will be paid in $25 increments upon the completion of (1) Week 1 assessments, (2) Interview 1, (3) Week 8 assessments, and (4) Interview 2. Volunteers will also be allowed to keep the Omron 5-Series Upper Arm blood pressure monitor that they received to use throughout the study ($50 value).

Upon completion of Week 1 assessments, the study coordinator will mail the participant's ClinCard and, once the volunteer confirms receipt of the card, will load the first study payment. At each subsequent payment timepoint, the study coordinator will verify that the volunteer has access to their original ClinCard and load the payment within 2 business days of timepoint completion. If needed, a new ClinCard will be mailed to the volunteer.

12.0 Withdrawal of Participants

12.1 Withdrawal Circumstances: Participants are free to withdraw from participation in the study at any time upon request. An investigator may discontinue a participant from the study for the following reasons:

- The PI and intervention therapist determines that they are consistently not following safety plans associated with the activities that are planned during intervention. An example of this would occur when the safety protocol that the volunteer and intervention therapist agreed to during the prior intervention session requires the participant to have their caregiver/support person present when they engage in an activity, and the participant subsequently reports that they completed the activity alone.
- The volunteer is re-hospitalized for any medical reason during the assessment or intervention period. Depending on the circumstances of the re-hospitalization, the volunteer may be offered partial withdrawal (i.e., terminate intervention but complete the Week 8 assessments and/or study exit interview).

12.2 Withdrawal Procedures: Volunteers who notify study staff verbally and/or in writing that they wish to withdraw from the study will be offered the choice of full withdrawal or partial withdrawal. Full withdrawal constitutes no further intervention sessions or data collection. Data that were collected prior to the date and time of the volunteer's notification to study staff will be maintained under their study ID code for analysis. Partial withdrawal constitutes no further intervention sessions and agreement to be contacted for subsequent assessment and interview timepoints. The staff member whom the volunteer notifies will document the conversation in the study record, including whether the volunteer has elected full or partial withdrawal, and (if the staff member notified is not the PI) will notify the PI. If the volunteer notifies the study in writing that they wish for their previously collected data to be destroyed, the study team will destroy all previously collected data (including REDCap record, activity monitoring files, and audiorecorded interviews and intervention sessions)

12.3 Termination Procedures: If the study is suspended or terminated, the study team will cease all research activities. The study team will immediately take the following steps to notify volunteers based on their status in the study:

- Currently wearing activPAL Monitor during Week 1 or Week 8 assessments: The study team will contact volunteers and request that they immediately remove the activPAL monitor and return it to the study team using the pre-paid envelope that is provided with each device.
- Currently completing intervention sessions: The study team will contact the volunteers to notify them that the study has been terminated and that all scheduled intervention sessions have been cancelled.
- Scheduled for upcoming assessment sessions (Week 1, Week 8) or interviews (Interview 1, Interview 2): The study team will contact the volunteers to notify them that the study has been terminated and that all scheduled assessment sessions and interviews have been cancelled.
- Scheduled for upcoming informed consent meeting: The study team will contact the interested volunteer to notify them that the study has been terminated and that enrollment has been closed to new volunteers.
- All data collected prior to study termination will be maintained in its coded form to allow data analysis. Identifiers will be destroyed and data will be maintained in its deidentified form after it is confirmed that the study is permanently closed to new enrollment.

13.0 Risks to Participants

13.1 Foreseeable Risks:

- **Distress or fatigue associated with clinical questionnaires, performance measures, interviews, or intervention performed as part of participation in the study:** Questionnaires, performance measures, interviews, and intervention will be delivered by research assistants trained and supervised by the PI, an occupational therapist with more than 10 years of experience working with the stroke population. Participants who experience distress, embarrassment, or fatigue will be able to take breaks during testing and intervention session. If needed, testing may be completed in multiple short sessions.
- **Discomfort or mild skin irritation associated with the activPAL activity monitoring protocol:** The adhesive used to adhere the ActivPAL monitor to the participant's thigh is a common adhesive used in the healthcare setting. Participants who have a history of skin irritation are excluded from the study. Participants will receive instructions to monitor their skin for signs of irritation. If skin irritation occurs during the study, the participant will be instructed to transfer the activPAL to the opposite leg and continue to monitor for signs of irritation. Should irritation persist, participants will be instructed to remove the device and alternative strategies for activity monitoring will be explored (e.g., alternative wearing

schedules, use of non-adhesive strategies for maintaining device position).

- **Risk for injury (such as a fall-related injury) while engaging in daily activities planned during intervention processes:** Intervention processes will be supervised by the PI, a licensed occupational therapist with more than 10 years of experience in stroke rehabilitation. While planning activities, participants will be directly prompted to identify possible safety concerns and develop plans to assure safety (e.g. involve support person). Activities planned during intervention are daily activities that stroke survivors encounter in daily life outside of intervention. As such, engaging in these activities pose minimal risk. In addition, during activity planning, the study interventionist will also follow a safety protocol that clarifies whether the presence of a support person is required when completing the participant's chosen activity (see Appendix A). In the event of an injury associated with intervention, participants will be instructed to seek appropriate medical care.
- **Identification of severe depressive symptoms.** During the assessments, we will use the Neuro-QOL Depression Short Form to measure depressive symptoms. This is a validated measure of depressive symptom load among people with stroke [62]. A raw score of ≥26 on this measure indicates that the participant is experiencing severe depressive symptoms. If the participant meets or exceeds this score of 26 on this measure, the study team will verbally discuss the results with the participant, provide the participant with a packet (via electronic mail) which contains mental health crisis support information and an education sheet on mental health after stroke published by the American Congress of Rehabilitation Medicine, and encourage the participant to discuss these symptoms with their primary care physician
- **Inconvenience caused by study visits and telephone calls:** Study visits and telephone calls will be scheduled according to the participants' preferences, including options for evening and weekend visits. We will also minimize inconvenience by using individual participants' preferred forms of contact for scheduling and session reminders (e.g. telephone call, email, text messaging).
- **The potential for breach of confidentiality:** All identifiable information will be stored separate from the participant's research data. Each participant will be assigned a unique study ID number. Electronic data will be stored in an encrypted and password-protected database (REDCap) and in the UMN University Box Secure Storage.

13.2 Reproduction Risks: Not applicable

13.3 Risks to Others: Not applicable

14.0 Potential Benefits to Participants

14.1 Potential Benefits: There is potential that participants may derive benefit from participation in the teleABLE intervention, however there is no guarantee. Participants may experience improvements in sedentary behavior and health-related quality of life.

15.0 Statistical Considerations

15.1 Data Analysis Plan: The purpose of this formative research is to refine our research and intervention protocol based on (1) qualitative analyses of stakeholder data and (2) descriptive analyses of process data.

(1) **Stakeholder data:** Audiorecorded interviews will be transcribed and interview transcripts, intervention session notes, and therapist reflective logs will be read by two researchers who will identify codes and, subsequently, themes that guide research protocol refinement and intervention protocol refinement. Discrepancies will be resolved through discussion with a third researcher.

(2) **Process data:** Audiorecorded intervention sessions will be rated against the teleABLE Intervention Checklist by an independent assessor to indicate the presence or absence of the intervention components in each session. Study documentation related to attendance (sessions/week) and safety (adverse event count), and participant rating of satisfaction (Client Satisfaction Questionnaire-8) will also be computed. Descriptive process data will be compared against pre-established benchmarks.

15.2 Power Analysis: Because the focus of this research is to refine our research and intervention protocol, the sample size was selected based on the data required to inform these protocols rather than tests of statistical significance. All volunteers will complete assessments at 2 time points, 12 intervention sessions, and 2 interviews. Once data are collected from 5 volunteers (60 intervention sessions, 10 interviews), thematic analyses will be initiated. Additional volunteers will be recruited as needed to achieve thematic saturation. We anticipate achieving thematic saturation with 5-10 participants (60-120 intervention sessions, 10-20 interviews).

15.3 Statistical Analysis: Descriptive sample statistics will be computed to describe (1) presence of intervention components in each session, (2) number of sessions attended/week, (3) adverse event count, and (4) satisfaction [Client Satisfaction Questionnaire-8]. These scores will be compared against pre-established benchmarks for (1) intervention components present in ≥90% of sessions, (2) 1.5

to 2.5 sessions attended/week, (3) ≤ 1 adverse event, and (4) mean Client Satisfaction Questionnaire-8 score ≥3.

15.4 Data Integrity: Data will be collected and monitored using strategies to assure data integrity.

Data collection: Questionnaire-based data and interviews will be collected over synchronous videoconferencing where the volunteer provides verbal response and the assessor directly enters the response into REDCap (questionnaires) or audiorecords (interviews). At the end of the assessment or interview session, the assessor will complete a checklist to confirm that all questionnaires and interviews were completed, and that the interview was uploaded to the appropriate secure folder. Reasons for missing data will be documented. Instructions for activPAL monitoring will also be provided during the assessment session, and the assessor will follow up with the participant via telephone within 48 hours to confirm that the monitor was donned appropriately. Intervention documentation will be entered by the treating therapist in REDCap as soon as possible following session completion, with the expectation that session documentation will be completed within 48 hours.

Data monitoring: The PI will meet with the study team on a weekly basis to review the status of the study. This will include reviewing the results of (1) chart audits of study records of completed volunteers to assure completeness of data and contemporary documentation of reasons for missingness, (2) data reports from baseline and post-intervention timepoints to identify and resolve data entry errors (e.g., scores outside of possible range), and (3) monitor current volunteer status in study including an opportunity for the assessor and/or interventionist to identify problems and solutions that may have occurred during data collection.

16.0 Health Information and Privacy Compliance

16.1 Select which of the following is applicable to your research:

☐ My research does not require access to individual health information and therefore assert HIPAA does not apply.

☒ I am requesting that all research participants sign a HIPCO approved HIPAA Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

Appropriate Use for Research: N/A

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

16.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

☒ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

☒ I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

☐ Other. Describe: N/A

16.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

PHI data will only be collected directly from volunteers who have provided informed consent to participate in the study. Data retrieved from the Informatics Consulting Service through the CTSI for recruitment will be filtered by Informatics Consulting Service staff to include only those patients who have agreed to have their information used for research. However, providers who have a treating relationship with the patient ***may*** discuss research opportunities during a clinical encounter regardless of research opt-out status and opt-out status will not matter if a participant contacts us first.

16.4 Approximate number of records required for review: 3,700

16.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

☒ Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants.

Throughout the course of the study, communication with research volunteers will occur via mail, telephone calls, videoconferencing, and if requested by the volunteers to minimize burden, text messages and/or emails.

Mail: The study team will mail paper copies of the informed consent document, study materials (workbook, activity monitoring supplies), and study remuneration materials (ClinCard).

Telephone calls: The study team will use telephone calls for the purposes of scheduling study visits, appointment reminders, study screening, and general study communications as needed.

Videoconferencing: The study team will use the University of Minnesota Health Care Component Zoom account to interact with participants on their own devices to complete study assessments, interviews, and intervention sessions.

Text messages: The study team will use text messages on a limited basis for the purpose of sending appointment reminders and scheduling. Text messages will only be used if the participant specifically requests method of communication.

Emails: The study team will use email on a limited basis for the purpose of sending blank informed consent documents in preparation for the study consent meeting and sending appointment reminders. No PHI will be sent using email. Email will only be used if the participant specifically requests to receive materials and/or appointment reminders using this modality. We are requesting a waiver of the use of encrypted email to send study appointment reminders and blank informed consent documents

16.6 Explain how the research team has legitimate access to patients/potential participants:

The research team will not access medical records of enrolled volunteers. Private information about volunteers who are enrolled in the study will be collected by study staff directly from the volunteers themselves. Because the volunteers have enrolled in the study, signed a HIPAA authorization form at the time of informed consent and are willingly providing the information as approved by the IRB, the study team has legitimate access to these data.

16.7 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☒ In the data shelter of the Information Exchange (IE)

☒ Store ☒ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store ☐ Analyze ☐ Share

☒ In REDCap (recap.ahc.umn.edu)

☒ Store ☒ Analyze ☒ Share

☐ In Qualtrics (qualtrics.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐ In OnCore (oncore.umn.edu)

☐ Store ☐ Analyze ☐ Share

☒ In the University's Box Secure Storage (box.umn.edu)

☒ Store ☒ Analyze ☒ Share

☐ In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

☐ Store ☐ Analyze ☐ Share

☐☒ In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices: We are working with HST IT to establish access to a remote HST/Citrix desktop which will be used to store, access, and analyze identifiable data through REDCap and Box.

☐☒ Store ☐☒ Analyze ☐ Share

☐ Other. Describe:

Describe in detail the location and whether the data / specimens will be stored, analyzed, or shared, and in what ways.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐ I will use a server not previously listed to collect/download research data

☒ I will use a desktop or laptop not previously listed: Research staff will use university-owned DWELL Laboratory laptops supported by the College of Education and Human Development IT team to analyze deidentified data using local programs (e.g., SPSS, R, NVivo, PalTechnologies). Deidentified datasets and output from analyses will be stored on BOX.

☐ I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

16.8 Consultants. Vendors. Third Parties.

BrightOutcome: The electronic version of the Activity Card Sort (ACS3) is completed using an online system managed by BrightOutcome (Buffalo Grove, IL, USA). The data collected using this system will only be identified using the study ID code. No direct identifiers will be entered. The ACS3 is encrypted using AES-256-CBC. Data will be exported from BrightOutcome via .csv files and stored in the University of Minnesota Box Secure folder.

PalTechnologies: Data collected using the activPAL monitors will be processed and data visualizations will be created using PalAnalysis (PalTechnologies, Glasgow, Scotland). The data collected using activPAL monitors will only be identified using the study ID code. No direct identifiers will be entered. This software is downloaded and runs locally using a university-owned computer.

16.9 Links to identifiable data: Numeric study codes will be assigned by the research team sequentially upon volunteer enrollment into the study. The only place where the volunteer's name and number will be linked are the linking file stored in the REDCap database. All fields on the linking file form will be marked as identifiers. The linking file form will be deleted from the REDCap database by the PI after the study is completed and the federal requirements for record retention has lapsed.

16.10 Sharing of Data with Research Team Members. Research team members will be granted access to the REDCap database, BrightOutcome portal, and/or shared University of Minnesota Secure Box folder based on the data that they require to complete their role in the study. Team members will only access these files and portals from a university-owned laboratory device

16.11 Storage of Documents: Paper documents generated as a result of this research project will be stored in a locked filing cabinet in Dr. Kringle's private locked office in the School of Kinesiology (located at Cooke Hall). Electronic documents generated as a result of this research project will be stored on the University of Minnesota Secure Box folder and on DWELL Laboratory devices.

16.12 Disposal of Documents: All data will be retained for a minimum of 3 years, in alignment with the NIH retention policy. After 3 years, the linking file will be destroyed as described in section 16.9. Deidentified data and audiorecordings of interviews and intervention sessions will be retained on the University of Minnesota Secure Box folder in perpetuity to allow for secondary analyses of the data and to support future laboratory staff training to the intervention protocol.

17.0 Confidentiality

17.1 Data Security: Data collected electronically will be stored in the University of Minnesota Box Secure Storage and REDCap. These data will be accessed using University-owned password-protected computers and access to research data stored in these systems will be provided to trained study staff who require access to data relevant to their role on the study. All data will be stored using a study ID code, and the only place where the participant's name and study ID code are linked will be in the REDCap linking form. All fields in the REDCap linking form will be marked as identifiers to prevent the export of identifiers. Paper documentation generated as a result of this study will be stored in a locked file cabinet in the locked DWELL Research Laboratory in the School of Kinesiology. Informed consent will be completed electronically and completed consent documents will be stored in a REDCap project separate from the participant's study data. A copy of the consent form will **not** be placed in the participant's medical record. Only study staff who require access to electronic or paper files will be granted access. These staff will be required to complete HIPAA, ISP, and CITI training modules on Good Clinical Practice prior to receiving access to these data. This is an NIH-funded study, and therefore all data are protected under a certificate of confidentiality.

17.2 Data Sharing: There are no current plans for data sharing. Upon completion of the study, a master de-identified dataset will be created and stored in the study BOX site. This dataset will include questionnaire data, raw and processed activPAL data, and transcribed interview data. Upon request for data sharing, the PI will follow procedures to establish a data use agreement that provides only the necessary data from the master de-identified dataset.

18.0 Provisions to Monitor the Data to Ensure the Safety of Participants

18.1 Data Integrity Monitoring. Data integrity will be monitored by the PI, who has over 10 years of experience working with people with stroke-related disability in clinical (as an occupational therapist) and research settings. The following strategies will be applied:

1. The study team will notify the PI of new study enrollments and the PI will review the screening documentation form within 2 business days to confirm eligibility to proceed with the informed consent meeting.

2. Procedural checklists will be reviewed for completeness following each study visit by the study staff responsible for each visit. Reasons for missing data will be documented in REDCap.
3. The PI will hold weekly meetings with the study team to review study enrollment, monitor volunteer progression through study procedures, review case report forms, and monitor adverse events. Meetings will be documented and meeting minutes will be stored electronically with the study files in the University of Minnesota Box Secure Storage.

18.2 Data Safety Monitoring. This study will be overseen by a data safety monitor external to the trial and institution who has expertise in neurorehabilitation trials. The PI will meet with the data safety monitor every 6 months to review a report that includes: participant accrual, adverse events data, and data completeness. Adverse events data will be collected at two timepoints during the study: (1) during the interview 1 session, and (2) during post-intervention assessments. Data will be collected over the telephone or Zoom using a questionnaire. Ad hoc reports of adverse events will also be collected by any study staff who become aware of an adverse event during any study interaction. Whomever first identifies the adverse event will complete an ad hoc form and notify the PI who will determine appropriate follow-up actions and reporting.

19.0 Provisions to Protect the Privacy Interests of Participants

19.1 Protecting Privacy: Participants' privacy will be protected throughout all interactions with the study team and in the handling of data.

Study interactions: All study visits will take place using the University of Minnesota Health Care Component Zoom portal, which is HIPAA-compliant. Participants will be encouraged to access Zoom from a private space of their choosing with no others present. If they prefer, they may use headphones to enhance privacy. Study staff will interact with participants from a private space in the School of Kinesiology or a room in their home with no other people present and a closed door (if working remotely). If not on campus, study staff will access Zoom using a private/secure internet connection. Before each assessment session and interview, participants will be reminded that they are not required to answer the questions posed, and that they may tell the study staff that they do not wish to answer particular question/s at any time during the session.

Data handling: All data collected from participants will be entered into the study database, approved web applications (REDCap, BrightOutcome), or saved to the University of Minnesota Secure BOX storage using university-owned computers. Data will be stored using the study ID code rather than participants' names. Only study staff who require access to the data to complete their study-related tasks will be granted access to the data.

19.2 Access to Participants*:* All data will be provided to the research team by the study participants. Participants will be fully informed of the ways in which their data will/may be used during the informed consent process. The research team has been trained in conducting these conversations and the participants are also assessed for their understanding of consent prior to initiating any study procedures.

20.0 Compensation for Research-Related Injury

20.1 Compensation for Research-Related Injury: In the event that research-related activities result in an injury, treatment will be provided to the participant (e.g., first aid, emergency treatment, and follow-up care as needed). Care for such injuries will be billed in the ordinary manner to the participant or the participant's insurance company.

20.2 Contract Language: N/A

21.0 Consent Process

21.1 Consent Process (when consent will be obtained): Informed consent will occur in a phased manner throughout (1) telephone screening, and (2) study enrollment, (3) ongoing consent.

1. Telephone screening: Participants who contact the DWELL Laboratory to express interest in participating in the study will provide verbal informed consent prior to completing the screening questions. Consent to complete telephone screening will be obtained by study staff who are trained and supervised by the PI. During the telephone screening call, participants will receive general information on the study procedures, detailed information on the telephone screening process, including their right to decide not to participate, and be informed of the risks associated with completing the telephone interview (i.e., breach of confidentiality, mild distress related to questions). Screening questions will be asked only after the potential participant has received this information, been offered an opportunity to ask questions, and verbally indicated that they would like to complete the telephone screening process. We are requesting a <u>waiver of documentation of informed consent</u> for this screening process (see below).
2. Study enrollment: Participants who are deemed eligible to participate in the study based on the telephone screening will be scheduled for a Zoom meeting with a study staff member who is trained and supervised by the PI. The potential participant will be encouraged to invite a support person to this meeting, and to join the meeting from a location where they will be comfortable discussing their possible participation in the study. Prior to the meeting, a blank copy of the

consent form will be sent to the potential participant in either hard copy or electronic format (based on the potential participant's preference). This form will contain the combined HIPAA Authorization/Consent document (HRP-593). During this meeting, the study staff member will review the informed consent document and provide opportunities for the potential participant and their support person to ask questions. Questions will be actively invited, and once all questions have been answered, the study staff will provide time for the potential participant and their support person to discuss their decision without study staff present (i.e. Zoom camera and microphone muted). If the potential participant decides to provide informed consent, the study staff will ask the potential participant 3 teach-back questions: (1) what are they being asked to do if they agree to participate in the study, (2) what risks are associated with the study, and (3) if they decide they no longer wish to participate in the study, how would they go about withdrawing. After the potential participant has responded to these questions accurately, the study staff will send a survey link to the eConsent form to allow the potential participant to sign electronically via REDCap.

3. Ongoing consent: At the beginning of each study visit, the study staff who are leading the visit will explain the purpose of the visit, the estimated time that the visit will require, and obtain verbal affirmation/permission from participant regarding their willingness to complete the study visit

21.2 Waiver or Alteration of Consent Process (when consent will not be obtained): N/A

21.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained):

We are requesting a waiver of written informed consent to screen interested potential participants over the telephone. The telephone screening poses no more than minimal risk. Participants will respond to questions related to their age, stroke diagnosis, mobility status, daily activities, depressive symptoms, and medical comorbidities. In addition, it is impractical to ask people who have stroke-related disability to travel to the university to complete written consent for a 15-minute questionnaire for the purpose of determining their eligibility. The telephone screening will be conducted by a member of the research team supervised by Dr. Kringle, who is a licensed occupational therapist with 10 years of clinical and research experience directly interacting with people with stroke-related disability. During the telephone screening call, participants will receive general information on the study procedures, detailed information on the telephone screening process, including their right to decide not to participate, and be informed of the minimal risks associated with completing the telephone

interview. If the participant verbally agrees to answer the screening questions, verbal consent will be documented electronically by the research assistant and the telephone screening questions will be completed.

21.4 Non-English Speaking Participants: N/A

21.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): N/A

21.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent: N/A

21.7 Adults Unable to Consent: N/A

22.0 Setting

22.1 Research Sites:

1. The research team will primarily identify volunteers through: (1) distribution of flyers through the Allina Health System/Courage Kenny Rehabilitation Institute's Stroke Program and community stroke support groups. We will also partner with Fairview Research Administration to mail study invitations to potential participants identified through the University of Minnesota's Clinical and Translational Science Institute's (CTSI) Clinical Data Repository (CDR) that is hosted by the Academic Health Center Information Exchange (AHC-IE).

   People who learn about the study through flyers or invitation letters and who are interested in participating in this study will reach out to the research team via email or telephone.
2. All study activities will completed from the participant's home using their personal device to access Zoom videoconferencing to interact with the study team.
3. There is currently no community advisory board for this study.
4. Apart from distributing recruitment flyers and study invitation letters, all study activities will take place in the Disability and WELLness Laboratory which is part of the School of Kinesiology at the University of Minnesota.

   Allina Health System/Courage Kenny Rehabilitation Institute: Following approval of the University of Minnesota IRB application, the approved IRB will be submitted to the Determination of Engagement Review Process during which the Allina Health System IRB will determine whether its staff may distribute flyers to patients in that health system.

22.2 International Research: N/A

23.0 Multi-Site Research

N/A

24.0 Coordinating Center Research

N/A

24.1 Role: N/A

24.2 Responsibilities: N/A

24.3 Oversight: N/A

24.4 Collection and Management of Data: N/A

25.0 Resources Available

25.1 Resources Available: This research is funded by an NIH K23 award (K23 HL159240). In addition, the study has access to the following resources:

Access to potential participants: Dr. Kringle has an established relationship with providers at Courage Kenny Rehabilitation Institute/Allina Health System which provides care to approximately 2700 stroke patients annually. In addition, Fairview Health System treated approximately 5000 stroke patients within the past year. These systems will support recruitment of 5 to 10 participants over 3 to 6 months.

Staff support towards this project: Dr. Kringle is supported by an NIH K23 award which provides 75% effort dedicated to this research. In addition, the Disability and WELLness (DWELL) Laboratory team, which is led by Dr. Kringle, consists of a research occupational therapist who has experience with the intervention under study and a part-time research coordinator who will dedicate 8 to 10 hours/week to this research.

Study facilities and supplies: All study visits are completed remotely. The study team members will use university-owned devices to conduct study visits. The DWELL Research Team has access to private space in the School of Kinesiology from which study visits will be held. Study staff who are work remotely will identify a private work space that has a door and private/secured internet connection from which they will hold study visits.

Medical or psychological resources: If a participant reports an event that requires medical attention, they will be advised to seek care at the healthcare facility that they would typically access and/or the nearest emergency medical center. If a participant scores ≥26 (raw score) on the NeuroQOL Depression questionnaire, they will be provided with information on accessing mental health resources, including national mental health crisis line information and an educational page regarding mental health after stroke published by the American Congress of Rehabilitation Medicine and which contains additional information on accessing mental health resources.

Study personnel orientation: All personnel who are assisting with this research will complete a study onboarding process led by Dr. Kringle that includes a broad overview of the study protocol (including access to the full study protocol) and training to criterion in the research procedures that the individual study staff

member is responsible for carrying out. In addition, all personnel will receive initial and ongoing training in the responsible conduct of research, adverse event identification and reporting, Good Clinical Practice, HIPAA compliance, and information security and data safety practices. Initial training will be guided by an onboarding checklist. Ongoing training will occur as part of routine laboratory meetings.

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