

**The Feasibility, Usability, and Acceptability of Using the Oculus™
Virtual Reality Gaming Technology in Stroke Survivors for Upper Extremity and
Cognitive Rehabilitation**

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Protocol Title: The Feasibility, Usability, and Acceptability of Using the Oculus™ Virtual Reality Gaming Technology in Stroke Survivors for Upper Extremity and Cognitive Rehabilitation

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Population: Stroke survivors and caregivers (n= 20 dyads) reflecting a range of stroke subtypes, disabilities, and races/ ethnicities will be recruited.

Number of Sites: 1 – Aging in Place (AIP) apartment, University of Texas Health Science Center at Houston

Study Duration: November 2022 – October 2023

General Information

- Primary Specific Aims (See Figure 1):
 - **S.A.1.** To test the (a) feasibility, (b) usability, and (c) acceptability of using the Oculus VR for chronic stroke survivors (6 months-5 years) who have mild-moderate cognitive and unilateral arm impairment to administer upper extremity and cognitive rehabilitation (n=20 dyads).-
 - **SA 2:** To calculate the change in upper extremity (Fugl-Meyer, ARAT) and cognition (MoCA) scores on standardized measurements per standard of care (n=20 dyads).
 - **S.A.3.** To qualitatively explore the impact of engaging caregivers in supporting the stroke survivor's rehabilitation and the impact of this engagement on the stroke survivor and caregiver dyad using semi-structured interviews. (n=20 dyads).
- Objectives:
 - Our overall objective in this application is first to determine whether Oculus VR is feasible, usable, and acceptable to stroke survivors who have chronic mild-moderate cognitive and upper extremity deficits. Our secondary objective is to explore the impact of the rehabilitation sessions using the Oculus VR on the caregiver-stroke survivor dyad

Background/Significance

- **A.1 Stroke Patients Need Long-term Upper Motor and Cognitive Rehabilitation.** Over half of stroke patients develop arm weakness post-injury.¹¹ A third to half of stroke patients develop cognitive impairment (CI) within the first 6 months of injury,^{2,3} and 1 in 5 stroke patients develop dementia.¹² These disabilities impact independence and impede returning to work. Stroke rehabilitation is the most important means for gaining functional recovery in stroke survivors.^{6,13} Chronic stroke survivors (\geq 6 months post-stroke) need upper extremity and cognitive therapies to prevent contractures and cognitive decline.⁶

- **A.2 Access to Stroke Rehabilitation is a Critical Health Care Problem.** In spite of the importance of stroke rehabilitation to functional outcomes, many stroke survivors have reduced access to stroke rehabilitation. More than half of all stroke survivors experience reduced mobility¹ and are often dependent on their caregiver for transportation. The average cost of outpatient stroke rehabilitation at \$17,000 during the first year after discharge from inpatient settings that is not covered by all forms of health insurance.⁷ Only a third of stroke survivors participate in outpatient stroke rehabilitation,¹³ and one study found that 57% of stroke survivors do not receive the recommended outpatient rehabilitation 6 months following discharge from inpatient facilities.⁸ Further, only 71% stroke patients who live in rural Texas have access to outpatient stroke rehabilitation services.¹⁴
- **A.3 Telerehabilitation Outcomes are Similar to Face-to-Face Rehabilitation.** Home-based stroke rehabilitation using telehealth technologies (e.g., telerehabilitation) increases access to stroke rehabilitation because it does not require transportation to a clinic, is accessible to stroke survivors who live in rural areas and is less costly¹⁵ than rehabilitation in the clinical setting. Studies have shown that stroke survivors who receive telerehabilitation have similar upper extremity⁹ and cognitive¹⁶ functional gains to those who received face-to-face rehabilitation.
- **A.4 Virtual Reality Enhances Stroke Rehabilitation Outcomes.** The VR gaming environment allows the user to interact with a computer-generated world.¹⁷ Studies have shown that stroke rehabilitation using gaming (e.g., Xbox) improves upper arm mobility^{18,19} and cognition.²⁰ Immersive VR using headsets allow the user to interact with and be fully immersed in a 3-D environment. A recent study used the HTC Vive headset in the clinical setting to deliver upper extremity stroke rehabilitation (n=12) who were 3 to 6 months post-stroke and found that there was significant improvement in arm mobility compared to stroke survivors who received standard of care (n=11; P<.05).²¹ However, the HTC Vive VR system is triple the cost of the Oculus VR and requires a computer and fixed sensors. Research is needed to determine the feasibility and usability of the Oculus VR for upper extremity and cognitive telerehabilitation in stroke patients.
- **A.5. Dual Tasking is a Novel Approach to Stroke Rehabilitation.** Combining motor and cognitive rehabilitation, known as dual-tasking, encourages neuro-stimulation and interaction between multiple brain regions. This is thought to promote neuroplasticity, the brain's ability to develop new neuronal connections and may lead to improved functional recovery.²² The use of cognitive stimulation in conjunction with physical exercise in older adults has been shown to improve episodic memory, visual attention, and functional mobility.²³ The Oculus VR is a novel way to promote dual-tasking for stroke rehabilitation.
- **A.6 Success of Remote Stroke Rehabilitation Depends on Caregiver Participation for Sustainability.** A significant barrier to stroke survivors accessing rehabilitation is the time burden and travel to appointments due to immobility, geographical distance, and caregiver work obligations.²⁴ During the COVID 19 pandemic, family caregivers of stroke survivors expressed uneasiness when unable to attend rehabilitation appointments due to COVID regulations.²⁵ Remote stroke rehabilitation may effectively address these barriers. Stroke survivors' motivation to engage in rehabilitation sessions has been shown to be positively influenced by positive reinforcement from the rehabilitation therapist.²⁶ Galvin and colleagues found that stroke patients (n=24) who received assistance/ feedback from a family caregiver during inpatient rehabilitation sessions had better motor outcomes than patients in the control group who did not receive input from a family member (n=20; P<.05).²⁷ Family members who participated during inpatient rehabilitation experienced lower caregiver stress than those in the control group (P<.01). Another study demonstrated that persons with dementia whose caregivers assisted with cognitive rehabilitation had improved memory as compared to the

control groups that did not involve caregivers.²⁸ Caregiver participation during rehabilitation may be essential for the sustainability of home-based cognitive and motor rehabilitation outcomes but has not been well-studied.

Population/ Sample Size

- Inclusion Criteria:
 - Ischemic, hemorrhagic, or subarachnoid hemorrhage (SAH) stroke diagnosis within 6 months to 5 years of enrollment. If the participant had a brain aneurysm then it must be secured. MRI report may be requested to confirm diagnosis or deficits as needed. Dyads will be included if they 1) are ≥ 18 years old; 2) can read, write, comprehend, speak English; and 3) are willing and able to provide informed consent. Caregivers must live in the home with the stroke survivor.
- Exclusion Criteria:
 - Stroke survivors will be excluded if they do not have score ranges that indicate mild to moderate severity on prior post-stroke neuropsychological tests, or the MoCA (15-25) using normative data based on education, age, and other standard demographic data, or other appropriate cognitive screening test selected by the speech language pathologist (also on this application) if the participant has aphasia, hemiopsia, other neurological or specific cognitive deficits, or demographic factors (e.g., education level) that prevents the participant from being accurately examined using MoCA or a modified MoCA; if cognition is within normal range then a FM (20-50), if they are unstable while standing unassisted, have a history of motion sickness/ vertigo/ dizziness/ seizures (a doctor's note will be requested for participants who do not believe their seizures will be triggered by the VR), claustrophobia, blind/deaf, and cannot hold the controller in their affected arm with or without the use of assistance.

Study Design/Methods

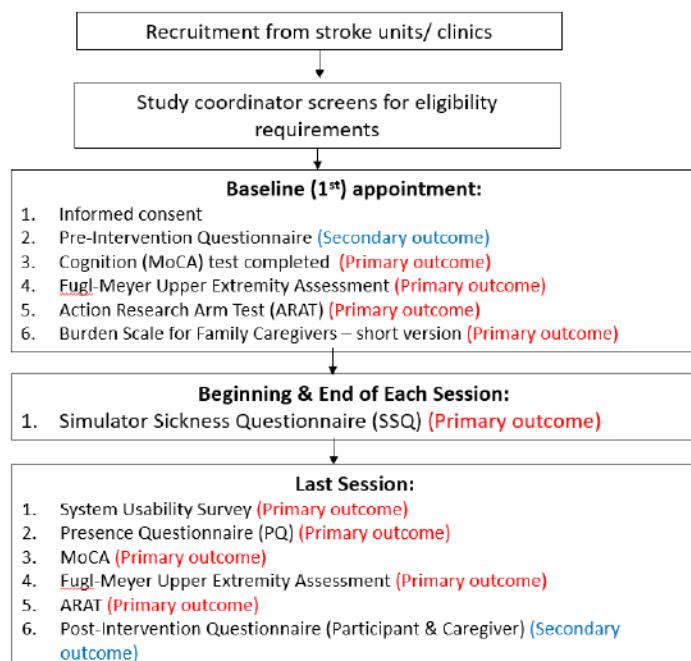


Figure 1: Study Schema

- Figure 1 depicts the overall study schema or flow as described below.

- Study Overview:
 - **S.A.1.** With the current drive for telerehabilitation and the advent of VR headsets, the examination of human factors perspectives is necessary before full implementation. End user perspectives regarding the impact, perceived usefulness, and perceived ease of use are essential, particularly in the older stroke population.
 - **S.A.2.** The rehabilitation team will measure changes on standardized measurements as part of standard of care.
 - **S.A.3.** Understanding the role of caregiver engagement upon stroke survivor rehabilitation outcomes and its potential impact on the quality of dyadic interpersonal relations is imperative for the sustainability of using VR for stroke rehabilitation in the home.
- Recruitment:
 - We will recruit 20 stroke survivor dyads (n=40) from the
 - Place: UT Physicians Department of Neurology Stroke Clinic, Brain and Behavioral Health Clinic, TIRR, Memorial Hermann, and Stroke Survivor Support Groups. In 2021, the clinic treated approximately 1000 stroke patients. Based on our knowledge of the clinic and previous experiences with stroke trial enrollment, enrolling 20 dyads over a 6-month recruitment period will be feasible. All rehabilitation sessions will take place in the Aging in Place (AIP) apartment.
 - Subjects meeting inclusion criteria will be offered participation incentives of \$100.00 (\$40 gift cards will be given at the first session and \$60 will be given at the final session) as well as parking reimbursement for each session to take place at the Cizik School of Nursing.
- Pre-Screening and Measurements:
 - Measurement objectives are to (1) determine study eligibility, (2) obtain demographic data, and (3) evaluate acceptability measures (4) assess perceived usefulness, ease of use, and attitude toward using the technology by conducting usability surveys and interviews. The informed consent document and quantitative measures will be available in English and accessible via REDCap.^{30,31}
 - Study personnel will determine if participants are cognitively able to consent by pre-screening participants with the following questions:
 1. *Have you/the participant ever been diagnosed by a doctor with dementia?*
 2. *Think about your/their abilities 10 years ago compared to the day before your/their stroke. Is your/their ability to make decisions on everyday matters better, the same, or worse?*
 - Please see Appendix A for the list of instruments and their psychometric data. See Figure 2 for primary and secondary outcomes and their timepoints.

Intervention

- The AIP apartment (See Appendix B) is a unique lab setting that simulates a real-world apartment. It is well-equipped with cameras to monitor the participant's rehabilitation session and their interaction with the therapist and caregiver and offers a typical living room with a smart television, an ideal setting for proof of concept of using the Oculus VR using the Job Simulator game (Appendix C) for remote stroke rehabilitation.
- Upon successful completion of this research, we expect our contribution to determine the

feasibility, usability, and acceptability of the Oculus VR for stroke rehabilitation in chronic stroke patients.

- This contribution is innovative because to the best of our knowledge no studies have evaluated the use of the Oculus VR in stroke patients stroke rehabilitation.
 - The Oculus VR engages two brain domains simultaneously and this may prove to be a novel and effective form of stroke rehabilitation.
- Our intervention has been developed in partnership with experienced stroke rehabilitation experts so that it can be easily implemented in any setting.
- We believe that this study will generate an estimate of the effect that can be used to inform the development of randomized controlled studies (RCTs).
 - This study will also generate RCTs examining the use of the Oculus VR as a form of stroke rehabilitation that is scalable to the participant's home setting.
 - There are few studies that have examined the role of caregiver engagement on the success of remote stroke rehabilitation.
- The caregiver will be encouraged to use Caregiver Cues (Appendix D) as this will help the caregiver to engage with the participant using encouragement or positive cues to the stroke participants to support them during the session.
- The therapist or RA (who will be trained by the therapist) who is conducting the session will use the Therapist Guided Cues (Appendix E) to guide the stroke participant with problem solving and planning for performing home exercises that will be provided to the participant at the first session.
- The data we obtain from caregivers and stroke survivors (dyads) will inform future studies that examine ways to best support the dyads to improve stroke rehabilitation outcomes and reduce stress in the caregivers. (See Appendix F)

Statistical Analysis

- To address S.A.1., feasibility, usability, and acceptability of the Oculus VR headsets for upper extremity and cognitive therapies will be analyzed as follows: Feasibility: Assessed from the number sessions attended and time spent using the Oculus VR. The minimum number of sessions expected for a user are 2 per week (8 sessions) and the minimum time spent playing Job Simulator is 1 hour per week (4 hours) through the end of the study. Descriptive statistics of the participation rates and measures including frequencies, median and interquartile ranges for sessions attended and time spent using the game. Usability: Descriptive statistics for demographic and clinical data and participant scores on the SUS and PQ will be calculated. (See Appendix G and H) We will refrain from using inferential statistics since this is a pilot study and hypothesis testing is not the objective. Acceptability: Descriptive statistics for scores on the SSQ will be calculated at baseline and after each session (See Appendix I). We will examine the trend of symptoms for each participant.)
- To address S.A.2. As part of standard of care, we will calculate change in arm and cognitive scores for each stroke participant from the following tests: MoCA, FM, and ARAT. (See Appendix J, K, and L) After inspection of the distribution, either the paired t-test or the nonparametric Wilcoxon signed rank test will be used to evaluate the significance of the difference score. However, statistical inference is not the primary interest of this pilot study. The effect size provided by Cohen's d measure, i.e., the standardized difference of mean score, will provide a preliminary measure of the effectiveness of Oculus VR in this pilot study. Similarly, standardized differences in the BSFC-s scores will provide the effect sizes for the change in caregiver burden.
- To address S.A.3., interview data will be analyzed following methods for thematic analysis.^{34,35} Using a qualitative data analysis program, Atlas.ti,³⁶ 2 researchers will review transcripts to gain a sense of the whole, identify codes, categories, and generate higher order themes to describe

the role of caregiver engagement during the session. Reasons for non-participation will be obtained from those eligible participants who decline participation. Unacceptable components and reasons for non-participation will be considered in the planning and designing of future trials.

Outcomes

- Upon completion of these aims, the expected outcomes are to develop randomized control trials (RCTs) to determine the effectiveness of the Oculus VR for stroke rehabilitation. We anticipate using the information from the dyadic interviews to develop qualitative studies and RCTs examining the role of the caregiver on remote stroke rehabilitation outcomes.
- Please see Table 1 (below) for the outcomes with timepoints.

Primary and Secondary Outcomes with Timepoints			
Primary	Timepoint	Secondary	Timepoint
MoCA (Appendix J)	Baseline and Last Session	Pre-Intervention Questionnaire (Appendix R)	Baseline Session
Fugl-Meyer (Appendix K)	Baseline and Last Session	Therapy Follow-Up Checklist (Appendix M)	Session 2 – Last Session
ARAT (Appendix L)	Baseline and Last Session	Post-Intervention Questionnaire (Appendix S)	Last Session
Caregiver Burden Scale (for caregiver only; Appendix F)	Baseline and Last Session		
Simulator Sickness Questionnaire (Appendix I)	Session 1 – Last Session		
System Usability Scale (Appendix G)	Last Session		
Presence Questionnaire (Appendix H)	Last Session		
Number of sessions attended; Duration (minutes) of session	Session 1 – Last Session		

Table 1

Potential Problems and Alternative Approaches

- If the participant cannot complete the study, then we will offer home exercises selected by the therapist from Appendix N and they will exit the study.
- Stroke survivors will be encouraged to take a brief break every 20 minutes due to potential for visual fatigue. If the participant develops simulator sickness (e.g., nausea, dizziness, etc.) or wishes to stop the session for any reason, we will immediately stop the session and allow the participant to rest until the symptoms subside.
 - If the participant's symptoms do not resolve immediately, then we will take the patient's blood pressure, pulse, and/ or temperature as appropriate.
 - We will call 911 should the participant require immediate assistance. If the participant does not require immediate care, we will encourage the participant to be evaluated at an urgent care and/ or their doctor's office.

- All adverse events will be monitored, documented, and reported to the ethics committees. Progress addressing adverse events will be recorded until their resolution.

Data Management

- We will record the Oculus gaming sessions using the camera located in the living room for the therapists to review after the session to evaluate the participants' progress.
- Informed consent documents and de-identified, demographic and participant satisfaction surveys will be stored electronically via REDCap,™ following UTHealth security procedures. Qualitative interview data will be digitally recorded; these raw audio files will be stored in a secure folder of the PI's UTHealth, OneDrive. Transcribed, de-identified interview data will be managed and analyzed via Atlas.ti.™

Collaboration and Interaction Plan

- The proposed interdisciplinary project brings together highly experienced investigators in diverse areas of research and clinical practices.
- The project is built from developing new collaborations between investigators across institutions including the University of Texas Health Science Center at Houston (UTHealth).
- The team will be led by
 - Seema Aggarwal, PhD, APRN, AGNP-C (Assistant Professor, UTHealth, Cizik School of Nursing), a gerontology nurse practitioner, nurse scientist, and Director of the Vascular Cognitive Impairment research program at the UTHealth, Institute for Stroke and Cerebrovascular Disease, has experience clinically evaluating and researching cognitive impairment in patients with acquired brain injuries including stroke and traumatic brain injuries.
 - Co-Principal Investigator, Mary Russell, DO, (Assistant Professor, UTHealth, McGovern Medical School), Medical Director of Inpatient Rehabilitation at TIRR Memorial Hermann-The Woodlands has expertise in stroke rehabilitation.
 - Xiaoqian Jiang, (Professor at UTHealth School of Biomedical Informatics) has well-funded experience in data analytics and artificial intelligence.) Carina Katigbak, PhD, MS, ANP-BC (Associate Professor, UTHealth, Cizik School of Nursing), has expertise in community-based interventions addressing health outcomes in vulnerable and underserved groups.
 - Co-Investigator, Emily Stevens, (Research Coordinator, UTHealth, UTHealth, Institute for Stroke and Cerebrovascular Disease), a licensed occupational therapist with expertise in the assessment and rehabilitation of upper extremity injuries in stroke patients.
 - Co-Investigator, Heather Smith, (Research Coordinator, UTHealth, UTHealth, Institute for Stroke and Cerebrovascular Disease), a licensed speech-language pathologist with expertise in the assessment and rehabilitation of functional expressive and receptive language, functional cognition, and visual attention in stroke patients.
 - Co-Investigator, Sean Savitz, MD (Professor, UTHealth, McGovern Medical School), Director of the UTHealth, Institute for Stroke and Cerebrovascular Disease and a neurologist with extensive experience in stroke care and a notable background in clinical stroke research.

Budget and Timelines

- Please see Appendix O for the budget, Appendix P for the overall study timeline and Appendix Q for the Timeline with the Study Outcomes and Endpoints.

Extramural Funding Plan

- Although descriptive, the proposed project would be the first to use the Oculus VR for upper extremity and cognitive therapies in stroke survivors while engaging their informal caregivers. The proposed project uses an innovative approach to stroke rehabilitation in a simulated home

environment.

- The data will serve as preliminary data for subsequent competitive, peer-reviewed extramural grant applications that address telerehabilitation in stroke survivors within the home and the role of their caregiver.
 - Specifically, the proposed project addresses priorities outlined by institutes (e.g., National Institute of Neurological Disorders and Stroke, National Institute of Aging and National Institute of Nursing Research) within the National Institutes of Health (NIH) by investigating innovative approaches to promote health and well-being in patients and their informal caregivers living within the confines of a chronic disease. Specifically, stroke survivor acceptability data and knowledge derived from commercially available VR headset technology are needed to demonstrate:
 - The technology is acceptable for at-home use in stroke populations
 - The technology is capable of effecting improvement in upper extremity motor movement and cognition in stroke survivors.
- We will use the data from the proposed project to determine and complete the needed modifications to the home rehabilitation program using the Oculus VR headset in the post-stroke population.
- The data from this study will be used to plan an RCT to test the effectiveness of the intervention on improving upper extremity functionality and cognitive outcomes that can lead to improved independence during activities of daily living.
- We also plan to examine the role of the caregiver on home rehabilitation outcomes and the impact of caregiver participation during home rehabilitation sessions on stroke survivor-informal caregiver dyads and on caregiver burden.
- We anticipate submitting grant applications to the NIH and other appropriate foundations within 3 months from the time this project is completed.

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Appendices

- A. Description of Instruments
- B. Facilities & Equipment
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- D. Caregiver Cues
- E. Therapist Guided Cues
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- G. System Usability Survey (SUS)
- H. Presence Questionnaire (PQ)
- I. Simulator Sickness Questionnaire (SSQ)
- J. Montreal Assessment of Cognition (MoCA)
- K. Fugl-Meyer Assessment - Upper Extremity
- L. Action Research Arm Test (ARAT)
- M. Therapy Follow Up Checklist
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- O. Budget Justification
- P. Timeline
- Q. Timeline of Study Events with Outcome Measures and Timepoints
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Appendix A
Description of Instruments

Variables	Specific Aims	Stroke Participants	Informal Caregiver	Data Collection Procedures
		Measures/Descriptions	Measures/Descriptions	
Pre-Intervention Questionnaire (Appendix R; Secondary Outcome)		Demographic data will be collected via survey (e.g., age, sex, race, education, health history, prior technology use, etc.)	Demographic data will be collected via survey (age, sex, race, education)	Baseline (RedCap), The PI, therapist, and/ or RA will review the data with the participants)
Feasibility (Primary Outcome)	SA1	Number of sessions attended; Duration (minutes) of session	N/A	Continuous – PI, therapist, and/ or RA will maintain log
Usability (Appendix G; Primary Outcome)	SA1	The System Usability Scale (SUS) ¹ measures the impact, perceived usefulness and ease of use, and user control of the technology using a 5- point Likert scale (1= strongly agree to 5= strongly disagree) with a score range 0-100. Higher scores (>68) indicate higher perceived usability. The SUS is a widely-used 10-item validated instrument with a Cronbach's alpha of .91. ²	N/A	Post-intervention (RedCap)

Variables	Specific Aims	Stroke Participants	Informal Caregiver	Data Collection Procedures
		Measures/Descriptions	Measures/Descriptions	
Usability (Appendix H; Primary Outcome)	SA1	The Presence Questionnaire (PQ ver.3) evaluates the user's level of presence in the VR environment on a 7-point scale with 1 being the lowest and 7 the highest level of presence. The PQ is widely-used in VR research is a validated instrument with a Cronbach's alpha of .91. ³		of 87% in detecting mild cognitive impairment ⁶ .
Acceptability (Appendix I; Primary Outcome)	SA1	The Simulator Sickness Questionnaire (SSQ) ⁴ is comprised of 16 items that capture physical symptoms commonly associated with prolonged activity in a simulator. Each symptom is ranked in order of effect on the user (none, slight, moderate, severe.). The SUS is widely-used in VR research is a validated instrument with a Cronbach's alpha ranging from .84-.94 on subdimensions. ⁵		
Cognitive Assessment (Appendix J; Primary Outcome)	SA2	The Montreal Cognitive Assessment (MOCA) is a 30-item screening tool used to detect cognitive impairment that takes 10 minutes to complete. It measures cognition measures including attention and memory. The MOCA has good evidence of internal consistency (Cronbach's alpha = .82) and test-retest reliability (r = .92) ⁶ . At a cutoff score of 26, MOCA has a sensitivity of 90% and specificity		

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nuous – the participant
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SSQ by PI, therapist, or
RA before and after the
intervention

Baseline & Post-
Intervention - the PI,
therapist or RA will
conduct the cognitive
evaluation

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Variables	Specific Aims	Stroke Participants	Informal Caregiver	Data Collection Procedures
		Measures/Descriptions	Measures/Descriptions	
Upper Limb Assessment (Appendix K; Primary Outcome)	SA2	The Fugl-Meyer Assessment-Upper Extremity ⁷ is scored on 7 domains on a 3-point scale (0 - cannot perform, 1 -performs partially, 2 - performs fully) for a total of 66 points. It is a validated instrument with a Cronbach's alpha of .88-.90. ⁸	N/A	Baseline & Post intervention – the occupational therapist and/ or RA will conduct the upper extremity assessment
Upper Limb Assessment (Fine motor) (Appendix L; Primary Outcome)	SA2	The Action Research Arm Test (ARAT) has 19 items with 4 subscales (grasp, grip, pinch, and gross movement) and arranged in order of decreasing difficulty. Scoring is recorded on a 4-point scale (0 – no movement, 1 – movement is partially performed, 2 – completed task but abnormally long amount of time, 3 – movement is normal) for a total of 57 points. It is a validated instrument Cronbach's alpha of .98. ^{9,10}	N/A	Baseline & Post intervention – the occupational therapist and/ or RA will conduct the upper extremity assessment
Caregiver Burden (Appendix F; Primary Outcome)	SA3	N/A	The Burden Scale for Family Caregivers (BSFC-s) is a 10-item questionnaire using a 4- point Likert scale (1= strongly agree to 4= strongly disagree). BSFC-s has a Cronbach's alpha of .92 and adequate evidence of convergent and discriminant validity (Giessen Symptom Complaints List-24: r = 0.68; Caregiver Strain Index: r =	

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Variables	Specific Aims	Stroke Participants	Informal Caregiver	Data Collection Procedures
		Measures/Descriptions	Measures/Descriptions	
Post-Intervention Questionnaire (Appendix Secondary Outcome)	SA1& SA3 S;	A semi-structured interview will be conducted to gather information on the stroke survivors' attitudes towards the intervention. Additional questions will be asked about the caregiver-stroke survivor dyad.	A semi-structured interview will be conducted to gather information on the caregiver's attitudes towards the intervention. Additional questions will be asked about the caregiver-stroke survivor dyad.	Post-intervention – conducted by PI, therapist, and/or RA

Appendix B

Facilities & Equipment



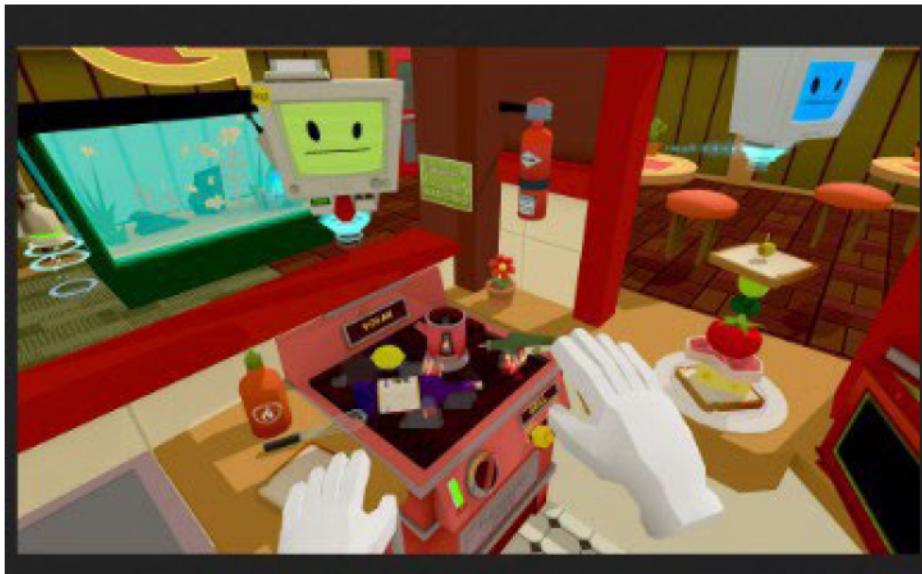
The Aging in Place apartment simulates a real-life apartment dwelling. The stroke survivor will be connected to the Oculus Quest VR in the living room area in front of the television. The television on the wall will be used to project the user's activities on the Oculus Quest Virtual Reality System so that the therapist(s) and caregiver can provide feedback during the rehabilitation sessions. There is a camera in the living room that can be accessed using a HIPAA-compliant technology web-based application.

Each member of the Investigative Team has dedicated office space equipped with computers, printers, scanners, and projectors to support study meetings as well as access to needed software (e.g., R, SAS, etc.). The team space is equipped with white boards, phone conferencing, and video-conferencing capabilities. Study staff have access to work-issued office phones, desktop computers, and laptops as needed. Conferencing software (e.g., WebEx) and support is available to all UTHealth employees.

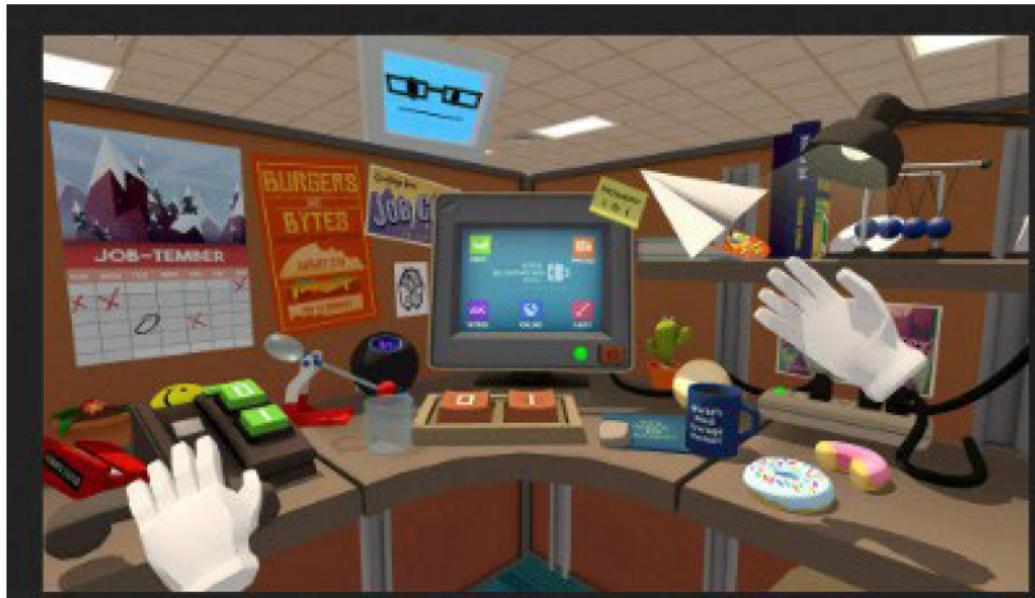
Each office is equipped with a desk, filing cabinets, dual processor PC computer, phone, and access to fax machines, printers (both black and white and color LaserJet), photocopiers, and scanners. The Center for Nursing Research provides secretarial, accounting, editorial, library, and administrative support to all faculty members and supportive staff. University provided secure server space and SecureStor for secure email will be provided. All software needed for machine learning and secure server space for “big data” projects are provided by UTHealth. Information Technology teams are available for support.

Appendix C

A. Gourmet Chef



B. Office Worker



Examples of the Job Simulator Games. The white gloves in the pictures are the user's hands that are directed by the user's hand game controls that will be used for gross upper extremity rehabilitation. The user can interact with the environment such as cooking on the stove in a kitchen (A) or using a computer or telephone in an office (B). The floating computer with a face interacts with the user to provide a sequence of instructions on how to interact in the virtual environment (e.g., make a sandwich) and uses aspects of cognitive rehabilitation such as planning, sequencing, judgement, and memory.

Appendix D

Cues to be Given to the Stroke Participant by the Caregiver

Helpful Tips to Encourage Partner:

- Summarize instructions and have partner repeat prior to starting the session
- Speak slowly and clearly in simple sentences – don't talk down or use "baby talk"
- Use animation/emotion while talking
- Speak how you expect to be spoken to – be a good model
- Focus on the positive
- Encourage positive self-talk phrases such as "I can do this if I take my time."
- Encourage saying steps aloud to stay on task and stay focused

If partner is getting frustrated or confused:

- Prior to giving complete direction, ask leading questions such as:
 - "Did you look all the way to the right? Was there anything on the bottom shelf that could help you heat the tea? Can you show me where WE keep the _____ (e.g., cheese for cooking task), look in there."
- If partner has difficulty expressing what they need or are frustrated about:
 - Establish topic first - For example: "Is this about the activity? No. Is it about a person? Yes. A family member?"
- Give as much assistance as is required to ensure good comprehension and for your loved one to remain relaxed:
 - reword
 - prompt
 - gesture
 - point
 - encourage
 - smile
 - give time for responses
 - try to let partner answer as much as possible
- If they become upset, check whether they wish to stop and take a brief break
- If more frustrated than normal, check:
 - Pain
 - Hunger/thirst
 - Fatigue
 - Emotions/worries
 - Room/temperature
- Focus on the positive
- Reassure them that any positive or negative feelings are valid
- If the experience has caused any distress, reassure them that there will be improvement from where they are today
- Discuss what will happen in next session including how you might deal with any issues – write these down to discuss with therapist
- Take notes on any questions you may have for therapist at next session. Consider discussing with each other, writing down, and discussing with therapist: "What helps?" and "What makes it harder?"

Appendix E

Therapeutic Guided Cues Protocol^{12,13} for the Stroke Survivor Participants to be Used by the Research Assistant .

During the session:

Problem solving:

- What will you gain by doing exercises at today's session?
- (Reinforce with the patient) Flexible coping strategies include:
 - define the problem and goal
 - generate multiple solutions
 - select a solution
 - implement and evaluate

Decision making:

- What will you do if you start to feel dizzy or not well during today's session?

Resource utilization:

- How will you seek assistance from your caregiver today during the session?
- You can ask me to assist you during the session. How will you signal to me that you want to stop?

Partnership with rehabilitation therapist/ RA:

- Do you understand what I am asking you to do?
- Would you like to practice the arm/ hand movements (or using the hand controller) with me before starting the session?

Planning and taking action:

- How will you use the hand controller?
- How will you put the headset on? Who will assist you?
- How many times this week will you come to the AIP apartment for your rehabilitation session?

For arm/ hand exercises at home:

Problem solving:

- What will you gain by doing arm/ hand exercises at home?

Decision making & Planning and taking action:

- Where/ when/ what/ how will you do your arm/ hand exercises?
- How will you know if you are doing your arm/ hand exercises correctly?
- How will you know when to stop doing your hand/ arm exercises?

Resource utilization:

- Can a friend or family member assist you with your arm/ hand exercises?
- Do you have a non-slippery surface at home where you can do your exercises?
- Do you have slip-resistant shoes?

Appendix F
Burden Scale for Family Caregivers – short version

We are asking you for information about your present situation. The present situation comprises your caregiving deduced from the illness of your family member (or friend).

The following statements often refer to the type of your assistance. This may be any kind of support up to nursing care.

Please draw an "X" for the best description of your present situation.
Please answer every question!

	strongly agree	agree	disagree	strongly disagree
1. My life satisfaction has suffered because of the care.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I often feel physically exhausted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. From time to time I wish I could "run away" from the situation I am in.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Sometimes I don't really feel like "myself" as before.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Since I have been a caregiver my financial situation has decreased.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. My health is affected by the care situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. The care takes a lot of my own strength.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I feel torn between the demands of my environment (such as family) and the demands of the care.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I am worried about my future because of the care I give.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. My relationships with other family members, relatives, friends and acquaintances are suffering as a result of the care.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix G
System Usability Scale (SUS)

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I think that I would like to use this headset frequently	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found this headset unnecessarily complex	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I thought this headset was easy to use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think that I would need assistance to be able to use this VR experience	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the various functions in this headset were well integrated	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I thought there was too much inconsistency in the headset	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would imagine that most people would learn to use this headset very quickly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the headset very cumbersome/awkward to use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel confident using the headset	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I needed to learn a lot of things before I could get going with this headset	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appendix H

Presence Questionnaire Version 3 (RedCap)

Version 3 of the PQ uses a seven-point Likert-type scale, although response choices differ slightly for each item stem (e.g., for item 2, 1 = “not responsive,” 7 = “very responsive;” for item 7, 1 = “not compelling,” 7 = “very compelling”). The 29 items are divided into four components as follows:

Involved

1. How much were you able to control events?
2. How responsive was the environment to actions that you initiated (or performed)?
3. How natural did your interactions with the environment seem?
4. How much did the visual aspects of the environment involve you?
5. How natural was the mechanism which controlled movement through the environment?
6. How compelling was your sense of objects moving through space?
7. How much did your experiences in the virtual environment seem consistent with your real-world experiences?
8. How completely were you able to actively survey or search the environment using vision?
9. How compelling was your sense of moving around inside the virtual environment?
10. How well could you move or manipulate objects in the virtual environment?
11. How involved were you in the virtual environment experience?
12. How easy was it to identify objects through physical interaction, like touching an object, walking over a surface, or bumping into a wall or object?

Sensory Fidelity

13. How much did the auditory aspects of the environment involve you?
14. How well could you identify sounds?
15. How well could you localize sounds?
16. How well could you actively survey or search the virtual environment using touch?
17. How closely were you able to examine objects?
18. How well could you examine objects from multiple viewpoints?

Adaptation/Immersion

19. Were you able to anticipate what would happen next in response to the actions that you performed?
20. How quickly did you adjust to the virtual environment experience?

21. How proficient in moving and interacting with the virtual environment did you feel at the end of the experience?
22. How well could you concentrate on the assigned tasks or required activities rather than on the mechanisms used to perform those tasks or activities?
23. How completely were your senses engaged in this experience?
24. Were there moments during the virtual environment experience when you felt completely focused on the task or environment?
25. How easily did you adjust to the control devices used to interact with the virtual environment?
26. Was the information provided through different senses in the virtual environment (e.g., vision, hearing, touch) consistent?

Interface Quality

27. How much delay did you experience between your actions and expected outcomes?
28. How much did the visual display quality interfere or distract you from performing assigned tasks or required activities?
29. How much did the control devices interfere with the performance of assigned tasks or with other activities

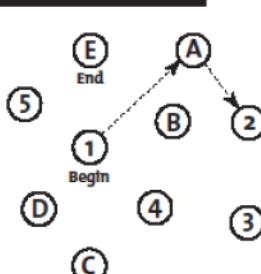
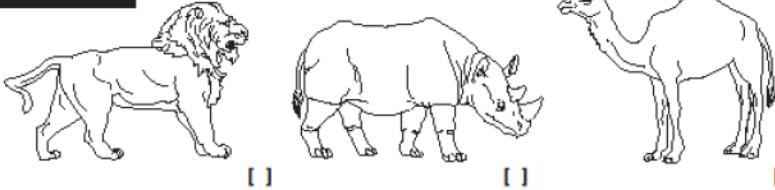
Appendix I
Simulator Sickness Questionnaire (SSQ)

Simulator Sickness Questionnaire (SSQ) items

SSQ items	Likert Scale		
	Slight	Moderate	Severe
General Discomfort			
Fatigue			
Headache			
Eyestrain			
Difficulty Focusing			
Increased Salivation			
Sweating			
Nausea			
Difficulty Concentration			
Fullness of Head			
Blurred Vision			
Dizziness (eye open)			
Dizziness (eye closed)			
Vertigo			
Stomach Awareness			
Burping			

Appendix J

Montreal Cognitive Assessment (MoCA)

MONTREAL COGNITIVE ASSESSMENT (MOCA)		NAME : _____	Education : _____	Date of birth : _____	Sex : _____	DATE : _____									
VISUOSPATIAL / EXECUTIVE 			Copy cube <input type="checkbox"/> [] Contour <input type="checkbox"/> [] Numbers <input type="checkbox"/> [] Hands	Draw CLOCK (Ten past eleven) (3 points)	_____ / 5										
NAMING 		_____ / 3													
MEMORY Read list of words, subject must repeat them. Do 2 trials. Do a recall after 5 minutes.		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">1st trial</td> <td style="width: 15%;">FACE</td> <td style="width: 15%;">VELVET</td> <td style="width: 15%;">CHURCH</td> <td style="width: 15%;">DAISY</td> <td style="width: 15%;">RED</td> </tr> <tr> <td>2nd trial</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	1st trial	FACE	VELVET	CHURCH	DAISY	RED	2nd trial						No points
1st trial	FACE	VELVET	CHURCH	DAISY	RED										
2nd trial															
ATTENTION Read list of digits (1 digit/sec). Subject has to repeat them in the forward order <input type="checkbox"/> [] 2 1 8 5 4 Subject has to repeat them in the backward order <input type="checkbox"/> [] 7 4 2		_____ / 2													
Read list of letters. The subject must tap with his hand at each letter A. No points if 2 or more errors <input type="checkbox"/> [] F B A C M N A A J K L B A F A K D E A A J A M O F A A B		_____ / 1													
Serial 7 subtraction starting at 100 <input type="checkbox"/> [] 93 <input type="checkbox"/> [] 86 <input type="checkbox"/> [] 79 <input type="checkbox"/> [] 72 <input type="checkbox"/> [] 65 4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt		_____ / 3													
LANGUAGE Repeat: I only know that John is the one to help today. <input type="checkbox"/> [] The cat always hid under the couch when dogs were in the room. <input type="checkbox"/> []		_____ / 2													
Fluency / Name maximum number of words in one minute that begin with the letter F <input type="checkbox"/> [] _____ (N ≥ 11 words)		_____ / 1													
ABSTRACTION Similarity between e.g. banana - orange = fruit <input type="checkbox"/> [] train - bicycle <input type="checkbox"/> [] watch - ruler		_____ / 2													
DELAYED RECALL Has to recall words WITH NO CUE <input type="checkbox"/> [] FACE <input type="checkbox"/> [] VELVET <input type="checkbox"/> [] CHURCH <input type="checkbox"/> [] DAISY <input type="checkbox"/> [] RED <input type="checkbox"/> []		Points for UNCUED recall only <input type="checkbox"/> []	_____ / 5												
Optional Category cue <input type="checkbox"/> [] Multiple choice cue <input type="checkbox"/> [] <input type="checkbox"/> [] Date <input type="checkbox"/> [] Month <input type="checkbox"/> [] Year <input type="checkbox"/> [] Day <input type="checkbox"/> [] Place <input type="checkbox"/> [] City		_____ / 6													
© Z.Nasreddine MD Version November 7, 2004 www.mocatest.org		Normal ≥ 26 / 30 TOTAL _____ / 30 Add 1 point if ≤ 12 yr edu													

Appendix K

Fugl-Meyer Assessment - Upper Extremity

FMA-UE PROTOCOL

Rehabilitation Medicine, University of Gothenburg

FUGL-MEYER ASSESSMENT
UPPER EXTREMITY (FMA-UE)
Assessment of sensorimotor function

ID:

Date:

Examiner:

Fugl-Meyer AR, Jaasko L, Leyman I, Olsson S, Steglind S: The post-stroke hemiplegic patient. A method for evaluation of physical performance. Scand J Rehabil Med 1975; 7:13-31.

A. UPPER EXTREMITY , sitting position		
I. Reflex activity	none	can be elicited
Flexors: biceps and finger flexors (at least one)	0	2
Extensors: triceps	0	2
Subtotal I (max 4)		
II. Volitional movement within synergies, without gravitational help	none	partial
Flexor synergy: Hand from contralateral knee to ipsilateral ear. From extensor synergy (shoulder adduction/ internal rotation, elbow extension, forearm pronation) to flexor synergy (shoulder abduction/ external rotation, elbow flexion, forearm supination).	0	1
Extensor synergy: Hand from ipsilateral ear to the contralateral knee	0	2
Shoulder elevation	0	1
Elbow external rotation	0	1
Forearm flexion	0	1
Forearm supination	0	1
Shoulder adduction/internal rotation	0	1
Elbow extension	0	1
Forearm pronation	0	1
Subtotal II (max 18)		
III. Volitional movement mixing synergies, without compensation	none	partial
Hand to lumbar spine hand on lap	0	1
Shoulder flexion 0°- 90° elbow at 0° pronation-supination 0°	0	1
Pronation-supination elbow at 90° shoulder at 0°	0	1
Subtotal III (max 6)		
IV. Volitional movement with little or no synergy	none	partial
Shoulder abduction 0 - 90° elbow at 0° forearm pronated	0	1
Shoulder flexion 90° - 180° elbow at 0° pronation-supination 0°	0	1
Pronation/supination elbow at 0° shoulder at 30°- 90° flexion	0	1
Subtotal IV (max 6)		
V. Normal reflex activity assessed only if full score of 6 points is achieved in part IV; compare with the unaffected side	0 (IV), hyper	lively
biceps, triceps, finger flexors	2 of 3 reflexes markedly hyperactive or 0 points in part IV 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive	1
Subtotal V (max 2)		
Total A (max 36)		

Approved by Fugl-Meyer AR 2010

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Updated 2015-03-11

Appendix L

Action Research Arm Test (ARAT)

ACTION RESEARCH ARM TEST

Patient Name: _____
Rater Name: _____
Date: _____

Instructions

There are four subtests: Grasp, Grip, Pinch, Gross Movement. Items in each are ordered so that:

- if the subject passes the first, no more need to be administered and he scores top marks for that subtest;
- if the subject fails the first *and* fails the second, he scores zero, and again no more tests need to be performed in that subtest;
- otherwise he needs to complete all tasks within the subtest

Activity	Score
-----------------	--------------

Grasp

1. Block, wood, 10 cm cube (If score = 3, total = 18 and to Grip)
Pick up a 10 cm block

2. Block, wood, 2.5 cm cube (If score = 0, total = 0 and go to Grip)
Pick up 2.5 cm block

3. Block, wood, 5 cm cube

4. Block, wood, 7.5 cm cube

5. Ball (Cricket), 7.5 cm diameter

6. Stone 10 x 2.5 x 1 cm

Coefficient of reproducibility = 0.98

Coefficient of scalability = 0.94

Grip

1. Pour water from glass to glass (If score = 3, total = 12, and go to Pinch)

2. Tube 2.25 cm (If score = 0, total = 0 and go to Pinch)

3. Tube 1 x 16 cm

4. Washer (3.5 cm diameter) over bolt

Coefficient of reproducibility = 0.99

Coefficient of scalability = 0.98

Pinch

1. Ball bearing, 6 mm, 3rd finger and thumb (If score = 3, total = 18 and go to Grossmt)

2. Marble, 1.5 cm, index finger and thumb (If score = 0, total = 0 and go to Grossmt)

3. Ball bearing 2nd finger and thumb

4. Ball bearing 1st finger and thumb

5. Marble 3rd finger and thumb

6. Marble 2nd finger and thumb

Coefficient of reproducibility = 0.99

Coefficient of scalability = 0.98

Provided by the Internet Stroke Center — www.strokecenter.org

**Grossmt (Gross Movement)**

1. Place hand behind head (If score = 3, total = 9 and finish)

2. (If score = 0, total = 0 and finish)

3. Place hand on top of head

4. Hand to mouth

Coefficient of reproducibility = 0.98

Coefficient of scalability = 0.97

Appendix M
Therapy Follow Up Checklist

**Please answer the following questions regarding therapy visits
that have been received since the last study visit**

Occupational Therapy	YES/NO	# of sessions	Session Length
<i>Therapy addressed:</i>	<input type="checkbox"/> Home exercise program <input type="checkbox"/> Self-care (dressing, toileting, etc) <input type="checkbox"/> Household tasks (cooking, cleaning, etc) <input type="checkbox"/> Return to worktasks <input type="checkbox"/> Coordination <input type="checkbox"/> Community tasks (shopping, using public transportation, etc) <input type="checkbox"/> Cognition (memory, multi-tasking, attention, etc)	<input type="checkbox"/> Transfers <input type="checkbox"/> Casting/splinting <input type="checkbox"/> Vision <input type="checkbox"/> Sitting/standing balance <input type="checkbox"/> Arm/hand exercises - Number of repetitions: _____	
Physical Therapy	YES/NO	# of sessions	Session Length
<i>Therapy addressed:</i>	<input type="checkbox"/> Walking <input type="checkbox"/> Running <input type="checkbox"/> Vestibular exercises <input type="checkbox"/> Leg exercises - Number of repetitions: _____	<input type="checkbox"/> Rolling in bed <input type="checkbox"/> Standing balance <input type="checkbox"/> Transfers <input type="checkbox"/> Casting/bracing - Number of repetitions: _____	<input type="checkbox"/> Sitting balance <input type="checkbox"/> Home exercise program <input type="checkbox"/> Getting in/out of bed <input type="checkbox"/> Core exercises - Number of repetitions: _____
Speech Therapy	YES/NO	# of sessions	Session Length
<i>Therapy addressed:</i>	<input type="checkbox"/> Cognition (memory, multi-tasking, attention, etc) <input type="checkbox"/> Communication (speaking and/or understanding) <input type="checkbox"/> Swallowing		

Appendix N

Home Exercises that the Rehabilitation Therapist will Select for the Stroke Survivor

HEP2GO Home Exercise Program
Created by Emily Stevens, OTR Apr 15th, 2022

View videos at www.HEP.video

Total 11

SCAPULAR RETRACTIONS
Move your shoulder blades back and down.
Hold, relax and repeat.

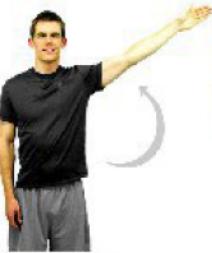
Repeat 10 Times
Hold 5 Seconds
Complete 2 Sets
Perform 4 Times a Week



AROM SHOULDER ABDUCTION
With your affected arm starting at your side with your thumb pointed upward, raise up your arm to the side.

Repeat 10 Times
Hold 5 Seconds
Complete 2 Sets
Perform 4 Times a Week

Video # VVNFC7TNL



AROM FLEXION
While sitting or standing with your arm at your side, slowly raise it up and forward towards overhead.

Repeat 10 Times
Hold 5 Seconds
Complete 2 Sets
Perform 4 Times a Week

Video # VVBNSZXGV



Total 13

**SHOULDER - ISOMETRIC EXTERNAL ROTATION**

Gently press your hand into a wall using the back side of your hand. Maintain a bent elbow the entire time.

Repeat 10 Times
Hold 5 Seconds
Complete 2 Sets
Perform 4 Times a Week

**SHOULDER - ISOMETRIC FLEXION**

Gently push your fist forward into a wall with your elbow bent.

Repeat 10 Times
Hold 5 Seconds
Complete 2 Sets
Perform 4 Times a Week

**SHOULDER - ISOMETRIC ABDUCTION**

Gently push your elbow out to the side into a wall with your elbow bent.

Repeat 10 Times
Hold 5 Seconds
Complete 2 Sets
Perform 4 Times a Week

**ELASTIC BAND FLEXION - SELF FIXATION**

While holding an elastic band in front of you and on your leg with your unaffected arm, pull the band upward towards the ceiling with your affected arm as shown.

Video # VVVRN4D7C

Repeat 10 Times
Complete 2 Sets
Perform 4 Times a Week

**ELASTIC BAND SHOULDER DIAGONAL - FLEXION ABDUCTION - SELF FIX**

Start by holding an elastic band down by your side to fixate it with your unininvolved arm. Next, using the involved arm, draw the other end of the band upwards and towards the opposite side as shown.

Video # VV7BGW6RU

Repeat 10 Times
Complete 2 Sets
Perform 4 Times a Week

**ELASTIC BAND BILATERAL EXTERNAL ROTATION - ER**

While holding an elastic band with your elbows bent, pull your hands away from your stomach area. Keep your elbows near the side of your body.

Video # VVEL2H3YQ

Repeat 10 Times
Complete 2 Sets
Perform 4 Times a Week

Appendix O

11. **What is the primary purpose of the *Journal of Clinical Endocrinology and Metabolism*?**

For more information, contact the Office of the Vice President for Research and Economic Development at 515-294-6450 or research@iastate.edu.

For more information, contact the Office of the Vice President for Research and the Office of the Vice President for Student Affairs.

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11. **What is the primary purpose of the *Journal of Clinical Endocrinology and Metabolism*?**

Black box

[REDACTED]

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Appendix P
Proposed Study Timeline December 2022 – November 2023

Activity	Month											
	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov
Create study documents	X											
Create & test REDCap database	X											
Obtain IRB approval		X										
Recruitment			X	X	X	X						
Ongoing data collection			X	X	X	X						
Ongoing qualitative data analysis			X	X	X	X						
Quantitative data analysis							X					
Dissemination (publication)								X	X	X		
Grant writing									X	X	X	X

Appendix Q
Timeline of Study Events with Outcome Measures and Timepoints

BASELINE (Video Call or in person)	Initial & Date completed
Informed Consent documents will be available in English. The consent form will be accessible via REDCap. This visit is to ensure the participant understands the basis of this voluntary study and provides consent to participate in the research study.	
Pre-First Visit (Video Call or in person at 1 st visit)	
We will ask the stroke survivor about their medical history and give the stroke survivor the Montreal Cognitive Assessment (MoCA) or other appropriate cognitive screening test if the participant has aphasia, hemiopsia, and other neurological deficits that cannot be examined using MoCA or a modified MoCA that will assess their cognitive capabilities. We will arrange a time to meet with the stroke survivor and their caregiver on a video call using the computer and this will take only 15 or 20 minutes. We will offer the option to complete the Pre-Intervention Questionnaire of the stroke survivor participant and Burden Scale for Family Caregivers depending on participant and caregiver preferences. This will take 15-20 additional minutes. F	
<ol style="list-style-type: none"> 1. Assess stroke survivor's medical history 2. Cognition (MoCA) test completed (Appendix J) 	
<u>Inclusion Criteria</u>	
<p>Patients must meet the following criteria for study entry:</p> <ul style="list-style-type: none"> • Ischemic, hemorrhagic, or SAH stroke diagnosis within 6 months to 5 years of enrollment. • Dyads will be included if they <ul style="list-style-type: none"> ◦ Are \geq 18 years old ◦ Can read, write, comprehend ◦ Speak English ◦ Are willing and able to provide informed consent • Caregivers must live in the home with the stroke survivor. 	
<u>Exclusion Criteria</u>	
<u>General</u>	
<ul style="list-style-type: none"> • Stroke survivors will be excluded if they do not have score ranges that indicate mild to moderate severity on prior post-stroke neuropsychological tests, or the MoCA (15-25) using normative data based on education, age, and other standard demographic data, or other appropriate cognitive screening test selected by the speech language pathologist (also on this application) if the participant has aphasia, hemiopsia, other neurological or specific cognitive deficits, or demographic factors (e.g., education level) that prevents the participant from being accurately examined using MoCA or a modified MoCA; if cognition is within normal range then a FM (20-50) • Have a history of: <ul style="list-style-type: none"> ◦ Motion sickness ◦ Vertigo ◦ Dizziness ◦ Seizures (a doctor's note will be requested for participants who do not believe their seizures will be triggered by the VR) ◦ Claustrophobia ◦ Blind/deaf • Cannot hold the controller in their affected arm. 	

	IRB NUM: ER: HSC-SN-22-08 8
	IRB APPROVAL DATE: 03/06/2024

1st Session (Week 1)	Initial & Date completed
<p>3. Pre-Intervention Questionnaire will be given during the first session. (Appendix R)</p> <p>4. Cognition (MoCA or other appropriate) test completed (if not completed during pre-first visit) (Appendix J)</p> <p>5. Fugl-Meyer Upper Extremity Assessment (Appendix K)</p> <p>6. Action Research Arm Test (ARAT) (Appendix L)</p> <p>a. 3,4, and 5 will be completed as a part of standard of care.</p> <p>7. Burden Scale for Family Caregivers – short version will be given to the caregivers of the stroke subjects via REDCap. (Appendix F)</p>	
<input type="checkbox"/> Recruit from stroke units/clinics	
<input type="checkbox"/> Study coordinator screens for eligibility requirements	
<input type="checkbox"/> Obtain Informed Consent Documents from Dyads	
<input type="checkbox"/> Complete the Cognition (MoCA) test (pre-intervention) (Primary Outcome; Appendix J)	
<input type="checkbox"/> Complete the Fugl-Meyer Upper Extremity Assessment (pre-intervention) (Primary Outcome; Appendix K)	
<input type="checkbox"/> Complete the Action Research Atm Test (ARAT) (pre-intervention) (Primary Outcome; Appendix L)	
<input type="checkbox"/> Have the Caregivers complete the Burden Scale for Family Caregivers (Primary Outcome; Appendix F)	
<input type="checkbox"/> Arrange sessions schedules with Dyads for the length of the study (2 sessions/week each being an hour minimum in length). Reserve smart room for duration of study.	
<ul style="list-style-type: none"> _ Complete the Pre-Intervention Questionnaire (Secondary Outcome; Appendix R) 	
<ul style="list-style-type: none"> _ Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the first 1-hour session (Primary Outcome; Appendix I) 	
2nd Session (Week 1)	Initial & Date completed
<ul style="list-style-type: none"> _ Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome; Appendix M) 	
<ul style="list-style-type: none"> _ Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the second 1-hour session (Primary Outcome; Appendix I) 	
3rd Session (Week 1)	Initial & Date completed

<ul style="list-style-type: none"> Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome; Appendix M) 	
<ul style="list-style-type: none"> Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the third 1-hour session (Primary Outcome; Appendix I) 	
4th Session (Week 2)	Initial & Date completed
<ul style="list-style-type: none"> Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome; Appendix M) 	
<ul style="list-style-type: none"> Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the fourth 1-hour session (Primary Outcome; Appendix I) 	
5th Session (Week 2)	Initial & Date completed
<ul style="list-style-type: none"> Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome; Appendix M) 	
<ul style="list-style-type: none"> Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the fifth 1-hour session (Primary Outcome; Appendix I) 	
6th Session (Week 2)	Initial & Date completed
<ul style="list-style-type: none"> Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome; Appendix M) 	
<ul style="list-style-type: none"> Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the sixth 1-hour session (Primary Outcome; Appendix I) 	
7th Session (Week 3)	Initial & Date completed
<ul style="list-style-type: none"> Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome; Appendix M) 	
<ul style="list-style-type: none"> Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the seventh 1-hour session (Primary Outcome; Appendix I) 	
8th Session (Week 3)	Initial & Date completed
<ul style="list-style-type: none"> Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome; Appendix M) 	
<ul style="list-style-type: none"> Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the eighth 1-hour session (Primary Outcome; Appendix I) 	

9th Session (Week 3)	Initial & Date completed
<ul style="list-style-type: none"> _____ Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome; Appendix M) _____ Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the ninth 1-hour session (Primary Outcome; Appendix I) 	
10th Session (Week 4)	Initial & Date completed
<ul style="list-style-type: none"> _____ Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome; Appendix M) _____ Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and the end of the tenth 1-hour session (Primary Outcome; Appendix I) 	
11th Session (Week 4)	Initial & Date completed
<ul style="list-style-type: none"> _____ Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome; Appendix M) _____ Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the eleventh 1-hour session (Primary Outcome; Appendix I) 	
Pre-Last Visit (Video Call or in person)	
We will give the stroke survivor the Montreal Cognitive Assessment (MoCA) that will assess their cognitive capabilities. We will arrange a time to meet with them on a video call using the computer and this will take only 15 or 20 minutes.	
1. Cognition (MoCA) test completed (Primary Outcome; Appendix J)	
12th Session (Week 4, last session; in the event that the study participant and/ or caregiver are unable to complete any post-intervention items, we will request a video call to complete any missing items that were not completed on the last session at a time convenient to the stroke participant or caregiver)	Initial & Date completed
<ul style="list-style-type: none"> _____ Research Assistant complete the Therapy Follow Up Checklist with Subject before the start of the session. (Secondary Outcome, Appendix M) _____ Have the stroke survivor complete the Simulator Sickness Questionnaire (SSQ) at the beginning and end of the last 1-hour session (Primary Outcome; Appendix I) _____ Complete the System Usability Survey (SUS) via REDCap (Primary Outcome; Appendix G) _____ Complete the Presence Questionnaire (PQ) (Primary Outcome; Appendix H) 	

<input type="checkbox"/> Complete the Cognition (MoCA) test (post-intervention, if not completed during the Pre-Last Visit) (Primary Outcome; Appendix J)	
<input type="checkbox"/> Complete the Fugl-Meyer Upper Extremity Assessment (post-intervention) (Primary Outcome; Appendix K)	
<input type="checkbox"/> Complete the Action Research Atm Test (ARAT) (post-intervention) (Primary Outcome; Appendix L)	
<input type="checkbox"/> Complete the Caregiver Burden Questionnaire (Primary Outcome; Appendix F)	
<input type="checkbox"/> Complete the Post-Intervention Questionnaire (Participant and Caregiver) (Secondary Outcome; Appendix S)	

Appendix R

Pre-Intervention Questionnaire (Red Cap)

DEMOGRAPHIC INFORMATION

1. Name: _____ Study ID: _____

2. Date of Birth: _____

3. Gender: _____

4. Race/ Ethnicity (check one):

White/ Caucasian Black/ African American Asian/ Pacific Island

Hispanic/ Latino Other: _____

5. Highest level of education: _____

6. Type of dwelling/ residence: House Apartment or Condominium Other: _____

Address: _____

7. Phone number: _____

8. Email address: _____

9. Preferred form of communication: _____

PAST MEDICAL HISTORY

10. **Check those questions to which your answer is yes (leave others blank).**

Motion Sickness, Dizziness, Vertigo (moving vehicle, playing games, roller coaster rides, etc.) _____

Previous brain injuries (e.g., trauma): _____

Falls: _____

Seizures, Blackouts: _____

Claustrophobia: _____

Sensitivity to light: _____

Sensitivity to loud noises: _____

Glasses Contact Lenses Cataracts Hearing aides

STROKE HISTORY

11. Date of most recent stroke: _____

12. Description of Paralysis:

13. Description of Cognitive Impairment:

14. Prior Occupational and Cognitive Rehabilitation (when/ where, goals focused on)

13. Treating medical provider _____

14. Prior stroke history _____

Current Medications & Supplements

Hospitalization History

CAREGIVER INFORMATION

15. Relationship to the Patient: _____
16. Does the caregiver live with the participant? _____
17. Who lives in the participant's household? _____
18. Date of Birth: _____
19. Gender: _____
20. Highest level of education: _____
21. **Race/ Ethnicity (check one):**

White/ Caucasian Black/ African American Asian/ Pacific Island

Hispanic/ Latino Other: _____

PRIOR TECHNOLOGY EXPERIENCE USE OF THE STROKE SURVIVOR PARTICIPANT

22. Do you have internet access at home? Type: _____
23. How many hours a day do you use computers, tablets, or smartphones during the day?
 0-2 hrs 3-4 hrs 4-8 hrs More than 8 hrs
24. Have you ever played video games previously? If so, please describe

25. Have you ever used a virtual reality headset? If so, please describe

Appendix S
Post-Intervention Questionnaire

Stroke Survivor Participant Questions

What did you enjoy the most about using the VR headset for stroke rehabilitation?

PROBES: (1,2, 4,7, 8 from original list)

- Can you describe the Job Simulator games that you played?
- How well did these activities simulate “real-life”?
- Describe how often you might use the VR headset at home for stroke rehabilitation?

What did you enjoy the least about using the VR headset for stroke rehabilitation?

PROBES: (Q's 3, 5,6, 9 from original list)

- Can you discuss any symptoms or aspects of the VR headset that would prevent you from using the VR headset again?
 - How did it feel to use the VR headset?
 - Can you describe how the tutorial provided at the first session assisted you in understanding how the headset works? What could we do differently?

Do you have any other comments that you would like to share regarding the rehabilitation session with the VR headset?

Stroke Survivor's Perspective on Relationship

IF THE CAREGIVER STAYED REGULARLY TO OBSERVE THE SESSIONS

- How would you describe your caregiver's participation in the rehabilitation session upon your own progress?
- How do you feel that your caregiver's participation will impact your progress during home rehabilitation sessions using a VR headset?
- How do you feel about your caregiver's encouragement during your rehabilitation session?
- What type of intervention with your caregiver would you prefer during your rehabilitation sessions using a VR headset?

PROBE:

- Can you describe how your caregiver's participation in the rehabilitation sessions have /have not improved your level of connection to one other? In what ways?
- Can you describe how your caregiver's participation in home rehabilitations sessions using a VR headset may impact your level of connection to one another? In what ways?

- Is there anything else you would like to share about the quality of your relationship with your caregiver? Any ideas on how this VR technology may be used to improve the quality of your relationship?
- Do you have any other thoughts or comments about using the VR headset in a home setting?

IF THE CAREGIVER DID NOT STAY REGULARLY TO OBSERVE THE SESSIONS

- Would you have preferred for your caregiver to stay and observe your rehabilitation sessions using the VR headset?
- Do you feel that having your caregiver observe or participate during the VR sessions would have helped you feel more engaged during the sessions?
- Do you feel that having the VR headset at home would give you an opportunity to connect with your caregiver? What about other family members or friends?
- Do you have any other thoughts or comments about using the VR headset in a home setting?

Caregiver Questions

Tell me your thoughts about your stroke survivor using the VR headset for their rehabilitation sessions.

PROBE: What are your thoughts on using the VR headset for home rehabilitation?

IF THE CAREGIVER STAYED REGULARLY TO OBSERVE THE SESSIONS

1. Do you think that the stroke survivor would use the VR headset for home rehabilitation?
2. How did you feel about your involvement during the rehabilitation sessions?
3. How do you feel about being involved in stroke participant's rehabilitation sessions using a VR headset in the home environment?
4. Describe how your participation in your stroke survivor's rehabilitation sessions have /have not improved your level of connection to one other? In what ways?
5. Describe how your participation in your stroke survivor's rehabilitation sessions using the VR headset may impact your level of connection to one another? In what ways?
6. Is there anything else you would like to share about the quality of your relationship with your stroke survivor? Any ideas on how this VR technology may be used to improve the quality of your relationship?

IF THE CAREGIVER DID NOT STAY REGULARLY TO OBSERVE THE SESSIONS

1. Do you think that the stroke survivor would use the VR headset for home rehabilitation?
2. How do you feel about being involved in stroke participant's rehabilitation sessions using a VR headset in the home environment?
3. Describe how your participation in your stroke survivor's rehabilitation sessions using the VR headset may impact your level of connection to one another? In what ways?
4. Do you think that other family members and/ or friends would be interested in

participating in the home rehabilitation session using the VR headset?

- Do you think that the VR headset is a good way to emotionally connect with the stroke survivor? Why/ why not?

EXPLORING STROKE SURVIVOR TREATMENT BURDEN AND CAREGIVER STRESS

Thank you for taking the time to discuss your perspectives and experiences in caring for someone who has had a stroke.

We are also very interested in learning more about caregivers' day to day experiences in caring for their stroke survivor. From helping with activities of daily living (like dressing, bathing) to navigating medications, therapy appointments, and insurance issues – we believe that very little is known about these issues and how stroke survivors and their caregivers can be better supported.

My role here is to listen to your experiences and identify areas where CGs could be better supported. I am not here to judge or criticize anything that you share with me. However, I am obligated to inform you that Texas state law requires that I report suspicions of current mistreatment.

I want to reassure you that anything that you share with me today is completely anonymous. Although I am recording this interview to ensure that I am accurately capturing what you're saying, the data that you provide won't be shared outside of my research team. The transcripts that we produce will be de-identified. Do you have any questions?

Interview Questions	Probe
1. Tell me about your relationship with the stroke survivor that you care for.	<ul style="list-style-type: none"> How long have you known them? When did stroke occur (how long have you been caring from them since their stroke)? How have roles changed in this relationship since the person has had a stroke.
2. The level of assistance that stroke survivors require as they recover can depend on the type of stroke, and the person's level of function before the stroke. Tell me about the type of support that you've provided (e.g., physical, emotional, healthcare logistic related etc.) for your stroke survivor.	<ul style="list-style-type: none"> How prepared were you in providing this support? What helped you along the way to become more comfortable in providing this care? What was/is most challenging about this?
3. Navigating stroke care is a new experience for many people. Walk me through how the experience was for you and your loved one to: <ul style="list-style-type: none"> Transition home from the hospital Interact with others involved in your stroke care (e.g., stroke care team, PT, OT etc.) Manage and organize treatment <ul style="list-style-type: none"> Traveling to appointments Time off from your own work 	<ul style="list-style-type: none"> How prepared were you to deal with this? <ul style="list-style-type: none"> What types of supports were offered? What would have helped the most at that particular time?

<ul style="list-style-type: none"> - Managing care plans for other chronic conditions - Medication management 	
<p>4. Caregiving can be a stressful and challenging journey. It's not uncommon for caregivers to feel angry, frustrated, or hopeless from time to time.</p> <p>Can you please describe a time when you might have felt overwhelmed with your CG activities?</p>	<ul style="list-style-type: none"> • What was the context? • How in-control of your emotions did you feel during this time? • Did you act/behave in a way that you wouldn't normally? • Tell me about a time when you might have pushed your loved one's buttons out of frustration. • How do you think this affected your loved one and their care? • Looking back, is there anything you would have liked to do differently?

Conclude interview and thank participant for their time.