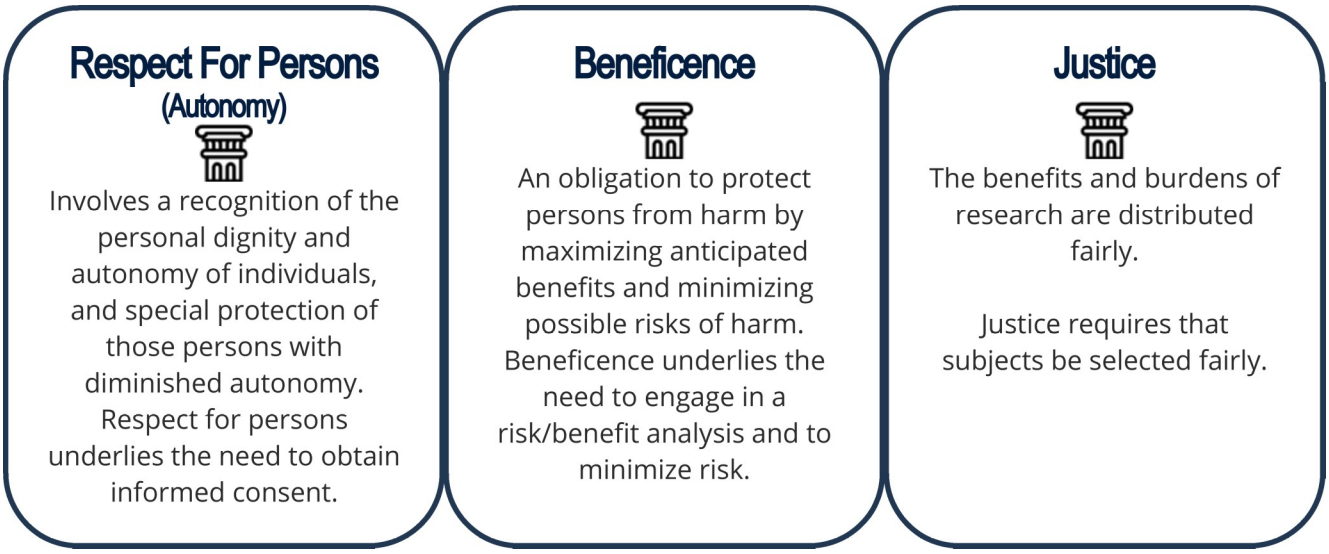
Research Protocol Application

This form must be reviewed and completed in its entirety. A complete description of planned research, in laymen's terms (non-scientific and non-technical language understood by someone with no scientific background), needs to be submitted to determine if all regulatory policy requirements are met. All fields should contain information. Descriptions should be limited to two to three paragraphs. **Avoid technical jargon.** Indicate **N/A** when not applicable.

The IRB will not consider any research that does not fulfill ethical principles reflected in the Belmont Report. These three basic ethical principles are:



Please type and submit this form along with **final** copies of all project related materials via IRBNet. Attention to these details will facilitate the IRB's review of your project.

Additional revisions to this document after submission should be in **red**. You may compose revisions in a separate document then copy and paste into the applicable field.

For further guidance or assistance, please contact the IRB office at (915) 747-6590 or by email at irb@utep.edu.

For more information, please see the **Investigator Manual for Human Subjects Research.**
(Ctrl+click to follow the link)

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UTEP IRB

Research Protocol Application

(A) Project Information

Principal Investigator: Shashwati Geed

University Title: ☒ Faculty/Staff ☐ Student

Department: Physical Therapy and Movement Sciences

Email Address: sgeed@utep.edu **Phone Number:** 7289

Protocol Title: Efficacy of Tele-CPASS, a telerehabilitation intervention using Critical Periods After Stroke Study (CPASS) compared to in-person CPASS for Upper Extremity Motor Recovery.

Human Subjects Research Training Completed: ☒ Yes ☐ No

Anticipated Start Date: 12/1/2023 **Anticipated End Date:** 8/31/2028

If the **Principal Investigator is a student,** the faculty advisor must indicate knowledge and approval of this submission. By electronically signing the package in IRBNet, the faculty advisor certifies that the study is under their direct supervision and that the faculty advisor is responsible for ensuring that all provisions of the IRB approval are complied with by the investigator.
Student PI: Remember to share the package with your Faculty Advisor.
External Researchers should use the section below to designate their UTEP "sponsor".

Faculty Advisor: N/A

University Title: Click or tap here to enter text.

Department: Click or tap here to enter text.

Email Address: Click or tap here to enter text. **Phone Number:** Click or tap here to enter text.

Human Subjects Research Training Completed: ☐ Yes ☐ No

(B) Type of Project

☒ Faculty Research	☐ Thesis	☐ Dissertation
☐ Presentation/Conference	☐ Capstone	☐ Internal Evaluation Non-Publishing
☐ Publication Click or tap here to enter text.	☐ Other Click or tap here to enter text.	

Funding	☒ **Federal***	☐ FDA	☐ NIH	☐ NSF	☐ ED	☐ DOE	☒ DHHS	☐ OTHER Click or tap here to enter text.
		☐ DOJ	☐ DHS	☐ DOD	☐ EPA	☐ DOL	☐ DVA	
☐ **Non-Federal**	☐ State	☐ Industry	☒ Department	☐ Personal				
☐ Other Click or tap here to enter text.								

*All federally funded human subjects research studies must comply with the U.S. Department of Health and Human Services (DHHS) human subjects research regulations.

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OR#: Click or tap here to enter text.	**Principal Investigators (PIs) are responsible for notifying the IRB**

(C) Project Site(s)

Check all that apply. This includes subject **recruitment**, subject **enrollment**, **data collection**, and **data analysis**.

***Please include the Site Authorization Letter(s) indicating permission to conduct project in the submission package**

☒	Project will be conducted at UTEP.
☒	Research will be conducted at another institution. *****
	☒ Project will be reviewed by other institution IRB and/or Ethics Committee
	Provide the institution name and contact person Texas Tech University Health Sciences Center of El Paso (TTUHSC-EP), site PI: Dr. Paisith Piriyawat, MD; University Medical Center of El Paso (UMC-EP) site PI: Dr. Paisith Piriyawat, MD.
	Has permission(s) and/or IRB review been obtained? ☐ Yes ☒ No
	If NO, expand on the status: Will submit for TTUHSC-EP approvals to screen and recruit on their campus once this amendment is approved. UTEP serves as the board for UMC-EP for UTEP PIs.
☒	Multi-Site Study *****
	Is UTEP the lead institution? ☒ Yes ☐ No
	If NO, list the lead institution: Click or tap here to enter text.
☒	Other * Study screening and recruitment will be done at UMC-EP and at the TTUHSC-EP stroke clinic. All other research procedures will be completed on the UTEP campus.
☐	International-Please complete the section below.

Identify where the research will be conducted. Provide information regarding local customs, laws, and regulations of the site(s). Clarify if your research requires local ethics committee review and approval and/or if permission is required from a government entity. **Consult with the Export Control division of the Research Protections office to ensure that countries or foreign individuals that are involved in research are allowed to collaborate in that research.**

Click or tap here to enter text.

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Key for project study personnel roles in Sections D & E: (1-4) Involves interaction with human subjects. (5) Does not involve interaction with human subjects
1) Involved in the recruitment process of participants.
2) Involved in the consent process of participants.
3) Involved in the monitoring of or interaction with participants.
4) Involved in raw data collection, entry, or analysis.
5) **No human subject interaction**. Working with de-identified data only.

(D) Additional Study Personnel

Project Team Members- UTEP affiliation

Name	Title	Email	Role (Check all that apply)				
			1	2	3	4	5
Dr. Alvaro Gurovich	Co-PI; Professor and Chair of Physical Therapy and Movement Sciences	agurovich@utep.edu	☒	☒	☒	☒	☐
Dr. Cecilia Fierro	Study therapist; Clinical Associate Professor of Occupational Therapy	cfierro6@utep.edu	☒	☒	☒	☒	☐
Estevan Nieto	Research assistant	emnieto3@miners.utep.edu	☒	☒	☒	☒	☐
Crystal Mendoza	Research assistant	camendoza15@miners.utep.edu	☒	☒	☒	☒	☐
Yazbel Arriaga	Research assistant	yarriaga2@miners.utep.edu	☒	☒	☒	☒	☐
Natalie Pravinkumar	Study therapist	npravinkumar13@gmail.com	☒	☒	☒	☒	☐
Kenya Flores	Research assistant	Kflores22@miners.utep.edu	☒	☒	☒	☒	☐
Pablo Velador Valdez	Research assistant	pvaldezvel@miners.utep.edu	☒	☒	☒	☒	☐
Mia Montelengo	Research assistant	memontelongo2@miners.utep.edu	☒	☒	☒	☒	☐
Alejandra Hernandez Rodriguez	Research assistant	ahernandezrod@miners.utep.edu	☒	☒	☒	☒	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐

(E) External Personnel

Please list external study team members who will interact with participants or access identifiable data.

Name	Title	Email	Role (Check all that apply)				
			1	2	3	4	5
Israel Alba	Clinical research coordinator at TTUHSC-EP	Israel.alba@ttuhsc.edu	☒	☒	☐	☐	☐
Dr. Paisith Piriyawat, MD	Medical Director, Rehabilitation Services, UMC-EP; Associate Professor of Neurology, TTUHSC-EP	Paisith.piriyawat@ttuhsc.edu	☒	☒	☐	☐	☐

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(F) Ethical Considerations

1	Will this project be conducted anonymously? **(In person studies and/or collection of personal identifying information are not anonymous)**	☐ Yes ☒ No
If YES, how will anonymity be preserved throughout the duration of the study? N/A		
2	Will you attempt to re-identify participants or link a key to identifiers?	☒ Yes ☐ No
If YES, explain: Each participant will be linked to a randomly generated study ID #. This linkage file will be encrypted and stored on an encrypted device in the PI's lab on a computer that does not connect with the internet. The linkage file will be kept for five years once the study is completed, in case study publications and/or manuscript reviewers require additional participant data.		
3	Does the project include children as research subjects?	☐ Yes ☒ No
4	Does the project include a protected group(s)? **(UTEP employees, UTEP students) Maybe.**	☐ Yes ☒ No
5	Does the project focus on **prisoners**, **fetuses**, **pregnant women, human in vitro fertilization**, or persons with **impaired decision making**?	☐ Yes ☒ No
6	Does the project **specifically** select economically/educationally disadvantaged individuals?	☐ Yes ☒ No
If YES, explain: Click or tap here to enter text.		
7	Does the project involve more than minimal risk? **(As defined in 45 CFR 46.102(j) (July 19, 2018))**	☐ Yes ☒ No
8	Does the project involve deception?	☐ Yes ☒ No
If YES, upload a Request for a Waiver of Documentation or Alteration of Consent form to alter consent and explain your compliance with 45 CFR 46.116(f).		
9	For research conducted **outside** of the **UTEP** campus, is the Principal Investigator (PI) and/or member(s) of the research team affiliated with the external site, institution, or organization?	☐ Yes ☒ No
If YES, explain: Click or tap here to enter text.		

The following sections outline types of research activities. Please check the box(es) **ONLY** if **ALL** activities involving human subjects fall into one or more of the applicable categories.

(G) Behavioral Study Activities

☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices. **(EX1)**
This category may include research on effectiveness as well as comparisons about educational strategies, techniques, curricula, or classroom management. Educational tests, such as cognitive, diagnostic, aptitude, achievement tests

Notes: The research must **not** adversely impact students' opportunity to learn required educational content.
The research must **not** adversely impact the assessment of educators who provide instruction.
A study information sheet or abbreviated consent document should be used.

☐ Research that **ONLY** includes surveys, interviews, focus groups, or observation of public behavior with adults who can consent for themselves and covering **benign** topics. **(EX2) (LIM)**

Notes: The term "benign" describes activities that are brief, not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive, and not likely to have a lasting adverse impact.
Interventions are **not** allowed.

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	A study information sheet or abbreviated consent document should be used.
☐	Research involving **benign** behavioral interventions in conjunction with the collection of information from an **adult** subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection. **Benign** research on perception, cognition, motivation, communication, social behavior, behavioral games, or **minimal risk** performance tasks. (**EX3) (LIM)** Notes: A study information sheet or abbreviated consent document should be used.
☐	Secondary research not requiring consent. Secondary research use of identifiable private information or identifiable biospecimen originally collected for other purposes. **(EX4)** Notes: When the identifiable private information or biospecimens are publicly available. The information is recorded by the investigator in such a way that the identity of subjects **cannot readily be ascertained**, and the investigator **does not** contact the subjects or try to re-identify subjects.
☐	Taste/Food quality evaluation and consumer acceptance. **(EX6)**

General Notes: The above research may involve randomization between groups if disclosed to participants. The above research may be recorded on **audio only** or **video**, if the subject agrees, if identities are not shared, and the confidentiality of the information is properly protected.

Exempt category 5 is not listed as it applies to projects conducted or supported by, or subject to, the approval of Federal department and agency heads. Please contact the IRB office if you feel your project meets these criteria. UTEP will not implement exemption categories 7 & 8 at this time.

(H) Biomedical Study Activities

☒	Prospective collection by **non-invasive procedures** such as ultrasound, MRI without contrast, Doppler, MEG, EEGs, ECGs, eye tracking that requires hardware.
☐	Clinical studies of drugs and medical devices where an investigational application is not required or that are cleared for marketing and being used as directed. **(XP1)**
☐	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture. **(XP2)**
☐	Non-invasive collection of biospecimens for research purposes. **(XP3)**
☒	Moderate exercise, muscular strength testing, body composition assessment in healthy adults **(XP4)**
☐	Non-invasive tests, not including x-rays or microwaves, used in clinical practice (BP, pulse) **(XP4)**
☐	Research involving materials (data, documents, records, or specimens) that have been, or will be, collected solely for non-research purposes (such as medical treatment or diagnosis). **(XP5)**

(I) Use of Medical Devices

Medical devices must be cleared/approved for marketing by FDA. Approvals may be in the form of Premarket Notification [510(k)], Premarket Approval (PMA), Humanitarian Device Exemption (HDE), or De Novo classification.

Are you using devices as part of a clinical intervention or patient outcome?	☐ Yes ☒ No

If **yes**, list all devices below

Device Name	Manufacturer	Approval Number
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
If the above doesn't apply, is your device investigative?		☐ Yes ☐ No*
Is it a Nonsignificant Risk (NSR) Device?		☐ Yes ☐ No*

***Answering no to questions marked by an asterisk requires you to contact the FDA.**

Device Name	Manufacturer	IDE Number
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter

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		text.

(J) Project Hypothesis, Objectives, or Goals

Briefly state the purpose of the study (research questions and/or study objectives).

We test the central hypothesis that 20-hours of intensive upper extremity motor training (therapy) based on patient-preferred activities provided remotely (called tele-CPASS) will lead to significant improvements in upper extremity motor function. We propose a non-inferiority design to test tele-CPASS because our prior phase II RCT, the Critical Periods After Stroke Study (CPASS) has already demonstrated superiority of in-person CPASS intervention over current standard of care.[1] Therefore, it is ethical to use an "active control" rather than a standard of care control group. We will provide 20-hours of upper extremity motor training because our prior work work[1,2] shows 20-hours is a feasible, tolerable, and safe dose of neurorehabilitation post stroke when patients are particularly vulnerable to fatigue (Dromerick & Geed et al. 2021).

Aim 1: Test the efficacy of tele-CPASS with respect to in-person CPASS to improve upper extremity motor function. Primary outcome for aim 1 is the Action Research Arm Test (ARAT), a commonly used clinical test of upper extremity motor function. A wrist-worn accelerometry outcome called the "amount of functional upper extremity use will be tested as a secondary outcome.

a. Hypothesis 1.1. Trajectory of upper extremity motor function is no different in tele-CPASS compared to the in-person group, measured using ARAT at baseline, post-intervention, 6-months, and 12-months post intervention.
b. Hypothesis 1.2. Trajectory of the amount of functional upper extremity use measured using accelerometers on the impaired and non-impaired wrist is no different in the tele-CPASS compared to the in-person CPASS group.

Aim 2: Test the efficacy of tele-CPASS with respect to in-person CPASS to improve social participation measured using the Stroke Impact Scale (SIS) participation at baseline, post-intervention, 6-months and 12 months.

(K) Background

Briefly describe why the study is important to individual subjects or society at large in **laymen's terms** (non-scientific and non-technical language understood by someone with no scientific background). Do not describe experimental procedures in this section. Description should be limited to no more than two to three paragraphs. **Avoid technical jargon**.

Current state of the art and gaps in stroke rehabilitation: An estimated 795,000 individuals in the US suffer a stroke annually.[2] Nearly two-thirds of the stroke survivors encounter difficulty using their impaired upper extremity (UE) in daily activities six months post-stroke, a period when spontaneous recovery tends to plateau.[3,4] This results in substantial functional limitations and potential lifelong disability.

Despite the pressing demand for effective post-stroke rehabilitation, only a handful of UE stroke trials have exhibited discernible gains in UE motor function compared to the standard of care.[5-20] CPASS therapy improves UE motor function if intervention is applied within 0-6-months post stroke. Patients also show recovery on multiple domains of self-reported health-related quality of life outcomes measured using the Stroke impact scale, irrespective of the timing of the CPASS intervention post stroke. In contrast with the long line of neutral stroke trials,[5-20] CPASS provided the first clinical evidence of heightened responsiveness to CPASS intervention. CPASS randomized individuals with stroke <28-d-prior to 1 of 4 groups, to receive 20-extra hours of study therapy starting 30-days (acute), 2-3-months (subacute), 6-months (chronic group); a control group received standard rehabilitation. Over 12-months, the subacute (+6.87±2.63, p=0.009) and acute (+5.25±2.59, p=0.043) groups showed significant, clinically meaningful improvement on ARAT compared to standard care. The chronic group was no different from controls (+2.41±2.25, p=0.29) despite receiving the same study therapy as the acute/subacute groups, suggesting patients are preferentially responsive to CPASS intervention within the acute and subacute window of time post stroke (0-6 months post stroke). Although CPASS is a UE motor intervention,

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intensive motor training and associated UE motor function recovery contributed to recovery on multiple health domains captured by the Stroke Impact Scale (SIS). Newly analyzed data CPASS shows patients receiving the CPASS intervention (but not controls receiving standard care) showed significant recovery on multiple domains of health-related quality of life measured by the Stroke Impact Scale. In unpublished results from CPASS, acute and subacute groups (but not chronic) showed significant improvements compared to controls on multiple SIS domains including global recovery (acute: 8.5±4.03, p=0.035; subacute: 9.07±4.1, p=0.027), and social participation (acute: 12.7±4.3, p=0.003; subacute: 11.3±4.04, p=0.005). These results from our prior studies form the rationale for testing efficacy of tele-CPASS on motor function recovery (aim 1) and social participation (aim 2) compared to in-person CPASS intervention.

Home-based telerehabilitation is effective and feasible.[13,21-26] A multicenter RCT in US showed intensive training produced substantial gains in UE motor function irrespective of whether training was home-based or in-clinic.[13] A recent telerehab RCT showed home-based training more than doubled the therapy dose that could be provided early post stroke.[27] A systematic review[21] of 22 home-based stroke telerehabilitation trials suggests telerehab interventions have better or equal effects on motor, higher cortical, and mood compared with face-to-face therapy. *Considering feasibility, telerehabilitation readiness, acceptance,* and *usability* in patients and caregivers is favorable.[26] Telerehabilitation mode of delivery has shown to be as efficacious as in-person care in several studies to date, costs a fraction of the in-person therapy, and shows similar outcomes in recovery as in-person care.[11,17-21] Timely consistent access to an outpatient clinic is one of the weakest links in the current rehabilitation set up that an effective telerehabilitation model can mitigate. A tele-CPASS intervention is crucial to test because it improves accessibility of therapy to those who need it the most but are unable to attend conventional outpatient rehabilitation, in their own home environments. A tele-CPASS version of the in-person CPASS intervention can supplement the conventional rehabilitation because it can be delivered anywhere that an individual has access to reliable internet and a supportive caregiver.

Need for an accelerometry-based outcome in addition to the clinical test: measurement of functional UE use with wrist-worn accelerometers: Rehabilitation effectiveness is currently measured using clinical scales like the Action Research Arm Test (ARAT).[28] However, clinical scales do not directly capture the desired rehabilitation outcome, "*How much did the individual actually use their affected upper extremity in their home and community environment?*" Clinical scales also suffer from ceiling and floor effects, which blunt the measurement sensitivity.[29] Self-reports, such as the Motor Activity Log[30] are riddled with problems such as recall bias. To address these shortcomings in the measurement of UE motor function, we have developed and clinically validated an accelerometry measure of the "amount of functional UE use" in individuals with stroke.[31-35] We recently established concurrent validity of our method against clinical scales of impairment, function and real-world use.[36] Our machine learning based accelerometry approach is methodologically rigorous and thus ready for implementation in clinical trials to quantify community-based functional UE use, as proposed here.

(L) References/Literature Review

List 10, or less, references that are pertinent to the study.

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15. Saposnik G, Cohen LG, Mamdani M, et al. Efficacy and safety of non-immersive virtual reality exercising in stroke rehabilitation (EVREST): a randomised, multicentre, single-blind, controlled trial. *Lancet Neurol.* 2016;15(10):1019-1027.
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31. Tran T, Chang LC, Almubark I, et al. Robust Classification of Functional and Nonfunctional Arm Movement after Stroke Using a Single Wrist-Worn Sensor Device. Paper presented at: 2018 IEEE International Conference on Big Data (Big Data); 10-13 Dec. 2018, 2018.
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(M) Research Method, Design, & Proposed Statistical Analysis

Brief overview of research methodology (e.g., experimental, correlational, qualitative) and specific study design and proposed analysis of the research data.

The proposed study is a single-blind, randomized, parallel group, longitudinal controlled study to test noninferiority of the tele-CPASS intervention to the in-person CPASS intervention in a cohort of individuals with stroke.

SITE-SPECIFIC STUDY ACTIVITIES:

Texas Tech activities:

1. Study screening and recruitment procedures will be completed at TTUHSC Neurology clinic by the TTUHSC clinical research coordinator (Israel Alba).
2. Any patients seen by Dr. Piriyawat who meet study screening criteria (described in study activities) will be contacted by the TTUHSC clinical research coordinator (Israel Alba) to introduce the study for potential participation.
3. Informed consent will be conducted at TTUHSC (by Israel Alba), at which time participants will be provided with the project information such as location map and study flyer prior to their first project visit at UTEP's Geed Lab. Should patients require more time to decide, project information will be provided to them by Dr. Piriyawat or their research coordinator, and a follow up visit to the Geed lab at UTEP for further study information will be scheduled by the TTUHSC clinical research coordinator.
4. Once consented, all study therapies and testing procedures will be completed in the Geed lab at UTEP.
5. There is no compensation provided to patients from TTUHSC or while they are at TTUHSC. Participants will receive a $12.50 cash stipend per assessment visit for a maximum total of $*50* from UTEP for completing the study activities.
6. Once an individual is consented and enrolled all study activities will occur at UTEP as described below in detail in the activities section.

UMC activities:

7. Study screening will be conducted by Dr. Piriyawat or his team for patients under his care at UMC. If a patient expresses interest in learning more, this will be communicated to the clinical research coordinator. The clinical research coordinator will then follow up with the patient with an informed consent to discuss potential participation.
8. Informed consent will be conducted at UMC. If UMC EP inpatients are not ready to consent at that time, the study coordinator will contact them while they are still in hospital (if that is agreeable to them) and provide them with UTEP study staff contact information (or a study flyer) for follow up.
9. A copy of the consent form will be left with the inpatient that is considering study participation so that they have the opportunity to discuss it with family, friends, treating physicians, etc.) before deciding to participate.
10. Once consented, all study therapies and testing procedures will be completed in the Geed lab at UTEP.
11. There is no compensation provided to patients from UMC or while they are at UMC as mentioned in item #5. Participants will receive $12.50 cash stipend per assessment visit for a maximum total of $*50* from UTEP for completing the study activities.
12. Once participant is consented and enrolled all study activities will occur at UTEP as described below in the

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activities section.

Description of study activities:

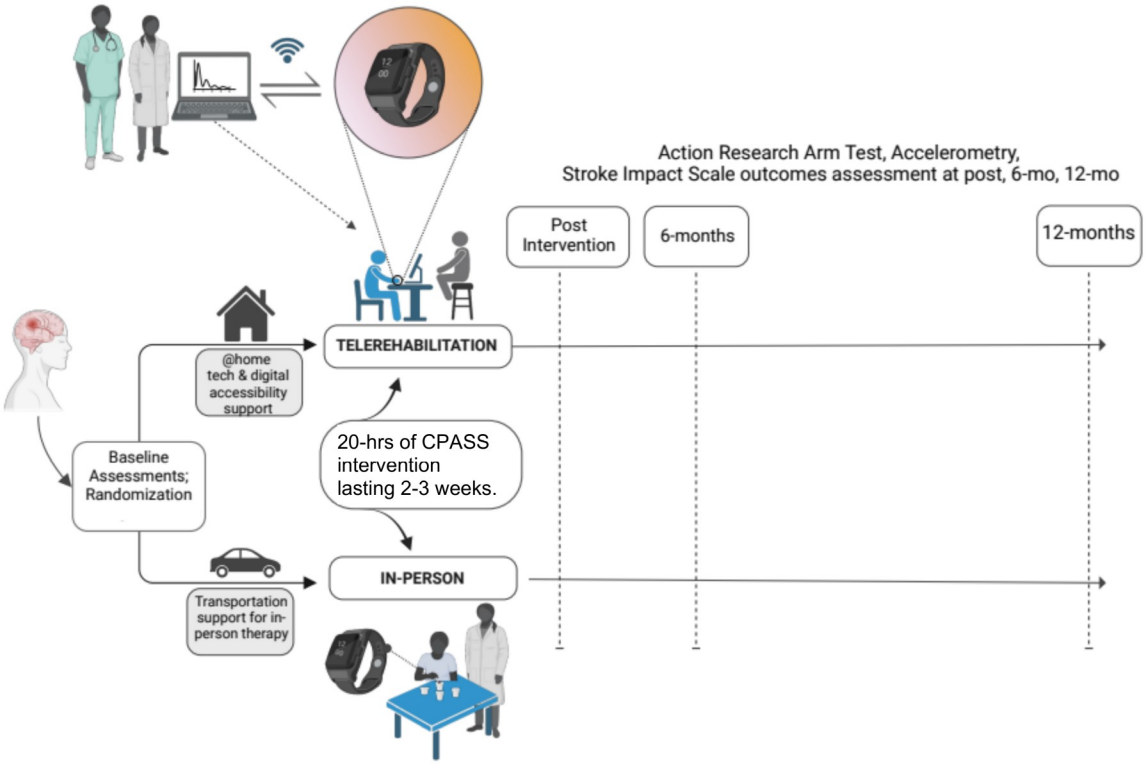


Figure 1 above shows the study design and the sequence of study activities. Following informed consent, participants will undergo in-person baseline/pre-intervention assessments in the lab (Action Research Arm Test (ARAT), Stroke Impact Scale (SIS), Activity Card Sort Test, Accelerometry activity script) at UTEP. In addition, covariate information on handedness, date of stroke, age, race, sex, education level will be collected at this baseline assessment. Following baseline assessment, these covariates will be entered into the patients' REDCap record to be used for randomization. We implement covariate adaptive randomization scheme[37,38] where a new participant is sequentially assigned to a particular treatment group by accounting for the specific covariates and previous assignments of participants. Participants will be randomized to either an in-person CPASS intervention group, or a tele-CPASS intervention group. Both groups will receive the same 20-hrs of study therapy.
The study therapist will make a home-visit to the tele-CPASS group participants with the study team to assist in any supports needed for technology access, assess suitability of the home environment for telerehabilitation and to adjust the treatment plan as needed. An activity script will be completed at home as part of this assessment.
When study therapy ends, patients will complete a post-intervention assessment, 6-month, and 12-month

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assessments comprised of ARAT, SIS, accelerometry.

Procedures for stroke groups:

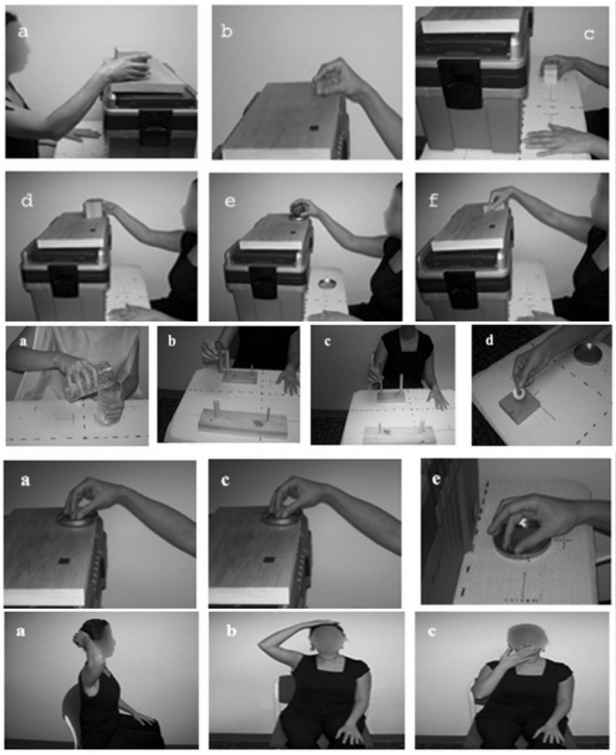
Outcome measures: The Table below outlines *study outcome measures, covariates, and randomization variables.*

Measure	Domain	Type, Time to Complete	Baseline	Post	6-mo	12-mo
Primary and Secondary outcomes						
Action Research Arm Test	Motor Function	Likert scale, 20-min	x	x	x	x
Stroke Impact Scale [28]	Stroke-specific participation	Likert scale, 15-min	x	x	x	x
Accelerometry [44]	Amount of functional UE use	3-d, remotely	x	x	x	x
Baseline Randomization, Covariates/Confounds						
Age, Sex, Race, Education	Covariate	Continuous	x			
Edinburgh Handedness[55]	Covariate	Continuous, 5-min	x			
NIH Stroke Scale [56]	Stroke severity	Continuous,15-min	x			
Activity Card Sort [57]	Activity, Participation	Continuous, 60-min	x	x	x	x
Activity Script	Accelerometry	Continuous, 45-min	x	x	x	x

Outcomes assessment: Study assessments will be completed in-person for both groups in the PI's lab in the Dept. of Physical Therapy and Movement Sciences at each assessment time point. Procedure for each study outcome assessment is described briefly in the paragraphs below:

Action Research Arm Test (ARAT): is the primary outcome for aim 1. ARAT will be administered at Baseline/preintervention, post-intervention, 6-month, and 12-month assessment timepoints in person, in the PI's lab. The trajectories of ARAT between groups will be assessed to test hypothesis 1.1. The fig on the right shows the 4 domains of prehension (grasp, grip, pinch, and gross-motor) tested in a study participant. The 19 tests of the ARAT are distributed across 4 sub-scales, with 3 to 6 tasks each. Each task runs until the subject completes the task or until reaching a time limit of 60 seconds. The quality of the task is rated on an ordinal 4 point-scale from 0 to 3. The maximum score for the ARAT is 57 for each arm, with a higher score indicating better arm motor status. A score of 0 is given when the subject is unable to complete any part of the hand or arm movement components within the 60 seconds allotted for examining each task. A score of 1 is given when the subject only partially completes the task within the 60 seconds allotted for examining each task, regardless of the quality of hand and arm movement components or posture requirements. A score of 2 is given when the task is completed but either "with great difficulty or takes abnormally long." "Great difficulty" is defined as task completion in the setting of either (1) abnormal hand movement components (e.g., use of wrong grasp), (2) abnormal arm movement components (e.g., the elbow does not flex as required), or (3) abnormal body posture

Fig shows grasp (rows 1-2), grip (row 3), pinch (row 4), and gross motor (row 5) tests used in ARAT for upper extremity motor function assessment.



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(e.g., used as a substitute for impaired arm movements). A score of 3 is given when the task is performed normally. This requires the task be completed in less than 5 seconds, appropriate body posture, normal hand movement components, and normal arm movement components. Study participants receive instructions for the task verbally by the study therapist.

Accelerometry and activity script, video annotation for machine learning modeling: participants from both groups will complete an "activity script" wearing accelerometers on both wrists in-person in the PI's lab and at home at each assessment time point (baseline, post-, 6-months, 12-months). Participants are videotaped while completing the activity script (the focus of the camera will be on the participants arms/hands and accelerometers during task performance).

- The video data recorded concurrently with in-lab accelerometry will be annotated offline using our previously published methods.[33,35] Briefly, the PI and study research assistants will watch the videos offline. When an arm movement is seen, the video is stopped and rewound to mark the start and end of the movement. All frames between the start and end frame of each movement will be labeled according to the 5 FAABOS categories (FAABOS scale is attached to list of instruments).
- Five FAABOS categories will be collapsed these into 3 categories: functional, nonfunctional, or unknown by each annotator. The functional category includes purposeful upper extremity movements like gesturing, reach to grasp, pushing open a door, and so on. The nonfunctional category includes arm movements associated with gait, sit-to-stand, or other whole-body movement that did not include a functional arm movement. The no-movement periods between these periods of arm movement are labeled nonfunctional. In case video frame labels disagree between the two annotators, third study personnel (Gurovich) will be consulted to resolve the label conflict.
- The goal for accelerometry during activity script in lab is to develop machine learning models (training data) to identify activities and instrumental activities of daily living from accelerometry data. The annotated frame-by-frame video data (in #1.2.1 and #1.2.2) will be processed with concurrently recoded accelerometry to "train" the classifiers to recognize purposeful upper extremity movements from 3-day accelerometry data streams collected in the community.
- The video data will be accessed only by study team; therefore, face and name de-identification will not be necessary. In case the video needs to be shared for research collaboration, we will use "deface", an automatic command-line tool for anonymization of faces in videos (https://github.com/ORB-HD/deface). It first identifies all human faces in a video frame then applies an anonymization filter (blur or black box) on each face region. All audio tracts are discarded by default. The video data files will be stored in encrypted computers in the PI's lab.
- For the tele-CPASS and in-person groups, we will video record upper extremity movements during the therapy sessions. These are no different from the video recordings completed during activity script testing, when patients perform activities and instrumental activities of daily living. These video recordings will be annotated using the FAABOS categories (by research assistants at UTEP) and used to train the accelerometry data for identifying purposeful movements.

Stroke Impact Scale: the stroke impact scale (SIS) is the primary outcome for aim 2. SIS is a self-report questionnaire that evaluates disability and health-related quality of life after stroke. SIS is a 59-item measure that assesses 8 domains, strength, Strength (4 items); Hand function (5 items); ADL/IADL (10 items); Mobility (9 items); Communication (7 items); Emotion (9 items); Memory and thinking (7 items); Participation (8 items). Each item is rated in a 5-point Likert scale in terms of the difficulty the patient has experienced in completing each item. Summative scores are generated for each domain; scores range from 0-100. An extra question on stroke

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recovery asks that the client rate on a scale from 0-100 how much the client feels that he/she has recovered from his/her stroke. Transformed scores will be calculated using the formula: Transformed Scale = [(Actual raw score - lowest possible raw score) / Possible raw score] * 100. A Spanish-version of the SIS will be administered to participants who prefer Spanish. Both English and Spanish language SIS instruments are included in the list of study instruments.

Statistical Analysis: intent-to-treat analysis will test for comparable efficacy of tele-CPASS compared to in-person CPASS based on a non-inferiority margin of 10% difference, a clinically meaningful difference in ARAT scores controlling for baseline scores and covariates (Table 2). Any variables differing at baseline will be included as covariates; alpha will be set to 0.05, multiple comparisons will be *Bonferroni* corrected as required.

Aim 1: will compare the ARAT trajectory between in-person and tele-CPASS groups. Hypothesis 1.1 will be tested using a mixed-effects model with *study group* (between subjects) and *time* (within subjects) as predictors, *race, age, sex, baseline arm impairment* (ARAT) and *number of days between stroke onset to randomization* as the covariates. Results will be presented as adjusted difference in means with associated 95% confidence intervals. Tele-CPASS will be deemed non-inferior to in-person CPASS if the adjusted mean difference between groups is <6.6 points (the minimal clinically important difference for ARAT). A similar approach but with "amount of functional UE use ratio" from accelerometry data in the community will be used to analyze the secondary outcome in hypothesis 1.2; a <10% difference between groups is set as the a priori non-inferiority margin.
Aim 2 will compare the SIS-Participation trajectories between tele-CPASS and in-person groups: similar statistical analysis approach as in Aim 1 will be used, except for use of SIS-Participation scores as the dependent variable.

(N) Sample

Identify the sources of potential participants, derived materials, or data.

Define the study sample (number of subjects to be enrolled, characteristics of subjects, inclusion, and exclusion criteria).

The trial aims to establish comparable efficacy of tele-CPASS based on a non-inferiority margin of 10% difference, a clinically meaningful difference in ARAT scores. We used the *powerlmm* package in R in the RStudio environment to perform power analyses for a longitudinal mixed effects model allowing random intercepts and slopes with four time points (at baseline, post, 6-mo, and 12-mo timepoints). Assuming a 12% drop off, mean difference between groups=6.6 points±11 points, we will enroll 42 individuals with stroke (21/group) for 80% power and alpha=0.05.

Recruitment Methods	☐ **Email**	☒ **Face to face**	☒ **Flyers**	☐ **Phone**	☐ **Online ads**
	☐ **Presentation**	☐ **Social media**	☐ **SONA**	☐ **Other:** Click or tap here to enter text.	

Explain how you will recruit, screen, and follow study participants.

Study screening criteria include age ≥21-years, neuroimaging confirmed stroke <40-days prior, and NIH Stroke Scale (NIHSS, motor arm item score 3 or less) on the impaired side. Screen-eligible candidates will be invited to complete the informed consent procedures for further assessment and randomization. Patients and their caregivers will be provided ample time to clarify their questions and concerns and discuss study participation with their primary physician and stroke neurologist. Informed consent procedure will be completed either at TTUHSC, UMC or at UTEP in the PI Geed's lab as described below and in site-specific activities.

TTUHSC-EP activities:

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1. Study screening and recruitment procedures will be completed at TTUHSC Neurology clinic by the TTUHSC clinical research coordinator (Israel Alba).
2. Any patients seen by Dr. Piriyawat who meet study screening criteria (described in study activities) will be contacted by the TTUHSC clinical research coordinator (Israel Alba) to introduce the study for potential participation.
3. Informed consent will be conducted at TTUHSC (by Israel Alba), at which time participants will be provided with the project information such as location map and study flyer prior to their first project visit at UTEP's Geed Lab. Should patients require more time to decide, project information will be provided to them, and a visit to the Geed lab at UTEP for further study information will be scheduled by the TTUHSC clinical research coordinator.
4. Once consented, all study therapies and testing procedures will be completed in the Geed lab at UTEP.
5. There is no compensation provided to patients from TTUHSC or while they are at TTUHSC. Participants will receive a $12.50 cash stipend per assessment visit for a maximum total of $50 from UTEP for completing the study activities. If a participant chooses to withdraw before completing the study, they will still receive $12.50 for each assessment completed prior to withdrawal.

UMC-EP activities:

1. Study screening will be conducted by Dr. Piriyawat or his team for patients under his care at UMC. If a patient expresses interest in learning more, this will be communicated to the clinical research coordinator. The clinical research coordinator will follow up with the patient with an informed consent to discuss potential participation.
2. Informed consent will be conducted at UMC. If UMC EP inpatients are not ready to consent at that time, the study coordinator will contact them while they are still in hospital (if that is agreeable to them) and provide them with UTEP study staff contact information (or a study flyer) for follow up.
3. A copy of the consent form will be left with the inpatient that is considering study participation so that they have the opportunity to discuss it with family, friends, treating physicians, etc.) before deciding to participate.
4. Once consented, all study therapies and testing procedures will be completed in the Geed lab at UTEP.
5. There is no compensation provided to patients from UMC or while they are at UMC as listed in item #5 above. Participants will receive a $12.50 cash stipend per assessment visit for a maximum total of $50 from UTEP for completing the study activities. If a participant chooses to withdraw before completing the study, they will still receive $12.50 for each assessment completed prior to withdrawal.
6. Once participant is consented and enrolled all study activities will occur at UTEP as described below in the activities section.

Inclusion/Exclusion criteria for stroke groups: Table below lists study inclusion/exclusion criteria.

	Study Inclusion
1	Age > 21-years.
2	Neuroimaging-confirmed stroke <40-days prior.
3	Able to participate in all study-related activities including the 1-year follow up.
4	Persistent hemiparesis leading to impaired upper extremity function, indicated by score of 0-3 on the NIHSS motor arm item score.
5	Score of ≤ 8 on the Short Blessed Memory Orientation and Concentration Scale
6	Able to follow 2-step commands; Montreal Cognitive Assessment (MoCA) >25
7	No upper extremity injury or conditions that limit use of upper extremity prior to the stroke.
	Study Exclusion
1	Inability to give informed consent.
2	Persistent disabling neurologic conditions such as multiple sclerosis, Parkinsonism, ALS, dementia requiring

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medication.
3 Clinically significant fluctuations in mental status in the 72-hours prior to randomization.
4 Active or prior psychosis within 2 years, active or prior substance abuse.
5 Dense sensory loss indicated by score of 3 or 4 on the NIH stroke scale sensory item.
6 Ataxia out of proportion to weakness in the affected arm as defined by score of ≥ 1 on NIH stroke scale ataxia item.
7 Not expected to survive 6 months due to other illnesses (cardiac, disease, malignancy).
8 Pregnancy.
9 Severe aphasia.
10 Receipt of Botox of expectation to receive Botox during study duration.

Is there a **possibility** of coercion or undue influence?	☒ Yes ☐ No

If YES, describe whether some, or all, the participants are likely to be vulnerable to coercion or undue influence, and if so, what additional safeguards are included to protect their rights and welfare.

What is your rationale for using participants whose ability to give voluntary informed consent may be in question.
Participants include students in one's class, people currently undergoing treatment for an illness or problem that is the topic of the research study, people who are cognitively impaired, and vulnerable populations.

N/A

(O) Informed Consent

The formal consent of each subject must be obtained before that subject is subjected to any study procedure.

Describe how participants will be fully informed of this research prior to their participation and how their voluntary consent will be documented.

Informed consent procedures will be completed by the study clinical research coordinator where the patient is located at the time of study presentation – at UTEP, UMC-EP, at TTUHSC-EP. If the patients need more time to decide on study participation, a follow up visit will be scheduled in the PI's lab (Geed) at the Dept of Physical Therapy and Movement Science at UTEP. The clinical research coordinator or PI will review each aspect of the informed consent form with the individual, explaining the study procedures. Potential participants will be provided ample time to review the consent form after this in-person review, provided time to consult with their families/care takers, and clinical team, as well as given time to ask questions to the PI. They will be explained the voluntary nature of their participation and explained that "they have the ability to stop study participation at any time". Consent will be documented using the IRB-approved informed consent form, signed by the participant and the study PI. A copy of the signed informed consent will be provided to the study participant for their record; the original copy will be stored in a locked cabinet in the PI's office at UTEP.

If you anticipate enrolling subjects whose primary language is not English, how will you obtain informed consent in the language of those participants.

Participants will be included if they meet the study eligibility criteria. Eligible participants may speak/read in either Spanish or English.

Identify who will be involved in the consent process and where this will occur.

The informed consent will be completed by the clinical research coordinator or the PI (Geed). All informed consents will be completed in either TTUHSC, UMC, or in the Geed lab at UTEP in the Dept. of Physical Therapy and Movement Sciences at UTEP.

You must request a waiver for non-exempt projects to add, change or remove parts of informed consent; provide verbal consent; post consent online with an option to consent by checking a box or clicking a button; or use deception or incomplete disclosure. Select only one option below then upload a Request for a Waiver of Documentation or Alteration of Consent form.

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☐	Waiver of the requirement to obtain documentation of informed consent **[45 CFR 46.117(c)(1)] (Signature)**
☐	Waiver of the requirement to obtain informed consent **[45 CFR 46.116(f)(1)]**
☐	Alteration of one or more of the required elements of informed consent. **[45 CFR 46.116(f)(2)]** **(Deception or Incomplete Disclosure)**

(P) Detailed Study Procedures

Outline step-by-step what will happen to the human subjects in this study.

What will you ask your participants to do?

1. Study procedures will be completed by the study PIs or study therapists.
2. **Preliminary screening**: once an individual expresses interest in the study, a brief screening will be conducted consisting of a review of the study inclusion/exclusion criteria with them in person. The informed consent procedures outlined in the study protocol will be completed.
3. **Behavioral testing**: stroke participants will complete a behavioral testing to assess the degree of upper extremity motor function impairment using the Action Research Arm Test (ARAT), NIH stroke scale score (NIHSS), and the stroke impact scale hand-arm questionnaire (SIS). Participants will also complete the Activity Card Sort Test, Handedness testing (right or left-handed), and the demographics form.
4. **Activity script**: all participants will complete the Activity script in home and in lab while wearing the accelerometers. The activity script takes approximately 20-40 minutes for completion depending on the patients' degree of arm impairment. The activity script will be video recorded by the study personnel or with a chest-worn camera; a frame-by-frame annotation of the activity script video will be completed by the study personnel based on the Functional Arm Activity Behavioral Observation System (FAABOS).[37] This annotation is essential to train the accelerometry data streams for classification of functional from non-functional movements.
5. Tele-CPASS group participants will be trained in the proper use of the accelerometers, including which sensor goes on which arm (they are labeled by R, L for right or left and different colors) and independently donning/doffing the sensors on both arms.
6. **Therapy planning and calendar of study events:** All participants will complete the Activity Card Sort Test with their study therapist to initiate the treatment plan. Participants will list their top ten priorities for motor function recovery using activities they used to do previous to their stroke, that is a priority for them, and they would like to regain this lost function via practice during the 20-hours of study therapy.
7. **Schedule of study activities:** following the initial study treatment planning session, participants in both groups will receive a calendar of study events including dates for assessments, the days, and times of therapy sessions, whom to call if the session needs canceling. Tele-CPASS group participants will also receive a telerehab therapy kit and an internet-enabled tablet with hardware for internet access if needed, to complete the therapy sessions from home.

When and where will they do it?

A schedule of activities will be provided to patients in both groups. Our prior experience suggests patients need roughly 12.4 sessions to complete 20 hours of study therapy. In-person therapy will be completed in the physical therapy department at UTEP, tele-CPASS will be completed in the patients' own homes.

How long will it take them to do it?

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We expect participants to complete all study therapy and assessments within 45-days of their primary endpoint.

Describe the type of research information that you will be gathering from your subjects, i.e., the data that you will collect.

We will collect data on patient demographics (age, sex, race, ethnicity, education), upper extremity motor function (ARAT), and patient-oriented outcomes like the stroke impact scale data. We will also record the amount of upper extremity movements they complete each day via wrist-worn accelerometers. Participants will need to wear the accelerometers during study therapy and for all waking hours during 3 days in any regular week except when they are washing themselves for the in-home data to estimate routine upper extremity use in the community. Finally, we will record patients' activity script sessions as the video data is essential to train our machine learning classifiers.

Identify the measurement/instrumentation. For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this project.

All the outcomes used in this study are psychometrically robust and used routinely in stroke rehabilitation.

Will you be audio or video recording during any portion of this project?	☒ Yes ☐ No

If **yes**, this information must be described in all pertinent sections and the ICF(s). YES.

Will subjects be **compensated** (payment, incentives, extra credit, etc.)?	☒ Yes ☐ No

If **yes**, details should be included here.

Participants will be compensated $12.50 for each assessment completed, for a maximum total of $50 if all four assessments are completed. Each assessment will take approximately 2–3 hours. If a participant chooses to withdraw before completing the study, they will still receive $12.50 for each assessment completed prior to withdrawal. No partial payments will be made for incomplete assessments. Patients will NOT receive any compensation from TTUHSC-EP or UMC-EP.

(Q) Privacy & Confidentiality

Describe how the project team will protect the privacy and confidentiality of study participants.

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **Confidentiality** pertains to the treatment of information or data that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Ensuring privacy of participants is different from confidentiality of data.

Each study participant will be assigned a randomly generated participant id. The linkage will be stored on encrypted files on encrypted devices that are not connected to the internet in the PI's lab. The personally identifiable health information will be similarly stored in linked file that is stored on encrypted devices. The remainder of the data will be digitized and stored under the randomly generated participant IDs. Paper versions of the clinical case report forms will only use the study IDs and will be stored in locked cabinets inside a locked room (PI's lab at UTEP (3333 N Mesa St.). Subjects will not be mentioned by name in any publications and their face will be blocked out in any images that are used for dissemination. In addition, all data with patient identifiers will be accessed only the study personnel (PI). Upon study completion, all subject documents will be stored in a locked drawer for five years before being shredded and disposed off. Electronic records will be deleted. Confidentiality will be maintained throughout the study duration.

(R) Data Handling, Record Keeping, & Data Analysis

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Describe how the project team will collect, manage, and analyze data.		
The study data will be collected by personnel listed on the protocol. Deidentified data may be shared with the PI's collaborators for publication purposes.		
Describe the type of research information that you will be gathering from your subjects, i.e., the data that you will collect.		
The study will collect demographic information, medical history relevant to stroke, clinical variables, and accelerometry data. The activity script (20-40 min long) will use video capture either by a chest-worn camera mounted to a chest-harness on the participant or by a handheld camera operated by the study research assistant, concurrently with accelerometry. Video capture is essential to do a frame-by-frame annotation of whether the activity seen in the video frame is a prehensile or non-prehensile activity. This annotation is used to train the machine learning classifiers for accelerometry data streams (data from participants' everyday arm use in their own communities). Our methods have been published extensively (Geed et al. 2022).		
Describe provisions that will be made to maintain **confidentiality** of the data. Will it contain subject names or images? (e.g., surveys, video, audio tapes, database).		
A single file containing the participants' personally identifiable health information (PHI) and demographics with a linked randomly generated study ID will be stored in an encrypted file on a computer (encrypted) that never connects with the internet, place in the PI's lab. This lab has restricted access. The remainder of the deidentified data from accelerometry or video capture (with facial blurring) may be shared with PI's collaborators as needed for publication.		
Describe the security plan for data, including **where** data will be stored, and **for how long**, noting that you may not keep identifiable data indefinitely (i.e., password protection, encrypted, locked filing cabinet, etc.)		
Any PHI data will be limited to a single file that links the subjects' PHI with a randomly generated study ID #. This linkage file will be password protected and stored on a password protected computer without any internet access in the PI's lab that also has restricted card access for a maximum of three years after the study closes to ensure any results from these data that might need revisiting patients' information can be traced to the patients for clarifications. The linkage file will be destroyed once this time is up. The remainder of the study data will use the randomly generated subjects ID #s and will be saved on password protected files on password protected computers at all times. Deidentified data may be shared with study collaborators for publications.		
Will you maintain a subject list that has direct identifiers linked to a unique study ID/code?	☒ Yes	☐ No
If **yes**, how will you secure this linked subject list?		
A list linking their names and randomly generated participant ID # will be kept in a password protected file on a password protected computer that does not access the internet in the PI's lab.		
Will **UTEP study personnel** electronically transmit identifiable **data** or identifiable **samples** to a **non-UTEP recipient**?		
If **yes**, provide the type of data and plans to secure them.	☐ Yes	☒ No
N/A		
What will happen to the **identifiable data** at the end of the study?		
[redacted]	☒	Identifiers permanently removed and destroyed.
[redacted]	☐	Recordings transcribed without identifiers and destroyed.
[redacted]	☐	Identifiable or coded (that can be linked) data are retained.

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(S) Risks

Most studies pose some degree of risk, even if the risk is minimal. A common risk is the loss of the confidentiality of participants' responses.

Describe **any** potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness

There are no to minimal risks with this study. Similar procedures have been used in our prior publications and in numerous research labs worldwide. Study procedures pertain to providing therapy to improve upper extremity motor impairment in individuals with stroke, these practices are not very different from what is experienced in an outpatient rehabilitation clinic.

Describe the procedures for protecting against (or minimizing) any potential risks and include an assessment of their effectiveness.

Negative incidents discovered during clinic visits, like a fall will be immediately reviewed by the PI (Dr. Geed) before the participant leaves the clinic. The subjects will be instructed to call the PI should any complications arise. An adverse event (any study-related unexpected event) that may increase harm to a participant or result in a breach of confidentiality will be reported to the UTEP IRB. We will immediately report to the IRB (within 24 hours) an unanticipated adverse event, with a brief summary of the event using email. The study will send a safety vent submission one week to the IRB. For a reportable serious adverse event, the study PI will notify the IRB within five business days of the PI becoming aware of the event. For any other nonserious adverse events, the study will keep a log of the event, preceding events, and subsequent effect if any on the participant via monthly phone calls with the study participant. These events will be submitted to the IRB during annual continuation of the protocol.

If the study involves a procedure that introduces a physical risk, specify arrangements for providing medical treatment if it should be needed.

See above.

If the study involves a procedure that introduces a psychological risk, such as the recall of a traumatic event, specify arrangements for providing psychological treatment if it should be needed.

N/A

Were there alternate and potentially less risky methods that were considered as possible methods; why were they not used?

The in-person version of this therapy has been tested in a phase II RCT and published. There is no alternative method, there are minimal risks with these methods, no more than what a patient might encounter in regular outpatient therapy.

If the research methods impose risks on the subjects, include evidence that may justify their use (such as previous experience with the procedures).

N/A

Could the information obtained or recorded about subjects place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, or reputation?	☐ Yes ☒ No

(T) Benefits

Describe and assess the **potential benefits** to be gained by participants (if any) and the benefits that may accrue to society in general because of the planned work. Discuss the risks in relation to the anticipated benefits to the participants and to society.

Study participants may experience improvement in their upper extremity motor function as a result of the in person or tele-CPASS participation, but this is not guaranteed. The proposed protocols will provide clinical evidence that a telerehabilitation approach is equally efficacious as an in-person intervention to improve upper

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extremity motor function after stroke. This is important because telerehabilitation may help mitigate health disparities by providing the needed care to patients who cannot always drive or have easy access to a therapist.

Note: Monetary compensation and extra credit **are not** a benefit.

(U) Research Resources

Please describe your research resources.

Discuss the staff, space, equipment, and time necessary to conduct research and how these needs are met.

The PI has access to the staff, space, equipment, and time necessary to conduct research studies in her lab at UTEP.

Please include a description of the proximity of any resources such as emergency facilities, emergency care or medical/psychological care, and any support services.

The research space is easily accessible to emergency personnel if needed.

If the study necessitates Environmental Health & Safety (EHS) or Institutional Biosafety Committee (IBC) oversight and approval, please describe here.

N/A

(V) Assurances- Conflict of Interest and Fiscal Responsibility

All UTEP researchers (faculty, staff, and students) and outside collaborators who will be conducting human subjects' research (intervention and/or interaction) must complete human subject research ethics training to conduct research with human participants.

Do you or any person responsible for the design, conduct, or reporting of this project have an economic interest in, or act as an officer or director of any outside entity whose financial interests may reasonably appear to be affected by this project?	☐ Yes ☒ No
If **yes**, explain any potential conflict of interest.	
Click or tap here to enter text.	
Do you or any person responsible for this project have existing financial holdings or relationships with the sponsor of this study?	☐ Yes ☒ No
If **yes**, explain any potential conflict of interest.	
Click or tap here to enter text.	

(W) Principal Investigator Certifications:

With this submission I certify that:

☒	I agree to fully comply with the ethical principles and regulation regarding the protection of human subjects in research.
☒	I agree that the information provided in this form, and all other supporting documents are accurate and complete.
☒	I accept responsibility for making sure all study personnel involved in the project have been appropriately trained. PI affirms responsibility for keeping training records on file for all study personnel.
☒	I understand that any changes in procedure with affect to participants must be submitted to the IRB for written approval prior to their implementation. Furthermore, I understand that any adverse events and significant changes in risk for participants must be immediately reported in writing to the UTEP IRB.

Copies of all required documentation of consent (if applicable) and any related to this research are securely

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stored as outlined above in Click or tap here to enter text. (UTEP database or building and office number).

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