Effects of Post-Stroke Upper Extremity Assistance

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1. PURPOSE OF THE STUDY

a. Brief Summary

The purpose of this study is to quantify the improvement of post-stroke individuals' ability to move their arms during and after robot assisted therapy.

While researchers know that robot assisted therapies improve motor performance over the course of weeks, they do not know how motor performance is affected over the course of minutes or hours. A better understanding of how robot assisted therapies affect motor performance on short time scales may help us to prescribe more effective therapy doses to maximize motor recovery after neurological injury.

The study will allow us to obtain a detailed understanding of the performance of the device as described above.

b. Objectives

Clinicians and researchers currently have a very limited idea of how to best manage motor recovery from stroke. Recent studies have sought to create robotic therapists to increase the dosage of physical therapy that patients are able to receive, since physical therapists have limited time and limited physical stamina for administering therapies. While these robotic assisted therapies have produced good results, they have often fallen short of expectations. One hypothesis is that rehabilitation doses remain low due to the expense and bulk of robotic devices. We have developed inexpensive, lightweight devices to provide similar assistance that will allow us to (1) examine the effects of a single dose of robot assisted therapy and (2) examine to the cumulative effects of multiple doses. The ultimate goal of this work is to prescribe a program of therapy that produces the largest rehabilitative effects, which is particularly important for patients recovering from stroke as they have a limited window of recovery of about 6 weeks.

c. Rationale for Research in Humans

This study seeks to understand the effects of assistive devices in rehabilitation in human stroke patients, necessitating the inclusion of human stroke patients.

2. STUDY PROCEDURES

a. Procedures

Patients admitted to Stanford Hospital for stroke (e.g., in the Stanford Neurology & Neurological Sciences Clinic) or receiving rehabilitation services (e.g., in the Stanford Physical Medicine & Rehab Clinic) or stroke survivors from the community who have indicated interest in participating in research studies at Stanford will be screened (under a waiver of authorization for recruitment) to determine eligibility. During this screening process, physicians and select coordinators may access medical records to check patient details against the inclusion/exclusion criteria specified.

Final determination of patient eligibility and approach to inform of eligibility will only be performed by treating personnel (e.g., physicians).

Once an eligible stroke survivor has agreed to participate, he or she will be placed in contact with one of the study's key investigators for a final telephone screening (see attachment). If everything is as expected, the subject will be scheduled for sensorimotor assessments described below. The study should take approximately 4 hours (including breaks),potentially over the course of multiple days. The first assessment will be to assess baseline without the compliant passive arm support and the second will be with the compliant passive arm support. Described in further detail below.

The research procedures used in this assessment do not include any experimental drug treatments or patient randomization. All subjects will receive complete standard of care.

When a participant arrives for the first study session, time will first be allocated to go through the consent document and answer any questions.

Once participants have granted their informed consent, a subset of non-invasive clinical assessments will then be administered by the study personnel. These assessment include one or more of the following: Mini Mental State Exam, Line Bisection Test, Fugl-Meyer Assessment (FMA), Modified Ashworth Scale (MAS), Action Research Arm Test (ARAT), Wolf Motor Function Test (WMFT), and simple tests for joint range of motion and visual/tactile neglect.

The sensorimotor assessment evaluates a subject's ability to move the arm to acquire targets and range of motion. While subjects are seated, their arm will be supported against gravity by compliant passive arm support (described more below) or another passive support (also described in more detail below). Motion will be recorded using an optical motion capture system (PhaseSpace). While seated, subjects will be asked to actively move their arm to acquire targets or explore the range of their workspace or will be passively moved by the experimenter.

The assessment will be performed using a subset of the following devices:

(1) Mor-Medical Euro Style Rehab Shower Chair: Subjects using the rigid arm support will be seated in a medical-grade rehab shower chair. The chair's caster wheels allow for

precise adjustment of the subject relative to the linkage; this is necessary for alignment of the subject's joints with those of the linkage. The wheels lock in place to secure the subject in an aligned position. The chair is adjustable to four discrete heights to accommodate subjects of different sizes.
A chest belt prevents motion of the torso relative to the rigid arm support.

(2) PhaseSpace motion-capture system: The motion-capture system measures the three-dimensional location in space of specialized markers. These markers will be strapped to a subject to record and analyze the kinematics of his/her limbs in space. The data is processed and saved remotely by a computer.

(3) Delsys surface EMG system: EMG records muscle activity via skin- mounted electrodes; these are passive and non-invasive. The signal recorded by the sensors are processed and saved remotely by a computer.

(4) Passive arm support: As a control for the compliant passive arm support, participants might be asked to perform the same reaching tasks while their arm is supported passively by an arm support. These passive arm supports will either consist of an arm rest mounted on bearings on top of a table such that the arm is free to slide across the table, but participants can rely on the arm rest for support against gravity.

Alternatively, the arm rest might be hung from the ceiling with high- strength nylon chord so that the height of the support can be adjusted while maintaining the low-friction gravity support.

(5) Compliant passive arm support: The device consists of two linkages, 1 vertical linkage that runs from the waist to the shoulder and 1 that runs from the shoulder to the elbow, and elastic bands connecting the two linkages to lift the upper-arm linkage upwards relative to the vertical linkage. The vertical linkage connects to a commercial posture brace at the waist while the upper arm linkage rests under the participant's arm and is secured with hook-and-loop fastener. The design of the device, with several compliant elements, ensures that one device fits many without joint alignment concerns.

Subjects may be asked to perform similar assessments on multiple days to check for lingering effects.

Video will be recorded for the study. Video may be processed to extract additional motion data, which will extract the relative locations of parts of the body, such as the hand, elbow, and shoulder. Any motion data presented from video recordings of the motion capture system will thus not include identifiable characteristics. We will also record video of participants as they perform the Wolf Motor Function Test (WMFT) in accordance with the WMFT protocol. In these WMFT videos, we will use blur the faces of all participants. All videos will be archived on an internal lab server. The videos will be transferred to a secure encrypted database, RedCap or Stanford's Google Drive (only researchers on this protocol will have access to the videos). No other people outside the study team will have access to the videos.

Between uses, all components that contact human skill on the device will be disinfected either two (purple top) Super Sani-Cloth wipes or a UV-C Sanitizing Wand. If the wipes are used, the surface will be wiped for a total of two minutes, ensuring the entries surface is wet the entire time. This will be repeated once more after drying. The device will be allowed to air dry for a total of two minutes.

We have active and completed protocols that have used similar devices and experimental procedures such as "Measurement of Post-Stroke Sensorimotor Performance" -- which uses similar participants, devices, and techniques as the current application -- and "Measurement of Biomechanical Response to the Use of Robotic Assistance Devices for Human Running" -- which uses similar measurement techniques as the current application.

b. Procedure Risks

Subjects will be recruited from the Stanford Neurology & Neurological Sciences and Physical Medicine & Rehab clinics – both outpatient, as well as from Stanford databases in which stroke survivors from the community have indicated their interest in participating in research studies. The study will not interfere with patient care; patients will be allowed to continue taking any medications and attending therapy over the course of the study. The study will use non-invasive measurement techniques to record the motion of the subject – the minimum data need to perform this study.

Appropriate cleaning procedures will be utilized to prevent the spread of COVID-19.

c. Use of Deception in the Study

No deception will be used.

d. Use of Audio and Video Recordings

Video will be recorded for the study. Video may be processed to extract additional motion data, which will extract the relative locations of parts of the body, such as the hand, elbow, and shoulder. Any motion data presented from video recordings of the motion capture system will thus not include identifiable characteristics. We will also record video of participants as they perform the Wolf Motor Function Test (WMFT) in accordance with the WMFT protocol. In these WMFT videos, we will use blur the faces of all participants. All videos will be archived on an internal lab server. The videos will be transferred to a secure encrypted database, RedCap or Stanford's Google Drive (only researchers on this protocol will have access to the videos). No other people outside the study team will have access to the videos.

e. Alternative Procedures or Courses of Treatment

We are not offering or withholding any standard treatment. Any courses of treatment offered by the Stanford Neurology & Neurological Sciences or Physical Medicine & Rehab clinics could be advantageous to participants.

These range from medication, such as Botox injections for spasticity, to physical therapy, such as targeted movement practice. Given that participants are recruited from the clinic

and/or are allowed to continue current medications and physical therapy, it is unlikely that there are alternative procedures or treatments known to be beneficial.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

Lab-developed devices used in this study are not intended as treatment but as tools for elucidation and quantification of the effects of assistance on movement. Should subjects find an activity performed during our study to be particularly helpful, they can consult with their physical or occupational therapists on ways to incorporate similar activities into their treatment.

g. Study Endpoint(s)

The study is not evaluating treatments.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

Stroke results from significantly reduced blood supply to part of the brain and is one of the leading causes of long-term adult disability [1]. Stroke survivors can suffer from a large range of negative effects such as pain, spasticity (continuous contraction of some muscles), muscle weakness, hemineglect (unawareness of half of space), and cognitive deficits. Some researchers believe that the main cause of post-stroke motor impairment is abnormal muscle co-contractions [2]. These abnormal muscle co-contractions were first observed as the coupling of shoulder abductor with elbow flexor muscles and shoulder adductor with elbow extensor muscles [3]. Since then, post-stroke abnormal muscle co-contraction patterns have been observed for a range of upper extremity tasks [4], as well as for walking [5]. While there is a highly nonlinear relationship between the electromyographical (EMG) signals on which these analyses are based and the resultant joint torques, abnormal joint torque couplings have been found that match the EMG-based results [6]. These researchers have also demonstrated substantial improvements in motor function, achieved by supporting the weight of the hemiparetic arm with an air bearing, which unloads the shoulder abductor muscles [7].

Many researchers are developing robots to work with humans with neuromotor impairments for assistance or re- habilitation. A large number of these robots are designed to help users repeatedly perform a task [8], [9], but this approach might not be optimal for stroke rehabilitation [10], [11]. Building on the results from [7], Ellis et al. [12] designed and built an impairment-specific rehabilitation robot, ACT3D, to provide shoulder abduction support. They then administered a therapy in which shoulder abduction support was gradually reduced over a period of eight weeks and found several motor improvements [12], [13]. However, the level of motor recovery is tied to the intensity of therapy, and most rehabilitation robots are expensive, unwieldy devices confined to the lab or clinic where patients have limited access to them.

Many of the robots currently being developed for rehabilitation are exoskeletal robots. Typical exoskeletal robots are constructed from rigid linkages acting in parallel with the

user's skeleton. These linkages are then attached at various points on the body by cuffs or straps to transmit forces and torques.

Motors or hydraulic actuators then actuate these linkages. By including linkages acting in parallel with the user's skeleton, an exoskeleton transmits many of the forces that would otherwise need to be transmitted through the user's skeleton. Such exoskeletal robots have already been developed for stroke rehabilitation [8], [12], [13]. These robots show promise in taking state-of-the-art rehabilitation out of the clinic. However, there are many difficulties associated with the design and operation of traditional exoskeletal robots, including cost, aligning operator and robot joint axes [14], safely handling the mass added by the exoskeleton, and ensuring stable interactions with human users [15], [16].

Further, exoskeletal robots might be excessive for tasks that do not require load-bearing beyond the capability of the human skeleton. To address the problems associated with traditional exoskeletal robots, several groups have recently built soft exosuits that forgo rigid linkages and directly apply forces and torques to the user's skeleton instead. Eliminating rigid link-ages allows exosuits to be constructed of primarily compliant materials that require less precise design and machining, are lightweight, and are generally inexpensive. However, without rigid linkages, applying forces and torques to the human body can be difficult. Some designs use inelastic cables intelligently placed on the body and anchor points to transmit loads to specific body parts [17], [18]. While these designs have proven effective, they increase the compressive load on the joints. Another take on this approach uses cuffs as attachment points for cables driven by motors located elsewhere (typically in a backpack or offboard) [19], [20]. However, this design requires large standoffs to increase the moment arm across the joint to be actuated that create a large device profile and might interfere with objects in the users' environments in daily life. Other approaches use pneumatically inflated bladders to push against two parts of the body, causing expansive forces and moments that extend the joint [21], [22]. Only a couple of these devices currently exist and they tend to focus on simple, single degree-of-freedom joints, such as the elbow.

We developed a lightweight (350 g), inexpensive externally-mounted actuator that behaves as a compliant arm support [23]. We constructed a prototype exomuscle by reinforcing a plastic bladder with a fabric bag that is sewn to supporting straps. The bladder can then be inflated with pressurized air to provide expansive forces between the user's torso and arm, supporting shoulder abduction. A seam acting as a hinge joint connects the exomuscle to the torso. We demonstrate that our exomuscle reduces muscular effort by 74% in isometric tasks and 72% in dynamic reaching tasks while minimally affecting the range of motion of the shoulder and elbow (average 4% reduction) on three users ranging from 165 to 188 cm tall. Now we are seeking to demonstrate the rehabilitative and assistive effects of our device. In a previous (IRB approved) study, we examined the effects of our device on a stroke subject who demonstrated a large increase in workspace after using our device. We were also surprised to find that he also demonstrated a lingering benefit after less than 10 minutes of training with our device that quickly dissipated. We did not expect this result. We would like to test a new compliant passive arm support to determine if it can provide similar effects and determine if this effect is common and characterize it.

[1] D. Mozaffarian, E. Benjamin, A. Go, D. Arnett, M. Blaha, M. Cushman, S. De Ferranti, J. Desprs, H. Fullerton, V. Howard, M. Huffman, S. Judd, B. Kissela, D. Lackland, J. Lichtman, L. Lisabeth, S. Liu, R. Mackey, D. Matchar, D. McGuire, E. Mohler, C. Moy, P. Muntner, M. Mussolino, K. Nasir, R. Neumar, G. Nichol, L. Palaniappan, D. Pandey, M. Reeves, C. Rodriguez, P. Sorlie, J. Stein, A. Towfighi, T. Turan, S. Virani, J. Willey, D. Woo, R. Yeh, and M. Turner, "Executive summary: Heart disease and stroke statistics — 2015 update: A report from the American Heart Association," Circulation, vol. 131, no. 4, pp.434–441, 2015.
[2] J. P. Dewald, V. Sheshadri, M. L. Dawson, and R. F. Beer, "Upper-limb discoordination in hemiparetic stroke: implications for neurorehabilitation," Topics in Stroke Rehabilitation, vol. 8, no. 1, pp. 1–12, 2001.
[3] J. P. Dewald, P. S. Pope, J. D. Given, T. S. Buchanan, and W. Z. Rymer, "Abnormal muscle coactivation patterns during isometric torque generation at the elbow and shoulder in hemiparetic subjects," Brain, vol. 118, no. 2, pp. 495–510, 1995.
[4] V. C. Cheung, A. Turolla, M. Agostini, S. Silvoni, C. Bennis, P. Kasi, S. Paganoni, P. Bonato, and E. Bizzi, "Muscle synergy patterns as physiological markers of motor cortical damage," Proceedings of the National Academy of Sciences, vol. 109, no. 36, pp. 14652–14656, 2012.
[5] D. J. Clark, L. H. Ting, F. E. Zajac, R. R. Neptune, and S. A. Kautz, "Merging of healthy motor modules predicts reduced locomotor performance and muscle coordination complexity post-stroke," Journal of Neurophysiology, vol. 103, no. 2, pp. 844–857, 2010.
[6] J. Dewald and R. F. Beer," Abnormal joint torque patterns in the paretic upper limb of subjects with hemiparesis," Muscle & Nerve, vol. 24, no. 2, pp. 273–283, 2001.
[7] R. F. Beer, M. D. Ellis, B. G. Holubar, and J. Dewald, "Impact of gravity loading on post-stroke reaching and its relationship to weakness," Muscle & Nerve, vol. 36, no. 2, pp. 242–250, 2007.
[8] T. G. Sugar, J. He, E. J. Koeneman, J. B. Koeneman, R. Herman, H. Huang, R. S. Schultz, D. Herring, J. Wanberg, S. Balasubramanian et al., "Design and control of rupert: a device for robotic upper extremity repetitive therapy," IEEE Transactions on Neural Systems and Rehabilitation Engineering, vol. 15, no. 3, pp. 336–346, 2007.
[9] G. B. Prange, M. J. Jannink, C. G. Groothuis-Oudshoorn, H. J. Hermens, and M. J. IJzerman, "Systematic review of the effect of robot-aided therapy on recovery of the hemiparetic arm after stroke," Journal of Rehabilitation Research and Development, vol. 43, no. 2, p. 171, 2006.
[10] H. G. Wu, Y. R. Miyamoto, L. N. G. Castro, B. P. Olveczky, and M. A. Smith, "Temporal structure of motor variability is dynamically regulated and predicts motor learning ability," Nature Neuroscience, vol. 17, no. 2, pp. 312–321, 2014.
[11] L. E. Kahn, P. S. Lum, W. Z. Rymer, and D. J. Reinkensmeyer, "Robot-assisted movement training for the stroke-impaired arm: Does it matter what the robot does?" Journal of Rehabilitation Research and Development, vol. 4, no. 5, pp. 619–630, 2006.
[12] M. D. Ellis, T. Sukal, T. DeMott, and J. P. Dewald, "ACT3D exercise targets gravity-induced discoordination and improves reaching work area in individuals with stroke," in IEEE International Conference on Rehabilitation Robotics, 2007, pp. 890–895.
[13] M. D. Ellis, T. Sukal-Moulton, and J. P. Dewald, "Progressive shoulder abduction loading is a crucial element of arm rehabilitation in chronic stroke," Neurorehabilitation and Neural Repair, vol. 23, no. 8, pp. 862–869, 2009.

[14] A. Schiele and F. C. van der Helm, "Influence of attachment pressure and kinematic configuration on phri with wearable robots," Applied Bionics and Biomechanics, vol. 6, no. 2, pp. 157–173, 2009.
[15] H. Kazerooni and T. J. Snyder, "Case study on haptic devices: Human-induced instability in powered hand controllers," Journal of Guidance, Control, and Dynamics, vol. 18, no. 1, pp. 108–113, 1995.
[16] V. Duchaine and C. M. Gosselin, "Investigation of human-robot interaction stability using Lyapunov theory," in IEEE International Conference on Robotics and Automation, 2008, pp. 2189–2194.
[17] M. Wehner, B. Quinlivan, P. M. Aubin, E. Martinez-Villalpando, M. Baumann, L. Stirling, K. Holt, R. Wood, and C. Walsh, "A lightweight soft exosuit for gait assistance," in IEEE International Conference on Robotics and Automation, 2013, pp. 3362–3369.
[18] A. T. Asbeck, R. J. Dyer, A. F. Larusson, and C. J. Walsh, "Biologically-inspired soft exosuit," in IEEE International Conference on Rehabilitation Robotics, 2013, pp. 1–8.
[19] Y. Mao and S. K. Agrawal, "A cable driven upper arm exoskeleton for upper extremity rehabilitation," in IEEE International Conference on Robotics and Automation, 2011, pp. 4163–4168.
[20] E. A. Brackbill, Y. Mao, S. K. Agrawal, M. Annapragada, and V. N. Dubey, "Dynamics and control of a 4-dof wearable cable-driven upper arm exoskeleton," in IEEE International Conference on Robotics and Automation, 2009, pp. 2300–2305.
[21] R. Natividad and C. Yeow, "Development of a soft robotic shoulder assistive device for shoulder abduction," in IEEE International Conference on Biomedical Robotics and Biomechatronics, 2016, pp. 989–993.
[22] V. Oguntosin, W. S. Harwin, S. Kawamura, S. J. Nasuto, and Y. Hayashi, "Development of a wearable assistive soft robotic device for elbow rehabilitation," in IEEE International Conference on Rehabilitation Robotics, 2015, pp. 747–752.
[23] C. S. Simpson, A. M. Okamura, and E. W. Hawkes, "Exomuscle: An inflatable device for shoulder abduction support," in IEEE International Conference on Robotics and Automation, 2017, pp. 6651- 6657.

b. Findings from Past Animal Experiments

N/A

4. DEVICES USED IN THE STUDY

a. Investigational Devices (Including Commercial Devices Used Off-Label)

Investigational Device 1	
Name:	Compliant passive arm support
Description:	The device consists of two linkages, 1 vertical linkage that runs from the waist to the shoulder and 1 that runs from the shoulder to the elbow, and elastic bands connecting the two linkages to lift the upper-arm linkage upwards relative to the vertical linkage. The vertical linkage connects to a commercial posture brace at the waist while the upper arm linkage rests under the participant's arm and is secured with hook-and-loop fastener. The design of the device, with several compliant elements, ensures that one device fits many without joint alignment concerns. No motors or other actuators add energy into the system, meaning that it is stable.
Significant Risk? (Y/N)	No
Rationale for Non-Significant Risk	The device is not intended as an implant, is not used

	to support or sustain human life, is not important for diagnosing, curing, mitigating, or treating disease, and does not present a potential for serious risk to the health, safety, or welfare of a subject.

5. PARTICIPANT POPULATION

a. Planned Enrollment

(i) Approximately 16 participants will be enrolled in the study, and 5 for the feasibility study.
(ii) Stanford is the only site.
(iii) All participants will be chronic stroke patients recruited from the Stanford Neurology & Neurological Sciences and Physical Medicine & Rehab clinics (both outpatient), as well as from Stanford databases in which stroke survivors from the community have indicated their interest in participating in research studies.

b. Age, Gender, and Ethnic Background

Participants will be of age 18+, male or female, of any ethnic background.

c. Vulnerable Populations

No potentially vulnerable subjects will be enrolled in this study.

d. Rationale for Exclusion of Certain Populations

The research will include women and minorities. Stroke in children is relatively rare, and demonstrates different recovery patterns than in adults. Children will not participate.

e. Stanford Populations

None

f. Healthy Volunteers

None

g. Recruitment Details

Candidate participants will be identified in one of the following manners:
(1) referral from treating physician through the Stanford Neurology & Neurological Sciences and Physical Medicine & Rehab clinics (both outpatient). Patients with clinic appointments and history of stroke will be screened under a waiver of authorization for recruitment, guided by inclusion/exclusion criteria). The charts of potentially eligible patients will be identified by the clinic physician members of the study team using EPIC if they are patients of members of our study team and STARR if they are being referred by another physician. The physician will discuss the study with the patient and if the patient agrees, a physician or coordinator from the study team will approach the patient after the patient's clinic appointment.

(2) through a database in which stroke survivors from the community have indicated their interest in participating in Stanford stroke research studies and filled out a form to add themselves to a RedCap database. Study personnel may contact individuals directly from that list.
(3) from a list of subjects who enrolled in other stroke research studies at Stanford and indicated on their ICF that they are interested in participating in more stroke studies. These are current patients of the study physicians. EPIC will be reviewed for eligibility. Study personnel may contact these individuals directly. Once identified, candidate participants will be contacted via phone call and asked to answer a few questions to establish eligibility and interest. The script for said phone call is attached (waiver for telephone screening). Participants will be scheduled only if they express interest and meet the inclusion criteria determined during the phone screening.

The flier which has been attached may be disseminated to potential participants found through the above methods.

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h. Eligibility Criteria

i. Inclusion Criteria

All participants must:
- be at least 18 years of age
- be greater than 6 months post stroke
- exhibit passive abduction to 90 degrees at shoulder
- exhibit reduced active flexion/extension at shoulder and elbow when shoulder is abducted to 90 degrees
- exhibit reduced active elbow flexion/extension
- fully vaccinated against COVID-19 or provide a negative COVID test within 72 hours of visit
- at least 5 feet tall
- able to return to study location for the duration of the study

ii. Exclusion Criteria

Participants will be excluded from all assessments if they:
- are unable to give informed consent
- are unable to comprehend and follow instructions
- have a condition (other than stroke) affecting sensorimotor function
- show evidence of unilateral spatial neglect
- are unable to sit in a chair (without armrests) for at least 2 hours (transfer from wheelchair acceptable)
- unable to passively abduct shoulder to 90 degrees without pain
- unable to actively flex or extend their elbow at all
- unable to stand by themselves or with the support of another individual
- unable to maintain a standing position for at least 15 minutes (even with a cane or leaning against a table)
- unable to change into a shirt by themselves or uncomfortable with a researcher or their caregiver helping them to change into a shirt
- Painful or difficult to wear a strap over shoulder

i. Screening Procedures

Stroke survivors from Stanford Hospital will be screened by their physicians according protected health information (PHI) under a waiver of authorization for recruitment. Stroke survivors from the community registered in Stanford databases as willing to participate in stroke research will also be screened based on their health information stored in an internal database. If a patient meets the inclusion/exclusion criteria, he or she will be informed by treating personnel (first his/her primary caregiver and then a team physician) about eligibility for the study. If the subject agrees to participate, his or her contact information will be passed along to the study's key investigators for a final phone screening.

j. Participation in Multiple Protocols

Participants can decide to enroll in any other study that does not yield changes to the above inclusion/exclusion criteria.

k. Planned Duration of the Study

The total study will last no more than 2 years, including the analysis of participant data. For each participant in the study: (i) 30-minute screening (in clinic & over phone), (ii) 4-hour active participation spread over two visits, (iii) we expect data analysis to require a month dedicated time including developing all necessary computer code – data analysis does not require involvement of the participant.

6. RISKS

a. Potential Risks

i. Procedures

As described, assessments require subjects to either actively move their arm within their reachable workspace (e.g., to acquire a target). There are no risks associated with these procedures.

ii. Physical well-being

Physical fatigue from repeated movement. There will be frequent scheduled breaks, in addition to rest as requested by the participant.

iii. Psychological well-being

Loss of privacy as a result of participation in the study and mental fatigue from repeated movements at the edge of the workspace. Again, there will be frequent scheduled breaks, in addition to rest as requested by the participant.

iv. Economic well-being

There should be no economic risk to participants.

v. Social well-being

There should be no social risk to participants.

vi. Overall evaluation of risk

Low

b. International Research Risk Procedures

N/A

c. Procedures to Minimize Risk

Participants will be closely monitored by the study team for any fatigue or discomfort that arises over the course of the study. Drs. Maarten Lansberg is reachable at all times for any medical questions that may arise.

All computers, external hard disks, USB thumb drives, tablet computers, smartphones with access to identifiable participant data are encrypted and password-protected in compliance with Stanford's security policies. Hard copies of consent forms will be locked in secure offices within the Mechanical Engineering Department. Digital PHI will be uploaded on RedCaps. Video files will be uploaded to Stanford's Google Drive which is secure for PHI according to Stanford IT.

d. Study Conclusion

The study will be terminated after data analysis is complete (no more than 2 years). Dr. Maarten Lansberg is reachable at all times for any medical questions that may arise.

7. BENEFITS

Participants will benefit from the knowledge that they are providing data that will be used to improve therapy for future stroke patients. As noted, the long-term goal of this line of research is to develop more effective post-stroke therapies.

8. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children’s Health.