Rehabilitation Using Community-Based Affordable Robotic Exercise Systems (Rehab CARES)

NCT05542121

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Investigational Plan Protocol

Sponsor: Recupero Robotics LLC via National Institutes of Health
Clinical Trails Principal Investigator: Pamela Cacchione, PhD
Medical Oversight Officer: Timothy Dillingham, MD
NIH Grant Principal Investigator: Michelle J. Johnson, PhD
Protocol: 853607

1 Purpose

This study is designed to further our understanding of how robots can be used to study the movement of persons with upper extremity impairments and with the help of health data to assist in personalizing how the robot should help guide the person's movements.

2 Protocol Summary and Informed Consent

This study will take place at the community-based, Mercy LIFE West Philadelphia center. Thirty-six stroke survivors will be randomized to either standard of care with 60-minutes of additional occupational therapy (control group) or standard of care with 60-minutes of additional robot therapy (robot group). For the study, participants will continue with their usual care therapy and a licensed occupational therapist will conduct the robot therapy or occupational therapy sessions. Participants will undergo 12 sessions of therapy and 4 sessions of assessments which will take place pre-therapy sessions, post-therapy sessions and 2 follow-up sessions at 2- and 4-week post therapy.

Before the session begins, study personnel will review the consent form and experimental procedure with the subject and answer any questions. The subject will then be given the opportunity to sign the consent form, with study personnel witnessing. Any subjects that decline to sign the consent form will be dismissed at that time. In addition to the written informed consent that patients will sign prior to commencing their first session at Mercy LIFE West Philadelphia. When a subject is contacted by a member of the research team, the pre-screen consent for will be read prior to asking questions. Participation in the study will include the following steps:

1. Consent and other information: Once participants have agreed to participate in this study and signed the consent form, you will be asked about demographic data and medical/ rehabilitation history.

2. Motor and Cognitive Assessments: At the beginning of the visit, their ability to use their affected limbs will be evaluated by a member of the research team. They will also be evaluated for depression, and a mental health assessment will be given to evaluate their ability to understand and complete the study.

3. Robot-Assessment session: They will be asked to use the robot platform under the guidance of a research team member. They will be asked to use the robot in several orientations and to complete assessment while wearable sensors to monitor muscle, compensatory movement and biometric data. Specifically, we will collect muscle activity with EMG sensors and/or ultrasound

sensors, trunk movement with inertial sensors, galvanic skin response to assess stress level, and heart rate. Robot forces and position data will also be collected. The sessions may be videotaped.

4. Post-assessment Surveys: After each assessment session, subjects will be asked about fatigue, exertion, pain, and other adverse events. They will then complete post surveys on usability and acceptability of the robot gym. The data from the assessment tasks will be used to identify a robot cog metric that best predicts cognition in terms of executive function and visual spatial tracking and a robot motor metric that best predict motor impairment.

5. Therapy Sessions (12 total)

a. Control group (n=18):

The research participants randomized to the control group for this trial will receive on top of their standard of care, 12 sessions of occupational therapy (60 mins/each, dosed 2-3x week over 4-8 weeks). The SOC will be set up as circuit training with 3-4 stations per session, rest breaks offered every 15 mins or sooner if needed based on client comfort and endurance. Stations will be adjusted for each client personally and will include:

- Therapeutic exercise for upper extremity (UE) gross motor skills focused on shoulder girdle stabilization and strengthening, and full arm movements (ex: Thera band, arm bike wall or mat exercised for shoulder stabilization, Passive Range of Motion (PROM)/Active Range of Motion (AROM)/Assisted active range of motion (AAROM)).
- therapeutic exercise for UE fine motor skills focused on intrinsic hand muscle and wrist strengthening, and grasp and release(ex: strengthening with Thera putty, repetitive training for grasp and release of gross and precision grips and supination/pronation, and PROM/ AAROM/AROM).
- activity-based therapy for functional retraining to generalize gross and fine motor skills to daily life activities. Activities to encourage crossing midline and bilateral/lateral UE use (ex: simulated food cutting, cleaning, clothing management, writing, zipper/button management, container opening, ball or balloon toss, etc.)
- Therapeutic activity for cognition and executive functioning (playing games such as checkers, cards, simulated medication management, following recipe instructions, scavenger hunt completion, etc).
- Neuromuscular re-education- sensory interventions for touch and proprioception and body schema awareness, pnf for functional movement retraining.
- After each therapy session, subjects will be asked to complete surveys about pain and exertion and report any adverse events.

b. Robot group (n=18): Participants will be seated at the robot and will be asked to play games using their upper extremity for 60 minutes. The robot will be configured in any of 3 positions to allow users to exercise the entire arm. Participants may choose to exercise solo or with another participant. All movements required of the user are customizable to the user abilities. The workspace of the game icon controlled by the robot is adjustable to each subject's range of motion. This allows users to complete or collaborate even with different movement ranges, speed, and strength. This also allows users to play with or against each other with their current abilities and be successful in the game. Participant's trunk will be restrained by a safety belt during each session with the robot. Sessions may be videotaped. After each therapy session,

subjects will be asked to complete surveys about pain and exertion, and report any adverse events.

6. Post Assessment session: Participants will be asked to return for an assessment after the 12th therapy session. The activities will consist of those discussed in steps 2 thru 4 above.

7. Follow-up #1 Assessment session: Participants will be asked to return for another assessment 2-weeks after your post-assessment session. Consists of steps 2 thru 4 above.

8. Follow-up #2 Assessment session: Participants will be asked to return for another assessment 4-weeks after your post-assessment session. Consists of steps 2 thru 4 above.

9. Focus Group session: Subjects may be asked to join a group of other participants (up to 6) to provide feedback on their overall experience in a group interview session or solo interview. They will be asked to assess overall hardware and software design features, experience with the robot, and barriers to use in home or community.

3 Description of devices and research instruments

Name of Device & Manufacturer	Development Status	Device Class (or predicate)	Protocol Use	Approved Use (or predicate)
Rehab CARES system of Haptic robots; Johnson Lab and Recupero Robotics LLC	Research use only	n/a	Assessment and Treatment of post-stroke upper extremity rehabilitation. The system uses off-the-shelf computer gaming wheels with force feedback to help reduce motor impairment and improve function in the arms of stroke survivors.	This is a custom research device is being built and will be located at the community-based research site Mercy LIFE West Philadelphia. The device is a non-significant risk research device.

Device descriptions and manufacturer qualifications can be located in our central device inventory file located in Rehab Robotics Lab.

4 Labeling

Procedure	Instructions for Use	Training Required
Rehab CARES system of Haptic robots; Johnson Lab and Recupero Robotics LLC	This is a custom research device. It is being built and will be located at the community-based research site Mercy LIFE West Philadelphia.	In-person training required for this research device

5 Risk analysis

	Potential Risks to subjects or users	Risk Likelihood	Risk Consequence	Risk Mitigation	Relevant info or supportive data references
Rehab CARES system of Haptic robots; Johnson Lab and Recupero Robotics LLC	Frustration Fatigue Discomfort from harness Discomfort due to the position of therapy devices Muscle fatigue Minor bruising Mild pain Soreness under electrode	3 4 1 2 4 2 2 1	1 2 1 1 2 2 1 1	Supervision with OT Rest between interventions. Introduce padding to handles; Give 15-minute breaks; Stop and attempt to remediate if an issue occurs.	Phase 1 pilot results

Risk Likelihood	Descriptor	Assigned value
Rare	Not expected but possible	1
Unlikely	Could occur occasionally	2
Likely	Could occur frequently	3
Expected	Expected to occur in most cases	4
Certain	Will occur on every occasion	5

Risk Consequence	Descriptor	Assigned value
No Health Hazard	No physical effect of the physiological complaints anticipated	1
Limited Health Hazard	Extended procedure time, Physiological complaints, Temporary minor physical effect	2
Moderate Health Hazard	Additional procedure required, Temporary but significant physical complaints, Permanent minor physical effects	3
Severe Health Hazard	Permanent significant physical effects	4
Catastrophic	Life threatening	5

6 Monitoring procedures

The clinical trial principal investigator, Dr. Pamela Cacchione will be the primary monitor of this protocol.
She and key study investigators will conduct monthly monitoring audits for adherence to the IRB-approved protocol. In compliance with UPENN IRB policy, we will review data regarding recruitment, summaries of randomized participants, demographics, clinical presentation procedure information, therapy records, complications/adverse events, and quality control.

Any adverse event that is reported to medical oversight officer, Dr. Timothy Dillingham and either the principal investigator or the designated research associates by the subject or the therapist caring for the subject will be documented as such and submitted to the IRB. The report will include a description of the event, when and how it was reported, as well as any official chart records or documentation to corroborate the event or its reporting. All severe and/or unanticipated adverse events will be immediately reported to the IRB (within 24 hours). All adverse events will be summarized annually and submitted to the IRB. This is a minimal-risk study.

Monitoring logs will be kept:

1. **Experimental session event monitoring log:** Events are documented on this form so that a record is established for equipment monitoring and teaching and correction. These events are situations that should be avoided in the future. An example would be equipment failure to function correctly during the therapy for whatever reason.
2. **Adverse Safety Event:** This form is used to document any personal injury or illness that may occur with subject or personnel during the study. For example, the study is started, and the subject starts to experience severe fatigue or severe pain or an injury to the arm. This form is an internal report. Any accidents causing injury to a person or damage to equipment will be reported to UPENN IRB which will be the IRB.
3. **Unexpected Events** Log (Report Equipment Failures of all kinds here and any changes to the protocol here).

7 IRB Information

This trial is conducted at the University of Pennsylvania – with site location is at the community-based center Mercy LIFE – West Philadelphia with IRB review by The University of Pennsylvania Institutional Review Board. The Penn IRB functions under Federal wide Assurance FWA00004028, all policies and procedures can be located on the Penn IRB website. University of Pennsylvania and Mercy Health have a reliance agreement to use Penn IRB as the IRB of record for studies completed at Mercy LIFE West Philadelphia.

8 Example of investigator agreement

The following investigators signed an investigator statement prior to participating in the study.

Clinical Trails Principal Investigator: Pamela Cacchione, PhD
Scientific Advisor/NIH Grant Principal Investigator: Michelle J. Johnson, PhD
Medical Oversight Officer: Timothy Dillingham, MD

9 Device billing information

We do not plan to charge for the devices.

10 Device Labeling

The labeling will include the statement “CAUTION – Investigational Device. Limited by Federal (or United States) Law to Investigational Use.”

The labeling will also contain adequate information for the purposes of the study, including:

- Name and place of business of the manufacturer: Recupero Robotics LLC
- The device is minimal risk.