RELEVANT PROTOCOL EXCERPTS FROM:

Soft Exosuits for Functional Gait Recovery in Acute Stroke Rehabilitation (NCT06231511)

Last Updated: 5/15/2025

PROCEDURES INVOLVED:

AIM 1: Identify Successful Patient Profile, Establish Controller Algorithm and Training Progression Strategy

- Testing with patients post stroke
- Pilot testing, evaluation and re-testing will allow for modification of the hardware and controller specific to stroke participant's needs
- Development of clinical training manual for use of these exosuits during therapeutic exercise and gait training.

We will recruit up to 15 individuals who have a history of stroke (<4 years) from inpatient and outpatient settings, who are capable of standing with assistance.

- In-Person Screening assessment to ensure that the patient meets eligibility criteria for the study. We will obtain medical clearance from their physician prior to the first testing session.

Testing:

- Following consent, we will perform a range of standard clinical assessments in order to capture the patient's functional capability. Walking assessments will be completed with the exosuit and without the exosuit.
    - 10 Meter Walk Test with GaitRITE for gait mechanics
    - 2 minute walk test
    - Manual Muscle Test: of the lower extremity muscles
    - Range of motion of the legs
    - Modified Ashworth Scale
    - Mini-Mental Status Examination
    - Burke Lateropulsion Scale
    - Type of stroke will be collected from patient's medical chart
    - Total Session time: up to 3 hours
    - There may be up to 3 testing sessions

Up to 8 Training/Tuning Visits:

- During these sessions, individuals will perform up to 60 minutes of walking with the exosuits on the treadmill, overground or completing stairs, with rest breaks as needed. Goals during these sessions are to modify and update the controllers for the exosuits to appropriately provide assistance to the patient while ambulating in collaboration with Dr. Conor Walsh's team at collaborating institution, Harvard University. We may also test clinical training progressions with the exosuits during walking training. Total session time for each session may be up to 2 hours.
    - Some part of the session may include walking with the exosuit assisting and other part of the session may include without the device assisting for comparison.
    - We may collect formal assessments such as 10 MWT and 2 MWT during these visits.
    - We will utilize suit data, such as IMU data which can provide kinematic and spatial temporal parameters, suit-generated force, position and timing measures to assist in accomplishing these goals.
    - Up to 8 Training/Tuning visits will be performed

2 additional buffer sessions will be used if needed to complete testing or tuning in the event of incomplete data collection, scheduling limitations, device failure, etc.

AIM 2: Evaluate the impact of the exosuit in combination with conventional therapy vs. conventional therapy alone during inpatient rehabilitation.

- In-Person Screening assessment to ensure that the patient meets eligibility criteria for the study and is able to fit within device specifications. Following consent, we will obtain medical clearance from their inpatient physician prior to visit 1.

Baseline Testing: Visit 1-measures will be collected by study staff either in person or through electronic medical record

- 10 Meter Walk Test
- Gait mechanics assessment using motion capture, Inertial measurement units, GaitRITE
- 6 Minute Walk Test with Cosmed for endurance and energy expenditure
- 2 minute walk test
- Fugl-Meyer
- 5x sit to stand
- Berg Balance Scale
- Functional Gait Assessment
- Functional Independence Measure
- PHQ-9
- Timed Stair Climb Test
- Manual Muscle Test of the lower extremity muscles
- Range of motion of the lower extremities
- Modified Ashworth Scale
- Total session time: Up to 4 hours

During the course of the patient's inpatient stay, these exosuits will be utilized in up to all physical therapy sessions. With the consideration that an inpatient stay may be up to 10 weeks, total number of sessions may be up to 75 visits. Sessions will vary from 30-90 minutes depending on inpatient therapy scheduling.

- During these sessions, we will capture walking mechanics, step count by using an activity monitor, velocity, and safety measures by tracking the number of adverse events.
- IMU data from the exosuit which will provide force, position and timing measures will also assist in tuning the exosuit optimally for the individual
- For participants who are randomized to the conventional arm (no exosuit), we will monitor walking mechanics, step count by using an activity monitor, velocity, and tracking the number of adverse events during their physical therapy sessions.

Post-Evaluation Visit: Prior to Inpatient Rehabilitation Discharge

- We will repeat the same clinical assessments performed at baseline to assess for immediate and lasting changes in neuromuscular functional ability.
- Total Session Time: Up to 4 hours

2 additional buffer sessions will be used if needed to complete testing in the event of incomplete data collection, scheduling limitations, etc.

We will enroll up to 65 individuals in AIM 2. With an estimated 20% attrition rate, we will complete 25 participants in each arm (exosuit + conventional therapy vs. conventional therapy alone) of the study for adequate power analysis.

All AIM 1 and AIM 2 visits will:

- Be conducted under the supervision of an IRB approved Physical Therapist who will actively monitor the participant to ensure that his/her physiological parameters stay within established guidelines.
- Utilize safety belts and harnesses as necessary to minimize the risk for trips/falls.
- Provide rest periods for the participants as needed/requested by the participant.

Photographs and video will be collected during AIM 1 and AIM 2 in order to assist with development in AIM 1 and data analysis in AIM 2. Videos and photographs will be stored on a password protected computer through the duration of the study. Because the devices involve the lower limb, these photographs and videos will focus on this area. Dr. Conor Walsh's team will be assisting with the development of the control algorithm and thus we may share videos/photographs with or without patient identifying features in order to assist in accomplishing this goal.