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Study Protocol

Stand-on Ride-on Power Mobility Devices for Children With Cerebral Palsy

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Study Design

This R03 study will utilize a pre-post quasi-experimental design in which participants will undergo detailed biomechanical analyses during balance (static and dynamic) and walking assessments (**Fig. 1**).

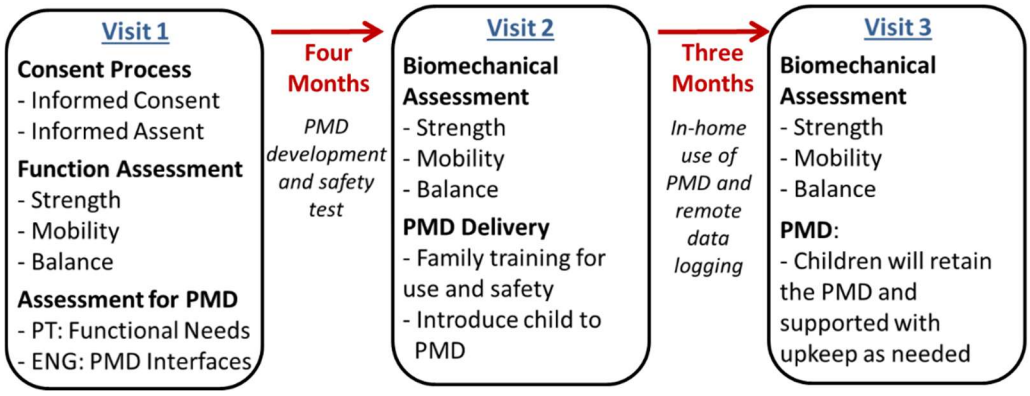


Fig. 1. Study design.

Institutional Review Board approval has already been secured (**UNF IRB#2002889-2**). Upon notification of grant funding, recruitment will initiate immediately. Parents of children with CP will be informed about the study via direct contact (and word-of-mouth) by Debra Depto-Hoffman, PT, DPT, PCS. A large pool of potential participants/families can be reached given Dr. Depto-Hoffman professional relationships with local pediatric rehabilitation hospitals and clinics. Recruitment of 10 children/families is expected to be completed by August 2024. We envision enrolling 10 participants within the first two months given number of available families of children with CP and GMFCS III that are aware of our research activities and have already demonstrated interest in participating.

During Visit 1 (Informed Consent Procedures), parents and children will be directed to meet with the PI Dr. Cesar at the Physical Therapy Research Laboratory. The laboratory is housed within an accessible facility and has a dedicated private room for the informed consent/assent procedures. During this first visit, we will seek parent/legal guardian informed consent, participant's informed assent, and we will provide explanation of research activities. Interviews with parents and children will be delivered in a manner that is appropriate for each participant's age and cognitive capabilities. The PI has extensive experience with administering interviews within this set-up given his research with children with and without disabilities.[50-64] We will also inform that participation is voluntary and no penalties of any form are involved in a decision to reject to participate. During Visit 1, we will also collect child's basic anthropometrics (height, weight) and, from parents/legal guardians, a general health screening information (i.e., age, medication, co-morbidities, via the Medical Screening Form) and a Photo/Video Consent form. Children will undergo a Function Assessment involving strength, mobility, and balance tests (that will also be performed during Visits 2 and 3). This assessment will provide the baseline function prior to the Pre-Intervention biomechanical evaluation (Visit 2). This data set will allow us to control for individual changes in performance due to maturation (in contrast to the use of the stand-on PMD).

Prior to engaging in research-specific activities, parents will be asked to contact the child's primary physician to secure child's clearance for participation in the research study (Physician Medical Clearance Form). Furthermore, to ensure proper modifications required to each adaptive toy car, assessment of children's range of motion, muscle tone and motor performance will be performed by Debra Depto-Hoffman, PT, DPT, PCS (and CITI-certified UNF DPT students). Dr. Depto-Hoffman has over thirty years of experience evaluating children with neurological impairments and is an APTA Board Certified Pediatric Specialist. Findings from this assessment will be to provide to Co-I Dr. Juan Aceros for PMD modifications to properly accommodate physical and functional deficits identified. The child's ability to operate different electrical or mechanical adaptive interfaces will also be tested. This will be done by allowing the child to try different commercially available Capability Switches under the direct observation and supervision of DPT research personnel (CITI-

trained students). This Visit is expected to last approximately 85 minutes.

After completion of Visit 1, an electrical and mechanical engineering team lead by Dr. Aceros will carry out the development of the PMDs. These devices will be based on commercially available ride-on toys to augment the child's postural control and allow the child to stand (adapted built-in harness) inside the device for play activities. These adaptations consist of trunk and limb support that, in combination with steering and activation engage the child in dynamic postural control during the operation of the device. In addition, mechanical adaptations will mitigate child's undesired abduction, adduction and excessive forward or backward motions. Common, safe, and off-the-shelf materials will be used to keep these adaptations economically viable. A microcontroller will be implemented to collect data regarding the use of the device and to activate sensory activities that help engage the child with the toy, such as lights and music through its multiple input and output peripherals. Depending on the need of the children, actuation of the devices will take place via a switch or a proportional control device. These adaptations are expected to be completed within the period of 4 months (timeline of completion based on previous NIH-granted project, PI: Aceros). Once adaptations are completed, parents and children will be invited to return to the Physical Therapy Research Laboratory for **Visit 2** where the first (Pre-Intervention) biomechanical assessment will occur. This visit is expected to last approximately 85 minutes. Children's anthropometrics will be re-measured. Then, kinematic markers and electromyography sensors will be taped to the child's skin over different body locations (e.g., shoulders, hips, knees, foot, and over leg muscles). We will use a small amount of medical grade tape to secure the markers and sensors to minimize any potential for skin irritation. After placement of markers for full body kinematics (Vicon®, Plug-in Gait) and electromyography sensors (Delsys®) for bilateral lower extremity (tibialis anterior, gastrocnemius, vastus lateralis, biceps femoris, gluteus medius) muscle activity pattern, the child will perform the following strength, mobility, and balance tasks in random order:

- *Five-Times-Sit-to-Stand Test* (performed 3 times, ~ 10 minutes). For this validated test of lower extremity functional strength and balance ability for children with CP,[65] five consecutive sit-to-stand-to-sit cycles will be performed as quickly as possible and timed with a stopwatch. Children will be seated in a height-adjustable chair with no arm rest and hands will be across the chest during the test.
- *Modified Timed-Up and Go Test* (performed 5 times, ~10 minutes). For this validated pediatric-modified test[66] of dynamic balance and mobility, children will be seated in a chair with a backrest without upper extremity support. The seat height will allow 90˚ of hip and knee flexion while the feet rest comfortably on the ground.[51,64] If assistive devices are used for usual ambulation, the upper extremities will not be on the assistive device, so participant can rise from chair without using the device; however, the device should be nearby to be used during the walking. Children will stand-up, walk forward 3 meters at their fastest pace towards a cone placed on the floor (we will not use the drawing of star placed on a wall at eye-level given children's use of an assistive devices), step around the cone and return to the bench. The emphasis on task completion at fast pace will be used to evaluate control of dynamic balance.[67] The test starts as participant's buttocks rise from the seat and stops as participant's buttocks touches the seat. The time to complete the trial will be recorded with a stopwatch.
- *NIH Toolbox® Standing Balance Test* (performed once, ~10 minutes). A set of five balance tests validated for individuals with neurologic conditions[68,69] will be performed. The tests involve controlling upright posture with unshod feet together on a firm surface with (1) eyes open and (2) eyes closed, on a compliant surface (foam) with (3) eyes open and (4) eyes closed, and (5) on firm surface with eyes open and tandem stance. Two attempts are allowed to control each posture for 50 seconds.[68,69]
- *10-Meter Walk Test* (performed three times at self-selected comfortable and three times at fast speed, ~10 minutes). Children will traverse a 4'x26' pressure-sensor instrumented mat (Zeno Walkway, ProtoKinetics, Havertown, PA) for the recording of gait spatiotemporal parameters (e.g., walking step length and width to assess dynamic balance[1]) and basic gait variables (e.g., percent of single-limb support time,[51,54] coefficient of variation of step length and width[1,70]).

Children will be offered as many rest breaks throughout the data collection as needed. One-minute rest breaks in between each trial is stipulated and we will allow longer breaks when needed. The scheduled rest breaks are built in the data collection session to ensure that high functioning and enthusiasm are maintained during data collection process.[50-63] Following the biomechanical data collection, children will receive their individually-adapted PMD. A dedicated time will be allotted for parents/child safety and harness donning training. This type of training will be comparable to currently employed training for the adaptive ride-on program at the University. It consists of hand-over-hand guidance to briefly demonstrate to the child the cause-and-effect relationship between the activation interface and toy movement. Simple one-word verbal labels are used in conjunction with the haptic guidance, e.g. Go, Stop, and Push. Following, the child is given the opportunity for random, free exploration of the motor activation and the consequent movement of the mobility device without further adult instruction. Children will take the PMD home for use for three months (i.e., intervention period). Actual time of device use will be tracked using embedded sensors and stored using local hardware memory devices within the ride-on without any identifier information. No GPS sensors or video/photo/ audio recording devices will be used in any of the mobility devices. The sensor data will be collected during visits by trained CITI-certified study personnel from the home or other location where PMDs may be kept. These data will be complemented by parent-report via written log. Bi-weekly follow-up phone calls will be given to maintain rapport with all families.

Once the three-month intervention period is completed, parents and children will return to the Physical Therapy Research Laboratory for **Visit 3** (Post-Intervention Assessment). This visit is expected to last approximately 65 minutes. Children will undergo the same procedures of Visit 2 and perform the same four tasks in random order while kinematic, kinetic, and electromyographic data are collected. Once research activities are completed, children will receive their individually-adapted PMDs as a gift for taking part in the study.