Title: Use of joystick-operated ride-on toys to improve affected arm use and function in children with hemiplegic Cerebral Palsy

NCT #: NCT05559320
Document date: 03/07/2024

SECTION B: OUTLINE OF PROPOSAL

SYNOPSIS/ABSTRACT

Cerebral palsy (CP) is the most common childhood-onset motor disability. It refers to a group of complex, neurodevelopmental disorders of movement and posture due to non-progressive damage to the growing brain leading to significant activity limitations and participation restriction, and frequently accompanied by impaired sensation, perception, cognition, communication, behavior, and secondary musculoskeletal problems.[1] Around 30% of children with CP have hemiplegia, with impairments predominantly lateralized to one side of the body.[2] As a result of impaired strength/control on the more-affected side as well as difficulties with bimanual coordination (i.e. ability to use both arms together), affected children struggle with even the most basic activities of daily living: feeding, self-care, grooming, school-work, and play.[3-5] Limited use of one side leads to early maladaptive neural and musculoskeletal changes that contribute to **"learned nonuse/disuse"** on the affected side that is difficult to reverse.[6-8] Moreover, lost movement opportunities in early childhood likely have cascading negative effects on a child's overall cognitive, perceptuo-motor, social, and emotional development.[7] The debilitating impact of CP on children's function, the associated economic burden on the health care system, and strong evidence for improved motor outcomes following early movement training together **underscore the importance of early and effective motor interventions in CP**.[8-10]

Contemporary evidence-based approaches to improve UE function such as Constraint Induced Movement Therapy (CIMT) and Bimanual Training (BT) while being effective rely on intense, repetitive practice of functional tasks.[11-13] Despite positive effects of contemporary approaches[6,13-19], these programs are very time-consuming, children frequently find activities to be boring and monotonous, training-related improvements are relatively short-term, and evidence for these approaches is often mixed.[20-23] Clinicians frequently struggle to retain child interest, ensure therapeutic compliance, and promote functional affected UE use beyond therapy sessions.[24] **Motivation is the single most influential factor** unrelated to the child's diagnosis **that determines changes in motor skills, function, and neural reorganization following therapeutic interventions in CP**.[25-27] Compared to healthy peers, children with CP have lower motivation and are more reluctant to try complex, challenging tasks during play.[26,28] Lack of motivation can limit a child's willingness to engage in activities with the necessary frequency and intensity needed to make functional gains. There is a **pressing need for developing stimulating therapeutic environments** that provide abundant opportunities to participate in **child-preferred, highly enjoyable, intrinsically motivating, and optimally challenging goal-oriented activities** to enhance engagement, active practice, and ultimately functional success.[10,29,30]

We propose to conduct a pilot study **to evaluate the efficacy of a home-based, child and family-centric training program using modified commercially-available, joystick-operated, ride-on-toys to improve UE function** in children with hemiplegic CP. Home-based programs have been used in children with CP to increase skill practice beyond therapy sessions, improve caregiver involvement in therapy, and facilitate retention of learned skills.[31] Given the continual challenges faced by clinicians to maintain children's motivation during therapy and ensure repetitive UE practice to induce neuroplastic changes, commercially available, joystick-operated powered ride-on-toy technologies can be adapted and incorporated into home programs to serve as innovative, child-friendly solutions to boost self-initiated UE use in children with impaired arm function. Our pilot data suggest that healthy children as young as 3 years learn to successfully control and navigate a ride-on-toy using joysticks following a brief 5-minute exploratory play period. Children find the experience very enjoyable, and with repeated practice, improve their accuracy of navigation (reduction in average and maximal deviation from optimal central path, number of path deviations, and percent distance spent outside the path).

In a second pilot study, our team provided the ride-on-toy training as part of an existing CIMT-based summer camp for children with hemiplegic CP. Eleven children received training 15-20 minutes/day, 5 days/week for 3 weeks. Training encouraged self-initiated use of the affected arm to move the joystick to navigate through obstacle courses and scavenger hunts. We found strong evidence for feasibility of program implementation and high participant motivation. Children immensely enjoyed the goal-oriented training and key stakeholders (children, clinicians and caregivers) universally reported that the experience was fun and child-friendly. Around 90% of caregivers and 75% of clinicians reported observable improvements in children's arm function (gross motor, fine motor, and bilateral coordination) and spontaneous use following the ride-on-toy training. Camp staff and caregivers indicated that the training was innovative, fun, built confidence in children, and encouraged them to use their affected UE without seeming like "work". However, the inherent design of the camp did not allow us to tease apart the differential effects of the ride-on-toy training versus those of the other regular camp activities. The proposed study will address this gap by **exploring the utility of a home-based, incrementally-challenging training program that incorporates ride-on-toy navigation, as an adjunct to conventional UE rehabilitation in children with hemiplegic CP.** Our premise is that joystick-operated, ride-on-toys can serve as effective, low-cost, easy-to-use adjuncts to conventional therapy that can be used by both clinicians and families to incentivize affected arm practice during enjoyable navigation-based activities in natural environments, ultimately leading to gains in manual function in children with hemiplegic CP.

BACKGROUND/RATIONALE

The World Health Organization (WHO) has identified CP as having the highest global burden of disease among all non-communicable diseases. It is one of the three pediatric-onset conditions included as part of WHO's "Rehabilitation 2030: A Call to Action" initiative aimed at developing a package of rehabilitation interventions to be part of 'Universal Health Coverage', a strategic WHO priority aligned with the Sustainable Development Goal 3 of the United Nations.[32,33]The healthcare costs per year for children with CP are estimated at $6 billion, and additional non-reimbursed costs incurred by families for adaptive equipment, services, and lost income run into thousands of dollars.[34] Despite the debilitating impact of CP on the society, a recent systematic review indicated a lack of clinical practice guidelines related to rehabilitation therapies for CP and a disproportionate emphasis of existing programs on remediating impairments in body structures or function rather than on enhancing activities of daily living, participation, and quality of life for children and families.[32] **There is a pressing need to develop evidence-based, effective, child-centric, and family-engaging interventions to promote function and participation in children with CP.**

Around 60% of children with CP have impaired upper extremity (UE) function relative to reach, grasp, release, and manipulation of objects.[35,36] **Limited hand use is the strongest predictor of limitations in daily function and participation in CP and is one of the most challenging rehabilitation goals for clinicians.**[37,38] A variety of interventions including task-oriented approaches such as CIMT[21,22]and BT[3] have been tested to assess effects on UE function[,7,17-20,23,39,40]. However, **the single most critical factor associated with improved clinical outcomes is treatment dose** (i.e. optimal, repetitive task practice) rather than the content of any particular treatment paradigm.[16,20,41,42] Therapists acknowledge that **achieving the optimal, intensive treatment dose per existing evidence-based guidelines is most challenging in clinical practice.**[18] This may be related to needed therapist expertise to deliver specific types of interventions and associated issues of availability, cost, time, and accessibility.[17,43,44] Hence, there is growing emphasis on exploring the effects of home programs and the role of caregivers as co-therapists as a pragmatic, cost-effective adjunct or alternative to conventional service delivery models.[17,20,41,43,45,46] Such programs allow skill practice in naturalistic environments, boost training intensity to exploit brain plasticity, facilitate transfer/retention of learned skills outside the clinic, and foster family involvement through collaborative researcher-caregiver partnerships.[31,47,48]

Another major barrier to rehabilitation with regard to reaching optimal dosing is child compliance and lack of motivation.[49,50] **Child motivation is a strong clinician- and caregiver-identified predictor of therapeutic improvements in children's physical and psychosocial functioning.**[23,51,52,] Although repetitive, goal-directed practice is key to functional success in CP, children frequently find conventional programs boring.[53-56] Therapists must develop activities and create environments that are stimulating, fun, challenging, meaningful, and intrinsically motivating for children, to maximize their engagement and compliance.[26,50] Higher child motivation will ensure greater active participation in rehabilitation, more practice, enhanced learning, and functional gains.[50] Contemporary motivational theories, including the Self Determination Theory and Expectancy Value Theory, also suggest that individuals are likely to persist with activities that are age-appropriate and intrinsically rewarding, foster autonomy and a sense of initial achievement/competence, afford social interactions, and provide the "just-right challenge".[50,57-59]

The above review highlights that achieving the optimal treatment intensity and enhancing motivation and compliance with therapy are the major barriers faced in UE rehabilitation in children with hemiplegic CP. There is an urgent need to develop novel training paradigms that align with child interests, are intrinsically rewarding, encourage intense functional task practice, and involve caregivers, to ultimately enhance child outcomes.[60-62] **The proposed study, based on principles of motor learning and motivational theories, evaluates the effects of a 6-week, home-based, child-friendly, innovative program that uses modified, commercially available, joystick-operated, powered ride-on-toys to promote spontaneous affected UE use and function in children with hemiplegic CP.** Ride-on-devices are very popular toys for children with and without disabilities.[63,64] The proposed project is highly innovative in the following ways: (1) we will adapt and customize commercially-available toys to individual children's postural control, safety, and arm control needs, (2) we will capitalize on children's intrinsic motivation for mobility and navigation to promote repetitive self-initiated arm use (gross arm movements and fine motor activities) through an incrementally-challenging training protocol grounded in motor learning and motivational theories, (3) the functional mobility training through real physical spaces will provide children with tangible, 3D real-world perceptual, action-related, and cognitive challenges, (4) training will be designed to promote active learning, problem solving, UE movement planning, and sensorimotor integration while providing immediate feedback and consequences of actions,[65] and (5) we will implement a researcher-caregiver co-delivered home-based intervention to facilitate training carryover into children's daily routines while allowing caregivers to receive ongoing coaching, feedback, and support from clinician researchers.

SPECIFIC AIMS

This proposal introduces an innovative, child-friendly, family-centric, home-based training program to promote UE function in 3-8-year-children with hemiplegic CP through goal-oriented games and activities that incorporate **purposeful, joystick-controlled navigation of real-world physical spaces using modified, commercially-available ride-on-toys**. Fifteen children with hemiplegic CP will be assessed at 3 time-points: (a) at pretest, (b) at the end of a 6-week, treatment-as-usual/conventional therapy control phase, and (c) at the end of a 6-week experimental intervention phase. The experimental intervention will involve an incrementally challenging training program that will incorporate **Ride-on-toy Navigation Training (RNT)** with joystick controls provided on the child's affected side. Training activities will involve navigational challenges that will require gross motor UE movements (shoulder, elbow, and wrist movements to move the joystick in different directions – forward, backward, left, and right) and include fine motor activities (grasp and control the joystick, pick up/pull/push/throw props, lift and manipulate different types of props like koosh balls, bean bags, cups, blocks, etc. during navigational games). Training activities will be progressed weekly to increase the navigational challenge (straight path, circular path, slalom path, mazes, obstacle avoidance tasks, timed challenges, etc.) and the movement control challenge (increase in required range of UE movements, muscle force control, and manual dexterity for completion of tasks). Children will continue to receive conventional therapy during this intervention phase.

Specific Aim 1: Treatment feasibility and acceptance. To assess treatment feasibility, adherence, fidelity, and satisfaction with a 6-week, researcher-caregiver co-delivered, home-based, training program using ride-on-toys for children with hemiplegic CP, based on child and family feedback. We hypothesize that children will find the experimental intervention phase more enjoyable than the control phase. The training will be acceptable to the family (children and caregivers), feasible to implement for both researchers and caregivers, and associated with high rates of treatment adherence, fidelity of implementation, perceived satisfaction, and perceived benefit as assessed using child- and caregiver-rated questionnaires.

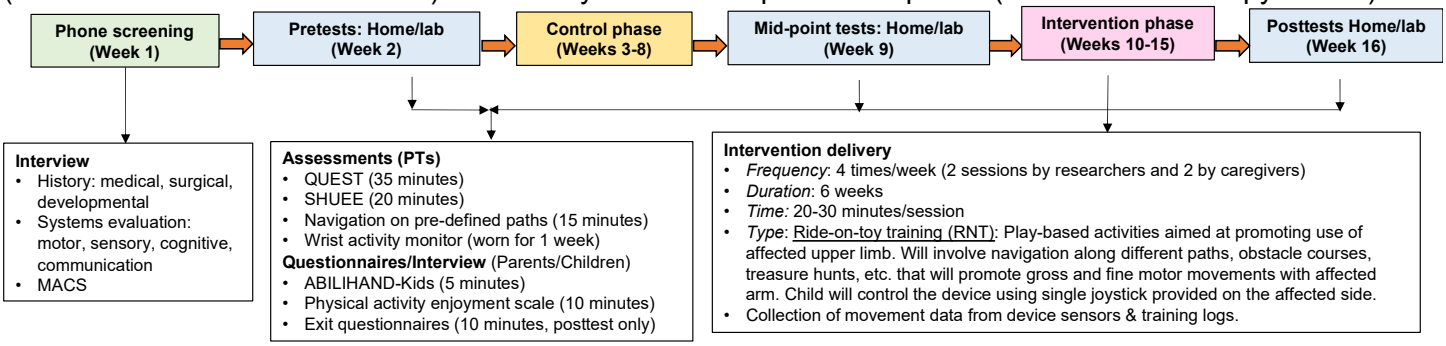
Specific Aim 2: Manual function. To evaluate the effects of the training program incorporating ride-on-toys on manual abilities and spontaneous use of the affected arm in children with hemiplegic CP as measured using standardized tests and objective/kinematic measures.

- **Aim 2A:** We hypothesize that there will be greater improvements in affected arm active movement control and spontaneous functional use as assessed using standardized tests (Quality of Upper Extremity Skills and Shriner's Hospital Upper Extremity Evaluation) and a parent-rated questionnaire (ABILIHAND-Kids), following the intervention phase compared to the control phase. During the intervention phase, children will also show improvements in movement control and maneuverability of the ride-on-toy from an early to a late training session.
- **Aim 2B:** We hypothesize that children will also show improved motor control and movement kinematics during reaching in terms of increased movement speed, smoothness, straightness, and symmetry, decreased movement variability, and improvements in peak and average velocity of reaching. Children will also show greater improvements in daily arm activity measured through objective wrist-worn activity monitors during the intervention compared to the control phase.

Clinical Impact: This project, led by an early career investigator, strategically leverages the expertise of an interdisciplinary team that comprises experts from physical therapy, occupational therapy, and biomedical engineering who are well suited to implement the proposed project. Our work aligns with the strategic plan of the AACPDM in (1) embracing innovative approaches to advance knowledge and practice in the field of CP and (2) fostering research that will generate new knowledge and evidence to inform care of people with CP. The proposed research will provide evidence to support an innovative, child-friendly, low-cost, home-based training program using commercially-available ride-on-toys that can be implemented by clinicians and families to promote spontaneous, self-initiated practice using the affected UE and improved manual function in children with hemiplegic CP.

RESEARCH METHODS/PLANS

1. Study design: Single group longitudinal design. Children will be observed for a 6-week control phase (conventional treatment-as-usual) followed by a 6-week experimental phase (conventional therapy + RNT).



2. Participants and screening procedures: Fifteen children with a diagnosis of CP, ages 3-8 years with clear asymmetry in UE strength/control will be recruited. Exclusion criteria include a recent history (< 6 months) of trauma/surgery to their UE, inability to sustain supported sitting for 15-20 minutes, blindness/visual impairment, fixed musculoskeletal deformities of the affected hand/wrist, no active control of the affected UE to allow at least brief activation of the joystick to move the toy, inability to follow 2-step verbal instructions, or weight that exceeds the limits of the ride-on-toy. At pretest, we will assess the child's use of their affected hand using the Manual Ability Classification System (MACS).[66]

3. Toy modification & retrofitting phase: Commercially available ride-on-toys come with 2 joysticks. The researchers will modify the toys to: (a) enable operation in a single joystick mode, (b) provide extra postural support (protective outer frame), (c) add a remote-controlled emergency stop, and (d) add sensors to collect toy use and motion data (speed, total time in operation, and motion path) to track the child's navigation efforts.

4. Testing protocol: Aim-wise primary and secondary measures are listed below:

4.1. Aim 1: The following measures will be used to assess treatment feasibility and acceptance –

1. Primary: Adherence – The toy will collect data on amount of use during training. Researchers and caregivers will also maintain logs during the intervention phase to document training duration and child engagement.

2. Primary: Treatment satisfaction and engagement – Children will complete the valid and reliable, 16-item Physical Activity Enjoyment Scale (PAES) to rate their experience.[67-69] Training sessions (one early, mid, and late session each) will be video-coded for child affect (i.e., smile rates, % duration of positive/interested and negative affect) and attention (i.e., % duration of attention to task-relevant targets). Children and/or caregivers will fill out exit questionnaires to assess training satisfaction, enjoyment, repeatability, and caregiver burden.

3. Primary: Treatment fidelity – An unbiased coder will randomly code video data (one each of early, mid, and late sessions) from researcher-delivered sessions using fidelity checklists to assess adherence to the training protocol. Trainers will also fill out posttest exit questionnaires to assess ease of implementation of RNT.

4.2.1. Aim 2A: Manual abilities and spontaneous affected UE use will be assessed as follows –

1. Primary: Quality of Upper Extremity Skills Test (QUEST)[70]– This criterion-referenced reliable and valid test assesses UE movement quality using unimanual items scored on a dichotomous scale in 4 domains: grasp, dissociated movement, protective extension, and weight bearing. The scale is valid up to 12 years of age.[71]

2. Primary: Shriner's Hospital Upper Extremity Evaluation (SHUEE)[72]– This video-based valid and reliable test assesses affected UE use spontaneously and on tester demand in 16 bimanual tasks in 3-18-year-old children. It has 3 parts: spontaneous functional analysis, dynamic positional analysis, and grasp-release analysis.

5. Secondary: Navigation control and accuracy – Early & late training sessions will be coded for (1) % duration of assisted (child needs trainer-provided manual assistance) versus independent navigation, (2) average duration and number/session of child-initiated, movement bouts normalized by driving time (a bout comprises 1 acceleration and 1 deceleration phase), and (3) rates/session of path deviations and obstacle bumps.

4. Secondary: ABILHAND-Kids[73]– This valid and reliable parent-rated questionnaire rates the child's difficulty level (3-point ordinal scale of 'impossible', 'difficult', or 'easy') in performing 21 bimanual skills independently.

4.2.2. Aim 2B: 1. Primary: Kinematic measures – Data will be collected during a unilateral and bilateral reach-grasp task at self-selected speed involving different objects (foam ball, rattle, and square block) placed at half arm's length (near) and at arm's length (far) on the table. Sensors (Inertial Measurement Units (IMUs)) will be placed on both hands, both forearms, both arms, and the C7 spinous process. We will assess the speed, smoothness, variability, and symmetry of reaching trajectories. Kinematic and motion data will also be obtained during weekly researcher-delivered training sessions and through toy-mounted sensors.

2. Secondary: Arm activity – Wrist-worn Actigraph activity monitors will be worn during first and last week of control and intervention phases to assess changes in daily arm activity over the course of the study.

5. Training protocol – Children will continue to receive conventional therapy such as physical and occupational therapy throughout the study. During the first 6-week control phase, researchers will keep track of

conventional therapy received (frequency, duration/session, type) on a weekly basis through parent interviews/training logs. In the second 6-week intervention period, in addition to conventional therapy, children will receive ride-on-toy navigation training (RNT). Researchers will provide 2 sessions/week and caregivers will provide 2 sessions/week each lasting 20-30 minutes. Training will occur at the child's home/school/community spaces like YMCA, playground, etc. Families without access to such spaces will have the option to visit the PI's lab for training. The toy can be driven on different surfaces, e.g., wood, grass, concrete, carpet, etc., allowing for flexibility in accommodating unique space-related constraints faced by families. During weekly visits, researchers will coach caregivers for caregiver-provided sessions. Trainer will fill out training diaries to log details of intervention delivery and child progress. Children will use only their affected arm to move the joystick and the unaffected arm will be enclosed in a soft restraint to encourage use of the affected side during RNT. Each session will include periods of "free play" (child can navigate freely through their physical environment using toy) and "structured play" (child will participate in multi-directional navigation games such as shape mazes, treasure hunts, and obstacle courses). The intervention is based on the motor learning- and family-centric practice-based training principles: variable and repetitive practice, progressive challenges tailored to child needs, activities promoting problem-solving and trial-and-error learning, immediate visual and auditory feedback, playful exploration, incorporation of child-preferred toys/themes into games to increase motivation, and involvement of caregivers and siblings during training. Training will emphasize active UE control of the joystick for starting and stopping the toy, moving steadily forward and backward, turning to the right and left, 180° and 360° turns on both sides, and avoiding obstacles. Activities will also involve small toys/props to encourage gross and fine motor movement and control of affected UE. Trainers will follow a least-to-most prompting hierarchy involving gestural, verbal, and finally hand-on-hand assistance per the child's needs during training. **6. Project timeline** – Please see detailed study timeline below.

Proposed study activities (Q indicates Quarter)	Year 1	Year 2			
	Oct - Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec
Intervention development and IRB Approval					
Ride-on-toy modifications and retrofitting					
Recruitment					
Testing/training: Round 1 (5 children)					
Testing/training: Round 2 (5 children)					
Testing/training: Round 3 (5 children)					
Data analysis					
Data dissemination & preparation for R21/R34 grant					

7. Dependent variables and Statistical analyses – For all coded video data, 2 independent coders will rate 20% of the data to establish inter- and intra-rater reliability of over 90%. Standardized tests will be compared between control and intervention phases, training-specific measures will be compared between early, mid, and late training sessions. All kinematic and activity data will be post-processed using custom MATLAB programs. Dependent variables from pretest-mid-point-posttest measures include: (a) total unilateral scores from affected and unaffected sides on sub-tests of the QUEST, (b) total and % scores on sub-sections on the SHUEE, (c) bilateral range of motion, maximum joint angles, peak and average velocity, total movement time, number of movement units, movement straightness, movement variability, and smoothness (e.g. jerk, dimensionless jerk, and log dimensionless jerk)[74,75] during kinematic tasks, and (d) raw scores on the ABILHAND-Kids and PAES questionnaires. Dependent variables for training-specific measures include: (a) rates of smiles and % duration of positive/interested versus negative affect, (b) % duration of assisted and independent mobility, (c) number and duration of movement bouts during navigation using the ride-on-toy, (d) outcomes derived from kinematic data (as listed in point (c) above) during the training-specific navigation test, and (e) activity counts collected from activity monitors. All data will be evaluated for assumptions of parametric statistics and general or generalized models will be selected accordingly. Variables that violate distributional assumptions of normality will be analyzed using generalized linear model (GLM) procedures, which enable the use of non-Gaussian error models. We anticipate limited missing data because attrition rates are typically low in home-based versus clinic-based programs.[76,77] When applicable, missing data will be evaluated to determine if it is completely at random. If random, multiple imputation by maximum likelihood estimation will be used.[78]

8. Power analysis – Being the first study to assess effects of ride-on-toy training on UE function in CP, we do not have prior effect size estimates for outcome measures. Therefore, our sample size estimates are derived based on large-sized effects detected in studies that aimed to improve UE function in CP using (a) innovative games such as virtual reality and video games and (b) home-based conventional therapy programs. Effect size estimates in these studies varied from 0.83-1.16 in favor of the intervention group.[46,79,80] Considering sources (a & b) and our data collection plan, we determined sample size estimates assuming fixed-effects analysis of variance on a 1x 3 design, 1 group and three time points. The study will include a total of 15 cases. The criterion for significance (alpha) has been set at 0.05 (two-tailed). The effect size estimate is 0.80, which yields power of 82% in the most conservative scenario of the effect size estimates we found in the literature.

PROPOSED INVESTIGATORS/SITES AND CONTRIBUTIONS

Dr. Srinivasan (PI) is a pediatric physical therapist (PT) with significant experience over the past 12 years in developing novel, creative movement interventions for children with disabilities and working as part of interdisciplinary teams of engineers, designers, and health professionals to develop assistive technologies for children. She also has expertise in designing and conducting clinical trials in patient populations specifically in children with developmental disabilities. Dr. Srinivasan will be responsible for project supervision and coordination of the study. She will be responsible for maintaining all study activities including recruitment, data collection, data analyses, and reporting. She will work closely with the Co-Is on all aspects of the study. She will be involved in intervention development and behavioral outcome assessments. She will also leverage her professional networks and alumni connections from the Doctor of Physical Therapy program at the University of Connecticut to assist with participant recruitment. Dr. Srinivasan will work with and oversee efforts of graduate and undergraduate students in her lab to train them on procedures related to participant screening and consent, data collection, data coding, and data analyses. She will also oversee ongoing procedures throughout the duration of the study related to ensuring fidelity of data collection and data coding methods.

Dr. Patrick Kumavor, Co-I on this project, has a background in both electrical and biomedical engineering and is presently faculty in the biomedical engineering department at UConn. Dr. Kumavor is an expert in biomedical instrumentation and control systems and will be leading the team's efforts directed towards modification of commercially-available ride-on-toys to allow flexible operation of the toys using one joystick. Dr. Kumavor's work on this project will be concentrated at the start of the project and then in an ongoing manner as car modifications are required. He will supervise the efforts of professional machinists directed towards making safety-related modifications to the external frame of the ride-on-toys. In addition, he will also supervise undergraduate engineering students who will be making hardware and software-related modifications to the controls of the ride-on-toys to allow single joystick controls, enable safety features i.e., emergency stop and speed control, as well as data capture from the toy during navigation. The PI has worked with Dr. Kumavor since Spring 2021 on this project to collect preliminary data from a ride-on-toy training program incorporated as part of an existing summer camp for children with Cerebral Palsy. Dr. Kumavor successfully modified and retrofitted multiple ride-on-toys for the purpose of the camp and will continue in this role in this study.

Dr. Kristin Morgan, Co-I on this project, is a faculty in biomedical engineering at UConn with expertise in human movement biomechanics i.e., both kinematics (analyzing joint motion) and kinetics (contribution of muscle forces to joint movement). She has extensive experience using motion capture systems and using advanced engineering and statistical techniques to assess human movement and control. In this project. Dr. Morgan will work with the PI and the research team to design data collection paradigms and tasks to obtain upper extremity kinematic data from participants using motion sensors, both while driving the toy as well as during a custom-designed reach-grasp task at pretest, mid-point, and posttest. Dr. Morgan will help with analyses of kinematic data to capture changes in joint motion and upper extremity control and symmetry following the training period. The PI has been in consultation with Dr. Morgan since Spring 2021 on our pilot study using ride-on-toys in children with CP. She will continue to work with the research team during this project.

Communication between the research team members

All investigators will provide inputs during protocol development and implementation phases relevant to their specific areas of expertise and project roles. The PI and Co-Is will meet once every week (virtually or in-person) in the initial stages of the study (first 4 months). All procedures related to the study including IRB approval, recruitment, screening and consent procedures, testing and training procedures, toy modifications, etc. will be discussed and finalized during these meetings. The training protocol will thereafter be manualized and shared with all research staff delivering the training with children in their homes/schools/community environments. Once data collection begins, the PI and Co-Is will meet once every month (virtually or in-person) to review ongoing study procedures, timelines, analyses, and study dissemination plans. The PI will meet regularly on a weekly basis with the research staff and will seek Co-I input as needed based on their areas of expertise. The PI will be responsible for training graduate and undergraduate students, checking fidelity of administered measures, ensuring that study procedures adhere to manualized testing and training protocols, developing behavioral coding schemes, and data coding. The PI along with Co-Is will also be responsible for overseeing device modifications, device safety, as well as collection and analysis of kinematic data, and data coming from sensors mounted on the ride-on-toys.

Recruitment Sites

We have identified area hospitals, clinical services, clinicians, and parent advocacy groups in Connecticut and nearby states that we will communicate with for help with recruiting families for the study. Undergraduate and graduate students and the PI will interact with these partners to recruit participants for this study.

RELEVANCE TO AACPDM

The proposed work is in line with the overarching goals within AACPDM's strategic plan pertaining to research, learning innovation, talent pool, partnership and collaboration, as well as service delivery and quality improvement. Improving affected UE spontaneous use and function is one of the most challenging rehabilitation goals for children with hemiplegic CP. We propose a novel therapeutic application of ride-on-toys as an adjunct to conventional UE rehabilitation in CP; our premise is that ride-on-toy navigation practice can incentivize affected UE use in children with hemiplegic CP for the following reasons: (a) ride-on-toys are easy-to-use for clinicians and caregivers alike and can be effectively integrated into the child's play at home, (b) mobility-based games are child-preferred and can promote self-initiated practice using the affected UE for navigation through the physical environment. If our hypotheses are upheld, this innovative project can generate new evidence that has clinical practice implications for management of young children with CP. The project leverages interdisciplinary partnerships across the fields of healthcare and biomedical engineering to develop assistive tools to aid rehabilitation efforts. Based on findings from the proposed project, we will develop future studies that will assess the use of ride-on-toys as therapeutic adjuncts in a variety of settings including school and out-patient settings and administered by a variety of service providers including clinicians, paraprofessionals, and caregivers to promote recovery of UE function in children with hemiplegic CP.

Projected Outputs: Throughout the course of the study, we will make efforts to disseminate study findings through a variety of sources including conferences, manuscripts, talks for local parent advocacy groups, and at events conducted by CP-specific organizations. We will disseminate the preliminary findings of this study at conferences including the annual meeting of the AACPDM, American Physical Therapy Association-Combined Section Meeting (APTA-CSM, Pediatric special interest group), International Motor Development Research, and Society for Research in Child Development, as well as through short articles written for the general audience and science blogs. We will publish 4 manuscripts from the final data collected as part of this project:

a) Report on overall feasibility and acceptance of the RNT from the perspective of children and caregivers.

b) Report on training-related changes in performance on standardized motor tests and parent questionnaires across control and intervention phases of the study.

c) Report on kinematic data of movement control and navigation accuracy across control and intervention phases of the study.

d) Report on changes in training-related measures of arm activity, movement control, and navigation accuracy from early to late training sessions.

Parental Permission Form for Participation in a Research Study

Principal Investigator: Sudha Srinivasan
Co-Investigators: Patrick Kumavor, Kristin Morgan
Study Title: Effects of a novel, home-based training program using a joystick-operated, modified, powered ride-on-car on bilateral upper extremity function in children with hemiplegic Cerebral Palsy.
Study Sponsor: Virginia Tech (American Academy for Cerebral Palsy & Developmental Medicine/National Institutes of Health); Grant number: 1P2CHD101912-01

Overview of the Research

You are being asked to provide permission to allow your child to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. Your child may say yes or no. Your child may change his/her mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.

This research is being done to explore if modified, commercially available, joystick-operated, powered ride-on-cars can be used to promote bilateral arm function in children with hemiplegic Cerebral Palsy (CP). This study consists of 2 phases: the control phase and the intervention phase. During the first 6-week control phase, we will contact you on a weekly basis to obtain information regarding different therapies your child receives both in and out of school. In the next 6-week intervention phase, we will visit your home twice a week to provide a training program involving joystick-operated ride-on-toys that will encourage your child to use their affected arm to control and navigate the ride-on-car through their physical environment. During the intervention phase the ride-on-car will be left at your home so that your child can practice driving the car under your supervision for additional days during the week. We will conduct testing sessions before and after the control and intervention phases of the study.

Prior to the start of the study, we will conduct a phone screening with you to confirm your child's eligibility to participate in the study. Once eligibility is confirmed, during the pretest session that will be conducted at the UConn Storrs campus (preferably) or at your home based on your convenience, your child will be asked to participate in standardized assessments that will evaluate their ability to use their affected arm for different functional activities. During this testing visit, we will also put small sensors on your child's arms and observe their movements as they complete a reaching task. In addition, we will ask you to provide information about your child's overall health, development, and their ability to use their affected arm for various activities of daily living. These assessments and questionnaires will be repeated again following the 6-week control phase, the 6-week home-based intervention phase, and again 1 month after completion of the training program. We will video record all testing and training sessions so that

we can score your child's performance later. We will ask your child to also wear wrist monitors on both hands to assess their habitual activity levels on dominant and non-dominant arms for 1 week at the pretest, at the mid-point assessment, during the first and last weeks of the training, at posttest, and then at follow-up.

Whilst the ride-on-car will be modified with safety features that will allow research staff or you to stop the device immediately whenever necessary, there is a slight risk because your child is in a mobility device that they are learning to control. Risks are described in more detail later in this form.
There may also be benefits from participation. If practicing with the ride-on-car is effective, your child may experience an improvement in their ability to use their affected arm and to use both arms for different types of daily activities. This research may also result in new information that supports the use of joystick-operated powered mobility devices as child-friendly, engaging, therapeutic tools that can be used to promote bilateral arm function in children with hemiplegic CP in the future. The study will include approximately 30-40 participants.

You can choose to withdraw participation from this study at any point during the study. A more detailed description of this research follows.

Introduction

Your child is invited to participate in a research study that will assess the utility of joystick-operated powered mobility devices to promote bilateral upper limb function in children with hemiplegic CP. Your child is being asked to participate because they are between 3 and 12 years old, have a diagnosis of Cerebral Palsy, and have limited ability in using one of their upper extremities for daily function.

This permission form will give you the information you will need to understand why this study is being done and why your child is being invited to participate. It will also describe what your child will be asked to do to participate and any known risks, inconveniences or discomforts that your child may have while participating. We encourage you to take some time to think this over and to discuss it with your child, other family members, friends and, if applicable, your child's doctor. We also encourage you to ask questions now and at any time during the study. If you decide to participate, you will be asked to sign this form, and indicate that your child has expressed interest in participating. The signed form will be a record of your permission to allow your child to participate. You will be given a copy of this form.

Why is this study being done?

The purpose of this research study is to assess changes in control of the affected arm as well as ability to use both arms together during functional tasks in children with hemiplegic CP following a 6-week, home-based, joystick-operated, ride-on-car navigation training program compared to a 6-week control phase where children only receive conventional therapy. We would like to see how children's functional hand use, upper extremity control, and bilateral function during tasks of daily living are influenced by a training program that involves practice using their affected arm to control a joystick-operated ride-on-car.

What are the study procedures? What will my child be asked to do?

Prior to the start of the study, we will conduct a phone screening with you to confirm your child's eligibility for the study. Once your child's eligibility is confirmed through the screening interview, we will send you the intake form and the parental permission and assent forms via email/mail based on your preference. We will set up a time to meet with you again via phone or Webex and take you through the intake form that will ask you questions about your child's ability to use their arm for daily activities and their overall developmental history. At this meeting, we will also take you through the parental permission form and answer any questions you may have about the study. Next, the pretest session will be scheduled at our lab in the UConn Storrs campus (preferably) or at your home (if you are not able to come to our lab). During this first pretest visit, we will ask you to sign off on the parental permission form and obtain your child's assent. We will also ask you to fill out a couple of questionnaires that will help us understand your child's baseline functional levels and the extent to which your child is using their affected arm for daily activities. During the pretest, your child will be asked to perform some standardized assessments that measure the control of their affected arm as well as their ability to use both hands together. In this same session, we will also put small sensors on your child's hands and observe their movements as they complete a reach-grasp task (that involves your child reaching for and grasping different objects such as a ball, rattle, small block). These same tests will be conducted after the end of the 6-week control phase (i.e., at the mid-point of the study), at the end of the 6-week intervention phase (at posttest), and then 1 month following the end of the program (at follow-up). The mid-point assessment, posttest, and follow-up test will also be conducted at our lab (preferably) or at your home (if you are not able to come to our lab). The mid-point and posttest sessions will be completed within 2 weeks following completion of the 6-week control phase and intervention phases respectively and the follow-up test will be conducted 1 month after completion the intervention program. All testing sessions will be video-recorded for further coding.

During the first 6-week control phase of the study, we will check-in with you every week via phone/web conferencing (based on your preferred mode of communication) to obtain information on the therapy your child received during that week (frequency, duration/session, type of session). We will use a training diary to keep track of this information on a weekly basis.

During the next 6-week intervention phase of the study, we will come to your home or to your child's school or neighborhood playground/community center that is convenient for your family. The training will last for 6 weeks with 4 sessions (2 researcher-delivered and 2 parent-delivered sessions) provided each week. The sessions will involve your child being encouraged to use either only their affected arm or both arms together to control and drive a joystick-operated ride-on-car. Please note that use of the ride-on-car is investigational. Training sessions will last for 30-45 minutes/day. During the researcher-delivered sessions, research staff will set up the games and work with your child to encourage practice using their arm/s. You can participate in researcher-delivered sessions to the extent that you feel comfortable. Each training session will involve a "free play" period where your child can freely navigate the device through their physical environment and a "structured play" period where your child will be asked to participate in different types of multi-directional navigational games such as shape mazes, treasure hunts, relay races, and obstacle courses. The goal of the training will be to encourage your child to use their affected arm to control the joystick to get the powered device to move around in the physical space. We will videotape all training sessions so that they can be scored later to

document your child's progress over time. We will let you keep the ride-on-car throughout the 6-week intervention phase of the study. The ride-on-car will be stored securely at your home after each use. We also ask that you work with your child for 2 more days every week to encourage your child to drive the toy. We will provide you with activity ideas for the caregiver-delivered sessions each week. We will continue to keep track of the therapies your child is receiving during the intervention phase through check-ins during our weekly visits to your home.

The battery of the ride-on-toy typically lasts for around 6 hours or so once fully charged. Therefore, we do not anticipate the need to charge the toy every day. We will leave the ride-on-toy to charge at the end of our researcher-provided training sessions and ask you to unplug the toy once fully charged. We will send you phone or text messages/emails (per your preference) to remind you to remove the battery from charging.

Prior to the training, we will ensure that the joystick-operated, powered ride-on-car is appropriately modified to fit your child's physical needs as needed, for instance, the provision of additional trunk supports or the use of Velcro mittens to ensure contact between their affected arm and the joystick. The device will already be retrofitted with safety features enabling you (for caregiver sessions) or the research staff (for researcher sessions) to stop the device by pushing an external switch at the back of the ride-on-toy in case of an emergency. We will ask your child to wear a safety helmet while driving the ride-on-car. If your child already has a bike helmet, we ask that the child to wear that helmet during the training. If you do not have a bike helmet for your child, we will provide a helmet for your child to use over the course of the study duration. Note that the child will wear this same helmet during the study training sessions as part of home program. At the end of the training, we will collect the helmet from your child. Similarly, if your child needs Velcro mittens for training, we will provide mittens that your child will use throughout the study duration.

At every testing visit (pretest, mid-point test, posttest, and at follow-up), we will provide your child with 2 wrist activity monitors (similar to wrist watches) called the Actigraph that we ask that your child wears on both wrists for one week. The activity monitors will allow us to track changes in your child's habitual arm activity levels over the course of the study. We will ask your child to wear the device continuously for 1 week (minimum 3 weekdays and 1 weekend day). Your child will have to remove the watch only when they will come in contact with water, for example, while bathing or going for a swim. We will ask your child to continue wearing the watch during the first week of the training. Similarly, we will request your child to wear the watches during the last week of training. All data from the activity monitors will be downloaded from the devices on password-protected computers in the PI's lab at UConn after the watches are brought back to UConn.

After completion of the study, we will ask you to fill an exit questionnaire that will ask you about your impressions regarding the ride-on-car training experience as well as your perceptions of changes in your child's upper extremity use and functional skills following the 6-week intervention program. We will also provide a couple of short exit questionnaires that we can fill out with your child in an interview format to learn how your child liked the training program.

In the light of the COVID-19 pandemic, for all testing and training visits, safety measures will be taken commensurate with University of Connecticut and state guidelines including pre-screening

research staff and participants for symptoms and history of exposure to COVID, use of face masks, social distancing measures, frequent hand washing and sanitizing, and disinfection of common touch point surfaces.

Your son/daughter will be allowed to engage in the activity to whatever degree he/she prefers and is able. Positive verbal reinforcement will be provided for any efforts made during practice, testing & training sessions. If your child shows any signs of not feeling comfortable or wanting to participate, they will always have the option of stopping or changing the activity based on their choice.

We ask that you discuss this study and the use of the device with your child to assure that they would like to take part. For example, you can say "We get a chance to drive a joystick-controlled car. We'll play with the car and see how you drive it. You can get a chance to drive the car every week for the next 6 weeks. Would you like that?" The research staff will always ask your child if they would like to participate, on the day of the testing and the training sessions.

The weekly check-ins during the control phase of the study will last for a maximum of 10-15 minutes/week. The weekly training sessions during the intervention phase will last for about 30-45 minutes per session per week for 6 weeks and would amount to a total duration of approximately 6-9 hours over the 6 weeks. Four assessment sessions will be conducted, i.e., pretest, mid-point assessment, posttest, and follow-up, each of which will last for 1-1.5 hour per session for a total duration of 4-5.5 hours across all testing visits. Therefore, the total time commitment for this study ranges from 11-16 hours over the total time span of 19 weeks of the study inclusive of follow-up.

What other options are there?

You or your child/ward can choose to stop participating in the study at any point during the study.

What are the risks or inconveniences of the study?

There is a small risk that your child may have a physical injury while using the ride-on-car in the same manner as other children playing with the device. The most likely risk is that your child may bump into an object. While your child will be safety-belted into the ride-on-car and encouraged to perform actions with good control and caution, there is a small possibility of injury if they bump into an object. The speed of the device will be set at the lowest possible speed. The child will always be accompanied by research staff during the researcher-delivered training sessions. All research staff will receive training in operating the device prior to the training. A safety checklist will be provided to staff to ensure safe operation of the device. Moreover, the device will be enabled with remote controlled safety features that would allow staff to stop the device or appropriately adjust the speed controls of the device remotely if needed. We ask that you follow similar precautions during the 2 caregiver-delivered sessions/week.

Your child may experience some inconvenience in wearing the wrist activity monitors on both wrists. If you child is not able to tolerate the monitors for any reason, they can remove it immediately. Your child may also experience some discomfort wearing the motion sensors during the testing visits. We can remove the sensors immediately if you child is uncomfortable wearing them.

You and your child may experience some inconvenience due to the time it takes for completing the testing sessions at pretest, mid-point assessment, posttest, and follow-up, each of which will take around 1-1.5 hours to complete. Similarly, you may experience inconvenience due to the biweekly training sessions during the intervention phase, each lasting between 30 to 45 minutes. We will work with you to schedule the testing/training visits at a time of your convenience. Moreover, we will give your child as many breaks as they need during testing/training activities. The pretest, posttest, and follow-up testing sessions will be conducted preferably at our lab in the UConn Storrs campus or at your home (if you are not able to come to our lab for some reason). If you choose to visit our lab at the UConn Storrs campus for the testing visits, you may experience inconvenience in terms of time and efforts to drive to the lab. We will be flexible with our timings and work with you to schedule the testing at a time that would work for your family. The training sessions will be conducted at your home or your child's school or a community center or neighborhood gym/playground based on your family's convenience. During the control phase, we will work with you to find times and a mode of communication that is most convenient for you for the weekly check-ins.

Your child may find some of the testing/training activities difficult. We will immediately stop the testing/training if you child experiences any discomfort or if they express a desire to stop the testing. Efforts will be made to have the testing be a pleasant experience.

You and your child may also find it time consuming to fill out the questionnaires provided as a part of the study. If it is more convenient for you, we can also administer the questionnaires in an interview format by scheduling a phone/Webex meeting with you at your convenience.

The researchers will tell you about any important new information that is learned during the course of this study, which might affect your child's condition or your willingness to continue permitting your child to participate in this study.

What are the benefits of the study?

Based on available information, your child has a likelihood of improving their ability to use their affected arm during daily activities following the training. The findings from this study will help us assess the utility of joystick-operated powered mobility devices to promote affected arm use and bilateral function in children with hemiplegic CP.

Will my child receive payment for participation? Are there costs to participate?

The training sessions will be conducted at your house. If you decide to visit the PI's lab for the testing sessions, you will have to incur the costs of fuel and mileage to drive to the UConn Storrs campus. When you visit the PI's lab in the UConn Storrs campus, you will be provided a

Research Subject parking pass and you will incur no costs for parking. You and your child will receive $45 in the form of a gift card at the end of the study for your participation in the study following completion of all testing and training sessions.

Could my child's information be used for future research without asking for my permission?

Yes. If all identifiers (name, date of birth, etc.) are removed, it is possible that the data collected for this study may be used for future research studies or distributed to another investigator for future research studies without your consent.

How will my child's information be protected?

The following procedures will be used to protect the confidentiality of the data collected from your child. Research records will be labeled with a randomly assigned 4-digit code, so your child's identity will be protected. The link between your child's identity and the codes will be kept separately in a locked area for five years. The research records will be stored on university computers that have high level security protection measures. Only the data stripped of identity will be saved for an indefinite time for analysis. Only the researchers will have access to the de-identified data and it will not be shared with any other parties. The study findings may be published. The information collected as part of the study will only be presented as a group and there will be no identifying information about the individuals who participated.

We will do our best to protect the confidentiality of the information we gather from your child but we cannot guarantee 100% confidentiality. If, during the course of this research study, however, a UConn employee suspects that a minor (under the age of 18) has been abused, neglected, or placed at imminent risk of serious harm, it will be reported directly to the Department of Children and Families (DCF) or a law enforcement agency.

You should also know that the UConn Institutional Review Board (IRB) and Research Compliance Services may inspect study records as part of its auditing program. The IRB is a group of people who review research studies to protect the rights and welfare of research participants. In addition, representatives from the Food and Drug Administration (FDA), the National Institutes of Health, and the Office of Human Research Protections may inspect the study records for auditing purposes.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by the National Institutes of Health. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time**.**

Additional confidentiality protections:
Certificate of Confidentiality. This research is covered by a Certificate of Confidentiality. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know.

- The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
- The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA).
- The Certificate also DOES NOT prevent your information from being used for other research studies if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What happens if my child is injured or sick because he/she took part in the study?

In the event your child becomes sick or injured during the course of the research study, immediately notify the principal investigator or a member of the research team. If your child requires medical care for such sickness or injury, your child's care will be billed to you or to your insurance company in the same manner as your child's other medical needs are addressed.

However, if you believe that your child's illness or injury directly resulted from the research procedures of this study, you may be eligible to file a claim on behalf of your child with the State of Connecticut Office of Claims Commissioner. For a description of this process, contact Research Compliance Services at the University of Connecticut at 860-486-8802.

Can my child stop being in the study and what are my and my child's rights?

Your child does not have to be in this study if you do not want them to participate. If you give permission for your child to be in the study, but later change your mind, you may withdraw your child at any time. There are no penalties or consequences of any kind if you decide that you do not want your child to participate. Your child does not have to participate in every test. Your child will be reminded that it's all right to stop or change the activity if they need to during each of the test & training sessions. Your child may be withdrawn from the study at any time if they have adverse reactions to the types of activities being done. In addition, researchers could end your child's participation in the study if they don't feel it is in their best interest or if the study is stopped early. They may also end your child's participation in the study if your child is not able to complete the study procedures due to non-compliance or disruptive behaviors. The consent discloses that when the subjects withdraw from the study, the data collected on them up until the point of their withdrawal remains part of the study database and may not be removed. If your family's participation ends early for any reason, we will make arrangements with you to collect the ride on toy from you by visiting your home or we will request you to drop off the toy at our lab, based on your convenience. We will work with you to identify a mutually convenient time for the drop off of the ride-on-toy.

Whom do I contact if I have questions about the study?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact the principal investigator/co-investigators, Sudha Srinivasan (Email: sudha.srinivasan@uconn.edu, Office Phone: 860-486-6192, Cell#: 860-617-0533), Patrick Kumavor (Email: patrick.d.kumavor@uconn.edu, Office Phone: 860-486-0369), or Kristin Morgan (Email: kristin.2.morgan@uconn.edu, Office Phone: 860-486-8118).

If you have any questions concerning your child's rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

Special Consents for Research Purposes

I understand that the researchers may contact me for participation in their future studies. I give them permission to retain my contact information for communication regarding future studies. I understand that my contact information will be retained for a period of 10 years after which it will be destroyed.
Yes _____ No _____ (Check one)
Parent or legal guardian initials here: _____

Parental Permission Form for Participation in a Research Study

Return Slip

Principal Investigators: Sudha Srinivasan
Co-Investigators: Patrick Kumavor, Kristin Morgan
Study Title: Effects of a novel, home-based training program using a joystick-operated, modified, powered ride-on-car on bilateral upper extremity function in children with hemiplegic Cerebral Palsy.

Documentation of Permission:
I have read this form and decided that I will give permission for my child to participate in the study described above. Its general purposes, the particulars of my child's involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw my child at any time. My signature also indicates that:

- I have received a copy of this parental permission form.
- I have discussed the study and the ride-on-car training program with my child and he/she indicates interest in participating.

_____
Child's Name

_____ _____ _____
Parent/Guardian Signature Print Name: Date:

Relationship to Child (e.g. mother, father, guardian): _____

_____ _____ _____
Signature of Person Obtaining Consent Print Name: Date:

Child Assent Form

Project Title: Effects of a novel, home-based training program using a joystick-operated, modified, powered ride-on-car on bilateral upper extremity function in children with hemiplegic Cerebral Palsy.

Investigators: Sudha Srinivasan, Patrick Kumavor, Kristin Morgan

Your parents have spoken to you about being in a research study. We want to see if practice playing with a joystick-operated, ride-on-car can help build strength in your arms and hands, help you move them more easily, and help you use both hands together for different activities. In the first part of the study, for 6 weeks, we will keep track of the kind of therapies you are receiving at school and outside school. We will collect this information from your parents. In the next 6 weeks of the study, you will get the chance to participate in a joystick-operated ride-on-car training program. The training will take place at your home or your school or a playground or community center/gym near your house.

At the beginning of the study, we will ask you to do some tests to check how well you can move your arms, how you can use both hands together, and how you can hold different objects with your hands. We will put small sensors on both of your arms and we will ask you to reach for different toys like a ball, block, and rattle. These tests will be done at our lab or at your home. These same tests will be repeated after the first 6 weeks of the study, then after you complete the ride-on-car training, and then 1 month after you finish the training. These tests will be videotaped so that we can score your performance later using your videos. We will also give you 2 wrist watches that we will ask you to wear on both wrists for 1 week. You will be asked to wear these watches at the start of the study, at the end of the first 6 weeks, during the first and last weeks of the training, and then after finishing the training. These wrist monitors can tell us about how much you move your arms on both sides during one week. At the end of the training study, we will ask you questions to find out if you enjoyed driving the ride-on-car. You can ask us as many questions as you want at any time during the entire study.

During the 6-week ride-on-car training program, we will come to your house/school/playground 2 times/week. During this time, you will get to drive a joystick-controlled ride-on-car for 30-45 minutes using your hands. We can help you if you need. You will need to push one or both joysticks to drive the toy. The researchers will always be with you when you drive the car around. During every session, you will play different types of games like treasure hunts, shape mazes, obstacle courses, etc. where we will ask you to use your hands to control movement of the car. You will also have some time to play freely with the ride-on-car and drive it anywhere withing your home/school/playground. Your parents may be with you as you drive the car around. The study researchers will be able to stop or slow down the car at any time if you are in any danger. We will also ask you to wear a helmet and put on the seatbelt when you drive the car. At the end of every training session, we will take note of how much practice you got and the different types of games you played that day using the ride-on-car. We will videotape all the training sessions every week so that we can keep track of your progress over the 6 weeks. In addition to us coming to your house to play with you, your mom/dad will also play with you 2 more times every week using the ride-on-car. The ride-on-car will stay at your home during the 6 weeks training. During the COVID-19 pandemic, we will ask you and we ourselves will follow safety guidelines including wearing masks, maintaining social distance, and hand washing, etc.

At the end of the program, we will also ask some questions to your parents to see if they felt that the ride-on-car training helped you move your arms better and helped you get stronger in your arms.
You can decide to not take part in this study or you can decide to stop taking part in the study at any time during the study. And if you decide to not take part in the study now or at any point in the future, your parents or anyone else will not be angry with you.

Do you want to take part in this study? Do you want to ask me any questions?

Participant/Patient: _____ Date: _____
Researcher's signature: _____ Date: _____

Reason why participant did not sign: Since some of the children may be in the process of learning to read, they may not be able to read and sign the assent form. In this case, we will obtain oral assent from the child and note down the reason for not being able to obtain written assent from the child.

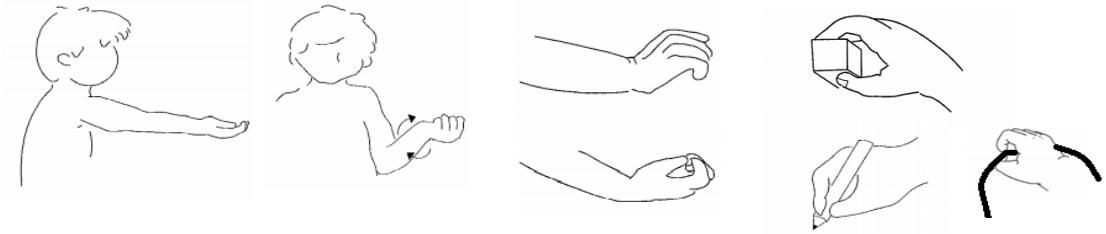
Child Assent Form

Project Title: Effects of a novel, home-based training program using a joystick-operated, modified, powered ride-on-car on bilateral upper extremity function in children with hemiplegic Cerebral Palsy.

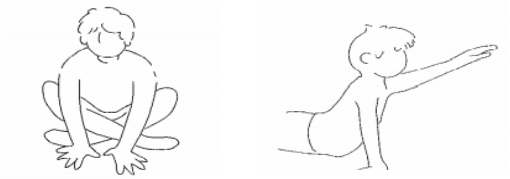
Principal Investigators: Sudha Srinivasan, Patrick Kumavor, Kristin Morgan

We want to see if practice playing with a joystick-operated ride-on-car can help build strength in your arms and hands, help you move them more easily, and help you use both hands together for different activities. During the first 6 weeks of the study, we will talk to your parents to find out about the therapies you are getting in school and outside school. During the next 6 weeks, you will get the chance of driving a ride-on-car every week. The study will take place at your home/school/playground or community center near your house. Below you can see pictures of some of the testing and training activities we will ask you to do as part of the study. The tests will take place at our lab at UConn or at your home at the start of the study, after 6 weeks, then after you complete the ride-on-car training, and then 1 month you finish the entire program. During the 6 weeks of training, we will come to your house 2 times each week to provide the training and your parents will practice activities with you 2 more times each week. Each session will go on for around 30-45 minutes. You will be asked to wear a helmet for your safety when you drive the car. At the beginning and end of the study as well as during the first & last week of training, we will ask you to wear 2 wrist watches (see picture below) that will help us track your activity in both arms during the study. During COVID, we will follow safety measures such as wear masks, keep social distance, wash hands, etc.

Testing activities: Movements of shoulder, elbow, wrist, hand, and fingers

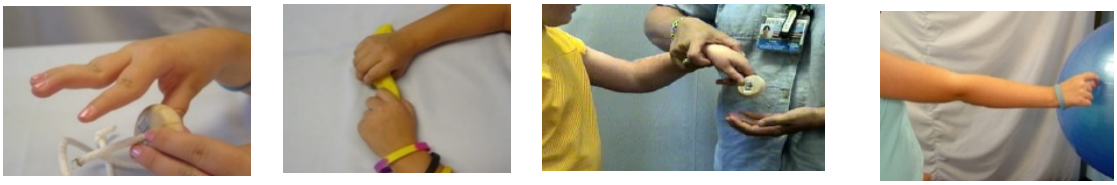


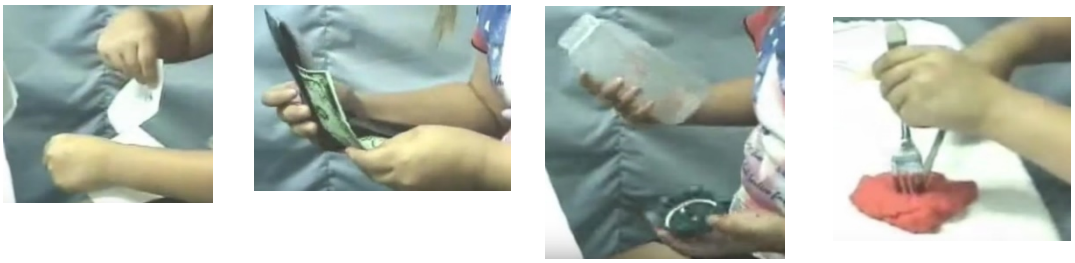
Weight-bearing activities on arms



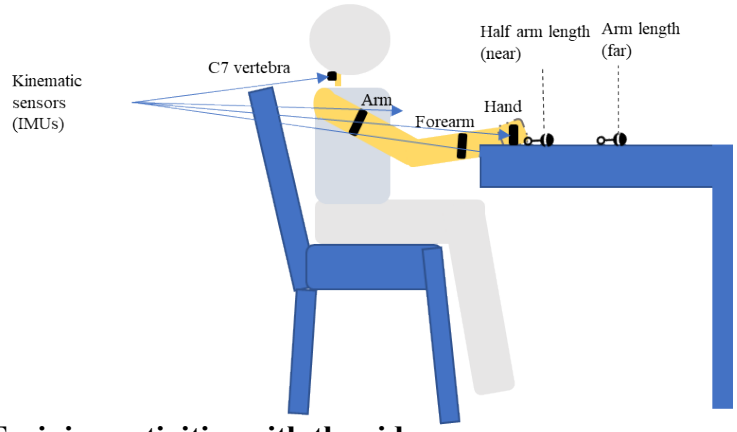
Wrist activity monitor

Functional tasks



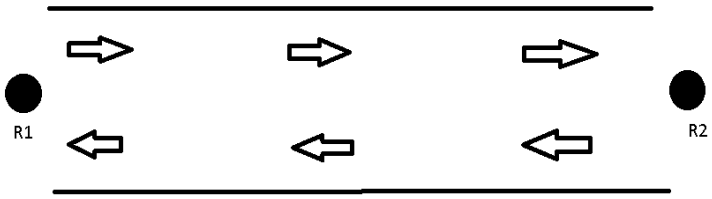


Reach-grasp task

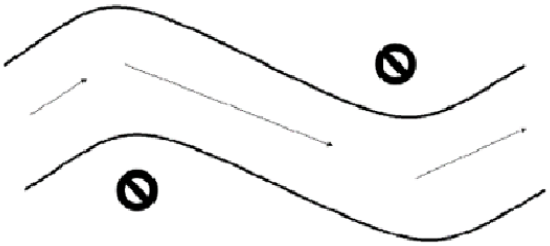


Training activities with the ride-on-car:

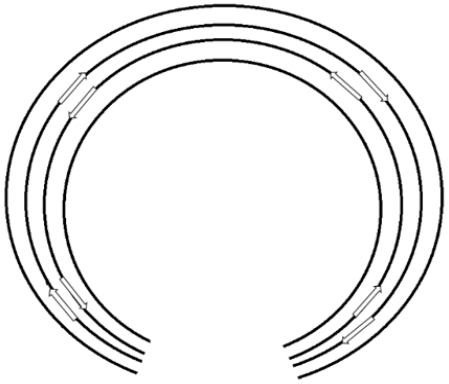
Relay races



Obstacle race courses



Circular navigation courses



You can take a break whenever you want. If you want to stop the device, you can stop at any time you wish. The research staff or your parents can also control the ride-on-car using remote controls to stop the car if needed.

You can decide to not take part in this study or stop at any time during the study. If you do not want to take part in the study, your parents or anyone else will not be angry on you.
Would you like to take part in this study? Do you want to ask me any questions?

The participant and caregiver have been taken through pictures of the activities that will be conducted during the test session

Printed name of participant_____ Date _____

Researcher's signature_____

Date_____

Reason why participant did not sign: Since some of the children may be in the process of learning to read, they may not be able to read and sign the assent form. In this case, we will obtain oral assent from the child and note down the reason for not being able to obtain written assent from the child.

Attention Parents and Children!
University of Connecticut is conducting a research study on
USE OF RIDE-ON-TOYS FOR IMPROVING ARM FUNCTION

Investigators: Sudha Srinivasan, PT, PhD; Patrick Kumavor, PhD; Kristin Morgan, PhD
UConn IRB Protocol#: H22-0059

You and your child are invited to participate in a research study that examines the effects of a home program involving joystick-operated navigation training using ride-on-toys on your child's bilateral upper extremity use & functional participation.

WHO CAN PARTICIPATE?

- Children with hemiplegic Cerebral Palsy between 3 and 12 years of age

WHAT WILL BE INVOLVED?

- This study will be conducted at your home or your child's school or in a playground/community center/gym close to your home based on your convenience. The first phase of this study is a 6-week control phase in which we will keep track of conventional therapy your child is presently receiving in and out of school (frequency, duration/session, type) through check-ins on a weekly basis. The next 6-week of the study is the intervention phase where your child will receive the ride-on-toy training.
- Training will last for 6 weeks with researchers providing 2 sessions each week lasting 30-45 minutes each. We will ask you to provide training to your child using the ride-on-toy for 2 more times every week.
- Prior to the start of the home program, we will conduct a phone screening with you to confirm your child's eligibility for participation in the study.
- The study will involve 4 testing sessions: pretest, mid-point assessment after the 6-week control phase, posttest after the 6-week intervention phase, and a follow-up session conducted 1 month after completion of the home program. Testing sessions will involve assessments to evaluate your child's ability to move their affected arm as well as their ability to use both hands together.
- Testing sessions will be conducted at our lab at UConn (preferably) or at your home if you are not able to visit our lab.
- All testing and training sessions will be videotaped so that we can score your child's performance later.

You can help by volunteering for our study. Please call us at 860-486-6192 or email sudha.srinivasan@uconn.edu

Research Study Photo/Video Release Form

Protocol #: H22-0059 Principal Investigator: Sudha Srinivasan, PT, PhD.

Protocol Title: Effects of a novel, home-based training program using a joystick-operated, modified, powered ride-on-car on bilateral upper extremity function in children with hemiplegic Cerebral Palsy

As part of this research study the University of Connecticut and those acting pursuant to its authority ("UCONN") may record your child's likeness and/or voice on a particular medium ("recordings") including but not limited to video, audio, photographic, digital, and electronic mediums during your child's participation in this research study. Please indicate what uses of these recordings you are willing to permit, by putting your initials next to the uses you agree to and signing the form at the end. The choice is completely up to you. We will only use recordings in the ways that you agree to. In any recording, your child will not be identified by name. The photo/videos will not be used for commercial purposes.

1._____ The recordings can be studied by the research team for use in the research project

2._____ The recordings can be used for scientific publications

3._____ The recordings can be used for scientific conferences or meetings

4._____ The recordings can be used for educational purposes

5._____ The recordings can be used for public presentations to non-scientific groups

6._____ The recordings can be posted to a UCONN website

7._____ The recordings can be used for reports/presentations to any research funding agencies

I understand that all such recordings, in whatever medium, shall remain the property of UCONN. My name will not be used in any publication. I agree that I will not be compensated for the use of the recordings.

I have read the above descriptions and give my consent for the use of the recordings as indicated by my initials above. **(Youth under 18 years of age must have a parent/legal guardian signature.)**

_____

(Name, please print)

_____ _____

(Signature of Subject) (Date : MM/DD/YY)

_____ _____

(Parent/Guardian Signature, if participant is a minor) (Date : MM/DD/YY)

_____ _____

(Signature of Person Obtaining Consent) (Date : MM/DD/YY)

Updated By: **Sudha M Srinivasan @ 27-Feb-2024 05:30:13 PM**

IRB-2 — Re-Approval/Completion

Page 1

UCONN | UNIVERSITY OF CONNECTICUT

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

(IRB-2) Re-approval/Completion Form

Institutional Review Board, Research Compliance Services

Whetten Graduate Center, Rm #214, 438 Whitney Road Ext., Unit 1246Storrs, CT 06269-1246860-486-8802

This form must be submitted at the time of continuing review or study completion. All questions relate to the *last* approval period.

SECTION 1: General Information

Type of Research: Faculty

Need Help ?

Study Title:
Effects of a novel, home-based training program using a joystick-operated, modified, powered ride-on-car on bilateral upper extremity function in children with hemiplegic Cerebral Palsy

PI and Correspondent Information:

Principal Investigator (PI)

Name: Srinivasan, Sudha M

* Department:
Kinesiology

* Preferred Phone #:
860-486-6192

Correspondent

Name:

* Department:
Kinesiology

Preferred Phone #:
860-486-6192

PI Emergency Phone # (Required Full Board, More than Min. Risk only):
860-617-0533

Status of Study:

Check **ONE** of the following:

☑ **On Going**

☐ **Data Analysis**

A study is considered to be in "Data Analysis" if data is being analyzed, and/or maintained for purposes of publication (i.e., a manuscript has been submitted but the publisher may ask for revisions that would require re-analysis of data).

☐ **Completed**

A study is considered to be "Completed" if data analysis is done, and there is no additional research beyond the original intent planned for this data. Use of this data for other research purposes requires submission of a new protocol application.

* Are participants still being enrolled in the study? ☑Yes ☐No

* Have all enrolled participants completed all study interventions? ☐Yes ☑No

* Is the research active only for long-term follow-up of enrolled participants? ☐Yes ☑No

Changes to UConn Key Personnel or Non-UConn Investigators:

* Since the last IRB approval (continuing or initial), have there been any changes in the personnel working on the study? ☑Yes ☐No

If so, create a separate amendment submission. Submit an IRB-3 Amendment Form with Appendix A - Personnel (to indicate whether the personnel are being added or removed).

* Has the funding source changed? ☐Yes ☑No

* Has the funding source ended? ☐Yes ☑No

SECTION IV: Study Summary and Progress Report

* **Findings**

Describe the current status of the research (e.g., phase 1 completed, phase 2 scheduled to start in two months); provide a summary of findings/analysis conducted during the approval period, state whether the findings are consistent with what you expected; and provide a brief description of the plans for the study during the upcoming approval period. IMPORTANT - Please note that it is not acceptable to simply copy last year's findings section. The IRB must review the activity that occurred within the last approval period. If no work was conducted on this study during the last approval period, please state so and explain why (e.g., too busy with other projects, delay in funding, unable to hire a graduate student to work on the project, etc.). If closing the study, please attach a copy of any publications or manuscripts resulting from the study.

The proposed project involves providing a single joystick-operated ride-on-toy navigation intervention within community settings in children with cerebral palsy. We have completed data collection with 12 children with cerebral palsy (11 completed all study procedures, 1 child partially completed study procedures). Presently, 4 children are at various stages of the study through this semester (2 children are in the intervention phase, 2 children are in the control phase of the study). Our plan is to complete data collection with these 4 children by the end of the Spring semester. We will work on data analysis during the remaining year into 2025. So far, our observations suggest that data collection is proceeding smoothly with no adverse events. We have also simultaneously begun analyzing data collected from children

in the study. We hope to have the study findings consolidated by 2025 and will work on publishing our results thereafter.

* Are there any new findings that may impact a participant's willingness to continue this study? Indicate "Yes" or "No." ☐Yes ☑No

If applicable, provide a summary of the findings of the data safety monitoring plans/board meetings and the date of the last DSMB meeting. Submit a copy of the most recent DSMB report.

* **Literature**
Provide a summary of the recent literature by other authors that provides new information bearing on this study's risk/benefit analysis, and attach copies of such articles to this form. If a search was conducted in good faith, and you believe that no such literature exists, indicate **"No literature exists"** in the space below this text border.
No such literature exists to the best of our knowledge.

Need Help ?

SECTION V: Amendments

* 1.Is the protocol being amended per this submission ☑Yes ☐No

An Amendment Review Form (IRB-3) needs to be completed

SECTION VI: Participants

For each participant population, please complete the following:

Identify each Participant Population in this column (if more than one, identify each)	**# of participants enrolled prior to the last approval period (TOTAL # from last IRB-2).**	**# of participants enrolled (signed a consent form or gave oral consent after reading an information sheet) since last IRB review.**	**Total # of participants enrolled to date (all previous years plus this year). See *"Important"* note below.**	
Children with Cerebral palsy	1	16	17	0
Total	1	16	17	

* Is enrollment proceeding as expected? ☑Yes ☐No

Important: If more participants were enrolled than was approved, please complete a Protocol Deviation Report (IRB-6), and submit with this Re-approval/Termination form.

Additionally, if you wish to increase the total anticipated enrollment, please complete an Amendment Review Form (IRB-3), and submit with this Re-approval/Termination form.

Report of Participants Screened (if applicable)

Identify each Participant Population in this column (e.g. Children, Adults)	**Since last IRB review, report total # of participants who...**		**Total # of participants screened *to date* who...**	
	Failed screen and were removed by PI	Passed screen and were enrolled into study	Failed screen and were removed by PI	Passed screen and were enrolled into study
Children with hemiplegia	1	16	1	17

Demographics

If data is available, state the number of participants enrolled to date in each of the categories below. This information is required for NIH funded research.

	American Indian/ Alaska Native	Asian	Black or African American	Hispanic or Latino	White	Native Hawaiian or Other Pacific Islander	More Than One Race	Unknown or Not Reported	New Total
Female	2	1		5		1			9
Male	1		2	4		1			8
Trans-Gender									
Unknown									
Total		3	1	2	9		2		

SECTION VII: Events to be Reported at Re-Approval

* Were adverse events and/or protocol deviations reported to the IRB during the last approval period? ☐Yes ☑No

SECTION VII: Events to be Reported at Re-Approval

Please Note: Adverse Events and Protocol Deviations, both anticipated and unanticipated, must be reported in writing to the IRB in accordance with the Adverse Event/Protocol Deviation policy. Please see the IRB website for further information.

1. Describe any *previously unreported* events that were not serious and were not related to study procedures.
None

2. Was the frequency of these events different from what you expected? ☐Yes ☐No

* 3. Did the PI or member of the research team remove a subject from the study during the last approval period? ☐Yes ☑No

* 4. Did any participant voluntarily withdraw from the study since the last IRB review? ☑Yes ☐No

* Indicate how many subjects withdrew, and at what point during the study they withdrew (i.e., after consenting but before study procedures were initiated). Describe if this number is more or less than expected. Also, if known, please state the reason(s) for withdrawal.
One participant withdrew from the study after completion of the pretest (1st testing session). The participant withdrew before initiation of the intervention phase of the study. The participant withdrew because they realized that they did not have enough time to devote to study procedures (they reported suddenly getting very busy and not being able to commit time to the study). A majority of the study participants have completed all study procedures to date (Out of the 17 enrolled families, 11 families have completed all study procedures, 4 families are in the process of completing study procedures presently, 1 family partially completed study procedures (pilot child completed 9 our of 12 training sessions and no testing sessions), and 1 family withdrew).

* 5. Were there any complaints about the research since the last IRB review? ☐Yes ☑No

SECTION VIII: IRB Review By Other Institutions

* Has another IRB reviewed this study? ☐Yes ☑No

Provide the name of the institution(s) and describe the outcome(s):

Name of Institution(s): Important - Indicate Approval Period: Please attach the current, unexpired approval/re-approval letters from each institution associated with this study.	**Outcome of Review (e.g. approved, require modifications, deferred, not approved). Important:. If the study was not approved or was deferred, please explain in the space below the table.**

Additional Notes:

SECTION IX: Comments From the Principal Investigator

If applicable, please provide additional comments that may be helpful in the IRB's evaluation of the continuation of this study.