Title Hand-Arm Bimanual Intensive Therapy in Virtual Reality Versus Standard Hand-Arm Bimanual Intensive Therapy

NCT Number NCT05867368

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STUDY PROTOCOL

EXPERIMENTAL DESIGN/METHODS

Specific Aim 1: Confirm that HABIT-VR increases upper-extremity function of children with cerebral palsy as much as or more than standard HABIT.

Rationale HABIT-VR will need to be compared to standard HABIT treatments to evaluate the effect of the software and quantify the improvements in upper-extremity function.

Experimental Design & Methods Sixteen children with cerebral palsy that have a hemiplegic or unilateral presentation will be recruited. Using the effect sizes from our preliminary study, ($\eta_p^2 \eta_p^2$= 0.234 for Box and Blocks test), a sample size of 16 (8 per group) will provide 80% power (G*Power, Düsseldorf, Germany). An additional four children (~20%) will be recruited to account for attrition, adverse responses to VR, and potentially unevaluable data, for a total of 20. All subjects will be between 7 and 15 years of age, be able to understand and perform the tasks, and have sufficient selective control of their upper-extremity with a motor control disparity. Children will be excluded if they have had an upper-extremity surgery in the last 6 months. These 20 children will participate in a pre-treatment session assessment using AHA, Box and Blocks test, and Nine Hole Peg test. The AHA assesses function and bimanual coordination [47]. The Nine Hole Peg test and the Box and Blocks Test assess manual dexterity and speed.

The children will then participate in a 10-day, 40-hour treatment session, with 10 participating in HABIT-VR and 10 participating in a standard HABIT treatment as a control group. Children will be assigned by order of enrollment and groups will be tested serially. These treatment sessions will be 4 hours a day. The children will have one-on-one treatment with an interventionist, supervised by a licensed occupational and physical therapist. These one-on-one interventionists will change between groups but will be supervised and trained by the same licensed occupational and physical therapist. The interventionist will be instructed to start by breaking the task into the role of each hand, or part-task practice, and scale the difficulty of the task appropriately by scaling the speed of the task relative to the child's baseline performance. Once the child has demonstrated improvements in their speed of the part-task practice by improving their time by at least 5%, the interventionist will then progress to whole-task practice, scaling the difficulty through changing the temporal and spatial parts of the task. The part- and whole-task performance will be recorded using practice record sheets [9]. While using the virtual environments, the interventionist will monitor what the child is doing on the attached computer screen and will scale task difficulty through the user interface and record when changes were made (See Major Equipment). Should a child experience adverse responses to VR, the child will take a break from the VR treatment until the effects subside. In the even that these effects are persistent in subsequent tries, the subject will be disenrolled from the investigation. Within a week after the treatment session, the children will undergo a post-treatment assessment using the AHA, Box and Blocks test, and Nine Hole Peg test. Dr. Willett and their team of therapists will provide the therapy treatment. Dr. Gehringer will process the behavioral data. Drs. Gehringer and Willett will interpret the results.

Expected Outcome Aim 1 will be successful if the HABIT-VR group has functional improvements at least as large as the standard HABIT group.

Specific Aim 2: Assess the acceptability of HABIT-VR as a treatment for upper-extremity functional disparities in children with cerebral palsy compared to standard HABIT.

Rationale HABIT-VR will be more effective if the children find the system and software acceptable. The children will be surveyed to assess their camp experience. These data will be coupled with objective measures, like physiological data, to ensure we are getting unbiased responses.

Experimental Design & Methods After each day of camp, both groups will complete a survey with a pictorial Likert scale to provide feedback on the activities they did that day, their enjoyment of the activities, mental and physical fatigue. These data will be coupled with the physiological responses recorded before, during, and after the camp. These physiological recordings will be used to validate each child's response in an objective way, as there are identifiable differences in physiological responses, like heart rate variability and galvanic skin response, for different emotions [48-53]. During the pre-assessments, a baseline physiological response will be recorded with an Empatica E4. This device records galvanic skin response at 4 Hz, blood volume pulse at 64 Hz, skin temperature at 4 Hz, and 3D acceleration at 32 Hz. The child will wear the device while sitting quietly for 20 minutes. During the camp, a daily baseline will be recorded for the first 5 minutes of all ten days of the camp while the child plans their day with their interventionist. The children will then continue to wear an Empatica E4 device throughout the day. Any time the child chooses to change activities, the child will be given at least a 2 minute break, to allow for these responses to normalize. The event mark button on the E4 will be pressed whenever a task changes, providing event-related markers, and at the end of the breaks between activities.

Expected Outcome Aim 2 will be successful if the HABIT-VR group has user experience survey scores and arousal responses no worse than the standard HABIT group, including lower average changes in galvanic skin response, skin temperature, and heart rate variability.

STATISTICAL ANALYSIS PLAN

Power Calculations.

Power Analysis: Forty children with cerebral palsy that have a hemiplegic or unilateral presentation will be recruited. To detect a medium effect (Cohen's f = 0.34) in the AHA scores after HABIT or HABIT-VR therapy for the repeated measures ANOVAs given 2 groups and 2 evaluations per participant, a sample size of 20 per group (40 total) will provide 80% power (G*Power, Düsseldorf, Germany). Forty participants will also provide 80% power to detect an effect size of r = .41 for the correlations.

Statistical Design for Stated Outcome Measures.

All data will be inspected to ensure that statistical assumptions are met (e.g., normality, skewness, outliers). In the case of non-normal distributions, data will be transformed, or non-parametric analysis methods will be used. We will compare the groups on demographic variables using chi-square tests and t-tests. We plan to balance the groups on participant characteristics, but if there are any differences ($p > .20$) then we will include those variables as covariates in all analyses. All of the data analyses described below will be performed in R. Analyses will be performed separately for each of the outcome variables.

Assisting Hand Assessment Linear mixed model analyses will be performed to assess the difference in upper-extremity clinical measures. The fixed factors will be intervention (HABIT-VR/HABIT), time (pre/post-therapy) for the AHA scores.

Box and Blocks Test Linear mixed model analyses will be performed to assess the difference in upper-extremity clinical measures. The fixed factors will be intervention (HABIT-VR/HABIT), time (pre/post-therapy) and hand (unaffected/affected arm) for the BBT and 9HPT will be performed to ascertain the effects of therapy on upper-arm function.

Nine Hole Peg Test Linear mixed model analyses will be performed to assess the difference in upper-extremity clinical measures. The fixed factors will be intervention (HABIT-VR/HABIT), time (pre/post-therapy) and hand (unaffected/affected arm) for the BBT and 9HPT will be performed to ascertain the effects of therapy on upper-arm function.

Engagement Scores A linear mixed model will be used with time (pre/post-therapy) and intervention (HABIT-VR/HABIT) as a fixed factors, participant as a random factor, and individual factor measure as a predictor variable, for clinical change values and engagements to identify if the individual factors predict the changes in the clinical outcomes or engagement.