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Telehealth virtual reality gaming on cardiometabolic health among youth with cerebral palsy

NCT05336227

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Background:

While there is a wealth of evidence demonstrating that exercise can improve cardiorespiratory fitness, musculoskeletal muscle strength and function, and gross motor skills (1-4), there are fewer than a handful of studies that have demonstrated improvements in cardiometabolic health in youth with cerebral palsy (YwCP) (e.g., body weight, blood pressure, lipids, and blood glucose or insulin) (5-8). Improvements to cardiometabolic health generally require regular participation in moderate-to-vigorous intensity exercise over at least a 1-3 month time frame (9, 10). This time commitment creates a need for exercise modalities that can successfully engage youth with disabilities in sustained exercise participation in their community, without the supervision by a clinician or specialist.

To address this gap, this exploratory pilot trial (NCT05336227) adapted the latest “off-the-shelf” virtual reality (VR) head-mounted displays to promote a usable health-enhancing volume of exercise among youth with cerebral palsy (YwCP). The study also included fully remote telehealth procedures to overcome common barriers to exercise such as lack of time and transportation, in the hopes of addressing a second critical gap in the literature: small sample sizes that prevent generalizable study findings (1-4).

Objectives:

1) Examine the preliminary efficacy of a 12 week, of home-based VR exercise training compared to a waitlist control group on indicators of cardiometabolic health and physical activity participation among YwCP.
2) Assess the feasibility of the program by evaluating safety, recruitment, adherence rates, and implementation challenges.
3) The tertiary purpose of the study is to generate a theory that reveals critical behavioral mechanisms of adherence to tele-exergaming.

Methods

Design

This study was a pilot randomized controlled trial with a 2-armed parallel group design, comparing an immediate start (IS) group versus a waitlist control (WC) group, where the wait group underwent their normal daily routines and activities (11).

Participants

Participants were recruited locally from a Children’s hospital and nationally through the Cerebral Palsy Foundation. The study was conducted from a single site and utilized completely remote procedures to allow participants to complete the study from their home. Inclusion criteria included a medical diagnosis of cerebral palsy, Gross Motor Function Classification System (GMFCS) level between I-IV, between the ages of 13-24 years (rationale: youth age range and the minimum age required for using the VR headset), and a physician’s clearance to participate. People were excluded if they were physically active (>150 minutes per week of moderate-to-vigorous intensity exercise in a typical week); classified as GMFCS level V; completely blind or deaf; and had contraindications to exercise.

Randomization, Sample Size, and Other Trial Considerations

Participants provided digital consent and assent through REDCap prior to participation. Participants were randomized with a 1:1 allocation ratio using a permuted block randomization approach. Participants were stratified based on their GMFCS level. The randomization sequence was generated by the project statistician using a computer-generated random schedule in permuted block (SAS V.9.4; SAS Institute). The project recruiter and outcome assessor were blinded to group allocation. The study started on June 6th, 2022, and the primary completion date was November 1st, 2024. Sample size determination was based on a power *estimate* calculation using a noncentral T distribution approach that is intended for pilot RCTs (11).

Seated Virtual Reality Exercise

The intervention included exergaming using a Meta Quest head-mounted display. The Quest 2 was used until the release of the Quest 3 (October 2023). Participants received accessories to enhance accessibility, if comfort and accessibility were identified as an issue in the first intervention week. Accessories included a controller knuckle strap to accommodate people who were unable to grip or hold onto the controllers and head strap to enhance comfort by relieving frontal face or neck pressure and increasing the ease of equipping the device. For exercise, participants received consumer-available fitness games with rhythmic movements, which often included music. Participants were asked to exercise as possible each week, with a minimum goal of 150 min/week of moderate-intensity exercise and an advanced goal of 300 min/week of moderate-intensity exercise (further details can be found elsewhere)(12). Participants received a heart rate monitor (Polar OH1) to record their average exercise heart rate during each session, using an app from the Android and Apple Play Store (VR Health or VR Health Exercise Tracker). The participant or their caregiver took a screenshot after each exercise session and sent the screenshot to the study telecoach. When receiving a screenshot, the telecoach would respond with an inspiring emoji or verbal praise. The telecoach also provided weekly, theory-based, behavioral coaching and technical assistance through brief phone calls (~10 minutes) and text messages (12). Participants in the wait control group received the same intervention, after waiting for a 12-week period with their normal daily activities.

Procedures and Outcomes

Quantitative data were collected 3 times: baseline (week 0), mid-intervention or wait (week 7), and post-intervention or wait (week 13). A qualitative interview was conducted in week 13. All assessment procedures were conducted remotely, with study outcomes detailed elsewhere (12).

Purpose 1: Blood-related Cardiometabolic Health.

Cardiometabolic health indicators included fasting insulin (μIU/mL), hemoglobin A1c (mmol/mol), high-sensitivity C-reactive protein (hsCRP; mg/L), fasting triglycerides (mg/dL), fasting cholesterol (mg/dL), and resting blood pressure (mmHg). These outcomes were measured by the participant and caregiver at home using a dried blood spot test kit, which was mailed to study staff and then mailed to the ZRT laboratory for analysis (12). Body weight was measured using a conventional bathroom scale that was shipped to participants. Blood pressure was measured using a sphygmomanometer (Omron 3 Series).

Purpose 1: Physical Activity Participation.

Self-reported activity was measured via the Godin Leisure Time Exercise Questionnaire (GLTEQ) at weeks 0, 7, and 13. The GLTEQ is a 7-day recall survey, scored using a health contribution metric, where only the moderate and vigorous components were scored using a multiplier of 5 and 9, respectively, and summed. An HC score of ≥24 can equate to the minimum aerobic guideline of 150 mins/week of moderate exercise (13, 14).

Purpose 2: Feasibility Metrics.

Metrics included recruitment and adherence rates, trial management challenges related to technology and telehealth procedures, and intervention safety, assessed through number of adverse events (e.g., falls or injuries or problems) and potential intervention effects on pain and fatigue (measured by NIH Neuro-QoL Pediatric short forms)(12).

Analyses

As a preliminary study, the study is not powered for effectiveness. Findings will inform sample size and design considerations for an effectiveness trial. Analyses were performed in an intent-to-treat manner.

Primary Aim

Descriptive statistics (means and SDs) were used to summarize participant baseline characteristics, and baseline variables were compared between groups using one-way analysis of variance. The primary analyses were conducted in an intent-to-treat manner, using linear mixed-effects models to compare between-and within-group changes (IS or WC). Models included fixed effects for the treatment group (IS vs. WC), time (baseline, week 7, and week 13), and their interaction. Random effects were included for participants to account for individual variability. Optimal model selection was based on Akaike's Information Criterion. Post hoc analyses were conducted using least-squared mean differences and 95% confidence intervals (CI). Mixed models for repeated measures data effectively handled missingness in outcomes, supplemented by multiple imputations by chained equation in Stata (StataNow/SE 18.5). Multiple imputations were performed by including outcomes, time, and auxiliary variables with 10 iterations. Estimations were combined using Rubin's rules (the STATA *mi* procedure). Blood spot specimens that were delayed longer than four weeks in the mail were excluded (due to potential degradation of the sample when not stored in ultra-low temperatures), resolved by missing imputation. Analyses were conducted using SAS software (version 9.4), with statistical significance set at $p<0.05$.

Secondary Aim

For the feasibility metrics (ie, recruitment, retention, and adherence rates), no a priori criteria for acceptability will be established. Questionnaire results will be descriptively reported, and changes across time will be explored using general linear mixed models techniques, such as mixed models repeated measures analyses. An appropriate structure for the covariance matrix (eg, unstructured) will be selected for these models using the final data. Post hoc analyses will be performed using the Tukey-Kramer multiple comparisons test.

Tertiary Aim

The qualitative component will follow Charmaz's constructivist grounded theory framework, guided by the following philosophical assumptions: critical realism ontological perspective and an interpretivism epistemological perspective. Data will be analyzed by two investigators. Data

analysis will include three phases: (1) generation of initial codes (ie, phrases that represent lines of text) and (2) focused codes (ie, phrases that represent one or more initial codes), and (3) creation of conceptual categories (ie, higher order phrases that represent focused codes) and linkages to construct a substantive theory.

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