NCT05935982

Virtual Reality Exercise in a Community High school for Children With Disabilities

2/13/2024

Design

This feasibility study was a community-based participatory research design with two phases, namely, a development phase and an implementation phase. The development phase included a 4-month preparation phase, where study staff worked with a community engagement group to modify a working Virtual Reality (VR) randomized controlled trial home-based protocol to a local public high school setting. The 9-month implementation phase utilized a "learn-as-you-go" approach with a single group pre- to post-trial design to test the implementation of the developed VR HMD (Head Mount Display) school-based protocol. The study was implemented at a public high school within the United States, which had adapted education support for children with special needs. The study was approved by the University Institutional Review Board prior to enrolling participants. Participants had to provide informed consent and assent documentation prior to joining the study. The principal of the high school approved and supported the study.

Community Engagement Group

The community engagement group included a case manager of the high school, a young adult with cerebral palsy (male; 19 years of age) with mild intellectual disability and mobility disability who was a student at the school, and his caregiver. The group was involved across the study, starting from the design in the development phase to the completion of the study in the implementation phase. The group met weekly with the research staff during the development phase, then biweekly during the first half of the implementation phase, and monthly thereafter. The purpose of the community engagement group was to make protocol modifications to intervention and data collection procedures of an existing clinical intervention that would best fit in real-world, daily operations at the school.

Participants

This feasibility study aimed to recruit a convenient sample of 12 participants, which is a general recommendation for exploratory studies targeting implementation process metrics, as opposed to group-effect comparisons that would need larger samples. Eligibility criteria are listed below. Participants were recruited through word-of-mouth and flyers by the community engagement group (case manager and young adult).

Inclusion criteria for the study included:

1. Between the ages of 10-19 years of age
2. Enrolled in school special education or self-reported disability
3. Note from physician permitting participation in moderate-intensity exercise or cleared for sports participation through physical examination that was on file by the school
4. Ability to communicate in English (or a caregiver)

Exclusion criteria for the study included:

1. Complete blindness or deafness

2. Condition that may make participation unsafe

Supplies

Participants used a VR HMD for exercise (Quest 3, Meta, USA), which came with two hand-held controllers. Active video games were purchased through the Meta Oculus digital cloud server. The games were purchased for a standard Meta account created for the study. Games included Beat Saber, Les Mills Body Combat, Creed: Rise to Glory, Smash Drums, Power Beats VR, and Thrill of the Fight.

Intervention Development and Protocol

During the development phase of the study, the community engagement group worked with the research team to modify a home-based VR HMD clinical trial protocol [20] to be more easily implemented in a high school setting. In summary, the original intervention prescription included 150 minutes of moderate-intensity activity per week using the Quest 3 at home, for a total of 12 weeks. Home exercise was supported by theory-driven behavioral tele coaching calls. In that study, caregivers were the primary intervention agents who managed their child's exercise schedules and study activities.

Through the four-month development phase for the present study, meetings with the community engagement group resulted in the following finalized exercise protocol to test in high school:

- Frequency: three times per week
- Intensity: moderate intensity exercise as indicated by a rating of perceived exertion of 5 to 7 on the Borg 0-10 scale
- Time: as many minutes of exercise as possible that could be fit within students' school schedules (e.g., either within their physical education period or a study hall or gap period)
- Type: VR exercise at home or in the school setting, at the choice of the caregiver and participant. At enrollment, caregivers were asked whether they preferred the child to perform the exercise at school or home with a borrowed headset. Home-based participants were not given more attention than those who exercised at school. For example, no behavioral coaching calls were given to home participants as is done in the protocol from which the present study was modified.

Intervention Procedures

Participants and their caregivers who were interested in the program were referred to study staff by the community engagement case manager. Participants were contacted by research staff and screened through phone calls. Eligible participants were directed to an online electronic data capture platform (REDCap) to provide informed consent and assent, participant demographics, and complete the physical activity survey. Next, they were scheduled for an onsite visit at the school to complete the physical fitness tests. Next, study staff scheduled the exercise sessions within a gap period or physical education period for participants who chose to exercise at school. Exercise sessions were performed

at the school for six weeks, and all sessions were supervised by at least one research team member. For participants who chose to exercise at home, they were provided with a Quest 3 with the preinstalled games in a convenient carrying case. They were provided with the same exercise prescription as those who chose to exercise in the school. Home-based participants were not provided with additional attention or behavioral coaching. Quest 3 headsets were returned to the school once the home-based participant completed the six-week program.

Measures

Participant Characteristics

Age, sex, height, weight, and ethnicity were descriptively reported for the enrolled participants. The use of a mobility device and wheelchair was recorded. As a gauge for how physically active participants were upon joining the study, physical activity level was measured using the NIH PROMIS Pediatric Physical Activity Short Form 8-item survey. The survey results in a total T-score. T-scores range from 20-80, with a mean of 50 ± 10. A higher T-score indicates high levels of participation in physical activity. Scores that were 0.5-1 SD below the mean indicate “mild” difference or impairment; scores 1.0-2.0 SD below the mean, “moderate” impairment; scores ≥2.0 SD below the mean, “severe” impairment.

Research Question 1: Exercise Output

Exercise volume was measured weekly by two variables, namely, mean “move” minutes and rating of perceived exertion. Move minutes were automatically recorded by the Quest 3. The Quest 3 includes a built-in fitness tracker application, referred to as Meta Quest Move. The application tracks calories and move minutes, and these data were stored in cloud-based Meta servers through end-to-end encryption. Meta does not provide specifics on how these data are calculated, but the calculations are reported by Meta to be estimated through an algorithm that includes basal metabolic rate along with the headset, controller, and hand movements. At school, the maximum possible number of active minutes that a participant could exercise each week was 75 minutes because of designated three-hour class periods. Home-based exercise participants were asked to match the school prescription (three sessions per week for a total of 75 minutes). Mean move minutes were averaged each week across the six-week program. To provide a measure of the intensity of the exercise, participants were asked immediately after exercise to provide a single rating of perceived exertion score that summarized each session, using the Borg 0-10 scale. In summary, a score of 0 represents “nothing at all,” a score of 3 is indicative of moderate intensity, a score of 5 indicates “strong” exercise, a score of 7 indicates “very strong,” and 10 indicates “extremely strong.” The mean calories were also used as an indicator of exercise output. Adverse events or problems were reported and documented in accordance with the policies established by the university.

Research Question 2: Student Attendance

Student attendance was expressed as a percentage value, measured by the number of exercise sessions attended, divided by the total sessions prescribed. The exercise prescription was a total of 18 sessions, broken up into three sessions per week for six weeks.

Research Question 3 and 4: Student Enrollment and Payment Incentives

Student enrollment was measured by the number of students enrolled per school semester. The program lasted a total of two school semesters and was completed prior to summer break. Payment incentives were planned to be increased if the target sample size of 12 was not met from the first school semester. Payment incentives started at $50 for each of the two data collection visits, for a total of $100. Because of inadequate enrollment in the first semester, the payment incentive for the second semester was increased to $100 per data collection visit, for a total of $200.

Research Question 5: Potential Effect Estimates of the Program on Physical Fitness Tests

Physical fitness was measured by walking endurance and hand-grip strength. Walking endurance was measured using a six-minute walk test (6MWT). A six-minute push test was planned to be used for students who used wheelchairs, but this was never utilized. The 6MWT measures the distance walked within six minutes around a designated course. The course was a long unobstructed hallway that allowed the participant to freely walk for the duration of the test. When participants reached the end of the hall they were instructed to turn and continue down the hallway. The rationale for choosing this location was that the study staff found there was limited space to set up and conduct a larger circular track during school hours, particularly without interference from other students. The 6MWT is suggested to be valid and reliable among children without disabilities. However, the 6MWT has conflicting evidence regarding validity for various pediatric clinical groups. Hand-grip strength was measured by the mean value of three maximal grip trials on a hand-held dynamometer (Camry Digital Hand Dynamometer, Camry, USA), while the participant was in a seated position. Grip-strength has evidence to support its use among children with intellectual disabilities.

Research Question 6: Ideal Exercise Environment

To identify the ideal method for how schools can implement the exercise program for students in a future trial, outcomes were compared between exercise settings (home versus school). Compared outcomes included enrollment, exercise volume, attendance, and fitness tests.

Research Question 7: Qualitative Evaluation of Factors for Future Trials

The qualitative component of this study utilized a mini-ethnographic design, whereby the interventionists were immersed in the culture at school with participants. At post-intervention, the interventionists were interviewed (semi-structured) to gain insight into

feasibility issues and possible programs that should be considered in a future trial. Specific questions were: 1) What were critical issues that impeded or facilitated the implementation of the program at school? and 2) What potential health or fitness-related benefits did participants experience throughout the program (particularly, benefits that were not measured)? When considering these questions, the interventionists were asked to recall and talk through their experience with each of the onsite exercise students. Interventionists were asked to take notes throughout the study. Interviews were audio recorded and analyzed by the lead interventionist, a qualitative analyst (BL), who had conducted more than 400 interviews related to disability and health.

Analyses

Descriptive statistics, including means, standard deviations, and confidence intervals, were obtained for all study variables. Changes in means were compared primarily using descriptive comparisons with 95% confidence intervals, with t-tests as appropriate. Analyses were performed using IBM SPSS Statistics version 29. Qualitative data were analyzed using a thematic analysis approach.