Effect of virtual reality-based training on postural control in youth with autism spectrum disorder

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Abbreviations

ASD	Autism Spectrum Disorder
VR	Virtual Reality/active video games
ASSQ	Autism Spectrum Screening Questionnaire
n	Number of participants
EHI-SF	The Edinburgh Handedness Inventory-short form
3D	Three Dimensional
PBS	Pediatric Berg's Balance Scale
HR	High resolution
Hz	Hertz
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
m	Meter
sec	Seconds
min	Minutes
mm	Millimeter
ANOVA	Analysis of Variance
SPSS	Statistical Package for the Social Sciences
IDE	Investigational Device Exemption
IRB	Institutional Review Board
ISO	International Organization for Standardization
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
AE	Adverse Event
CFR	Code of Federal Regulations
OHRP	Office for Human Research Protections
PI	Principal Investigator
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee

SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services

1.0 Background & Rationale

Postural control deficits, also referred to as balance deficits, are a noted example of impaired motor-skills and are increasingly considered as one of the primary markers for autism spectrum disorder (ASD)[1–5]. However, there are very few controlled clinical trials examining effects of balance interventions in individuals with ASD. Although balance appears to improve with increasing age in these individuals, it plateaus and never reaches that of a typically developing adult[6,7]. Interventions addressing the postural control delays in this population are pivotal to improving quality of life as they will reduce the risk and frequency of falls[8], improve ease and independence in performing activities of daily living[9], and improve participating in health-related physical activity[10]. However, to date there exist few effective interventions based on well-designed research that address balance deficits in youth with ASD.

Identifying home-implemented, cost-effective, generalizable, and enjoyable balance interventions that promote adherence has been an on-going challenge in the physical therapy profession[11]. Private insurance limits or altogether denies coverage of ASD-specific services such as physical therapy, occupational therapy, and speech therapy on the grounds that they are experimental, unproven or the responsibility of educational system[12]. The average annual cost of clinical therapies and related services for autistic individuals ranges between $40,000 to $60,000 per person[13] and so may not be cost prohibitive to many who need these services, especially considering the other supports this population requires for every-day functioning. It is imperative that scientists and clinicians develop research-based best practices for balance interventions that are also cost-effective and accessible to better address the rehabilitation needs of not only those with ASD, but also anyone with balance deficits.

Virtual reality/ active video games (VR) are an approach to addressing balance deficits, that is both culturally relevant and highly desirable among youth, including those with ASD[14,15].

This tool also presents an opportunity to provide youth with ASD an effective, enjoyable, and cost-effective balance intervention. Postural control/balance training should be based on the proven theories of motor learning and motor control[16,17]. Preliminary studies in people with ASD have used various techniques such as using a robotic arm to move a target on the screen[18], wearing prism goggles[18] , video modelling and video feedback[19], music therapy[20] to explore the following motor learning theories: implicit and explicit learning[18,21], feedback-based mechanisms[19,22], principles of joined movements[20], and goal directed movements with the knowledge of results and performance[16]. Most of these studies were based on non-randomized, non-controlled, and/or pre-posttest designs and thus the findings are insufficient to provide evidence regarding which of the motor learning theories is most effective for designing an intervention[23].

The foundation of many VR active games involve motor learning/control tenets as the require an individual to control their center of gravity over the base of support to successfully complete game-required movements, consequently providing an opportunity for training postural control skills[24]. It has been shown to be effective in improving static and dynamic balance in those with ASD[25,26] and other types of disabling conditions such as developmental coordination disorder[24] and cerebral palsy[27]. The therapeutic elements of VR active gaming typically incorporate the motor learning principles of feedback and task-specificity. Also, therapeutic VR tools engage the person in repetitive motor practice at variable intensity by constantly providing knowledge of performance and knowledge of results[28]. These components of neurorehabilitation help in facilitating restoration of movement capabilities[29,30] and some studies have reported the potential of VR to alter neuroplasticity[29]. Additionally, VR active gaming provides variability of learning by allowing multiple tasks at varying difficulty targeting center of pressure movement of the individual's body to emphasize dynamic balance skills, while also maintaining high levels of interest and motivation which is required for promoting adherence to the intervention[9]. Virtual reality active gaming enables the delivery of a stimulus in a standardized and reproducible manner and can be adapted according to the participant's needs[31,32]. This approach also utilizes visual and proprioceptive information which are often heavily relied upon for maintaining balance by individuals with ASD[33]. Despite the fact that VR active gaming incorporates scientific mechanisms for improving balance, there exist few, evidence-based best practices that use this method to address balance in youth with ASD.

In addition to being based on principles of motor learning/control, commercially available VR active gaming can be a cost-effective, at-home intervention. Commercially available systems cost from $200 to $1000 for the consoles with an additional $50 to $100 for individual games, which could be a one-time investment. About 67% of U.S (United States). households already own at least one VR system[34] and, if there is valid and reliable evidence to support therapeutic outcomes, insurance may pay for these devices. Additionally, children tend to enjoy active gaming and this approach may provide an advantage over traditional therapeutic approaches regarding various accessibility issues (e.g., transportation issues), adherence, and at-home use[14,26]. Therefore, VR active gaming should be explored further as a stand-alone treatment or an adjunct to conventional balance rehabilitation approaches.

There are few well designed studies using VR-based interventions to address balance in children and youth with ASD. Previous research in this area consists mainly of quasi-experimental studies [26,35,36], which, although useful in providing descriptive information, are limited in providing strong, best-practice evidence. These studies have demonstrated improvements in certain balance variables such as one- and two-footed balance[26,35], heel-toe walking distance[26], and balance components of certain clinical motor assessments (e.g., Movement Assessment Battery for Children-2nd ed[25], Bruininks-Oseretsky Test of Motor Proficiency, 2nd ed[35]).

To date only two control group design studies have used VR active gaming-based interventions to improve balance in individuals with ASD. Milajerdi and colleagues compared three conditions in children with ASD (n=20 per group): physical activity intervention, active video gaming, and usual therapies. After 24 sessions over 8 weeks, throwing and catching skills, but not balance skills, improved and there were no differences between conditions[25]. There are several factors that may have contributed to the lack of significant balance skill improvement in this study. First, only one VR game (tennis) was used, and this can be played standing with minimal center of pressure movement, also reducing the variability of training and variability in the task, and consequently restricting motor learning. Second, only providing one game option does not allow for choice and this can impact motivation, participation, and engagement[15]. Third, adherence, enjoyability, and motivation were not reported and therefore no conclusions could be drawn regarding either retention of treatment effects or long-term use.

Caldani and colleagues used an open-case control design to test the hypothesis that short-term balance training using VR would lead to neuroplastic changes in the cerebellum leading to improvements in postural control in youth with ASD[37]. They compared the effect of 6 minutes of postural control training using 2 customized active-video games with 6 minutes of rest between each trial (n=20 each in intervention and control groups). The specifically designed game consisted of moving a dot on a screen, which represented the participant's center of pressure. The subject moved the dot to either a pre-defined target or to avoid the pre-defined target by standing on a force platform. The control group rested for the duration of the intervention. The researchers reported a reduction in postural sway immediately after the intervention under both eyes open and eyes closed conditions but speculated that the changes were due to test-retest. This outcome could have been predicted and it is unfortunate that the researchers did not plan for this accordingly. This test-retest response limits translation of the intervention over longer duration as the dose, that is duration of the intervention, is insufficient to cause behavioral changes[17].

Overall, out of the five studies using VR active gaming interventions in youth with ASD, including the previously described studies using some type of control group, three reported it to be beneficial for improving balance[26,35,37] and two were inconclusive[25,36]. Findings from all of these studies are compromised due to 1) lack of randomized controlled trials[17,25,37], 2) lack of objective balance measures[26], 3) variability in intervention duration, 4) small sample sizes (10-29 subjects), 5) limited game options, 6) lack of clear identification of motor learning/control principles in the research design, (7) variability in game design (i.e. 3 were not commercially available[35–37]), and 8) no assessment beyond immediate-post intervention. The current published literature does not provide sufficient evidence for the use of VR active gaming as a modality to address postural control/balance deficits in individuals with ASD.

The purpose of this study is to deliver a VR active gaming-based static and dynamic balance intervention to children and youth with ASD that addresses several of the aforementioned gaps in the literature by: 1) using a controlled clinical trial design, 2) using objective measures of static and dynamic balance, 3) using select commercially available VR active games that incorporate specific motor learning principles that impact balance, 4) using a participant sample based on a power calculation to ensure a robust statistical analysis, and 5) assessing retention effects 4 weeks post-intervention. Addressing these gaps will significantly contribute to the knowledge base by verifying if VR active gaming interventions are effective in improving static and dynamic balance in youth with ASD.

2.0 Objectives

2.1 Primary Objective

H1: Participation in VR active video gaming incorporating explicit and implicit learning, feedback and knowledge of results, and knowledge of performance motor tenets will lead to increased postural control, as reflected by improved static and dynamic balance. This hypothesis will be tested by Specific Aim 1: to assess the effect of a short-term (3 days/week for 2 weeks) VR active video gaming intervention on static balance, versus traditional balance training exercises, in youth with ASD.

H2: Participation in VR active video gaming incorporating explicit and implicit learning, feedback and knowledge of results, and knowledge of performance motor tenets will reduce the deviation in the spatiotemporal parameters of the gait due to increased dynamic balance and improved motor coordination. This will be tested by Specific Aim 2: to assess the effect of a short-term (3 days/week for 2 weeks) VR active video gaming intervention on spatiotemporal parameters of gait, as a measure of dynamic balance, versus traditional balance training exercises, in youth with ASD.

3.0 Outcome Measures/Endpoints

3.1 Primary Outcome Measures:

1. High resolution pressure mat: Static balance will be objectively measured using an HR Mat pressure mat (Tekscan Inc.). The center of pressure will be measured at 100Hz using the center of pressure coordinates by inbuilt software[50]. The area of the postural sway and direction of the sway will be measured as indicators of static balance with participants standing on the pressure mat with hands at their side under 2 conditions: eyes open and eyes closed for 30 seconds each condition[51]. A member of the research team will stand beside the participant and provide balance support as needed.

2. Qualisys Motion Capture system: Step length, stride length, step-width, double support period, cadence and velocity are the gait parameters that will be measured as indicators of dynamic balance using Qualisys motion capture system[36,37]. The

Qualisys motion capture system will be used to assess gait as a measure of dynamic balance. The system is composed of 13-infrared cameras that capture light reflected by passive markers at a frequency of 100 Hz. It is a reliable and a valid tool for gait assessment[46,47]. The biomechanical model of feet will be constructed using Visual 3D software for gait analysis. Participants will wear the same sneakers/sports shoes for each assessment. Nine markers will be placed bilaterally (18 total) at the following points: distal aspect of the great toe, 1st metatarsal, 5th metatarsal, top of the foot, medial malleolus, and lateral malleolus, proximal heel, distal heel, and lateral heel. A comfortable walking speed for each participant will be recorded using a stopwatch to measure the time it takes them to walk back and forth on a 15-meter-long-platform 3 times and the average of the 3 trials will be calculated. Participants will then walk at the same speed at least 5 times or until the entire gait cycle is captured by the infra-red camera system twice. Gait cycle is defined as heel-strike to heel strike on the dominant foot. A couple of practice trials will be performed to ensure understanding of the procedure and verbal prompting will be used to remind the participant to walk typically. Biomechanical models of feet will be constructed using Visual 3D software for gait analysis. If the participant is unable to perform this assessment as described, it will be rescheduled up to two times before study dismissal.

3. Pediatric Balance Scale (PBS): The PBS will be used to assess static and dynamic balance. It is a valid and reliable clinical balance assessment tool for children and youth with motor impairments[48,49]. It is a 14-component battery that evaluates daily living tasks such as sitting to standing, transferring from one chair to another, and sitting and standing without support. Item numbers 1-3 and 9 -14 are specific to dynamic balance while item numbers 4-8 are specific to the static balance. Participants are graded as 0-4 on each component of the scale with 56 being the highest total score achieved. A higher score indicates better postural control. Interpretation of the scores is as follows: 41 to 56 denotes a low fall risk, 21 to 40 a medium fall risk, and 0 to 20 a high fall risk. The PBS takes fifteen to twenty minutes to administer[48]. A different researcher from the study team will record the PBS to

avoid any assessment bias. The researcher will demonstrate each task and the participant will be allowed 1-2 practice trials before official assessment as per the instructions provided in the tool. The researcher is well trained in administrating the PBS. Inter- and Intra-rater reliability will be checked at least four times throughout the course of the study by scoring a videotaped administration of the tool. An intraclass correlation of 0.9 must be achieved to avoid retraining on the PBS.

3.2 End points:

1. Primary endpoints: Reduction in PBS total score by 3.7 points. This is in accordance with the MCID range reported by Chen et al, 2013 as 3.66-5.83 for PBS in children with neuromotor impairments.
2. For static balance: 1) reduction in the sway area of 95% confidence ellipse for center of pressure, 2) reduction in mediolateral direction of the postural sway.
3. For dynamic balance: Reduction in 1) step width, 2) double support period. Increase in 1) step length, 2) Cadence, 3) Gait velocity
4. Secondary endpoints: Safety.

4.0 Eligibility Criteria

4.1 Inclusion Criteria

a) age 7-22 years[38,39],

b) existing ASD DSM-5 level 1 or 2 diagnosis confirmed by medical record/ educational services categorized under ASD/ therapeutic services categorized under ASD/ any other official document indicating the diagnosis of ASD,

c) able to follow instructions and

d) able to stand unsupported for at least 20 minutes.

4.2 Exclusion Criteria

a) epilepsy or other medical conditions which can be exacerbated by looking at a screen,

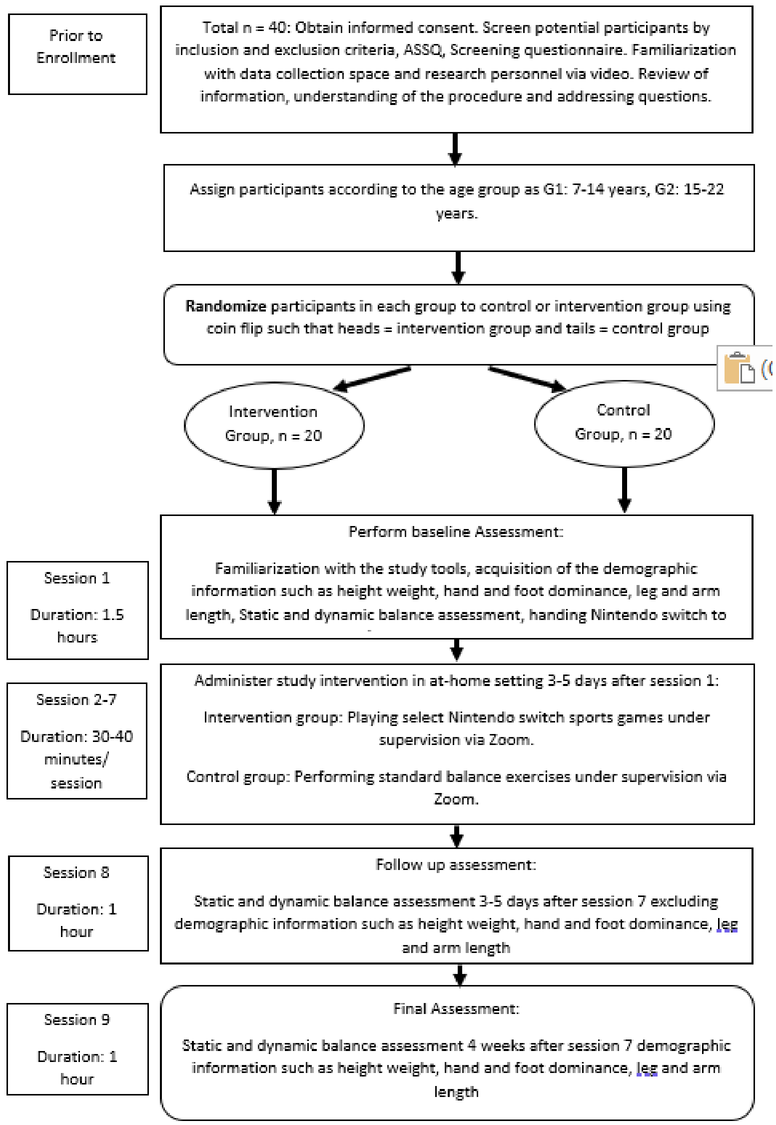
b) Uncorrected vision loss or any other eye condition prohibiting looking at the screen for a prolong time,

c) co-occurring musculoskeletal conditions such as joint or muscle pain or stiffness that limits mobility, implanted plates, pins, or screws that limit mobility, fractures or recent surgeries or any other physical condition that could interfere with the ability to play an active video game
d) co-occurring neurological conditions such as numbness or muscle weakness, temporary loss of vision, speech or strength, loss of consciousness (black out), Dizziness or lightheadedness, Impaired memory or confusion, any other cooccurring diagnosis that could be negatively impacted by playing an active video game
e) any other health conditions that are contraindicated to or may interfere with physical activity such as impaired hearing (uncorrected), medically documented balance disorder, Any heart condition prohibiting exercise, chronic pain or any pain at the time of testing, need assistance to stand for 20 minutes or more,
f) aggression or other severe behaviors that may limit the ability to safely participate in the intervention.
As participants in the intervention group will be using hand-held and not a head-mounted device for VR active video gaming, we are not anticipating any VR sickness. There are no other VR/ active gaming related issues reported in the literature which can negatively impact participants' health due to 20-minute intervention duration.

5.0 Study Design

Single blinded randomized controlled clinical trial design will be used. After obtaining the consent material, potential participants will be screened using inclusion and exclusion criteria, ASSQ and screening questionnaire. Co-PI will create and administer the assignments. Participants will be blinded to the allocation process to either the intervention or the control group.

Flow diagram for randomized, controlled trial



6.0 Enrollment/Randomization

40 school age children and youth with ASD will be recruited through local community agencies (e.g., schools, churches, and rehabilitation centers), social media platforms (e.g., Facebook and Reddit) and direct contact. Participants will be divided into 2 groups based on their age such as, group 1: 7-14 years and group 2: 15-22 years. Co-PI will allocate participant based on the coin flip such that heads = intervention group and tails = control group. The next participant in the same age range (range 1: 7-14 years, range 2: 15-22 years) will be assigned to the other group.

The process will continue till there are 10 participants in each age range for each intervention and control group (total n = 40).

7.0 Study Procedures

1. Prior to day 1: Informed consent materials, a screening questionnaire, and Autism Spectrum Screening Questionnaire (ASSQ) will be sent electronically to parents/caregivers. Participants and parents/caregivers in both groups will be given access to a video of the data collection space, intervention space setting, and a short introduction of the research personnel for review. If the participants are 18 years or older, this information will be shared with the participants directly and they will fill the questionnaires. If the participant is less than 18 years old, the information will be shared with the parent/legal guardian to be completed. Additionally, The ASSQ is a commonly used valid and reliable 27-item checklist to be filled in by parent/caregiver for assessing symptom characteristics of ASD[41–43]. The ASSQ can be completed in 10 minutes using a 3-point Likert scale with possible score range being 0 of 54 with 19 being a cut off for a parent/caregiver rating identifying ASD[44]. This tool will be used as a part of demographic screening of the participants prior to the pre-intervention day and used to better describe individual autism symptoms than is available in a medical or educational diagnosis. The researcher will subsequently contact participants and parent/caregiver to review the information, check for understanding, (particularly the terminology used in the ASSQ), assess eligibility via screening tool and address any other questions prior to study inclusion and visit.

   Study participation will require 9 visits: 1 pre-intervention visit, 6 intervention visits, 1 post-intervention visits and 1 retention visit. Participants will receive $10 Amazon or Kroger gift card after completing each session with total possible compensation of $90.

2. *Pre-intervention/ session 1:*

2.1 As part of familiarization, participants will be shown and allowed to handle the different data collection instruments and ask questions. The intervention group will be shown the Nintendo Switch to get familiarized with their operation and functions. Parents/caregivers of the participants (under 18 years of age) in the intervention group will be handed over the Nintendo Switch Sports to be connected at their home for the duration of intervention. Participants 18 years of age or older will be given the device. Researchers will provide any technological assistance required for this purpose.

2.2 Weight will be recorded using a calibrated scale and height measured using a stadiometer. The Edinburgh Handedness Inventory-short form (EHI-SF) will be used to assess hand-preference. It is a valid and reliable 4-item checklist of everyday tasks and participants score their hand preference on 5-point Likert scale (for each item, always right= 100, usually right= 50, usually left= 50, always left= -100)[45]. A researcher will read the rating scale to those with low literacy level[45]. Handedness will be determined using a laterality quotient. The laterality quotient is interpreted as left handers (-100 to -61), mixed handers (-60 to +60) and right handers (61 to 100). Hand length will be calculated using a tape cloth, measured from greater tuberosity to distal end of middle digit on the right hand and leg length iliac crest to ground on the right leg.

Participants will be shown the different data collection instruments to handle, get familiarized and ask questions. Participant's hand dominance will be recorded using the Edinberg Handedness Inventory-short form[23,24]. Participant's foot dominance will be recorded by asking them to kick an imaginary ball placed on the ground in front of them. Practice trials for balance and gait assessments will be conducted to ensure understanding of the protocol. Baseline assessments for posture and gait will be performed.

2.3 Dynamic balance assessment: Dynamic balance will be assessed as previously described using Qualisys motion capture system and dynamic components of PBS. The biomechanical model of feet will be constructed using Visual 3D software for gait analysis. Participants will wear the same sneakers/sports shoes for each assessment. Nine markers will be placed bilaterally (18 total) at the following points: distal aspect of the great toe, 1st metatarsal, 5th metatarsal, top of the foot, medial malleolus, and lateral malleolus, proximal heel, distal heel, and lateral heel. A comfortable walking speed for each participant will be recorded using a stopwatch to measure the time it takes them to walk back and forth on a 15-meter-long-platform 3 times and the average of the 3 trials will be calculated. Participants will then walk at the same speed at least 5 times or until the entire gait cycle is captured by the infra-red camera system twice. Gait cycle is defined as heel-strike to heel strike on the dominant foot. A couple of practice trials will be performed to ensure understanding of the procedure and verbal prompting will be used to remind the participant to walk typically

2.4 Static balance assessment: Static balance will be assessed as previously described using pressure mat and static components of PBS. The area of the postural sway and direction of the sway will be measured as indicators of static balance with participants standing on the pressure mat with hands at their side under 2 conditions: eyes open and eyes closed for 30 seconds each condition[51]. A member of the research team will stand beside the participant and provide balance support as needed.

3. Intervention/ session 2-7:

Session 2 will occur 3-5 days after the baseline assessment.

3.1: Intervention group: Participants will choose 2 interactive video games on the Nintendo Switch Sports from golf, Frisbee, beach tennis, soccer, Volleyball, badminton, bowling, and chambara. The researcher will supervise the sessions via zoom. These games address motor learning principles as follows. First, they cause movement of the body's center of pressure in mediolateral-, anteroposterior-, and diagonal directions without the participant paying active attention to the directional changes, leading to implicit and explicit learning. Second, they display the score achieved by the participant during- and after- each game leading to the participant having knowledge of the performance and the results. Third, playing 2 games provides task and training variability.

Games will be played for 10 minutes each with a 5-minute break in between. The same 2 games will be played each session. Participants will stand at least 3 meters away from the TV while playing the games. Verbal prompts /motivators will be provided during the games. Each session will take approximately 40 minutes. The caregivers will be present at one-hands distance from the participant to prevent any falls. Additionally, participants will be asked to place a chair at a reachable distance which they can hold on to prevent falls. Ideally, each session will occur with an off day in between, however this may not be realistic depending on participant and caregiver schedules and so sessions will occur at participant/caregiver convenience.

Control group: Control group participants will receive balance instruction from the researcher at home via Zoom. The following standard balance exercises[52] will be performed for 15 minutes with 5 minutes of warm and cool down each. Breaks will be given as per the participants' need and verbal prompts/motivators provided. The caregivers will be present at one-hands distance from the participant to prevent any falls. Additionally, participants will be asked to place a chair at a reachable distance which they can hold on to prevent falls.

Warm up exercises: Neck flexion-extension, shoulder flexion-extension, shoulder abduction-adduction, shoulder clockwise rotation, elbow flexion-extension, hip flexion-extension, hip abduction-adduction, knee flexion-extension, ankle plantar flexion- dorsi flexion, trunk flexion-extension. All exercises will be done by standing holding the back of a chair for 5 repetitions bilaterally.

Balance exercises: Standing with feet together for 10 seconds 5 times, standing with 1 foot in front of other for 10 seconds 5 times on both sides, standing on one leg for 10 seconds 5 times on both sides, walking with one foot in front of other on a 1-meter-long line for 5 repetitions and standing on a balance board for 30 seconds for 3 repetitions.

Cool down exercises: Stretching of calf muscles, quadriceps, hamstrings, lateral trunk flexors, truck extensors, shoulder abductors, shoulder adductors for 10 seconds each for 5 repetitions bilaterally. All stretches will be done by standing holding the back of a chair whenever necessary.

4. Post-intervention/ session 8 and 9:

Static and dynamic balance will be reassessed as previously described to examine retention effects of the VR active gaming intervention (see study calendar). Session 8 will be at least 3-5 days after session 7. Parent/caregiver will return the Nintendo Switch Sports to the researcher. Session 9 will be 4 weeks after session 7. Each session will be for approximately 60 minutes.

8.0 Study Calendar

Prior to Day 1	Session 1	Session 2-7	Session 8	Session 9
Familiarization video	Familiarization with study tools	3-5 days after baseline assessment	Reassessment of dynamic and static balance 3-5 days after session 7 excluding	Reassessment of dynamic and static balance 4 weeks after session 7 excluding

			demographic parameters such as EHI-SF, leg and arm length, weight, height.	demographic parameters such as EHI-SF, leg and arm length, weight, height.
Informed consent material, Screening questionnaire and ASSQ	Acquisition of demographic information	Intervention group: Playing select video games under supervision via Zoom	Duration: 1 hour	Duration: 1 hour
Autism spectrum screening questionnaire	Baseline dynamic and static balance assessment	Control group: Performing standard balance exercises under supervision via Zoom		
Researcher-parent/ caregiver interaction	Duration: 1.5 hours	Duration: 30- 40 minutes per session		

9.0 Reportable Events

Any event that requires prompt reporting to the IU IRB per the IU HRPP Policy on Reportable Events will be reported within five business days in compliance the IU HRPP Policy. Minor noncompliance and minor protocol deviations not meeting the requirements for prompt reporting will be reported at time of protocol renewal.

For questions about the rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU

(Indiana University) Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

10.0 Study Withdrawal/Discontinuation

After reviewing the consent and/or assent form and having their questions answered, participants may decide to sign the forms and participate in the study. Or they may choose not to participate in the study. The decision is up to the participants. If they choose not to participate in this study or change their mind after signing the consent document, it will not affect their usual medical care or treatment or relationship with Indiana University.

If participants change their mind and decide to leave the study in the future, the study team will help them withdraw from the study safely. If they decide to withdraw, they should contact one of the a researchers to make them aware. Researchers will instruct the participant to stop playing the Nintendo Switch Sports and the researcher will collect the gaming console from the participant.

The researchers may stop the participation in the study even if participant do not want to stop if there is any incidence which leads to participant acquiring any exclusion criteria of this study such as any neurological or orthopedic condition affecting balance, epilepsy, or any type of injury that prevents you from continuing your participation during the data collection process of the study.

The PI will be responsible for data and safety monitoring. The study team will meet at least bi-weekly to discuss any difficulties while conducting the experimental protocols and review the data. Dr. Frey will always be available online when data collection is occurring. Minutes of each of the meetings will be maintained on the designated One-Drive folder for the Physical Activity Research lab.

11.0 Statistical Considerations

According to prior research study examining the similar paradigm using Xbox games (Ghobadi et al. 2019), we predict the medium effect size (f=0.25) to detect significant changes within groups, between groups and effect of timepoint on static and dynamic balance. Power analysis (using G*power 3.1.9.7 software) indicates 14 subjects in each group to have 0.8 power to detect this effect (alpha 0.05). To account for the likelihood of attrition and noncompliance, total 40 participants are being recruited. Data from participants who engage in all the intervention sessions will be included in the analysis.

SPSS (Statistical Package for the Social Sciences) and MATLAB will be used for processing and analyzing the data. Participants demographic and health characteristics will be compared using paired sample t-tests. Intention to treat analysis will be used for addressing effects of treatment or control on static and dynamic balance. The dependent variables for static balance include: 1) sway area of 95% confidence ellipse for center of pressure(mm^2), 2) direction of center of pressure sway as anteroposterior and mediolateral (mm). The dependent variables for dynamic balance are: 1) step length (m), 2) stride length (m), 3) step width (m), 4) double support period (sec), 5) cadence (steps/min) and 6) gait velocity (meters/min). Total PBS score will be dependent variable for both static and dynamic balance.

Two-way repeated measures ANOVA (analysis of variance) will be used to determine 1) within intervention and control group, for assessing the main effect of group, 2) between intervention and control group for assessing main effect of time, and 3) between - within interaction for assessing the interaction term. Statistical significance will be declared if $p \leq 0.05$ (two-tailed).

Dr. David Koceja (koceja@indiana.edu) will assist with the statistical considerations.

12.0 Data Management

Qualisys motion capture system, visual 3D and HR mat use the inbuilt software for collecting and cleaning the data. HR mat data will be exported to MATLAB for analysis of postural sway. The data will be stored on an access-controlled computer situated in laboratory 70 E of the School of Public Health building in Indiana University Bloomington. Only approved study personnel will have access to this data.

13.0 Privacy/Confidentiality Issues

Participants will be recruited through flyers posted in the community and various Indiana University Buildings. Subjects will be assessed in the private setting of Physical activity and

Biomechanics labs in the School of Public Health building. Informed consent form will be obtained from the subjects prior to the research procedure online via Qualtrics. All phone conversations regarding the consent/ assent process will occur in the private setting of the researcher's office behind the closed doors. The intervention will take place at participants own home ensuring privacy. All the data collected for this study will be placed in a locked cabinet in laboratory 70 E of the School of Public Health building in Indiana University Bloomington. The only people that will access this information are approved study personnel.

14.0 Follow-up and Record Retention

Session numbers 8 and 9 will be follow-up and retention assessment sessions. Session 8 will occur 3-5 days after the last intervention day and session 9 will occur 4 weeks after the last day of intervention. The data will be retained for 3 years after the end of the study.

15.0 References

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16.0 Appendix

1. Recruitment Flyer:

Details: The study consists of 9 sessions occurring over 7-8 weeks, 6 at-home intervention sessions (30-40 minutes) and 3 testing sessions (1.0-1.5 hour) at the School of Public Health.

If you find this study interesting, and you think you would like to participate, please contact Surabhi Date <dates@iu.edu> for enrollment screening.

Thank you!

Surabhi Date <dates@iu.edu>

Surabhi Date <dates@iu.edu>

Surabhi Date <dates@iu.edu>

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Surabhi Date <dates@iu.edu>

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Surabhi Date <dates@iu.edu>

Surabhi Date <dates@iu.edu>

2. ASSQ:

Autism Spectrum Screening Questionnaire (ASSQ)

Please read the statement below and indicate by answering, No, Somewhat, or Yes if this your child/you stands out as different from other children/adults of his/her age in the following ways:

		No 0	Somewhat 1	Yes 2
1	is old-fashioned or precocious			
2	is regarded as an "eccentric professor" by the other children			
3	lives somewhat in a world of his/her own with restricted idiosyncratic intellectual interests			
4	accumulates facts on certain subjects (good rote memory) but does not really understand the meaning			
5	has a literal understanding of ambiguous and metaphorical language			
6	has a deviant style of communication with a formal, fussy, old-fashioned or "robotlike" language			
7	invents idiosyncratic words and expressions			
8	has a different voice or speech			
9	expresses sounds involuntarily; clears throat, grunts, smacks, cries or screams			
10	is surprisingly good at some things and surprisingly poor at others			
11	uses language freely but fails to make adjustment to fit social contexts or the needs of different listeners			
12	lacks empathy			
13	makes naïve and embarrassing remarks			
14	has a deviant style of gaze			

15	wishes to be sociable but fails to make relationships with peers			
16	can be with other children but only on his/her terms			
17	lacks best friend			
18	lacks common sense			
19	is poor at games: no idea of cooperating in a team, scores "own goals"			
20	has clumsy, ill coordinated, ungainly, awkward movements or gestures			
21	has involuntary face or body movements			
22	has difficulties in completing simple daily activities because of compulsory repetition of certain actions or thoughts			
23	has special routines: insists on no change			
24	shows idiosyncratic attachment to objects			
25	is bullied by other children			
26	has markedly unusual facial expression			
27	has markedly unusual posture			

3. Screening Questionnaire (Qualtrics survey)

Screening questionnaire: Effect of virtual reality-based training on postural control in youth with autism spectrum disorder (ASD)

Q1 Name of the participant:

____

Q2 Do you have any of the following documents confirming autism diagnosis:

▢ Document provided by the physician (1)
▢ School services categorized under ASD (2)
▢ Seeking therapeutic services categorized under ASD (3)
▢ Any other official documents indicating the diagnosis of ASD, please specify: (4)
____

Q3 Will you be willing to provide researcher with a copy of those document under HIPPA safety regulations?

- o Yes (1)
- o No (2)

Q4 Does participant currently receive any medications?

- o Yes (1)
- o No (2)
- o If yes, please mention the medications: (3)
____

Q5 Does the participant currently have any of the following musculoskeletal conditions?

	Yes (1)	No (2)
Joint or muscle pain or stiffness that limits mobility (1)	o	o
Fractures or recent surgeries (2)	o	o
Implanted plates, pins, or screws that limit mobility (3)	o	o
Any other physical condition that could interfere with the ability to play an active video game (4)	o	o

Q6 Does participant currently have any of the following neurological symptoms?

	Yes (1)	No (2)
Numbness or muscle weakness (1)	o	o
Temporary loss of vision, speech or strength (2)	o	o
Loss of consciousness (black out) (3)	o	o
Dizziness or lightheadedness (4)	o	o
Impaired memory or confusion (5)	o	o
Epilepsy or seizures (6)	o	o
Any other cooccurring diagnosis that could be negatively impacted by playing an active video game (7)	o	o

Q7 Does participant currently have any of the following symptoms?

	Yes (1)	No (2)
Uncorrected vision loss or any other eye condition prohibiting looking at the screen for a prolong time (1)	o	o
Impaired hearing (uncorrected) (2)	o	o
Medically documented balance disorder (3)	o	o
Any heart condition prohibiting exercise (4)	o	o
Chronic pain or any pain at the time of testing (5)	o	o
Aggression or other severe behaviors that may limit the ability to safely participate in this study (6)	o	o
Assistance to stand for 20 minutes or more (7)	o	o

Q8 Does participant currently receive physical or occupational therapy specifically for improving balance?

- o Yes (1)
- o No (2)

Q9 Has participant received physical or occupational therapy in the past specifically for improving balance?

- o Yes (1)
- o No (2)

Q10 Do you perceive participant having any challenges with balancing self such as frequent tripping while walking, frequent falls, uses support while walking or standing unsupported?

- o Yes (1)
- o No (2)
- o If yes, please specify: (3) ____

Q11 Does participant currently play any video games?

- o Yes (1)
- o No (2)
- o If yes, specify the gaming consoles: (3) ____

Q12 What the frequency of playing the video games?

____

____

____

____

____

Q13 Does participant currently play active video games (which involves participant moving his body to move the avatar on the screen)?

- o Yes (1)
- o No (2)
- o If yes, what is the frequency and average duration: (3) ____

Q14 Does participant currently have access to Nintendo Switch Sports (2022) game?
- o Yes (1)
- o No (2)

Q15 Does participant have any other challenges that may limit their ability to engage in this study such as will he/she be able to engage in video game activity for 10 minutes without getting distracted?

____

____

____

____

____

Q16 Will the participant need any individualized motivation such as visual schedule, checklist, sticker chart, etc. for engaging in this research? Please specify:

____

____

____

____

____

4. Consent form:

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Effect of virtual reality-based training on postural control in youth with autism spectrum disorder

IRB Protocol Number:19116

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

Further reference "you" in this document refers to either yourself (if you are a participate 18 years of age or older) or your child, if they are participating.

WHY IS THIS STUDY BEING DONE?

We are doing this study because we are trying to find out more about the effect of using commercially available virtual reality-based balance training (like Nintendo Switch) in children and youth with autism spectrum disorder (ASD) regarding the ability to balance and walk**.**

You are being asked to participate in this study because you indicated you are diagnosed with Autism Spectrum Disorder and are interested in video games.

The study is being conducted by Dr. Georgia Frey, and Surabhi Date, M.P.T. from Indiana University, School of Public Health, Department of Kinesiology.

WHAT WILL HAPPEN DURING STUDY?

We want to tell you about some things that will happen if you decide to participate in this study. This study will take place at the Physical Activity and Biomechanics Labs at the School of Public Health, Indiana University, Bloomington, and your home. We think it will last for about 9 sessions spread over the period of about 7-8 weeks.

If you want to be in this study, here are the things that we will ask you to do:

Prior to visit 1:

- A screening questionnaire will be sent to you to complete electronically. If you less than 18 years old (a minor), your parent/guardian will complete the questionnaire on your behalf for accuracy. The screening questionnaire will ask various questions about any medications you may take and your medical history to make sure you are healthy enough to participate.

- You will be sent the Autism Spectrum Screening Questionnaire (ASSQ) to be completed electronically which will also be completed by your parent/guardian if you are a minor. The questionnaire is used as an initial screening for high functioning ASD.

- The study team will then contact you to review the information, check for understanding, assess eligibility via screening tool and address any other questions prior to study inclusion and visiting research laboratories.

- If it is determined that you are eligible to participate, you will be given access to a video which will give you information about the lab where you will be coming to do some of the study activities, and a short introduction of the research personnel.

- You will then be randomly assigned (like flipping a coin) to one of two groups: the Virtual Reality Group, or the Exercise Group. This will determine what activities or exercise you complete for the upcoming sessions.

Session 1/Pre-intervention, approximately 1.5 hours (this session takes place at the lab):

- Your height and weight will be measured.

- You will be asked some basic questions to determine which hand you prefer to use to complete daily tasks such as writing, throwing a ball, and brushing your teeth. For determining the foot dominance, you will be asked to kick an imaginary ball placed on ground in front of you.

- The length of your hand and length will be calculated using a tape cloth, measured from your right shoulder to end of your middle finger on the right hand and leg length from waist to ground on the right leg.

- We will then measure your “postural sway.” You will be asked to stand on a large mat that has sensors. You will stand on the mat for 30 seconds with your eyes open, and then for 30 seconds with your eyes closed. The mat will measure your body's natural unconscious small movements (or "sway"), that happen around your center of gravity.

- Next, your balance will be assessed using the Pediatric Berg's balance Scale (PBS) to determine your ability to safely balance during daily activities. You will be asked to complete activities like sitting and standing without help, standing with your eyes closed, reaching forward with your arms stretched in front of you, placing your right then left foot on a stool, standing with alternating foot in front, and standing on one foot, alternating right and left. The researcher will demonstrate each task, and you can practice1-2 times before the test begins.

- After this, measurements will be taken of you walking using special cameras. You will be instructed to walk on a pathway with removable markers placed at your lower back using a special tape over your cloths/shoes, at the base of your big toe, sides of both ankles, on your knees and both of your heels. You will walk 3 times at your typical speed and the average speed will be calculated. Then video recording will be done when you walk the distance back and forth at your average walking speed to record how you walk. You will be instructed to walk till 5 trials are completely recorded by the camera system. A couple of practice trials will be performed to ensure understanding of the procedure and a study team member will remind you to walk like you normally do. If you are not able to do this assessment, it will be rescheduled up to two times before it is decided you should be withdrawn from the study.

- We will set up a recurring zoom meeting link for future visits and share it with you at the end of this visit.

- Lasty, if you were randomized to the Virtual Reality Group, you will be given the controller for the Nintendo Switch© system so that you can familiarize yourself with how the controller works and the various buttons. Study personnel will also show you how to use the controller and will answer any questions you may have. You will be handed over the Nintendo switch console and sports game to take home. You will also be given instructions on how to set it up if needed.

Sessions 2-7/ Intervention: 3 times a week for two weeks, 30-40 minutes each (these sessions take place at home):

The first session will be about 3-5 days after the lab visit.

Virtual Reality Group: These sessions will occur at your home while a researcher supervises via Zoom. If you are in this group, you will choose 2 interactive video games on the Nintendo Switch from golf, Frisbee, beach tennis, soccer, Volleyball, badminton, bowling, and chambara. Games will be played for 10 minutes each with a 5-minute break in-between. The same 2 games will be played at each session in the same sequence. Researchers will provide verbal prompts and encouragement during the games. Each session will take approximately 30-40 minutes. Ideally, each session will occur with an off day in between, however this may not be realistic depending on your schedules and so sessions will occur at your convenience.

Exercise Group: If you are in this group, you will receive instructions from the researcher at home via Zoom. The following standard balance exercises will be performed for 15 minutes with 5 minutes of warm and cool down each. Breaks will be given as needed and verbal prompts/motivators will be provided.

Warm up exercises: Free body movements such as bending your neck backward and forward, shoulder clockwise rotations, bending and straitening elbows, moving ankles up and down. All exercises will be done by standing holding the back of a chair for 5 repetitions on each side.

Balance exercises: Standing with feet together for 10 seconds 5 times, standing with 1 foot in front of other for 10 seconds 5 times on both sides, standing on one leg for 10 seconds 5 times on both sides, walking with one foot in front of other on a 1-meter-long line for 5 repetitions and standing on a pillow for 30 seconds for 3 repetitions.

Cool down exercises: Stretching of certain body parts such as calf muscles, knee and hip muscles, shoulder muscles for 10 seconds each for 5 repetitions bilaterally. All stretches will be done by standing holding the back of a chair whenever necessary.

Sessions 8 and 9/ post-intervention: approximately 1 hour each (these sessions take place at the lab):

- 3-5 days after session 7, you will complete all the balance and walking measurements as of session #1 excluding parameters such as hand and foot dominance, leg and arm length, weight, height. It will take approximately 1 hour.
- Session #8 will occur 3-5 days after session #7 and session #9 will occur 4 weeks after session #7.

You will not receive the results of any of these tests or procedures because they are being done only for research purposes.

WHAT ARE THE RISKS OF TAKING PART IN THIS STUDY?

1. Physical discomfort- You may feel uncomfortable or pain in your legs or feet due to standing for 10 minutes at a time. You may also feel discomfort in your hands from using the controller for an extended period of time if you are in the Virtual Reality Group. If this is the case, you can ask to take a break at any time. You can also ask to sit at any point, or can you decide that you want to discontinue the visit.

2. Risk of falling- There is a slight risk that you may fall during physical exercise and/or while playing virtual reality games. If you are a minor, you will have a parent present at all times during the sessions to ensure your safety as well as a chair nearby to hold onto to steady yourself or sit as needed. Study personnel will be able to see you at all times via Zoom while you are doing the tasks and will give safety prompts as needed.

3. Loss of confidentiality- As with any study, there is a possible risk of loss of confidentiality. All study data will be stored on an encrypted password protected computer and in a locked area. Only approved study personnel will be able to access your study information.

Not all of these things may happen to you. None of them may happen. Things may happen that researchers do not know about yet. If they do, we will make sure that you get help to deal with anything bad that might happen.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

If you are injured as a result of participating in this study, you will be responsible for seeking medical care and for the expenses associated with any care received. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. No money or funds are set aside to pay for these types of injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled by signing this Informed Consent form.

WHAT ARE THE BENEFITS OF TAKING PART IN STUDY?

We do not think you will have any personal benefits from taking part in this study, but we hope to learn things that will help other people in the future.

WILL I BE PAID FOR PARTICIPATION?

You will receive a $10.00 Amazon gift card each time you complete a session, for a total possible compensation of $90.00.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?

The following individuals and organizations may receive or use your identifiable information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US government or agencies as required by law

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact researchers Surabhi Date, at 812-603 - 8031 or Dr. Georgia Frey at 812-855-1262. After business hours, please call Dr. Georgia Frey at 812-855-1262.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Indiana University.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, please contact one of the above researchers to make them aware.

The researchers may stop your participation in the study even if you do not want to stop if there is any incidence which leads to you acquiring any exclusion criteria of this study such as any neurological or orthopedic condition affecting your balance, epilepsy, etc. or any type of injury that prevents you from continuing your participation during the data collection process of the study.

PARTICIPANT'S CONSENT

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

For participants 18-22 years old:

Participant's Printed Name: ____

Participant's Signature: _______________________________________Date: ___________

Printed Name of Person Obtaining Consent: __________________________________

Signature of Person Obtaining Consent: ____________________________Date: __________

For participants 15-17 years old:

Printed Name of Child: ____

Printed Name of Parent: ____

Signature of Parent: ____ **Date: __________**

Printed Name of Person Obtaining Consent: __________________________________

Signature of Person Obtaining Consent: ____________________________Date: __________

5. Assent Form:

Indiana University Assent to Participate in Research

Effect of virtual reality-based training on postural control in youth with autism spectrum disorder

IRB protocol number: 19116

We are doing a research study. Research study is a special way to learn about something. We are doing this research study because we are trying to find out more about the effect of using a video game system (like Nintendo Switch) in children and youth with Autism Spectrum Disorder (ASD) on their ability to balance and walk**.**

Why am I being asked to be in this research study?

You are being asked to be in this research study because you or your parent/guardian have indicated that you are diagnoses with autism spectrum disorder and are interested in video games.

What will happen during this research study?

We want to tell you about some things that might happen if you are in the study. This study will take place at the Physical Activity and Biomechanics Labs at School of Public Health, Indiana University, Bloomington, and your home. We think it will last for about 9 sessions spread over 7-8 weeks.

If you want to be in this study, here are the things that we will ask you to do.

Before you come to the lab:

Your parent/guardian will complete a couple of questionnaires that will be ask questions about any medications you take and about your physical health to make sure it is safe for you to participate in the study. They will also answer questions that are used to determine if someone might have ASD.

You will be shown a video which will give you information about the lab where you will be coming to do some of the study activities, and information about the people that will be working with you during the study.

You will then be randomly assigned (like flipping a coin) to one of two groups: the Virtual Reality Group, or the Exercise Group. This will determine what activities or exercise you will do for the upcoming sessions.

During your first visit to the lab, about 90 minutes:

We will measure your height, weight, and length of your arm and leg. You will also stand on a large mat that has sensors that will measure how much your body moves back and forth while you are standing. You will stand on the mat for 30 seconds with your eyes open, and then for 30 seconds with your eyes closed.

Then, we will measure how well you are able to balance by having you do some activities like sitting and standing without help, standing with your eyes closed, reaching forward with your arms stretched in front of you, placing your right then left foot on a stool, standing with alternating foot in front, and standing on one foot, alternating right and left. The researcher will show you how to do each of these, and you can practice a couple of times before the test begins.

You will then do some walking in the lab with special sensors that are attached to your lower back and feet. This will measure how you walk. The sensors are attached with special tape and are not painful. A special camera will take pictures as you walk, and video recording will be done as well. You will do this several times and will be reminded to walk at a normal pace.

Lastly, if you are in the Virtual Reality Group, your parent/guardian will receive the Nintendo switch™ console and the sports game to take home.

At home, 3 times a week for two weeks for 30-40 minutes:

- If you are in the Virtual Reality Group, you will choose 2 video games on the Nintendo Switch from golf, Frisbee, beach tennis, soccer, Volleyball, badminton, bowling, and chambara. Games will be played for 10 minutes each with a 5-minute break in-between. The same 2 games will be played at each session in the same sequence. Researchers will provide verbal prompts and encouragement during the games as they watch you via Zoom. Each session will take approximately 30-40 minutes. Ideally, each session will occur with an off day in between, however this may not be realistic depending on your schedules and so sessions will occur at your convenience.

- If you are in the Exercise Group, you will perform balance exercises for 15 minutes with 5 minutes of warm and cool down each. Some of the exercises are standing with one foot in front of the other for 10 seconds, standing on 1 foot for 10 seconds, standing with feet together etc. Breaks will be given, and you will be given instructions and encouragement by the study personnel who will be watching via Zoom.

Second and third visit to the lab, about an hour:

Session #8: 3-5 days after session 7, you will complete all the balance and walking measurements that you did in session #1 excluding parameters such as EHI-SF, leg and arm length, weight, height. It will take approximately 1 hour.

On session #9: 4 weeks after session #7, you will once again complete all the same activities you completed during visit #8. It will take approximately 1 hour.

Are there any bad things that might happen during the research study?

Sometimes bad things happen to people who are in research studies. These bad things are called "risks." The risks of being in this study might be

1. Physical discomfort- You may feel uncomfortable or pain in your legs or feet due to standing for 20 minutes at a time. You may also feel discomfort in your hands from using the controller for an extended period of time if you are in the Virtual Reality Group. If this is the case, you can ask to take a break at any time. You can also ask to sit at any point, or can you decide that you want to discontinue the visit.

2. Risk of falling- There is a slight risk that you may fall during physical exercise and/or while playing virtual reality games. You will have a caregiver present at all times during the sessions to ensure your safety as well as a chair nearby to hold onto to or sit as needed. A member of the study team will be able to see you at all times via Zoom while you are doing the activities and will give you instructions on how to be safe as needed.

3. Loss of confidentiality- As with any study, there is a possible risk that someone outside the study could see your private information. All of your information will be kept on computers that only people working on the study will be able to see and use.

Not all of these things may happen to you. None of them may happen. Things may happen that researchers do not know about yet. If they do, we will make sure that you get help to deal with anything bad that might happen.

Are there any good things that might happen during the research study?

We do not know for sure if you will have any personal benefits. We hope to learn something that will help other people someday.

Will I get money or payment for being in this research study?

You will receive a $10.00 Amazon gift card each time you complete a session, for a total possible compensation of $90.00.

Who can I ask if I have any questions?

If you have any questions about this study, you can ask your parents or guardians or the researcher. Also, if you have any questions that you did not think of now, you can ask them later. For questions about the study or a research-related injury, contact researchers Surabhi Date, at 812-603 - 8031 or Dr. Georgia Frey at 812-855-1262. After business hours, please call Dr. Georgia Frey at 812-855-1262.

What if I do not want to be in the study?

If you do not want to be in this study, you do not have to. It is up to you. If you say you want to be in it and then change your mind, that is OK. All you have to do is tell us that you do not want to be in it anymore. No one will be mad at you or upset with you if you do not want to be in it.

My choice:

If I write my name on the line below, it means that I agree to be in this research study.

__________________________________ __________________

Subject's signature Date

____

Subject's printed name

__________________________________ __________________

Signature of person obtaining assent Date

____

Name of person obtaining assent

6. Edinburgh Handedness Inventory-short form

Edinburgh Handedness Inventory - Short Form

Please indicate your preferences in the use of hands in the following activities or objects:

	Always right	Usually right	Both equally	Usually left	Always left
Writing					
Throwing					
Toothbrush					
Spoon					

7. Pediatric Berg's Balance Scale:

Pediatric Balance Scale	
1	Seated position to standing position
2	Standing position to sitting position
3	Transfer
4	Standing without support
5	Sitting without support
6	Standing with eyes closed
7	Standing with your feet together
8	Standing with one foot in front
9	Standing on one foot
10	Rotating 360 degrees
11	Turning to look back
12	Picking up an object off the floor
13	Placing alternate foot on step / footrest
14	Reaching forward with extended arm