Immersive virtual reality visuomotor skill assessment

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RESEARCH METHODS/PLANS

Design: Cross-sectional, repeated-measures design.

Participants: We will recruit children aged between 7 and 16 years old with a diagnosis of hemiplegia (due to CP or stroke) at Gross Motor Function Classification System (GMFCS) Levels I-III and Manual Ability Classification System (MACS) Levels I-II. We will also recruit a comparison group of age and gender-matched typically developing peers. Inclusion criteria include the ability to read and write English. Children need to be able to see, hear and respond to auditory and visual cues. As such, exclusion criteria are a greater than 10-degree elbow or shoulder flexion contracture in the affected arm, uncorrected visual deficits (e.g., homonymous hemianopsia, oculomotor disturbance, or cortical visual impairment), uncontrolled photosensitive seizures (occurrence of at least one seizure in the last 3 months), hemineglect or cognitive impairments that would prohibit participation (as judged by a parent).

Recruitment and sites: The research assistant (RA) will consult the child's electronic medical records and the clinic MD to determine eligibility. They will approach eligible children and families and provide an overview of the study. Children and caregivers will complete informed assent and consent. Recruitment and data collection will take place at Maine Medical Center Pediatric CP clinic (Portland, ME), Spaulding Salem Outpatient Center for Children CP clinic (Salem, MA), and Massachusetts General Hospital Pediatric Stroke clinic (Boston, MA). In addition, we will email the families of the 62 children with CP or stroke in our lab database to invite them to participate in the lab. Typically developing children recruited via emails from our database will also be tested in the ReGame-VR Lab.

Sample size and power*:* We will recruit a convenience sample of 40 children with hemiplegia and 40 typically developing children. This pilot study is designed to obtain estimates of within- and between-child variability for effect size calculations to power a subsequent, more rigorous study design.

Institutional Research Board Approval: IRB approval will be obtained from Northeastern University, facilitating a shared and expedited agreement with IRBs of participating sites.

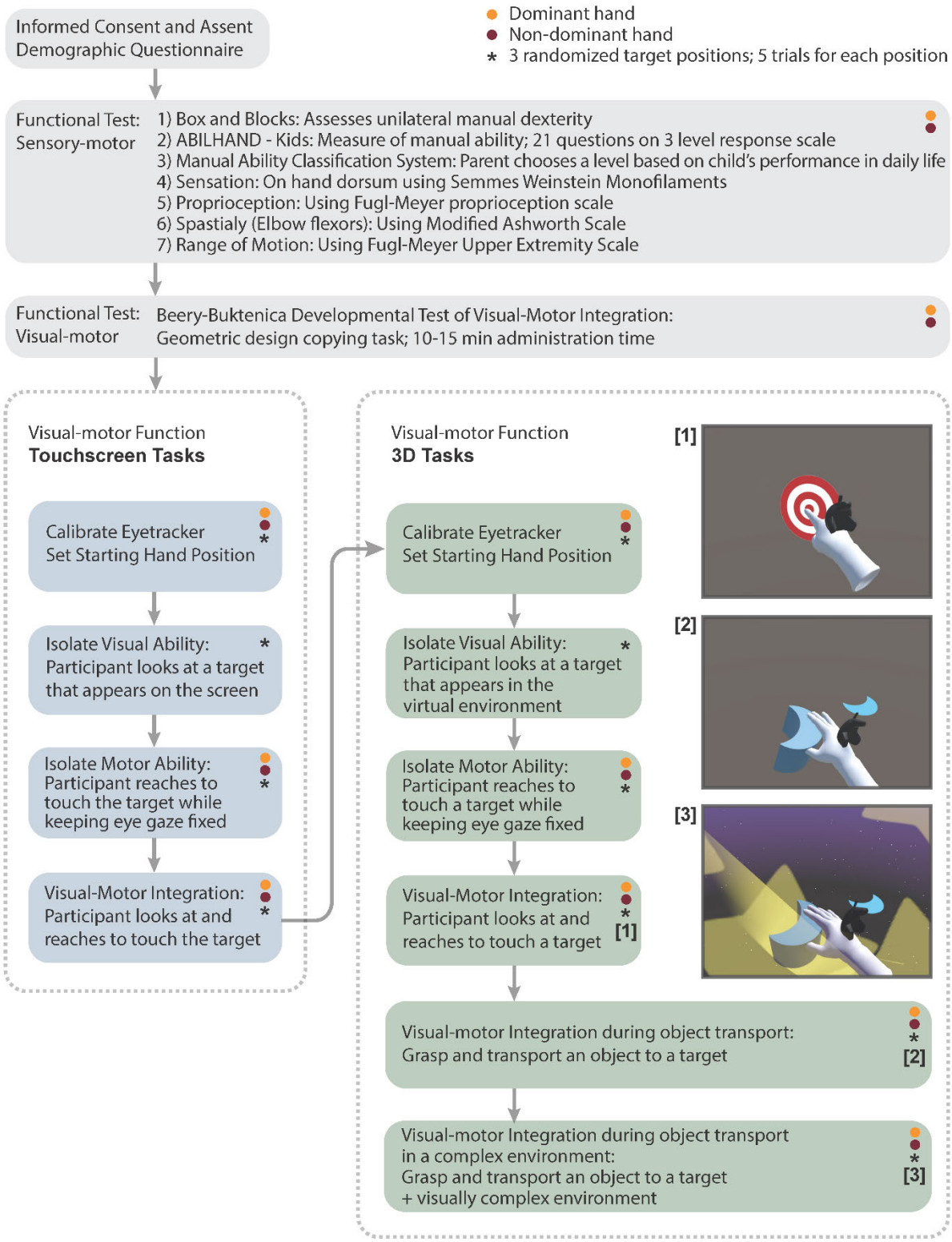
Materials and tasks:

HMD-VR: We will use the VIVE Pro EYE, the leading commercially-available immersive VR system, which has with a 110 degree trackable field of view and an embedded eye tracker. Arm movements are tracked by lightweight trackers attached via Velcro arm band to children's forearms and ManusVR motion tracking gloves worn on the hands. Head movements are tracked by position sensors in the HMD. Trackers and gloves enable upper extremity interaction with objects in the virtual world (see Figure 2). An Alienware m15 gaming laptop with an NVIDA GeForce RTX 2060 graphics card will run the task. All materials are easily transportable and will be sanitized between users; the HMD-VR will be thoroughly and quickly sanitized using Cleanbox VR.

Touchscreen computer: The task will be displayed on a 20" HP Spectre touch-screen laptop with an RTX 960 graphics card. Eye-tracking will be undertaken using a Tobii Eye Tracker 4C which integrates with Unity software. Kinematics of hand movement during reach to touch as well as head movements will be collected using an Orbbec Astra depth-sensing camera. Accuracy of touch is recorded by custom-written software tracking X-Y touch coordinates on the screen. All data collection modalities are synced and integrated using LabVIEW.

Task programming: Both 3D and touchscreen tasks will be programmed using the Unity Development Platform, an open-source VR development environment.

Study Procedures



Outcome measures

Aim 1: Feasibility will be determined by achievement of the following:

a. Recruitment of 40 children with hemiplegia in 24 data collection visits at study sites (average 2/visit: 3 sites, 2 visits/month, 4 months);
b. <5% of participants reporting adverse effects (dizziness or motion sickness) during or within 15 minutes post HMD-VR use; and
c. 90% of participants able to complete the whole protocol in the available clinic timeframe.

Aim 2: *2.a.Paper-and-pencil test:* Total score from the Beery-Buktenica VMI test 6th Edition Short form. 2.*b. Touchscreen computer and HMD-VR:* Eye-hand proximity, defined as the lag between eye end time and hand end time (i.e. eye movement time – hand movement time), is a gold-standard measure of visual-motor integration that quantifies the coordination of eye and hand movements.[23,51]

Aim 3: Total movement time during the visual-motor integration object transport task in HMD-VR with and without the complex environment.

Secondary outcomes. Multiple other temporal and spatial variables related to eye, head and hand movements will be collected for hypothesis-generating purposes.[51] These include reaction time, movement time, amplitude (eye and hand), touch and transport accuracy (hand), peak velocity, sub-movements and trajectory straightness (hand), and spatial position and pitch, yaw and roll orientations.

Data management and analysis: We will follow established procedures for eye tracking and kinematic data processing to discard trials in which artifacts are present or children are looking elsewhere and to determine head and hand movement start and end times. RStudio will be used for data analyses. We will check assumptions of normality for parametric analyses; if un-met, non-parametric equivalent tests will be undertaken. **Aim 1**: Feasibility outcomes will be recorded with counts and proportions. **Aim 2:** We will calculate the median of the 5 trials for each hand and target location. Of primary interest are estimates of variability as inputs needed for sample size calculations for the subsequent study. Recognizing lack of power, we will undertake inferential statistics for hypothesis generating purposes, including a multiple correlation using Pearson's t-test for each hand and target location. **Aim 3**: Paired t-tests per hand. Hypothesis-generating analyses for secondary outcomes will compare performance estimates within individuals (touch screen vs HMD-VR, dominant vs non-dominant hand) and between individuals (CP vs typically developing), accounting for age, lesion, and HMD-VR experience. **Equipment related: 1) Sanitization:** We use Cleanbox VR technology to disinfect VR headsets using UVC light. All peripherals will be sanitized with alcohol wipes and left to dry for a minimum of 15 minutes between users. **2) Transport/set up**: Potential difficulties transporting and setting up equipment in different settings can be mitigated by diligent equipment protection. We have transported equipment many times for other studies at the Boston Children's Museum. HMD-VR tracking accuracy is not affected by differing ambient light levels. **Study related: 1) Reliability of VMI scoring**: The PI (a pediatric physical therapist) will train for VMI scoring by using the VMI manual, attending a web-based presentation on scoring, and scoring practice tests. **2) Lack of experience with eye-tracking processing/analyses**: We will consult with Dr. Jon Matthis, Assistant Professor in the College of Science at Northeastern and eye-tracking expert, who will advise on analyses. Dr. Matthis was unable to be a named investigator on this grant due to budget restrictions. **3) Recruitment:** Previous recruitment at Boston Children's Hospital CP clinic (unfortunately not a site for this study due to lack of space for clinic VR assessments) yields 2-3 eligible participants/week for identical inclusion criteria. Estimates from other sites are between 3-10 eligible children per clinic. **4) Time for in-clinic assessment:** Recognizing the many demands on children and families' time in a busy clinic

environment, we will endeavor to approach families at their arrival and leverage positive relationships with clinic staff to determine the optimal testing time.

Participant related: 1) Previous experience with VR: This may impact performance; this information will be collected in the demographic questionnaire and included as a covariate in the analyses**. 2) Potential impact of HMD weight on head or reaching movements:** There are no studies of impact of HMD weight on children's movements; the short duration of our testing should mitigate any issue. **3) Left vs right-sided lesion differences in spatial abilities**: We will include hemispheric lesion side as a covariate in the analyses, but this is complicated by the fact that many children with unilateral impairments have bilateral lesions. Any hemispheric-specific differences will inform the next study. **4) Intra- and inter-individual variability in this population**: Children with hemiplegia are a heterogeneous population and their performance varies across repeated tests within individuals and between children. We will take this into account by basing sample size calculations for subsequent work on effect sizes from this study.