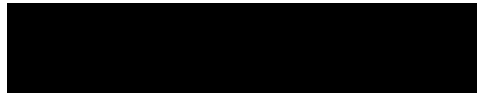


Immersive virtual reality visuomotor skill assessment

NCT 04612049

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Letter of Information and Consent – Parents

Northeastern University

Department of Physical Therapy, Movement and Rehabilitation Science

Investigator Name: Danielle Levac, PhD, PT

Title of Project: Immersive virtual reality for visuo-motor integration skill assessment in children with hemiplegia

Informed consent to participate in a research study

Your child is being asked to participate in a research study run by Northeastern University's Department of Physical Therapy, Movement and Rehabilitation Sciences. This form will tell you about the study, but the research assistant will explain it to you first. You may ask this person any questions that you have. When you are ready to make a decision, you may tell the research assistant if you want your child to participate or not. Your child does not have to participate if you do not want him/her to. If you decide that you want your child to participate, the researcher will ask you to sign this statement and will give you a copy to keep. Please read this form and ask any questions before letting your child participate in this study.

Why is my child being asked to take part in this research study?

We would like to include children with hemiplegia aged 8-16 years who can use both hands to reach for and pick up objects. In order to participate, children must be able to read and write in English and have normal (or corrected to normal) vision and hearing.

Why is this research study being done?

In this research study we want to learn more about how to evaluate eye-hand coordination difficulties in children with hemiplegia. Eye-hand coordination means how vision and movement work together to produce actions like pointing, reaching, printing, or drawing. Problems with eye-hand coordination can affect how children take part in activities of daily life. We want to understand how a new way of testing eye-hand coordination difficulties that uses a virtual reality headset compares to existing ways of testing that use paper-and-pencil tests or computer-based tests. The virtual reality headset allows children to look at and reach for virtual objects in ways that might be more like real life, as compared to paper or computer tests.

What will your child be asked to do?

If you and your child decide to join this research study, the following things will happen. You child will be asked to take part in a few different ways of testing your eye-hand movements. Your child will be sitting down for all of the tests. The first way is using a test that involves



looking at and copying shapes on a piece of paper. The second way involves reaching and touching targets on a computer screen. The third way involves wearing a virtual reality headset and reaching and touching virtual objects. In the virtual reality test, we will also ask you child to pick up and move a virtual object. You child will do each of these activities several times and repeat them with each hand.

Before the eye-hand movement tests, we will ask you child some questions about how your child use affected arm and hand during his/her regular activities. You child will also do a short game of moving blocks from one side of a box to another. A member of our research team will move your child's arm and hand to test how much movement and muscle tightness and will test how well you child feel things on his/her hand.

The study visit that will take about 1 – 1.5 hours. We will ask you to sign this consent form before we do any study procedures. The study doctor and/or their research staff will answer all of you and your child questions prior to signing the consent form and a copy of the signed and dated consent form will be given to you and your child.

If your child qualifies to take part in this study, they will take part in the following tests:

- Questionnaires: We will ask you and your child to each complete a demographic questionnaire and one that will assess the use of your hands and arms.
- Baseline Sensory-Motor Functional Tests: A member of the research team will explain and walk your child through several tasks including:
 - Box and block test where your child will move blocks over and obstacle with his/her dominant and non-dominant hand
 - Sensation task to test your child's sense of touch
 - Proprioception task to test your child's sense of knowing what position a joint is in space
 - Modified Tardieu Scale task to test spasticity or resistance to the flexing movement
 - Passive Range of Motion task to test range of motion by moving joints in the shoulder, elbow, forearm, wrist and fingers.
- Paper and Pencil Visuo-Motor Task to test to assess how well your child can use motor and visual skills at the same time through drawing shapes
- Touchscreen Visuo-Motor Task to assess how well your child can use motor and visual skills at the same time through looking at and touching a computer screen and tracking eye movements
- Use a virtual reality headset to assess how well your child can use motor and visual skills at the same time. Your child will wear a glove that tracks movement in virtual reality and reach to touch virtual objects. During this task we will take short breaks and he/she may take the headset off as needed.

After completion of the visit, your child will receive a \$25 gift card and sign a form indicating receipt of the gift card.



Where will this take place and how much of my time will it take?

The study will take place in the Rehabilitation Games and Virtual Reality (ReGame-VR) Laboratory on the 4th floor of Robinson Hall at Northeastern University. There is elevator access to the 4th floor. Each testing session will take approximately 1 – 1.5 hours.

Will there be any risk or discomfort to my child?

Surveys: It is possible that responding to the survey about hemiplegia may cause you some anxiety about your child's condition. We will discuss with you this issue, if you are concerned.

Reaching to targets: Minor discomfort or fatigue could result from repeated reaching to targets during this study. To minimize this discomfort, we will encourage your child to rest and take breaks as needed.

Wearing a virtual reality headset: Minor risk and discomfort is associated with wearing a virtual reality headset. There is the chance of dizziness or nausea during or immediately after use. To minimize this risk, we have created virtual reality tasks that do not involve a lot of head movements or objects moving in the virtual environment. Your child will be seated during the tasks. If your child feels dizzy or sick, please let us know and we will take off the headset and stop the study. We will wait with your child until s/he feels better, or call a doctor if your child needs it.

Risk of infection from wearing a headset that others have worn: We will sterilize the virtual reality headset thoroughly in between uses, as well as anything that your child touches or interacts with during this study.

Confidentiality: Since you will be sharing information and we will be collecting data, there is a possibility of a breach in confidentiality. We will take steps to minimize this, but it may still occur.

Will I or my child benefit by being in this research?

There are no direct benefits to you and your child from participating in this research study. The indirect benefits of participating in this study include contributing to increased knowledge and understanding of eye-hand coordination impairments in children with hemiplegia. We might learn information about using virtual reality to assess these impairments. We hope that by collecting this information, we will be better prepared for future research to understand how virtual reality might be a useful assessment and treatment technique for children with hemiplegia.

WHAT DO I NEED TO DO?



If you and your child choose to take part in this study, please sign this form when you come for the study visit, after asking the study investigators any questions you might have. We will explain the study to your child and give her/him the opportunity to ask questions as well. We will ask your child to read and sign an assent form which indicates their understanding of what is involved in order to participate in the study.

Who will see the information about my child?

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The partners ethics board or an ethics board outside partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to certain work for us, such as data storage companies, accreditors, insurers, and layers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

What will happen if my child suffers any harm from this research?

We will offer your child the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care your child get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Can I stop my child's participation in this study?

Your child's participation in this research is completely voluntary. Your child does not have to participate if they do not want to and your child can refuse to answer any question. Even if



your child begins the study, they may quit at any time. If your child does not participate or if they decide to quit, they will not lose any rights, benefits, or services that they would otherwise have.

What are my Rights as a Research Participant?

If your child chooses (with your consent) to be in this study, he or she has the right to be treated with respect. Your child may choose not to participate in this research study or can choose to stop participating in the study at any time. If he or she chooses to stop, no more information will be collected from them. We will ask if the information already collected from your child can be used.

Who can I contact if I have questions or problems?

If you have any questions about this study, please feel free to contact Dr. Danielle Levac, the person mainly responsible for the research, at 617-373-5198 or d.levac@neu.edu.

Who can I contact about my child's rights as a participant?

If you have any questions about your child's rights in this research, you may contact Nan C. Regina, Director, Human Subject Research Protection, 360 Huntington Avenue, Mail Stop 560-177, Northeastern University, Boston, MA 02115. Tel: 617.373.4588, Email: n.regina@neu.edu. You may call anonymously if you wish.

Will my child be paid for participation?

Your child will receive a \$25 Amazon gift card as a token of appreciation.

Will it cost me anything to participate?

There is no cost to participate in this study. We will reimburse you for parking at Northeastern University or for local (non-commuter) MBTA travel.



INFORMED CONSENT

Visuo-motor integration skill assessment study

Parental/Guardian Statement:

I am the parent or legal guardian of the child named below, who is under the age of 18 years.

There are two copies of the consent form, one of which is mine to keep.

I have read this form and the research study has been explained to me.

I agree to have my child take part in this research, in which they will be asked to take part in three different ways of testing eye-hand movements. The first way is looking at and copying shapes on a piece of paper. The second way involves reaching and touching targets on a computer screen. The third way involves wearing a virtual reality headset and reaching and touching virtual objects. My child will do this testing while seated. In the virtual reality test, my child will wear a head-mounted display to see the virtual environment, and wear sensors and gloves to track their movement. My child will do each of these activities several times and repeat them with each hand.

I have been given the opportunity to ask questions and my questions have been answered. If I have more questions, I have been told who to contact. I agree to allow my child to participate in this research study. I will receive a copy of this consent form after I sign it.

_____/_____
Parent's Name (PRINTED) / Signature

Date

_____/_____
Name (PRINTED) / Signature of Person Obtaining Consent

Date

I agree to be contacted about additional research participation opportunities in the ReGame-VR Lab in the future. Agreeing to be contacted does not commit me to participating in any future studies. The ReGame-VR lab will keep my contact information secure and will not share it with 3rd parties. I can choose to remove my name from this contact list at any point by sending an e-mail to **regamevrlab@northeastern.edu** or calling **617-373-5198**.

_____/_____
Parent's Name (PRINTED) / Signature

Date



ASSENT FORM FOR MINORS AGES 8-16

Northeastern University

Department of Physical Therapy, Movement and Rehabilitation Science

Investigator Names: Danielle Levac, PhD, PT

Study Title: How do kids' vision and movement work together to produce actions?

Dear Children,

WHY ARE WE DOING THIS PROJECT?

I want to tell you about a research study we are doing. A research study is usually done to find a better way to help people or to find out how things work. In this study, we want to know how vision and movement work together to produce actions like pointing, reaching, printing, or drawing.

We are asking you to be in this study because you are between 8 and 16 years, you have hemiplegia, and you speak English.

If you agree to join this study, we will ask you some questions to make sure that you can be in the study.

WHAT IF I HAVE QUESTIONS?

You can ask questions if you do not understand any part of the study. If you have questions later that you don't think of now, you can ask your parents to call Danielle, the study leader, again at 617-373-5198.

WHAT WILL HAPPEN AND WHAT YOU WILL BE ASKED TO DO

If you want to be part of this study, here is what we will ask you to do. You will come to our laboratory at Northeastern University for about an hour. When you come to the lab we will ask you or your parent to tell us some things about you, like your age, height, weight and grade in school.

You will be asked to take part in a few different ways of testing your eye-hand movements. You will be sitting down for all of the tests. The first way is using a test that involves looking at and copying shapes on a piece of paper. The second way involves reaching and touching targets on a computer screen. The third way involves wearing a virtual reality headset and reaching and touching virtual objects. In the virtual reality test, we will also ask you to pick up and move a virtual object. You will do each of these activities several times and repeat them with each hand.



Before you do the eye-hand movement tests, we will ask you some questions about how you use your affected arm and hand during your regular activities. You will also do a short game where you will move blocks from one side of a box to another. A member of our research team will move your arm and hand to test how much movement and muscle tightness you have and will test how well you feel things on your hand.

We will ask you to sign this consent form before we do any study procedures. The study doctor and/or their research staff will answer all of your questions prior to signing the consent form and a copy of the signed and dated consent form will be given to you.

After completion of the visit, you will receive a \$25 gift card and sign a form indicating receipt of the gift card.

WHAT ARE THE RISKS?

Sometimes bad things happen to people in research studies. The bad things are called “risks.” The risks of being in this study are small.

Surveys: It is possible that responding to the survey about hemiplegia may cause you some anxiety about your condition. We will discuss with you this issue, if you are concerned.

Reaching to targets: Minor discomfort could result from repeated reaching to targets during this study. To minimize this discomfort, we will encourage you to rest and take breaks as needed.

Wearing a virtual reality headset: Minor risk and discomfort is associated with wearing a virtual reality headset. There is the chance of dizziness or nausea during or immediately after use. To minimize this risk, we have created virtual reality tasks that do not involve a lot of head movements or objects moving in the virtual environment. You will be seated during the tasks. If you feel dizzy or sick, you can let us know and we will take off the headset and stop the study. We will wait with you until you feel better, or call a doctor if you need it.

Risk of infection from wearing a headset that others have worn: We will sterilize the virtual reality headset thoroughly in between uses, as well as anything that you touch or interact with during this study.

Confidentiality: Since you will be sharing information and we will be collecting data, there is a possibility of a breach in confidentiality. We will take steps to minimize this, but it may still occur.

WHAT ARE THE BENEFITS?



Sometimes good things happen to people who are in research studies. These good things are called “benefits.” A benefit of being in this study might be helping us to know how vision and movement work together to produce actions like pointing, reaching, printing, or drawing.

YOU CAN SAY NO

You do not have to be in this study. You can say no now or you can even change your mind later. You can stop at any time without anything bad happening.

WHAT YOU SAY AND DO WILL BE PRIVATE

We won’t share any information about you with anyone who does not work on the study.

WHAT YOU WILL GET

You will get a \$25 Amazon gift card for taking the time to be in this study.

WHAT HAPPENS AFTER THE STUDY?

When we are finished with this study we will write a report about what was learned and we can share it with you if you would like. This report will not include your name or that you were in the study.

WHO SHOULD I TALK TO IF I HAVE QUESTIONS?

If you are not happy with this study and want to talk to someone else other than the leader of the study Dr. Danielle Levac or the people helping Dr. Levac, you can talk to your parents. They can call the Northeastern University Institutional Review Board (IRB) Office at 617.373.4588.

Please give the consent form to your parent or guardian and ask him or her if it is okay for you to be in this study. If you have questions, please ask them now or at any time.



ASSENT

This study has been explained to me and I want to be in it. I will take part in three different ways of testing eye-hand movements. The first way is looking at and copying shapes on a piece of paper. The second way involves reaching and touching targets on a computer screen. The third way involves wearing a virtual reality headset and reaching and touching virtual objects.

- ☐ Yes, I agree to take part in this study:
- ☐ No, I do not agree to take part in this study.

_____/_____
Child's Name (PRINTED) /Signature Date

----- Please stop here -----

Check which applies below *[to be completed by the person administering the assent]*.

- ☐ The child is capable of reading and understanding the assent form and has signed above as documentation of assent to take part in this study.
- ☐ The child is not capable of reading the assent form, but the information was verbally explained to him/her. The child signed above as documentation of assent to take part in this study.

_____/_____
Name (PRINTED) /Signature of Person Obtaining Consent Date