

Cover Sheet

Document Type: Informed Consent Document

Study Title: VR-based EF Rehabilitation for Pediatric TBI

Registration No.: NCT03611062

Protocol ID: IRB18-00472

Secondary ID: 1K99HD093814-01A1

IRB Approval Date: April 17, 2019

STUDY TITLE: Virtual Reality-based Rehabilitation for Children with Traumatic Brain Injuries

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY TITLE: Virtual Reality-based Rehabilitation for Children with Traumatic Brain Injuries

PRINCIPAL INVESTIGATOR: Dr. Jiabin Shen

CONTACT TELEPHONE NUMBER: 614-722-3179 (Monday – Friday, between 9AM to 5PM)

STUDY SPONSOR: National Institute of Health

ClinicalTrials.gov Name and Identifier: VR-based EF Rehabilitation for Pediatric TBI; NCT03611062

SUBJECT'S NAME: _____ **DATE OF BIRTH:** _____

NOTE: The words “you” and “your” are used in this consent form. These words refer to the study volunteer whether a child or an adult.

Key Information About This Study

The following is a short summary of this study to help you decide whether or not to participate. More detailed information follows later in this form.

The purpose of this study is to see if virtual reality games are helpful after someone has a traumatic brain injury. This information may help us to learn strategies to help other kids' recovery in the future.

Study participation:

Subjects will play virtual reality games during intervention. They will also complete surveys and assessments at the 3 study visits. Parents/Guardians will complete surveys at the follow-up visit.

Study visits:

3 study visits at enrollment, completion of intervention, and follow-up will take approximately 1 hour. Intervention play will total a minimum of 15 minutes.

See a more detailed discussion later in this form.

Risks include common side effects of virtual reality which can include but are not limited to motion sickness, blurry vision, eye strain, headache, dizziness, fatigue, or nausea.

The benefit(s) of the study are your child may gain skills playing the game and have fun. We might also learn something to help other children in the future.

If you are interested in learning more about this study, please continue reading below.

STUDY TITLE: Virtual Reality-based Rehabilitation for Children with Traumatic Brain Injuries

1) INTRODUCTION

We invite your child to be in this research study because we are testing the feasibility and effectiveness of virtual reality games to help kids after a traumatic brain injury. Findings from this study will help us know how to best help each patient.

Participation is voluntary. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. Once you understand this study, we will ask you to decide whether you would like to participate or not. By signing this form, you agree to be in this study. If you do not want to be involved with this study, all regular and standard medical care will still be available to you here or at another institution. You also have the right to leave this study at any time, even if you agree to join now.

If your child is between 9 and 17 years of age, after the study is explained to them and if they agree to be in the study, they will be asked to sign this form to give Assent.

You will be given a signed and dated copy of this combined consent and assent form.

2) WHY ARE WE DOING THIS RESEARCH STUDY?

This is a study to find out if our virtual reality games will help kids regain skills after they have had a brain injury. We want to know how they work for different kids, so you and your child will be asked some questions.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at Nationwide Children's Hospital and we hope to enroll approximately 30 children with traumatic brain injury.

4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

This study is randomized. Randomized means that the study group will be picked by chance, like tossing a coin or drawing straws, and receive either one of the two virtual reality games we developed. No matter which game your child plays, he/she will keep receiving the standard therapies as usual.

The length of time for either intervention game will be a minimum of 15 minutes of total play. If your child is in the hospital, they will play approximately 15 minutes per day during their stay. If they have already been discharged from the hospital, the length of time is a minimum of 15 minutes of total play but can be more spread across your choice of days. This will take place at a location in the hospital.

During the course of the study (baseline, post-intervention, and one follow up visit done within 6 months), your child will complete standard cognitive and attention assessments as well as several questionnaires with a researcher. These assessments will take about 60 minutes. A researcher will invite the child and parent to answer questions about his/her experience with the game. The parent will be invited to complete several questionnaires regarding your child's behaviors in daily life at the follow up visit. This part will take about 30 minutes for the caregiver.

STUDY TITLE: Virtual Reality-based Rehabilitation for Children with Traumatic Brain Injuries

Procedures and Visits:

Visit	iPad Assessment	Computer Assessment	Virtual Reality Assessment	Child Surveys	Virtual Reality Intervention Game	Parent Surveys
Baseline	X	X	X	X		
Intervention Days				X	X	
Post-Intervention	X	X	X	X		
Follow-up	X	X	X	X		X

5) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study.

It is possible that your child might feel motion sickness using the virtual reality goggles. They might also experience other virtual reality side effects, which can include but are not limited to, blurry vision, eye strain, headaches, dizziness, fatigue, or nausea. Please understand that your child is free to switch back to standard therapies alone at any time during the study. Although unlikely, it is possible that you or your child could feel upset when answering questions about their/your experiences with the virtual reality game. It may be more likely that you find the questions a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to, and a researcher will be available to talk with you about this.

Although we will take every precaution, there is a small chance of loss of confidentiality of your study information.

If you are worried about anything while in this study, please speak to the researchers or please call the Principal Investigator at the telephone number on page 1.

Immediate help is available if thoughts or feelings of hurting oneself come up. If these thoughts or feelings occur, you should immediately call one of the numbers below or go to the closest Emergency Room.

**Nationwide Children's Psychiatric Emergency Evaluation Center 614-722-1800
Hopeline/Lifeline – 1-800-784-2433 or 1-800-SUICIDE**

There may be other risks of being in this research study that are not known at this time.

6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Possible benefits might be that your child may gain skills playing the game. Your child might have fun playing with electronics using this new technology. We might also learn something that could help others.

STUDY TITLE: Virtual Reality-based Rehabilitation for Children with Traumatic Brain Injuries

7) WHAT ARE THE COSTS AND REIMBURSEMENTS?

We will provide your child with

- \$30.00 for completing the baseline assessment
- \$40.00 for completing the designated training (or comparable VR game for the control group) and post-intervention assessment
- \$50.00 for completing the one follow-up assessment within 6 months.

In addition to the above honorarium provided to your child, we will provide you (the parent) with a one-time \$50.00 honorarium for completing the parent-report questionnaires at the follow-up visit.

All costs related to the research parts of this study will be covered by the research team.

8) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

9) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in this study at any time. If you decide to stop being in this study you may call the Principal Investigator or the study coordinator to see if there are any medical issues about stopping. If you stop being in the study, there will not be a penalty or loss of benefits to which you are otherwise entitled.

If at any time the Principal Investigator believes that this study is not good for you, the study staff will contact you about stopping. If the study instructions are not followed, participation in the study may also be stopped. If unexpected medical problems come up, the Principal Investigator may decide to stop your participation in the study.

10) OTHER IMPORTANT INFORMATION

Being in more than one research study at the same time may cause injury. Please tell us if you are in any other research studies, so a decision can be made about being in more than one study at the same time. We may need to notify the other study team to see if you can participate in this study.

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance appraisal will not be affected in any way if you decline to participate or withdraw your consent to participate in this study.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

If you are interested, the final study results will be shared with you once they are available. Please provide us with an email or address where we can send these results.

STUDY TITLE: Virtual Reality-based Rehabilitation for Children with Traumatic Brain Injuries

The Principal Investigator is being paid by Nationwide Children's Hospital for the time needed to do this study.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research helps us provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

14) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study includes information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to Dr. Jiabin Shen and the study staff to collect, use, and disclose your PHI for this research study and for future research purposes (including purposes that are currently unknown) unless otherwise allowed by applicable laws. Information collected is the property of Nationwide Children's Hospital, one of its affiliated entities, or the Sponsor.

PHI that may be used or disclosed:

- *Patient Name*
- *Medical Record Number*
- *Admission dates, treatment dates and birth dates*
- *Medical information pertaining to your child's injury*
- *Any imaging/testing that took place as a result of your child's injury*
- *Telephone numbers and email addresses*

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:

- PI and study staff
- The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
- Nationwide Children's Hospital internal auditors
- The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research).

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may be further disclosed by them and no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made: *To locate your medical chart. In order to link the assessments and surveys from each session.*

You may decide not to authorize the use and disclosure of your PHI. However, if it is needed for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at 700 Children's Drive, Columbus, OH 43205. If you

STUDY TITLE: Virtual Reality-based Rehabilitation for Children with Traumatic Brain Injuries

withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

PHI will only be shared with the groups listed above, but if you have a bad outcome or adverse event from being in this study, the Principal Investigator and staff or other health care providers may need to look at your entire medical record.

In the event of any publication regarding this or any future studies, your identity will not be revealed.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your PHI will not expire.

Certificate of Confidentiality

To help us protect your privacy, the National Institutes of Health has issued a Certificate of Confidentiality for this study. This Certificate will be used to resist attempts to force us to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

The Certificate cannot be used to resist a demand for information that is used for auditing or evaluation of federally funded projects or for information that must be disclosed to meet the requirements of the Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your participation in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we will release the information even though we have the Certificate of Confidentiality.

The Certificate of Confidentiality also does not prevent us from disclosing voluntarily, without your consent, information that would identify you as a participant in the research if required by state and/or federal law. In Ohio, if we have reasonable knowledge that a felony has been or is being committed we are required to notify state officials.

The Certificate does not protect study information that is placed into your medical records.

With your permission, we would like to store your PHI for future research purposes, and as part of such future research purposes, your PHI may be disclosed to people or entities not listed above, such as researchers not involved with this study, government agencies, research foundations, or pharmaceutical or device companies sponsoring future research. This future research may or may not be related to your medical problem. This future research may include sensitive information. Any future research projects will be reviewed and approved by an Institutional Review Board which protects the rights, welfare, and safety of human research subjects. If your PHI is used or disclosed in future research studies, absolute confidentiality cannot be guaranteed. Information shared for future research may be shared further with others and no longer be protected by federal privacy rules.

STUDY TITLE: Virtual Reality-based Rehabilitation for Children with Traumatic Brain Injuries

If you decide at any time that you do not want your PHI stored for future research, you must make this request in writing to the Principal Investigator at 700 Children's Drive, Columbus, OH, 43205. Once we receive your written request, we will destroy your PHI. However, if we have already shared your PHI with another individual or entity, we will not be able to destroy any of the PHI that are no longer in our possession.

Nationwide Children's Hospital retains the right to cease storage and destroy the PHI at any time without sending notice to you or obtaining your consent.

You do not have to agree to use of your PHI for future research in order to be in this study, and your decision will not affect the care you receive from the study doctors or Nationwide Children's Hospital.

I agree to allow my PHI to be stored and used for future research as described above: (initial)

_____ YES _____ NO

15) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about anything while on this study or you have been injured by the research, you may contact the Principal Investigator at 614-355-5878, Monday – Friday, between 9AM to 5PM.

If you have questions, concerns, or complaints about the research, if you have questions about your rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else - please call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (IRB, the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

STUDY TITLE: Virtual Reality-based Rehabilitation for Children with Traumatic Brain Injuries

Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

Printed name of child

Signature of parent or individual legally authorized to consent to the
child's general medical care

Date

Time

- ☐ Parent
☐ Individual legally authorized to
consent to the child's general
medical care (See note below)

Printed name of parent or individual legally authorized to consent to the
child's general medical care

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of person obtaining consent

Date/Time

Printed name of person obtaining consent

Assent

Signature of subject

Date

Time

Printed name of subject

- ☐ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.