



Project Title: **Rest Evaluation for Active Concussion Treatment (ReAct) study**
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WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to describe physical and cognitive rest among children who are recovering from a sports-related concussion, and to identify the optimal amounts of rest needed for safe return to play and school.

WHO WILL BE A STUDY PARTICIPANT?

Youth between the ages of 11 to 17 with a diagnosed concussion that is confirmed by a sports medicine professional or other physician will be eligible to participate. Additionally, the youth must have sustained the injury while participating in a sports-related activity. A parent/legal guardian will also participate in the study along with their child.

HOW LONG WILL STUDY PARTICIPANTS BE INVOLVED?

Study participants will be involved in the study for up to 45 days from the date of injury.

WHAT WILL HAPPEN DURING THE STUDY?

Youth will be invited to participate if they are age 11 to 17, and participate in an organized sport at his/her school. This study will be introduced to youth athletes and their parents at pre-season meetings, where they may ask questions and provide assent/consent if they are interested. If the youth sustains a concussion, the research team will confirm that they are eligible and still interested in participating.

Youth and parent participants will be asked to complete three assessments conducted by a member of the research team: 1) within 72 hours of injury; 2) day 7 post-injury; and 3) day 45 post-injury or when youth has resumed normal activities (whichever occurs first). Additionally, participants will be asked to wear devices that measure physical and cognitive activities for up to 7 days, and complete confidential, daily surveys on physical and cognitive activity for duration of study participation. A member of the research team will be available at all times to answer any questions by phone or email.

The timeline of participation following injury is as follows:

Assessment 1 – Within 72 hours of injury

This assessment will take about 1 hour to complete. The youth and parent will be asked to complete surveys regarding post-concussion symptoms and functional outcomes. The parent will also be asked to provide information regarding the child's behavior prior to the injury.

Following completion of the survey, research staff will demonstrate use of the study devices, including Actigraph, Narrative Clip, and laptop. Research staff will also train the youth and parent on how to use these devices, including how to upload narrative clip data to the laptop, how to review images, and how to delete unwanted images. Research staff will also emphasize the importance of not losing the devices and steps to take if devices are lost or stolen. The youth and parent will be asked to sign a form indicating that they fully understand what was explained to them, and that they received the study devices and laptop during the assessment.

Monitoring Physical and Cognitive Activity between Assessment 1 and 2

Youth will be asked to wear devices and complete confidential daily surveys between Assessment 1 and 2. Data uploading and daily surveys will take about 5 minutes each day to complete.

Assessment 2 – Day 7 post-injury

This assessment will take about 30 minutes to complete. The youth and parent will be asked to complete the same surveys as in assessment 1. At this assessment, the youth and their parent will be given a final opportunity to review the uploaded images prior to submitting all devices to the research staff member. After this, the study devices and laptop will be collected. Youth and their parent will be asked to sign a form that they fully understand what was explained to them during the assessment, and that they returned the study devices and the laptop.

Monitoring Physical and Cognitive Activity between Assessment 2 and 3

Youth will be asked to complete confidential daily surveys between Assessment 2 and 3. Daily surveys will take about 5 minutes each day to complete.

Assessment 3 – Day 45 post-injury or when youth resumes normal activities

This final assessment will take about 30 minutes to complete. Youth and parent will be asked to complete the same surveys as in assessment 1.

WHAT ARE THE RISKS OF BEING A PARTICIPANT?

We believe that the risks of participating in this study will not be greater than what participants experience in their daily life. Potential risk to bystander(s) may be introduced because of the images captured by the Narrative Clip. However, such risk is minimal because the pilot participants are instructed to inform the bystander(s) that they are wearing a camera, and to remove and cover the device if the bystander does not wish to be photographed. Participating in this study will not affect any recovery recommendations or treatments given to the youth following the injury.

WHAT ARE THE BENEFITS OF BEING A PARTICIPANT?

There are no known direct benefits for participants. However, the findings of study could help others. Our study will help us understand how children recover from sports-related concussions and will help us identify optimal levels of rest.

WHAT ARE THE COSTS AND REIMBURSEMENTS?

All costs related to the research parts of this study will be covered by the research team. However, the parts of the study that would be done for routine clinical care will not be covered by the research team.

Youth and parent participants will be compensated for their time.

IS BEING A PARTICIPANT VOLUNTARY?

Taking part in this research study is completely voluntary. Youth and their parent may choose not to participate. Anyone who decides to be a participant may stop participating at any time. Routine clinical care will not be changed if an individual chooses not to participate.

WHAT ABOUT CONFIDENTIALITY?

Any information collected during this study will be securely stored. Only members of the research team will be able to access this information. Information will not be disclosed to outside parties.

WHAT IF I HAVE QUESTIONS?

For additional information about the study and/or participation, visit <http://www.nationwidechildrens.org/react-study> or contact:

Study research team at ReActStudy@NationwideChildrens.org

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