Developing an implementation strategy for post-concussion communication with low health literacy parents in the emergency department

NCT Number: NCT04112914

Document Date: 4/29/2021

INFORMATION SHEET

Study Title: Developing an implementation strategy for post-concussion communication with parents in the emergency department

Principal Researcher: Dr. Emily Kroshus
Address: 2001 8th Ave, Suite 400,Seattle WA, 98121

The Research Team:

Name/Degree	Phone Number	E-mail
Emily Kroshus, ScD MPH	206-884-5326	Emily.kroshus@seattlechildrens.org
Mary Steiner, MPH	206-884-1485	Mary.steiner@seattlechildrens.org

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

Key Information: You have the option to take part in a research study. This is a consent, assent, and parental permission form. The goal of this form is to give potential participants the information they need to decide whether to participate in the research. The first portion of this form includes a summary of the key information about the research study. Participation in the study is voluntary.

Potential Teen Participants: This information sheet also serves as an assent form. That means that if you choose to take part in this research study, you would verbally confirm your choice. Your parent or legally authorized representative would also need to give their permission and verbally agree for you to join the study.

Potential Participants 18 years and older: This information sheet provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would verbally confirm your decision.

Parents/Legally authorized representatives: You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would verbally confirm your decision.

Joining the study as a parent (and/or Legally Authorized Representative): Parents also have the option to take part in this research study. This form also serves as a consent form for parent participation.

The word “you” in this form may refer to you and/or your child.

If you are interested in participating after reviewing the key information below, continue through the portion of the form containing the “Detailed Information” about the study. Feel free to take notes, write questions or highlight any part of this form.

What should I know about this study?

- This form explains what would happen if you join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your care at Seattle Children’s.
- If you say ‘Yes’ now, you can still change your mind later.
- You can quit the study at any time.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

What is the purpose of this study?

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing this research study to learn how to better share information with families post-closed head injury in the emergency department and urgent care. For this part of the study, we would like to answer the following questions:

- What are the experiences that families have seeking concussion care in the emergency department?
- How useful is the information that parents receive in the concussion education toolkit intervention?

How long would I be in the study and what will I need to do?

Parents: If you choose to take part in all the study visits, you would be in the study for approximately 2 weeks. You will be asked to complete 3 surveys and potentially a 45-minute interview. Children/Teens will not have an active role in this study.

More detailed information about the study procedures can be found under **“If I agree to join this study, what would I need to do?”**

What are the risks or discomforts if I join this study?

You might feel uncomfortable answering some questions. You could skip any questions you did not want to answer.

There is a risk that your/your child/teen's confidentiality or privacy could be breached. This would mean that someone other the research team or our collaborators may find out that you were in the research or see your answers or medical information. However, we will take every precaution to make sure that this does not happen.

Will being in this study benefit me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include learning more about concussions. We hope to use information we get from this study to benefit other families whose children sustain concussions.

What are the alternatives if I choose not to participate?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Why do I have the option of joining the study?

Parents have the option to take part in this research study because your child sustained a closed head injury and sought care in the Seattle Children's Hospital Emergency Department or Urgent Care. Teens have the option to participate because their parents have decided to participate in the study.

How many people will take part in the study?

We think that about 400 people will participate in this part of the research study at Seattle Children's. We anticipate that 1570 participants will take part this study overall at Seattle Children's.

If I agree to join this study, what would I need to do?

Parent participants: If you join the study, you will be randomized to the control or intervention group. If you are in the control group, you will receive concussion education as usual. If you are in the intervention group, you will receive the concussion education toolkit intervention, which consists of daily messages for the two weeks of the study period about how to best support your child's recovery. You can select how you would like to receive the messages (text, audio message, phone call) and engage with these messages as often as you would like.

No matter which group you are assigned to, you would complete 3 surveys. The first survey would be before your child is discharged from the Emergency Department (ED). The second survey would be the day after the ED visit, and the third survey would be two weeks later. We think that each survey will take about 10 minutes to complete. The surveys will ask about demographic information including literacy related questions, your experiences in the SCH ED, the information you've received about concussion, and how you used that information about concussion management at home. We will also ask you about your child's concussion recovery.

The first survey will be completed in person. For the second and third surveys, we will reach out by telephone, email, or text message and you may choose to complete it over the phone, or request the link to the online survey via email or text message.

If you are in the intervention group, we might also ask you to participate in an optional 45 minute interview to hear about your experiences receiving the education toolkit intervention. If we ask you for an interview, the interview will be audio-recorded and transcribed so that we can better analyze the information.

Child/Teen participants will not have active participation in the study, however your concussion and care at Seattle Children's will be discussed in the parent interview.

Parents/Teens: Identifiers will be removed from the identifiable private information and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

What are my responsibilities if I take part in this research?

Parents: If you take part in this research, you will be responsible to complete three surveys and if you are in the intervention group receive messages from the study team. You also may be asked to do an interview in you are in the intervention group. There are no responsibilities for teen participants.

What about confidentiality and privacy?

We will store all of your/your child/teen'sresearch records in locked cabinets and/or secure computer files. We will not put your name on any research data. Instead, we will label your information with a study number. The master list that links a person's name or any other

identifier to their study number is stored separately in a locked cabinet or on a secure computer file. We are using a texting service that will capture our text conversations, but these will be purged by the text system after the conversation is complete.

We would only use your information for research. These are some reasons that we may need to share the information you give us with others:

- If it is required by law.
- If we think you or someone else could be harmed.
- Sponsors, government agencies like the Department of Health and Human Services (DHHS) or research staff sometimes look at forms like this and other study records. They do this to make sure the research is done safely and legally. Anyone who reviews study records would keep your information confidential.

If you join the study, we will keep your information confidential as provided by law.

The following information pertains to the Protected Health Information for the child/teen:

You have certain privacy rights regarding your Protected Health Information (PHI). Only with your permission may we create, use, or share your PHI for this study. The following describes the types of PHI the study will create, use, or share, who may use it or share it, and the purposes for which it may be used or shared.

PHI may include things like:

- Past or future medical records,
- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history
- Medical or laboratory records related to this study, or
- Information specific to you like your name, address, birthday, ethnic origin, or identifying numbers like your social security number.

PHI may be created by, used by, or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers,
- Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Other people or organizations involved with your health care
- Review boards (such as Seattle Children's Institutional Review Board), data and safety monitoring boards, and others responsible for overseeing the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries, or

- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, or disability.

PHI may be created, used, or shared to:

- Study the results of this research,
- Check if this study was done correctly,
- Complete and publish the results of the study described in this form,
- Comply with non-research obligations (such as notifying others if we think you or someone else could be harmed), or
- Facilitate your health care.

You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of your PHI may not be available to you during the study. This does not affect your right to see what is in your medical (hospital) records.

Your permission for the use or sharing of your information will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, no new information will be collected about you. However, information that has already been collected may still be used and shared with others.

Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If your information will be banked as part of this study, it may be used in the future for other research. We will not ask for your permission prior to this future research.

We will follow privacy laws when creating, using, or sharing your information, but these laws only apply to doctors, hospitals, and other health care providers. Some people who receive your health information as part of this study may share it with others without your permission if doing so is permitted by the laws they must follow.

If the results of the study are published, information that identifies you/your child/teen will not be used.

Your permission is documented by verbally agreeing to participate in the study. If you decide that we cannot create, use or share your/your child/teen's information, you cannot participate in this study.

Permission for Use or Sharing of Your Information for Optional Procedures

This research includes optional procedures. The optional part(s) of this research is/are the optional interviews for parents who end up in the intervention group and complete all 3 surveys. You may participate in the main study even if you do not want to do the optional procedures. If you decide to take part in the optional procedures, we need your additional authorization to create, use, and share your PHI for the optional procedures. The same general confidentiality rules as discussed above will apply.

You will need to give verbal permission for the creation, use, and sharing of my health information for the optional procedures.

If you wish to cancel your permission for the optional procedures, you can do this by notifying us in writing. Your permission for the research study overall will remain in effect unless you tell the study team to cancel your permission for the research study overall too.

Certificate of Confidentiality

We have a Certificate of Confidentiality from the federal government. It means we can't be forced to give out information about you if you take part in this study. This is true even if we are asked to by a court of law. It's not likely that someone would ask us to give out your personal information but this Certificate helps protect it. However, there are times when we would still need to share information about you.

Even with the Certificate, your information could still be given out under these situations:

- Federal agencies, like the FDA, may review study records
- Seattle Children's or the funding agency may look at study records to make sure the study is being done well
- You or a family member could share information about you or your part in this research study
- You give written permission to an insurer, employer or other person to receive information about you
- We must report child abuse or if you intend to hurt yourself or others

Would it cost me money to be in the study?

If you take part in this study, there would generally be no cost to you and no cost to your insurance company for the research procedures. However, if you are in the intervention group and choose text messages to receive the intervention, your usual phone plan rates for texting would apply.

What if I were injured because I joined the study?

If you think you have been harmed from this study, please call 206-987-1520.

Would I be paid if I join this study?

Parents: To thank you for taking part in the study we would give you $10 after the first survey is complete and $10 after the third survey is complete. We would give you an additional $50 if you participate in an optional interview (intervention group). You would receive the payment on a

reloadable debit/gift card called a ClinCard. The study staff will provide you with additional information about how the ClinCard works. It is important that you do not lose the ClinCard. Costs for replacing a lost or stolen ClinCard will be your responsibility. The cost to replace the ClinCard is $7.

If I join the study, can I stop, or can I be removed?

If you join the study, you can decide to stop **at any time for any reason**. If you decided to stop, we ask that you talk with Dr. Emily Kroshus. You can contact this person by calling 206-884-5326.

If you choose to leave the study, it will not affect your care at Seattle Children's. You will not lose any benefits or be penalized if you choose to leave the study.

Who do I contact if I have problems, questions or want more information?

This study has been reviewed and approved by an Institutional Review Board (IRB). You may contact the IRB, see the information below.

If I have questions or would like to know about …	**You can call …**	**At …**
• **Emergencies** • **General study questions** • **Research-related injuries** • **Any research concerns or complaints**	**Dr. Emily Kroshus**	**Phone: (206) 884-5326**
• **Emergencies** • **General study questions** • **Research-related injuries** • **Any research concerns or complaints**	**Mary Steiner**	**Phone: (206) 884- 1485**
• **Your rights as a research participant** • **Study questions, concerns or complaints.** • **Contacting someone outside of study team**	**Institutional Review Board This is a group of scientists and community members who make sure research meet legal and ethical standards**.	**Phone: (206) 987-7804**

What would my agreement to be in the study mean?

Your agreement means:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
- **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.**
- By agreeing to be in the study, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
  - You agree to take part in the research study.
  - If the person reading this form is a parent/ legally authorized representative, you agree to have your child take part in this research study.
  - You permit the creation, use, and sharing of your and/or your child/teen's health information for the purposes of this research study as described in the "**What about confidentiality and privacy?"** section above.

Please Note: If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

For study team use only (fill out for any enrolled minors):

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

Original form to:
Research Team File

Copies to:
Participant