University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 2/17/2021
IRB Study # 21-0314
Title of Study: Popular Opinion Leaders as a Sports Concussion Prevention Strategy in Middle Schools - The TRAIN Study, a Randomized Control Study
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Funding Source and/or Sponsor: Centers for Disease Control and Prevention (CDC)

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Concise Summary
The purpose of this research study is to learn more about how to better prevent and manage concussions in middle school sports. The information we learn by doing this study may help us develop concussion education and management protocols targeted to middle school sports. Participants in this study will be parents of a child/children enrolled in middle school. Participants will be asked to complete two brief surveys, one of two online concussion education trainings and one virtual interview. There are no known risk of participation in this study. The benefits to you from being in this study may be improved knowledge about concussion. If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to learn more about how to better prevent and manage concussions in middle school sports. You are being asked to be in the study because you have a child enrolled in middle school who has participated in organized sports within the past two years.

Are there any reasons you should not be in this study?
You should not participate in this study if you do not have a child enrolled in middle school who has participated in organized sports within the past two years.

How many people will take part in this study?
A total of approximately 120 parents will participate in this study.

How long will your part in this study last?
You will be asked to complete two brief surveys, complete one of two online concussion education trainings and to participate in one virtual interview. (Surveys are approximately 10 minutes each, training is approximately 20-50 minutes and the interview is approximately 30 minutes). All study activities will be completed virtually.

What will happen if you take part in the study?
You will be asked to complete two brief online surveys, one of two online concussion education trainings and one virtual interview (surveys are approximately 10 minutes each, training is approximately 20-50 minutes and the interview is approximately 30 minutes). During the virtual interview, you will be asked about the information you learned in the concussion education training and to share feedback on the training. The virtual interview may be audio recorded so we can capture comments in a transcript for analysis. You may choose to not be audio recorded or stop recording at any time during the virtual interview.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be improved knowledge about concussion.

What are the possible risks or discomforts involved from being in this study?
There are no known risks associated from being in this study. There is a possibility that others could find out about your participation in the study. To protect against this possibility, all information will be held in strict confidence. Only the research team will have access to all data.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Participants will not be identified in any report or publication about this study. We may not use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

All data will be stored on password protected computers/servers or under lock and key in the Matthew Gfeller Sport-Related Traumatic Brain Injury Research Center or the Injury Prevention Research Center. After the interview has been transcribed, the audio recording will be destroyed.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will receive $75 for completion of two brief surveys, a concussion education training and one interview.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by the Centers for Disease Control and Prevention. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on 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 website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Check the line that best matches your choice:

_____ OK to record me during the study

_____ Not OK to record me during the study

_____ _____
Signature of Research Participant Date

Printed Name of Research Participant: _____

Email of Research Participant:_____

Phone Number of Research Participant: _____

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent