



Parental Permission for a Minor Child to Participate in a Research Study (Biomedical)

Preventing Lower-Extremity Injuries in Adolescent Soccer Players

INTRODUCTION

Your child is being asked to take part in a research study. Before you decide if you want your child to be in the study, you need to understand its risks and benefits so that you can make an informed decision. This is known as informed consent. Your child will be asked to sign a separate form, indicating that they also agree and wish to participate in the trial.

This consent form provides information about the research study which has been explained to you in the enclosed informational brochure. Once you understand what the study involves, you are asked to indicate if you want your child to participate or not. If you have questions about what the study means, you may call any of the people listed in the "Who is Leading this Study?" section below. Your decision to allow your child to take part in the study is entirely voluntary. This means that you are free to choose whether or not you want your child to be a part of this study.

DESCRIPTION OF THE RESEARCH AND ITS PURPOSE

Tears to the anterior cruciate ligament (ACL) of the knee are a common and potentially serious athletic injury. Athletes who play soccer are especially at risk for these and other lower extremity (foot and leg) injuries. The purpose of this research study is to examine the effectiveness of an injury prevention training programs on the lowering the rate of lower extremity injuries in the Montgomery Soccer Incorporated (MSI) soccer league & National Capital Soccer League (NCSL). Recognizing the need to prevent injuries, National Capital Soccer League (NCSL) & Montgomery Soccer Incorporated (MSI) have started an injury prevention program for your child's soccer team. Because your child is participating in NCSL or MSI soccer, your child will be performing this injury prevention program as a part of their routine warm-ups before each practice and game. The injury prevention program is a series of simple stretching, strengthening, jumping, and cutting exercises to help improve how your child moves during athletic activities.

The primary purpose of this research study is to compare the effectiveness of your team's injury prevention program with injury prevention programs that have been implemented by other teams. Another purpose is to assess if the training programs change your child's movement patterns during the season.

Your child is being asked to be in the study because they play in an MSI or NCSL league that has an injury prevention program.

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What will happen if your child takes part in the study?

All MSI or NCSL soccer athletes in your child's league will be doing the injury prevention exercises because the injury prevention program is part of their regular team practices. Since every player will already be doing the exercises, by allowing your child to participate in the study you are simply allowing us to keep track of your child's injuries and to watch how your child's movement patterns change during the season.

If your child participates in the study, we ask you to help your child fill out a short questionnaire. The questionnaire asks about your child's history of past injuries, sports participation, and exercise training. Other than the questionnaire, the only other extra things that you and your child would be asked to do will only happen if your child is injured.

Research assistants will be in weekly contact with the MSI & NCSL coaches. If your child is injured and is enrolled in the study, the project coordinator (Anthony Beutler) or a research assistant will contact you to ask for the details of the injury. You will not be contacted unless the injury is serious enough to cause your child to miss a practice or game.

If your child is injured and sees a doctor for diagnosis or treatment, we may ask you for permission to access the medical records of that appointment so that we can verify the type and severity of the injury. We would typically only ask to see health records if an injury caused your child to miss 3 or more consecutive practices or games. The permission forms would be faxed to you after you speak with the project coordinator (Anthony Beutler). You can choose to sign the authorization or not sign the authorization for us to have access to the injury records when it is faxed to you.

How many people will take part in this study?

Approximately 600 soccer athletes will be invited to participate in this research study.

How long will your child's part in this study last?

If your child participates in the study, the study period would begin on the day the consent form is signed. Your child's participation in the study will end when they no longer play for an MSI or NCSL soccer team. You may also choose to stop your child's participation in the study at any time by contacting the project manager (Anthony Beutler), the MSI, or NCSL office.

Who is Leading this Study?

The person in charge of this study is Dr. Anthony Beutler, Major, USAF, MC. Dr. Beutler is a Sports Medicine physician at the Uniformed Services University in Bethesda, MD. If you have any questions or concerns regarding this study, you may reach Dr. Beutler at (301) 295-9462. You may also reach Dr. Beutler via e-mail at abeutler@usuhs.mil

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Who will be included in or excluded from the study?

All youth soccer athletes over age 12 in MSI & NCSL leagues with an injury prevention program are being asked to participate in this study. No one will be excluded from this study based on race, gender, or history of previous injury.

POSSIBLE BENEFITS

There are no direct benefits to you or your child from participating in this research. However, your child's participation will have indirect benefits in allowing us to determine which injury prevention program is most beneficial for MSI & NCSL soccer athletes. This will allow us to prevent as many injuries as possible for future MSI & NCSL athletes.

POSSIBLE RISKS

There no physical risks to the health of your child from participating in this study. Your child's privacy is important. We will protect that privacy in the following ways:

- All records will be stored on a password protected, secure computer and/or in a locked filing cabinet in the Injury Prevention Research Laboratory.
- This consent form will be the only permanent piece of identifying information from you. Your child will be assigned a code number and this will be attached to all other data. The questionnaire and injury reporting forms will contain a coversheet identifying your child by name, but this will be torn off and destroyed as soon as your child's code number is written on the form.

Your child's privacy will also be protected as described in the Privacy and Confidentiality section below.

RIGHT TO WITHDRAW FROM THE STUDY

You may decide to stop your child's taking part in this study at any time. Deciding not to be in the study or leaving the study before it is done will not affect your or your child's relationship with the researcher, coach, or with MSI, or NCSL, or the Uniformed Services University.

PRIVACY AND CONFIDENTIALITY

All information you provide as part of this study will be confidential and will be protected to the fullest extent provided by law. Questionnaire and injury data related to this study will be accessible to those persons directly involved in conducting this study and members of the Uniformed Services University of the Health Sciences Institutional Review Board (IRB), which provides oversight for protection of human research volunteers. In addition, the Institutional Review Board at USUHS and other federal agencies who help protect people who are involved in research studies, may need to see the information you give us. Other than those groups, records from this study will be kept private to the fullest extent of the law. Scientific reports that come out of this study will not use your child's name or identify you or your child in any way.

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IF YOU HAVE QUESTIONS OR CONCERNS

If you have questions about this research, you should contact Dr. Anthony Beutler, the person in charge of the study. His phone number at USUHS is (301) 295-9462. Even in the evening or on weekends, you can leave a message at that number. If you have questions about your rights as a research subject, you should call the Director, Human Research Protections Program at USUHS at (301) 295-9534. He is your representative and has no connection to the researcher conducting this study.

If you sign this consent form, a study representative will contact you by telephone to ensure that all your questions have been answered regarding this research project.

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By signing this form you are agreeing you understand the information above and that you give your permission for your child to take part in this research. You understand that your child will only be enrolled in the study after a study representative has contacted you by phone to ensure that all your questions regarding this project have been answered.

I am the parent or legal guardian of _____
(print child's full name here)

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

Print your Full name here

Signature

Date of signature

Phone Number

Best Time to Call

To be filled out by USU Study Staff:

I certify that on this date, I contacted _____
Print Parent's Name here

points with him/her, and verified that he/she has no further questions regarding this form or this research study at this time.

Signature of Staff Member Making Phone Contact

Date

Printed Name of Staff Member

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