

PARTICIPANT INFORMATION SHEET

Study title: Sex hormones and non-contact Anterior Cruciate Ligament (ACL) injury in female athletes.

Researchers: Ms Elisa Nédélec and Dr Kirsty Elliott-Sale

Invitation:

We invite you to take part in our research study. Before you decide if you would like to take part, it is important that you understand why this study is being done and what we will ask you to do. Please read this leaflet carefully or ask someone to read it to you so that you can decide if you want to take part or not. You can talk about it with your family, friends, sports team's practitioners, or doctor if you want to. Please ask us if there is anything that you do not understand or if you would like more information.

Thank you for considering taking part in our research.

What is this study about?

Girls and women are more likely to experience an Anterior Cruciate Ligament (ACL) injury than boys and men and these injuries often happen between age 12 and 18-year-old. The ACL is a specific ligament [a ligament is a short band of tissue which connects two bones] located in the middle of the knee, which keeps your knee stable when you do sports. Your ACL can be torn during an accident or after movements involving speed and a change of direction.

Most ACL injuries happen during a non-contact situation, when there is no shock between your knee and a heavy object or someone else. The scientific community is still unsure why women get more ACL injuries than men. One of these causes might be due to changes in the sex hormone oestrogen, which changes on a daily basis in women (during the menstrual cycle) but not in men.

More girls and women are becoming professional athletes and we want to help you and them by studying one of the most common injuries for female athletes.

Why have I been chosen?

We want to invite female adolescents between **12 and 18 years old**, who have experienced an ACL injury lately to take part in this study. Because you are a woman, we will ask you about your menstrual cycle or which type of contraception you are taking.

Do I have to take part?

No, it is up to you and your parent(s) or guardian(s) whether you take part or not. You and your parent(s) or guardian(s) will be asked to sign a form to say that you are happy to take part. However, you can still change your mind and stop taking part in this study at any time.

What will happen during the study?

We will ask you to answer an online questionnaire, on our webpage (<https://fairaclproject.isrg.org.uk/>).

The questionnaire:

- As soon as possible after your ACL injury, we will ask you to go to our webpage: <https://fairaclproject.isrg.org.uk/>, either with your smartphone, your tablet, your laptop or your personal computer. We will explain how to create a shortcut from our webpage to the home screen of your smartphone, tablet, laptop, or personal computer in order to easily reach our questionnaire when you will fill it out. If you do not have a smartphone or a tablet, your parent(s) or guardian(s) will be happy to help you and will give you access to our webpage with their smartphone, their tablet, their laptop or their personal computer.
- You will either answer the questions alone or with the help of your parent(s) or guardian(s) if you prefer. If you do not understand a word or a question, do not worry; please ask for help from your parent(s) or guardian(s) or us. It is important for you to understand a question before answering it.
- You can also answer some questions with the help of your sports team's practitioners, if needed.
- You will have to answer a few questions depending on your own profile. It will take you approximately 20 to 25 minutes to answer our questionnaire. You can make changes to your answers as many times as needed before sending it to us.

Your questionnaire has four parts:

1. General information and your sport profile

The questions are about your competition level and some information about your sport.

2. Anterior Cruciate Ligament injury profile

The questions are about how your ACL injury happened and about any leg injuries that you have had in the past.

3. Menstrual Cycle or Hormonal Contraceptive profile

The questions are about your menstrual cycle. Some questions are about hormonal contraception, which you only need to answer if you use it.

4. Your general health on the week before your ACL injury

The questions are about how you felt during the week before your ACL injury happened.

What is good, and not so good, about taking part?

- ✓ With this study, we want to know more about hormones and non-contact ACL injuries. After our study, we will analyse your answers and the answers of many other female athletes who had an ACL injury, which will help us understand if we can give more advice to protect female athletes from this serious injury.

We do not think that taking part in our study will cause you any disadvantages or risks. However, if you feel stressed or upset as a result of completing the questionnaire, please feel free to take a break and to talk with your parent(s) or guardian(s) or us about it.

Is the research safe and who has checked it?

This study has been checked by an independent group of people called a Research Ethics Committee (Nottingham Trent University's Ethical Advisory Committee). This group of people have decided that this study is safe and fair for you to take part if you want to.

Who will know about my answers?

- The only purpose of our study is to understand how ACL injuries occur in female athletes. We will collect some personal information (such as your name, your email address, your preferred method to be contacted, your year of birth and some medical information). Your participation is confidential; neither information about you, your team nor your club will be identifiable [recognisable] to anyone other than the research team (Elisa and Kirsty). If you answer something that worries us, then we might have to share it with someone else. We will always let you know if we plan to do this.
- The information that you give to us, will be stored in secure folders on Nottingham Trent University servers (computers). We will also protect your information by removing any information that could identify you from your answers, and then saving your responses under a code. This code is a unique identifier that will allow us to re-identify you should you wish to drop-out from the study.
- You can drop-out from the study at any time, without providing a reason, up until the last day of our study, the 23rd of February 2022. You can do this by sending an email to the research team (elisa.nedelec2019@my.ntu.ac.uk). In your email, please

mention your full name for us to know which answers to delete. If you wish to drop-out from our study, before the 23rd of February 2022, we will automatically delete all answers and personal information collected from you.

- After the 23rd of February 2022, we will delete all your personal data. Therefore, you will not be able to ask for deletion of your data since it will be no longer possible for the research team to link you to the information that you have provided.
- Anonymised information (information without your name) collected during the study will be stored and publicly available for ten years on a data repository. This will allow anyone else to use the anonymised data for any purpose that they wish. You will not be identifiable [recognisable] from these data and future research in this area will further benefit from the reuse of these data.

What happens at the end of the study?

When the study is finished, Elisa (researcher at Nottingham Trent University), will write a research book (a doctoral thesis) about her research topic, including the results of this research project. The research team will write some articles in specific magazines for doctors and scientists and will present these results at professional research meetings. Your name will never be written or said in any of these works.

What do I do if I have any questions?

If you or your parent(s) or guardian(s) have any questions about any aspects of this study, you can speak to the researchers who will do their best to answer your questions.

- Ms Elisa Nédélec (principal investigator)

PhD Student

*Musculoskeletal Physiology Research Group
Sport, Health & Performance Enhancement (SHAPE) Centre
Erasmus Darwin Building, Room 259
Nottingham Trent University
Clifton Lane, Nottingham, NG11 8NS
Email: elisa.nedelec2019@my.ntu.ac.uk*

Or

- Dr Kirsty Elliott-Sale (project's supervisor)
Email: kirsty.elliottsale@ntu.ac.uk

Next step:

If you and your parent(s) or guardian(s) are willing that you participate in our study, please go to <https://fairaclproject.isrg.org.uk/> and start the survey.

Thank you for reading this and for your participation.