

PARENT/LEGAL GUARDIAN 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 your child/ward to take part in our research study, led by the Musculoskeletal Physiology Research Group at Nottingham Trent University. Before you and your child/ward decide to do so, it is important that you understand why this study is being done and what we will ask you and your child/ward to do. Please read this leaflet carefully so that you can decide if you want that your child/ward takes part or not. You can talk about it with your family, the sports team's practitioners of your child/ward or your doctor if you want to. Please ask us if there is anything that you do not understand or if you or your child/ward would like more information.

Thank you for considering taking part in our research.

What is the purpose of the study?

Girls and women are 3 to 6 times more likely to experience an Anterior Cruciate Ligament (ACL) injury than boys and men and are more often injured between 12 and 18-year-old. The ACL is a strong ligament located in the middle of the knee joint, which ensures a powerful stability in the knee when one does sports. When an ACL injury occurs, the ACL is torn during an accident or when a person executes a specific combination of movements with speed, landing and change of direction.

At least two-thirds of ACL injuries occur during a non-contact situation, when there is no shock between the injured knee and a heavy object or someone else. Many studies have shown different causes for why girls and women have more risk of ACL injury than boys and men. One of these causes is the different quantity of sex hormones that women and men produce during their lifespan. Sex hormones have multiple effects on physical functioning, especially during adolescence. The ACL might react to some of these hormonal changes and could change its form at certain points of the lifespan corresponding to different hormonal profiles.

The study aims to register the hormonal profile of the female athletes at the time of their non-contact ACL injury. More girls and women are becoming professional athletes and we want to help your child/ward and other female athletes by studying one of the most prevalent injuries for female athletes.

Why has your child/ward 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 your child/ward is a woman, we will ask more details about her menstrual cycle or which type of contraception she is taking, if applicable.

Does your child/ward have to take part?

It is entirely up to you and your child/ward to decide whether she takes part or not. If both of you decide to do so, we ask you and your child/ward to provide your consent by filling-up the 'Informed consent' section at the beginning of the questionnaire of your child/ward.

However, you and your child/ward can still change your mind and stop participating in this study at any time.

What would taking part involve?

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

The questionnaire:

- As soon as possible after your child/ward's ACL injury, we will ask your child/ward to go to our webpage: <https://fairaclproject.isrg.org.uk/>, either with her smartphone, her tablet, her laptop or her personal computer. We will explain how to create a shortcut from our webpage to the home screen of her smartphone, tablet, laptop, or personal computer in order to easily reach our questionnaire when she will fill it out. If your child/ward does not have a smartphone or a tablet, we kindly ask you to give her access to our questionnaire by accessing our webpage with your smartphone, your tablet, your laptop or your personal computer.
- Your child/ward will either answer the questions alone or with your help if she needs it. If your child/ward faces some difficulties when reading and/or answering the questionnaire, we would sincerely appreciate that you support your child/ward by helping her to understand either a word, a concept, or a question. We would also kindly ask to parents or guardians to help their child/ward to understand words and

questions without influencing their answers. If you and your child/ward do not understand a question, please feel free to ask us anytime.

- Your child/ward can also answer some questions with the help of her sports team's practitioners, if needed.
- Your child/ward will have to answer a few questions depending on her own profile. It will take your child/ward approximately 20 to 25 minutes to answer our questionnaire. Your child/ward can make changes to her answers as many times as needed before sending it to us.

Your child/ward's questionnaire has four sections:

1. General information and your child/ward's 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 in this category are about the rhythm and history of your child/ward's menstrual cycle. We also ask some questions about hormonal contraception, which your child/ward only needs to answer if she uses it.

4. Your child/ward's general health on the week before her ACL injury

The questions in this section are about how your child/ward felt during the week before her ACL injury happened.

What are the benefits of taking part to the study?

- ✓ With this study, we want to know more about hormones and non-contact ACL injuries. After our study, when we will have analysed your child/ward's answers and the answers of many other female athletes who had an ACL injury, we will understand if we can give more advice to protect female athletes from this serious injury.

What are the possible disadvantages and risks of taking part?

Participating in the research is not anticipated to either disadvantage you or your child/ward nor will she experience any discomfort or psychological harm beyond the experience of the everyday life.

However, if your child/ward feels any discomfort or distress at any moment of the questionnaire, we put in place a safeguarding system which follows the legal and ethics obligations when research projects are done with minors and vulnerable adults. Help can be provided by our research team in collaboration with designated safeguarding officers at Nottingham Trent University, by phone or email, or with external services such as NSPCC and Childline.

Important information:

- The only purpose of our study is to register circumstances of the ACL injury in female athletes. We will collect some of your child/ward personal information (such as her name, her and/or your email address, her preferred method to be contacted, her year of birth and some medical information). Your child/ward participation is confidential; neither information about her, the team nor her club will be disclosed to anyone other than the research team (Elisa and Kirsty). Please note that confidentiality will be maintained as far as it is possible, unless anything in her responses makes us worried that someone might be in danger of harm, we might have to inform relevant agencies of this. If this were the case, we would inform her and you of any decisions that might limit her confidentiality.
- The information that your child/ward gives to us, including her personal data, the information she provides about her medical profile and the circumstances of her ACL injury, will be stored in secure folders on Nottingham Trent University servers. We will also protect her information by removing any information that could identify her from her answers, and then saving her responses under a code. This code is a unique identifier that will allow us to re-identify her should she wishes to withdraw from the study.
- Your child/ward can withdraw from the study at any time, without providing a reason, up until the last day of our data collection, the 23rd of February 2022. She can do this by sending an email to the research team (elisa.nedelec2019@my.ntu.ac.uk). In her email, she will have to mention her full name for us to know which corresponding answers to delete. If your child/ward wish to withdraw from our study, within the timeframe mentioned above, we will automatically delete all answers and personal information collected from your child/ward.
- After the 23rd of February 2022, we will delete all your child/ward personal data, including the file containing the unique identifiers (codes) of all participants to anonymise the data. Therefore, your child/ward will not be able to ask for deletion of their data since it will be no longer possible for the research team to link your child/ward to the information that she has provided.
- Anonymised information collected during the study will be archived and publicly available for ten years on a data repository called Zenodo. This will allow anyone else (including researchers, businesses, governments, charities, and the general public) to use the anonymised data for any purpose that they wish, providing they credit the University and research team as the original creators. Your child/ward will not be

identifiable from these data and future research in this area will further benefit from the reuse of these data.

- Results of the research project will be published and available in Elisa's doctoral thesis and might appear in magazines for specialist doctors and scientists to read. Your child/ward name will never be included in any such publications.
- The study has been approved by Nottingham Trent University's Ethical Advisory Committee.

What happens at the end of the study?

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

What to do if you have any questions?

If you and/or your child/ward have any problem and/or 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

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Or

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

Next step:

If you and your child/ward are willing that she participates in our study, please go to <https://fairaclproject.isrg.org.uk/> and start the survey.

Thank you for reading this and for your child/ward's participation.