NOTTINGHAM TRENT UNIVERSITY

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, led by the Musculoskeletal Physiology Research Group at Nottingham Trent University. Before you decide to do so, it is important that you understand why this study is being done and what we will ask you to do. Please take the time to read the following information carefully. Please ask us if there is anything that you do not understand or if you would like to have 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 you do sports. When you have an ACL injury, the ACL is torn during an accident or after 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 your 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 you and them by studying one of the most prevalent injuries for female athletes.

Why have you been chosen?

We want to invite female athletes, who have experienced an ACL injury lately to take part in this study. Because you are a woman, we will ask more details about your menstrual cycle or which type of contraception you are taking, if applicable.

Do you have to take part?

It is entirely up to you to decide whether you take part or not. If you decide to do so, we ask you to provide your consent by filling out and sending the attached consent form to the research team. However, you can still change your mind and stop participating in this study at any time.

What would taking part involve?

We will ask you to answer to 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.
- You can answer the questions alone or with the help of your sports team's practitioners, if needed.
- If you do not understand a question, feel free to contact us.
- 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.

The questionnaire has four sections:

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 in this category are about the rhythm and history of your menstrual cycle. We also ask some questions 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 in this section are about how you felt during the week before your 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 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 disadvantage you nor will you experience any discomfort or psychological harm beyond the experience of the everyday life.

Important information:

- The only purpose of our study is to register circumstances of the ACL injury 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 disclosed to anyone other than the research team (Elisa and Kirsty). Please note that confidentiality will be maintained as far as it possible, unless anything in your 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 you of any decisions that might limit your confidentiality.
- The information that you give to us, including your personal data, the information you provide about your medical profile and the circumstances of your ACL injury, will be stored in secure folders on Nottingham Trent University servers. 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 withdraw from the study.
- You 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. 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 corresponding answers to delete. If you wish to withdraw from our study, within the timeframe mentioned above, 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, including the file containing the unique identifiers (codes) of all participants to anonymise the 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 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. You 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 name will never be included in any such publications.
- The study has been approved by Nottingham Trent University's Ethical Advisory Committee.

What to do if you have any questions?

If you have a concern and/or a question 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)

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  Sport, Health & Performance Enhancement (SHAPE) Centre
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  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 are willing to 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.