

## Inclusion criteria

The selection is carried out based on the following inclusion criteria :

- Aged between 18 and 65 years
- Accept to perform running training minimum once a week during the 6 months study
- Use of the pair of running shoes delivered by the SMRL for each running training session, and only for running activities
- Regular access to the internet for the report of sporting activities, injuries and pains within TIPPS
- Capable of performing 15 min of consecutive running
- No contraindication to running training and testing including cardiovascular/respiratory disease or running impeding injury/condition at the time of initial inclusion
- No history of surgery to the lower limbs or the back region within the previous 12 months or any degenerative conditions
- No use of insoles for physical activity
- No current symptoms
- Signed Informed consent

## Study Information

**Title: Effects of bodyweight and shoe cushioning on injury risk and running biomechanics: A randomised control trial.**

**Institution: Luxembourg Institute of Health – Sports Medicine Research Laboratory**

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**Head of unit: M. Daniel Theisen, PhD, tel. 26 970 824, e-mail: daniel.theisen@lih.lu**

Dear athlete,

We hereby kindly request your participation in the study “Effects of bodyweight and shoe cushioning on injury risk and running biomechanics: A randomised control trial” conducted by the Sports Medicine Research Laboratory (SMRL) of the Luxembourg Institute of Health (LIH). This document aims at providing you with all the important information about this study. Thank to this information, you will be able to decide if you wish to participate in the study. Please, read carefully the information provided through the next pages and ask questions, if any, to the project manager or to a member of the research team. Your participation to the present study is voluntary. If you agree to participate, you will be asked to sign an informed consent form. You will nevertheless be free to retire from the study at any time without justification of your decision.

The main goal of this project is to investigate the influence of shoe cushioning as well as bodyweight on the risk of running-related injury. This study will allow to determine if shoe cushioning needs to be adapted to the weight of the runner in order to minimise injury risk. More specifically, we will aim to compare the injury incidence between 2 groups of runners using footwear characterised by different cushioning properties (a “soft” model and a “hard” model). The influence of shoe cushioning properties on running technique will also be investigated. This project is carried out in partnership with a commercial sports equipment company wishing to remain anonymous.

This study consists of a follow-up period of 6 months, during which novice and experienced runners have unlimited access to a secured web-based training calendar named “Training and Injury Prevention Platform for Sports” (TIPPS) via a personalised username and password. During this 6-month follow-up period, you are required to perform a running activity at least once a week and to upload all your running as well as all any other sporting activity onto the TIPPS system on a weekly basis. Equally, any injury sustained during this period should also be uploaded onto the TIPPS system using the injury questionnaire provided on the website. You will also be asked to fill out a short questionnaire regarding your running experience and previous injuries. Uploading a session on the website takes less than 1 minute. Finally, the day of your visit, you will be invited to perform biomechanical test to analyse your running style. This test will be carried out by the SMRL, at 76, route d’Eich, L-1460 Luxembourg. Various anthropometric measurements (weight, height, leg length) will be taken, followed by 10 to 15 minutes of running on a treadmill at your usual running speed.

Before the beginning of the study you will receive a pair of running shoes free of charge. These shoes will either have a soft or hard sole. Both shoe versions have cushioning properties that correspond to the range of values from the shoes available on the market. They will be administered through random allocation, which means that **you will not be able to choose which type of shoe you receive**. Neither you nor the research team will know which type of shoe you receive, in order to respect the double-blinded methodology of this study. You will be required to use these shoes for **all running sessions**, and only for running activities. You will be asked to return the shoes if you decide to discontinue your participation in the study.

You are free to retire from the study at any time without justification of your decision. The results of this research will be subject to public talks and scientific publications. Your personal data will remain strictly confidential and will be pseudonymised according to a code that does not allow your identification. This code will be used by the SMRL for the statistical analysis. You preserve the right to access, modify or delete your personal data, in agreement with the modified personal data protection act of August 2<sup>nd</sup> 2002.

The acquired data shall only be passed on to our commercial partner once it has been pseudonymised and solely for scientific purposes. Your identity will never be given away. The data gathered in this study will be stored in a safe place during the project. The pseudonymised data will be stored for a maximal duration of 10 years. This research project has received the approval of the National Research Ethical Committee and has been notified to the National Commission for Data Protection.

We request your written and signed consent using the attached form. This document will equally be kept in storage by the project manager (Dr Laurent Malisoux, PhD), as well as your data. You can contact Laurent Malisoux (Tel. : +352 26 970 231) or Paul Gette (Tel. : +352 26 970 921) for further information.

Your participation is important, as you are the main source of data needed to carry out this study aiming to improve running-related injury prevention. This will help to make running practice even more attractive. We thank you for taking the time to read this information sheet, and hope to welcome as a participant in our study.