The use of wearable sensors to measure training load and running-related injury risk in recreational runners

The Cover Letter

Dear Mile2Marathon member,

This letter is to invite you to participate in a study that aims to examine the relationship between training load, biomechanics and running-related injury. The collected information will serve as a basis for developing safe and effective guidelines for future training programs.

WHO IS CONDUCTING THE STUDY?

This research is being conducted by the principal investigator, Dr. Christopher Napier (SFU). The study is not receiving funds from any external agency or sponsor.

YOUR PARTICIPATION IS VOLUNTARY

Participation in the study is completely voluntary. You may refuse to participate or withdraw from the study at any time with no effect on you. You are not obligated to provide any reason for your withdrawal, should you choose to do so. Participation in this study does not prevent you from participating in other research studies in the future. Further, you may ask to have your data permanently removed from our database at any time without penalty. If you are willing to be contacted in the future for other research studies, please indicate this on the Intake Form. You can always withdraw this consent to be contacted in the future, should you change your mind. In this case, your name and contact information will be removed from our records. Participation in any future research is completely voluntary and will have no bearing on the results of the current research project.

WHO CAN PARTICIPATE IN THIS STUDY?

You may participate in this study if you: 1) are between the ages of 18 and 60; 2) have been running for at least 3 months prior to study commencement; 3) have not had any lower extremity injury in the previous 3 months or currently have pain in your lower back or lower extremities while running; 4) have not previously undergone hip, knee, or ankle joint surgery; 5) are able to commit to a 6-month training program; and 6) are able to understand written and spoken English.

WHAT DOES THE STUDY INVOLVE?

By participating in this study, you are enrolling in a 6-month study that will track your training load and biomechanical parameters via a wearable device ("RunScribe") fitted to your shoe and weekly online questionnaires. You will be expected to attend a 30-minute orientation session at

the beginning of the study to provide you with instructions for uploading your RunScribe data, care and maintenance of the RunScribe sensors, and information on filling out the weekly questionnaires Following each run, you will be expected to upload the data from your RunScribe and rate the intensity of your run on a scale from 1-10. It is expected that this will take between 1 and 5 minutes to complete. In addition, you will be asked to fill out a weekly online questionnaire to report any missed runs or pain. It is anticipated that this will also take up to 5 minutes to complete.

Throughout the 6-month study period you are free to train as you normally would and in your regular running shoes. Should you meet the predetermined injury criteria, you will be assessed by a physiotherapist at no cost to you so that we can correctly diagnose the injury. All data that is collected either via the RunScribe sensor or questionnaires will be void of any personally identifying information and will only be recognized based on your unique coded identifier (i.e. not your name). These data will not be used for any other purpose than the research project without your explicit consent to do so.

Every measure will be taken to ensure your privacy. The data will only be used for research described in this consent form and will not be sold. The questionnaire data will be stored on a server within Canada and is administered by a company that is compliant with BC's Freedom of Information and Protection of Privacy Act (FIPPA).

WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS OF PARTICIPATING?

There are no foreseen harms or discomforts of participating in this study.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

You may not benefit directly from participating in this study. You will receive a personalized running profile (including training load and impact parameters over the course of the 6-month training period) following the conclusion of the study. The findings from this study may also contribute to our understanding of the relationship between training load, biomechanics, and running-related injuries.

You will receive no payment for taking part in this study, nor will you receive payment or money if this research ultimately leads to new knowledge or technology with commercial potential.

REIMBURSEMENT

You will not be reimbursed for your participation in this study.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

If you wish to withdraw from this study at any time, you may call Dr. Napier at 604-682-7788 and he will ensure that your data is located and removed from the database. If you prefer, you can also send Dr. Napier a letter (at the address listed at the bottom of this letter) or email, asking to be removed from the study, but this is not required. If you do choose to send a letter or email, Dr. Napier will destroy it to protect your privacy after it has been read. Any other information collected about you will also be destroyed. However, if your data has already been used in a study at the time you withdraw, it may be impossible to withdraw the results once they have been compiled with the results of others participating in the study or if they have been published.

WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his designate by representatives of the SFU Office of Research Ethics for the purpose of monitoring the research.

No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law. The final de-identified data set from the study may be uploaded to an online repository after completion of the study. All information received will be confidential.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

WHAT WILL THE STUDY COST ME?

You will not have to pay anything to be part of this study, nor will you be paid for participating in it.

WHAT HAPPENS IF SOMETHING GOES WRONG?

By consenting to this study, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions or desire further information about this study before or after participation, you can contact Dr. Napier at 604-682-7788.

WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A RESEARCH PARTICIPANT?

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, you may contact Dr. Jeffrey Toward, Director, Office of Research Ethics jtoward@sfu.ca or 778-782-6593.

If you are eligible to participate in this study, you will be contacted by the Principal Investigator (Dr. Napier) with further information. Please click on the following link to determine if you are eligible to participate:

Impact Training Load Study

Thank you in advance for your participation. Remember that your responses will be kept confidential.

Sincerely,

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