THE UNIVERSITY OF BRITISH COLUMBIA

Faculty of Medicine
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SUBJECT INFORMATION AND CONSENT FORM

THE ALTERNATE RUN STUDY

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Sponsor: BC Sports Medicine Research Foundation

Contact Person IN EMERGENCIES available 24 hours: Michael Ryan (604) 209-4573

You are invited to take part in this research project because you are a healthy runner who is interested in preparing for a half-marathon event.

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

If at any time you have any questions or concerns, we would be happy to answer them for you. It is our goal that you feel fully informed before commencing as a subject in this study.

The BC Sports Medicine Research Foundation has provided funding for this research.

The Principal and Co-Investigator's [Jack Taunton and Michael Ryan] have received financial compensation from The BC Sports Medicine Research Foundation for the work required in doing this clinical research and/or for providing advice on the design of the study/travel expenses/etc. Financial compensation to researchers for conducting the research is associated with obligations defined in a signed contractual agreement between the researchers and the sponsor. Researchers must serve the

interests of the participant and also abide by their contractual obligations. For some, the payment of financial compensation to the researchers can raise the possibility of a conflict of interest. You are entitled to request any details concerning this compensation from the Principal Investigator.

BACKGROUND

Very little is known about how to optimize training for recreational runners reconciling both the need to improve running fitness while minimizing injury risk. Two principal factors in any runner's training are the distribution of the workout-type and footwear usage. Despite significant changes to running footwear over the last 10 years, notably the shift from stability control to functional elements, there has been very little research on the clinical impact of alternating footwear with or without alternating workout types for runners.

PURPOSE

The purpose of this study is to understand how alternating both workout-type and footwear in recreational runners influences running-related pain and running performance.

Should you decline involvement in this study, you may contact Michael Ryan for information on alternative training programs for runners. You can withdraw from this study at any time. If you withdraw from the study any personal information you provide will be destroyed.

WHO CAN PARTICIPATE IN THIS STUDY?

Participants who are interested in beginning a running clinic that will prepare you to complete a half-marathon event in 13 weeks will be invited to join the study. Subjects between the ages of 19 and 60, have been running on a regular basis (minimum once per week) over the past 6 months, are able to run for 60 minutes continuously, could tolerate 20-40km per week in training, and have not experienced a running related injury requiring a stoppage of 2-weeks or more in the past 6 months can participate in this study..

WHO SHOULD NOT PARTICIPATE IN THIS STUDY?

Individuals should not participate if they have a history of surgery to their plantar fascia or Achilles tendon, a diagnosis of osteoarthritis or any other type of chronic condition that affects lower body function, take pain-relieving or anti-inflammatory medication 2 or more times per week over the past 4 weeks, and take part in high impact activities 2 or more times per week during the study period.

WHAT DOES THIS STUDY INVOLVE?

If you agree to participate in this study, you will take part in a 13-week run training program that will involve two group training sessions and 1-2 individual training sessions per week. A baseline testing session will take place prior to the start of the training program and will consist of an interview of your training and injury history and review of your current running related pain across selected body areas. We will also assess your lower body alignment, leg length and functional movements around the ankle and hip joint.

During this baseline session you will be randomly (i.e. decided by chance, like the flip of a coin) assigned to one of four different groups that will either: **1)** perform the same workout during each session in a week in the same model of running shoes, **2)** perform alternating workouts across each

session in a week in the same model of running shoes, **3)** perform the same workout during each session in a week but alternating across four models of running shoes (one high-profile shoe for long-runs, one soft-flexible shoe for recovery runs, one light and lower-profile shoe for speed work and one firm and responsive shoe for stead-state tempo runs), or **4)** perform alternating workouts across each session in a week in alternating models of running shoe. During your run training, if you feel you are experiencing running related pain that is directly related to the shoe you have been assigned and you feel will not be improved with continued shoe break-in, you may elect to forgo your assigned shoe and continue to run in your previous running shoes. Should you elect to forgo your assigned shoes, you may continue to participate in the run clinic with no consequence to your training.

Participation in our study will also require you to document on a weekly basis selected details from each of your runs, including run time, distance, perceived exertion, and injury status (if applicable). You will also be asked to assess body-area specific pain. All questionnaires administered after the baseline session can be completed remotely and returned to study personnel via email. It is important to understand that you are not required to answer any questions within these questionnaires if you are not comfortable doing so.

WHAT ARE MY RESPONSIBILITIES?

You will be asked to come to **The Run Centre**, **North Vancouver** (1200 Lonsdale Avenue, North Vancouver, BC, V7M 3H6) for the initial baseline session that will take approximately 60 minutes. During the training program you are asked to take part in **two group-lead workouts per week** that take place on Thursday evenings and Sunday mornings from **LadySport** (3545 W 4th Ave, Vancouver, BC V6R 1N9).

The running program will consist of between three and four run sessions per week varying in length from 15 - 100min, depending on your running speed. Every Sunday there will be a long run scheduled, and these runs will generally increase in distance (and duration) as you advance through the running program. In addition to the Sunday run, there will be three separate runs during the week that you will be encouraged to complete on your own time. One or two of these separate runs will be performed at a easy/recovery pace, while the remaining run will be used to improve your running speed, complete with specific instructions for completing the workout included in your running program. **At four times in the program there is a 12-min run (Cooper's Test) that you will be asked to perform in order to assess your run performance throughout the 13-week period**.

Your involvement with the running program itself will require between 2 to 3 hours each week, depending on your running pace and which point in the program you are (there will be a greater time commitment later in the program as your weekly running volume increases). The total expected time involvement for participants in this study is 27 hours.

WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS?

Participating in any running program brings with it a risk of experiencing a running injury. Previous research with runners training for the Vancouver Sun Run in a similar group format has reported that 29.5% of individuals self-reported experiencing an injury during a 13-week period. Most injuries (35.5%) in this study were classified as pain during a run, but not restricting distance or speed. Should you experience an injury in this study, you are encouraged to contact **Michael Ryan (604-209-4573)** for instructions on how to proceed with your run training. In the event of a severe injury, you will be provided with references to a sports medicine physician.

There is also a low risk of a cardiovascular event with any vigorous physical activity in previously healthy individuals is low. You will complete a physical readiness questionnaire called the PAR-Q to help us screen for at risk individuals. If you answer 'yes' to any question on the PAR-Q you will need to have clearance from your doctor to participate in this study. Jack Taunton MD, with the help of co-investigator Michael Ryan will provide medical oversight of study participants. Dr Taunton is a registered sports medicine physician and Michael Ryan is CPR certified and has 5-years' experience providing on-field first-aid to athletes.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

Participants in this study may experience an improvement in the ability to run longer distances or be able to run certain distances faster at the end of the study. Participants will also receive two pairs of running footwear, free entry into a running clinic, as well as be able to register for the Vancouver Historic Half-Marathon at a discounted rate.

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

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let your study coordinator know.

HOW WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Training, injury and performance data from this study will be analysed and may be shared with other researchers in the BC Sports Medicine Research Foundation, and their collaborators, for the purpose of pooling data from similar demographic groups. <u>However, all study related data that might be transferred outside of this study will be coded (this means it will not contain your name or personal identifying information) before leaving the study site</u>. By signing this consent form you are consenting to the transfer of your anonymized information to persons or groups outside of this study.

Any email documents sent to study personnel will be protected by HTTPS encryption, and that all data is saved in a password-protected Excel document that is stored in a password protected computer.

A scientific paper may be submitted to an appropriate peer-reviewed journal following completion of this research. Your confidentiality will be respected.

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 or her designate by representatives of The BC Sports Medicine Research Foundation and the Clinical Research Ethics Board of UBC 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.

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 coordinator.

WHAT IF SOMETHING GOES WRONG?

By signing this form, 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. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan and/or by The BC Sports Medicine Research Foundation.

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

If you have any concerns or complaints about your rights as a research subject and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

---------- NEXT PAGE FOR SIGNATURES----------

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Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

Participant's Signature	Printed name	Date

Signature of Person Obtaining Consent	Printed name	Study Role	Date