Effects Of Foot Strengthening on The Incidence Of Injuries In Long Distance Runners

Clinicaltrials.gov Identifier NCT02306148 (November 28, 2014)

May, 2015

INFORMED CONSENT TERM

Research project: ***"Effects of foot muscle training on the prevalence of injuries in founding runners: a randomized controlled clinical trial".***

I agree to participate in the research conducted by Profa. Dr. Isabel de Camargo Neves Sacco, by Physiotherapist Ulysses Tirollo Taddei and Physiotherapist Alessandra Bento Matias of the Laboratory of Biomechanics of Movement and Human Posture of the Department of Physiotherapy, Speech Therapy and Occupational Therapy, Faculty of Medicine, University of São Paulo. The results, kept as proper identifications and maintained confidentiality, will be analyzed and used solely and exclusively for scientific purposes.

This project aims to **investigate the effects of foot muscle training on the prevention of injuries in runners.**

Explanation of the procedures:

- Step 1:

This stage will take place in the Laboratory of Biomechanics of Movement and Human Posture of USP, located in the University City and has two questionnaires, an evaluation of his running and the strength of his feet. The questionnaire first identifies your name, age, height, weight, contact phone number, drug addresses that you have, type of sneakers, and details of your running training program (volume, frequency), and your history of injuries. The second questionnaire will assess the health status of your feet. For the evaluation of the race, we place markers (silver yatballs) in certain points of your body and you will walk a few times through the laboratory.

The strength of your feet will be assessed with the gentleman sitting in the chair moving his feet, ankles and knees and standing on a platform.

Finally, we will inform you if you are part of the Group that will receive training to strengthen the feet from now or at the end of the study and if you are part of the group that performs the MRI exam.

- Step 2:

The training for strengthening the feet lasts 8 weeks, with exercises performed in person and unsupervised. After 8 weeks of face-to-face intervention, runners will continue to practice exercises independently and not remotely supervised at home using the same software with individually programmed progressions, 3 times a week until the end of the study (for more than 22 months). The use of the software at home during the first 2 and 22 months following will be monitored for your access to the software and also according to the completion of the forms for performing the exercises. The completion should be performed weekly in the first 4 months from the beginning of the study and every two weeks from then until the end of the study.

- Step 3: You should return to the biomechanics laboratory of the Physiotherapy Department (USP) after 2 and 4 months of data beginning the study to reassess your strength, your running and application of the same questionnaires of the first visit.
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Discomfort and risk: the experiment does not involve any discomfort or risk to your physical and mental health, in addition to the risks found in the normal activities that you perform.

Benefits: If you are drawn for the exercise group, you will receive a free foot strengthening program for 24 months remotely, being supervised in person for 8 weeks (twice a week). If you are drawn to the control group (without the strengthening exercises), you will receive training to strengthen your feet. In addition to receiving the strengthening program, you will contribute to the understanding of the importance of feet in preventing injuries in runners.

Guarantee of access: At any stage of the study you will have access to the professionals responsible for the research to clarify any doubts. The lead investigator is a professor. Dr. Isabel de Camargo Neves Sacco who can be found in the Laboratory of Biomechanics of Movement and Human Posture, Department of Physiotherapy, Speech Therapy and Occupational Therapy, at Cipotânea Street, 51 , University City (phone 3091-9426) If you have any consideration or doubt about the ethics of research, please contact the Research Ethics Committee (CEP) – Rua Ovid de Pires, 225 - 5th floor - tel: 3069-6442 extensions 16, 17, 18 or 20, FAX: 3069-6442 extension 26 - E-mail: cappesq@hcnet.usp.br

The freedom of withdrawal of consent is guaranteed at any time and to stop participating in the study, without any prejudice to the continuity of its treatment in the Institution.

It is your right to be kept up to date on the partial results of research, when in open studies, or of results that are known to researchers.

Expenses and compensation: there are no personal expenses for the participant at any stage of the study, including exams and consultations. There is also no financial compensation related to your participation. If there is any additional expense, it will be absorbed by the search budget.

The verified results will be stored with their proper identifications and kept confidential, which will be used solely and exclusively for scientific purposes.

I believe that i was sufficiently informed of the respect of the information I read or that was read to me, describing the study **on investigating the effects of foot muscle training on the prevention of injuries in runners.**

I discussed with those responsible: Dr. Isabel de Camargo Neves Sacco and/or Ft. Ulysses Tirollo Taddei and Ft.. Alessandra Bento Matias on my decision to participate in this study. They became clear to me that these are the purposes of the study, the procedures to be performed, their discomforts and risks, the guarantees of confidentiality and permanent clarification. It was also clear that my participation is free of expenses and that I have guaranteed access to hospital treatment when necessary. I voluntarily agree to participate in this study and may withdraw my consent at any time, before or during it, without penalty or injury or loss of any benefit I may have acquired, or in my service on this Service.

I declare that I obtained in an appropriate and voluntary manner the Free and Informed Consent of this patient or legal representative for participation in this study.