

Effect of Educational Booklet for Foot-related Exercises for Prevention and Treatment of Foot Musculoskeletal Dysfunctions of People With Diabetic Neuropathy: FOOtCAre (FOCAtrial-II) Randomized Controlled Trial

ClinicalTrials.gov Identifier NCT04008745

Registered July 2, 2019.

ETHICS COMMITTEE OPINION

**Title:** Rehabilitation technology for musculoskeletal dysfunctions prevention and treatment of feet of people with diabetes: Randomized controlled trials FOOtCAre (FOCA)

**Responsible:** Isabel C. N. Sacco

**Institution:** School of Medicine, University of Sao Paulo

**CAAE:** 90331718.4.0000.0065

**Main funding:** CNPq funding 407252/2018-5

**DADOS DO PARECER**

**Number of the process:** 3.319.047

**Project Presentation:**

This is a project on a highly relevant topic that has the potential to positively impact the health of diabetic patients.

**Objective of the project:**

To apply rehabilitation technology for prevention of musculoskeletal dysfunctions and treatment for persons with diabetes: randomized controlled trials FOOtCAre (FOCA).

**Risk and Benefit Assessment:**

Risks are acceptable and small against benefits.

**Comments and Considerations about the project:** Relevant research with no obvious limitations

**Mandatory Terms Considerations:** Suitable

**Recommendations:** none

**Conclusions or To-Do List and Inadequacy List:** approve

**Opinion Status:** Approved

**Needs CONEP Appraisal:** No

Sao Paulo, May 10th 2019.

**Endereço:** DOUTOR ARNALDO 251 21º andar sala 36

**Bairro:** PACAEMBU

**CEP:** 01.246-903

**UF:** SP

**Município:** SAO PAULO

**Telefone:** (11)3893-4401

**E-mail:** cep.fm@usp.br

## INFORMED CONSENT FORM

Research project: "Effect of Educational Booklet for Foot-related Exercises for Prevention and Treatment in People With Diabetic Neuropathy (FOCA-II)",

\_\_\_\_\_ agree to participate in the research conducted by Profa. Dr. Isabel de Camargo Neves Sacco, by MSc. PT. Érica Queiroz da Silva, Jane Suelen Silva Pires Ferreira, Renan Lima Monteiro, PT. Ronaldo Henrique Cruvinel Junior and OT. Jady Luara Veríssimo of the Laboratory of Biomechanics of Movement and Human Posture (Labimph) of the Department of Physiotherapy, Speech Therapy and Occupational Therapy (FOFITO), Faculty of Medicine (FMUSP), University of São Paulo (USP). The results, with proper identification and confidentiality, will be analyzed and used solely for scientific purposes.

This project aims to evaluate the efficacy, safety and adherence of the use of rehabilitation technologies by through a foot and ankle exercise booklet and their effects on gait kinematic and kinetic responses, diabetic polyneuropathy, functional foot responses. and lower limbs and balance.

Explanation of Procedures:

- Step 1:

This stage will take place at USP's Laboratory of Human Movement and Posture Biomechanics, located in the University City and has questionnaires, an assessment of your gait and the strength and health of your feet. You will be interviewed to evaluate the signs and symptoms of diabetic polyneuropathy. You will complete a questionnaire that will assess the health of your feet. For gait assessment, we will place markers (silver balls) at certain points on your body and you will sometimes walk around the lab. The strength of your feet will be assessed with you standing by moving your toes against a platform of pressure. To check for vascular disease, blood pressure at your ankle and arm will be measured. Finally, we will inform you if you will be part of the group that will receive by a booklet the physical therapy treatment or if you will be part of the group that will not receive the treatment.

- Step 2:

The treatment will last 08 weeks of use of the booklet, 3 times a week. Weekly calls will be made to track technology usage. After 08 weeks of use of the technology, patients will continue to exercise at home independently, following the same study protocol, until the end of the study (after sixteen weeks of initial assessment).

- Step 3:

You should return to the Biomechanics Laboratory of the FOFITO after 08 weeks and 16 weeks from the study start date to evaluate your strength, gait speed and application of the same questionnaires at the first visit.

**Discomfort and Risk:** This research offers minimal risks that are the same as those found in normal activities that you perform daily. Any pain or discomfort that arises at the time of the assessment and the use of the tools, the assessment will be immediately interrupted and you should stop

performing the proposed exercises and immediately inform the research staff. If you have any damage caused by the practice of the exercises, you will be compensated by the survey as provided for in resolution 466 of December 12, 2012, which provides material damage repair coverage for the survey participant.

**Benefits:** If you are drawn to the intervention group, you will receive a free 8-week physiotherapy treatment, supervised by telephone calls for 08 weeks during the study period. If you are drawn to the control group (without treatment), you will contribute to understanding the importance of the feet and ankles in the health of neuropathic patients. After 16 weeks, you may have access to the same physical therapy treatment as the intervention group.

**Guaranteed access:** At any stage of the study you will have access to the professionals responsible for the research to answer any questions. The main investigator is Prof. Dr. Isabel de Camargo Neves Sacco to be found at the Laboratory of Human Movement and Posture Biomechanics, Department of Physical Therapy, Speech Therapy and Occupational Therapy, 51 Cipotânea Street, University City (phone 3091-9426) If you have any questions or concerns about research ethics, contact the Research Ethics Committee (CEP) - Ovídio Pires de Campos Street, 225 - 5th floor - tel: 3069-6442 extensions 16, 17, 18 or 20, FAX: 3069-6442 extension 26 - Email: [cappesq@hcnet.usp.br](mailto:cappesq@hcnet.usp.br).

**Freedom to withdraw consent** at any time and to cease participating in the study is guaranteed, without prejudice to the continuity of their treatment at 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.

**Cost and Compensation:** There are no personal costs for the participant at any stage of the study, including consultations and evaluations. There is also no financial compensation related to your participation. If there are any additional costs, as well as transportation and / or food, it will be absorbed by the research budget, as provided in resolution 466 of December 12, 2012.

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

I believe I have been sufficiently informed about the information I have read or read to me, describing the study that aims to assess the effectiveness, safety and adherence of using rehabilitation technologies through a foot and ankle exercise booklet and their effects on kinematic and kinetic responses in gait, diabetic polyneuropathy, foot and lower limb functional responses and balance.

I discussed with those responsible: Prof. Dr. Isabel de Camargo Neves Sacco and/or MSc. Érica Queiroz da Silva, Jane Suelen Silva Pires Ferreira, Renan Lima Monteiro, PT. Ronaldo Henrique Junior Cruvinel or OT. Jady Luara Veríssimo about my decision to participate in this study. It was clear to me what are the purposes of the study, the procedures to be performed, its discomforts

and risks, guarantees of confidentiality and permanent clarification. It was also clear that my participation is free of charge and that I am 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 loss or loss of any benefit I may have acquired or in my service on this Service

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Patient Signature / Legal Representative

Date     /     /

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Witness Signature  
(Only the project leader)

Date     /     /

I declare that I have appropriately and voluntarily obtained the Informed Consent Form of this patient or legal representative to participation in this study.

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Project Leader Signature

Date     /     /