Effects of Foot Muscle Strengthening in Daily Activity in Diabetic Neuropathic Patients

Clinicaltrials.gov Identifier NCT02790931 (March 21st, 2018)

21st March, 2018

INFORMED CONSENT FORM RESEARCH

I,_____, agree to participate in the research conducted by Prof. Dr. XXXXXXXXXX, for the MSc. Physiotherapist XXXXXXXXXXX and Physiotherapists XXXXXXXXXXX and XXXXXXXXX from 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, keeping the proper identifications and maintaining confidentiality, will be analyzed and used solely and exclusively for scientific purposes. This project aims to study the effects of physical therapy for the feet associated with the use of software on gait speed, the occurrence of foot ulcers, foot sensitivity, day-to-day functionality and gait of diabetic patients with neuropathy. peripheral. Explanation of procedures:

● Step 1: This step will take place at the Laboratory of Biomechanics of Human Movement and Posture at USP, located in Cidade Universitária and has questionnaires, an assessment of your walk, number of steps, assessment of sensitivity, range of motion, strength and health of your feet. . You will undergo an anamnesis to assess the signs and symptoms of diabetic polyneuropathy. You will answer a questionnaire that will assess the state of health of your feet and quality of life. For the assessment of gait during the walk, we will place markers (silver polystyrene balls) at certain points on your body and you will walk around the laboratory a few times. In addition, your walking speed will also be assessed, so you will walk in the laboratory without markers, and at the speed of your choice and fast. The strength of your feet will be evaluated with you standing on a platform and pushing with your toes. For the evaluation of the sensitivity of your feet, an equipment will be used that has a flexible rod and that we will touch your feet to know if you are able to feel it. A manual goniometer will be used to measure the range of motion of your ankle and foot. To check for vascular disease, blood pressure will be measured in your ankle and arm. In addition, to know how many steps you use daily, we will give you equipment, light and that does not generate discomfort, which you will use for a week. Finally, we will inform you if you will be part of the group that will receive physical therapy in person and via software or if you will be part of the group that will not receive the treatment.

● Step 2: The face-to-face physical therapy treatment will last 12 weeks and will be performed simultaneously with the use of the software. After the 12 weeks of face-to-face supervised intervention, patients will continue to exercise independently at home using the same software with individually programmed progressions, 2 times a week until the end of the study (one year after the initial assessment). The use of the software at home will be monitored by your access to the software and also according to the completion of the exercise forms.

● Step 3: You must return to the biomechanics laboratory of the Department of Physiotherapy (Cidade Universitária – USP) after 6 weeks, 12 weeks, 24 weeks and 1 year from the start of the study to reassess your strength, speed, gait, range of motion, sensitivity, ulcer risk, and application of the same questionnaires as in the first visit. Discomfort and Risk: The experiment will not involve any discomfort or risk to your physical and mental health, other than the risks encountered in the normal activities that you perform daily. Benefits: If you are selected for the exercise group, you will receive a free 12-week physical therapy treatment, being remotely supervised via software during the 12 months of the study (twice a week-). If you are selected for the control group (without treatment, you will contribute to the understanding of the importance of feet and ankles in the health of neuropathic patients).

Access guarantee: At any stage of the study you will have access to the professionals responsible for the research to clarify any doubts. The main researcher is prof. Dr. XXXXXXXXXXXX who can be found at the Laboratory of Biomechanics of Human Movement and Posture, Department of Physiotherapy, Speech Therapy and Occupational Therapy. The freedom to withdraw consent at any time and stop participating in the study is guaranteed, without any prejudice to the continuity of your treatment at the Institution. It is your right to be kept up to date on the partial results of the research, when in open studies, or of results that are known to the researchers.

Expenses and compensation: There are no personal expenses 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 is any additional expense, it will be absorbed by the research budget. The verified results will be kept with their proper identification and kept confidential, which will be used solely and exclusively for scientific purposes.

I believe I have been sufficiently informed about the information I read or read to me, describing the study that seeks to investigate the effects of physical therapy intervention in person and via web software, on daily activities, walking speed, on the incidence of plantar ulcers, on functionality and biomechanics of the ankle and foot in the gait of patients with diabetic polyneuropathy.

I discussed with those responsible: Prof. Dr. XXXXXXXXXXX and/or MSc XXXXXXXXX or XXXXXXXXX and/or Physiotherapist XXXXXXXXXXXXXXXXX about my decision to participate in this study. It was clear to me what the purposes of the study are, the procedures to be carried out, their discomforts and risks, the 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 this study, without penalty or prejudice or loss of any benefit that I may have acquired from, or in my attendance at, this Service.

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Signature of the patient/legal representative Date / /

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-- Witness Signature Date // (Only for the project manager)

I declare that I have properly and voluntarily obtained the Free and Informed Consent from this patient or legal representative to participate in this study.

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Signature of the person responsible for the study Date / /