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.

Aim

The primary aim of this randomized controlled trial was to investigate the effects of an 8-week home-based physiotherapeutic foot-ankle exercise program using an educational booklet on DPN symptoms and severity. The secondary goal was to investigate the effects of this intervention at 8 and 16 weeks on tactile and vibration sensitivities, foot health and functionality, foot muscle strength, functional balance, plantar pressure, foot-ankle kinematics, and lower limbs kinematics and kinetics during gait.

Methods/Design

Study design and data collection

This trial is designed as a single-blind, two-parallel arms RCT, wherein patients with DPN will be randomly allocated to either a control group (CG) or an intervention group (IG). This trial protocol follows all recommendations established by SPIRIT (2013) [47], has been approved by a research ethics committee (CAAE: 90331718.4.0000.0065), and was registered at ClinicalTrials.gov on July 2, 2019 (identifier NCT04008745).

Patients in the CG will not receive any specific intervention beyond the usual care, including treatment recommended by the medical team, pharmacological treatment, self-care guidelines, and a weekly telephone call to check on the adherence to care, which will be maintained in both groups [48]. Patients in the IG will perform a foot-related exercise program included in an educational booklet three times/week at home for 8 weeks. After 8 weeks, IG

participants will be encouraged to continue this exercise until the end of the study following the same schedule set in the intervention period. If proven effective, the benefits of the foot-related exercises protocol will be explained and offered to all control participants at the end of the study.

Patients from both groups will be evaluated for all outcomes at baseline (T0), 8 weeks (T8, end of intervention), and 16 weeks (T16, follow-up). All procedures in this study will follow the norms of the Operational Procedure Manual developed specifically for this research. The design and flowchart following the Consolidated Standards of Reporting Trials (CONSORT) guidelines [49] are presented in Fig. 1.

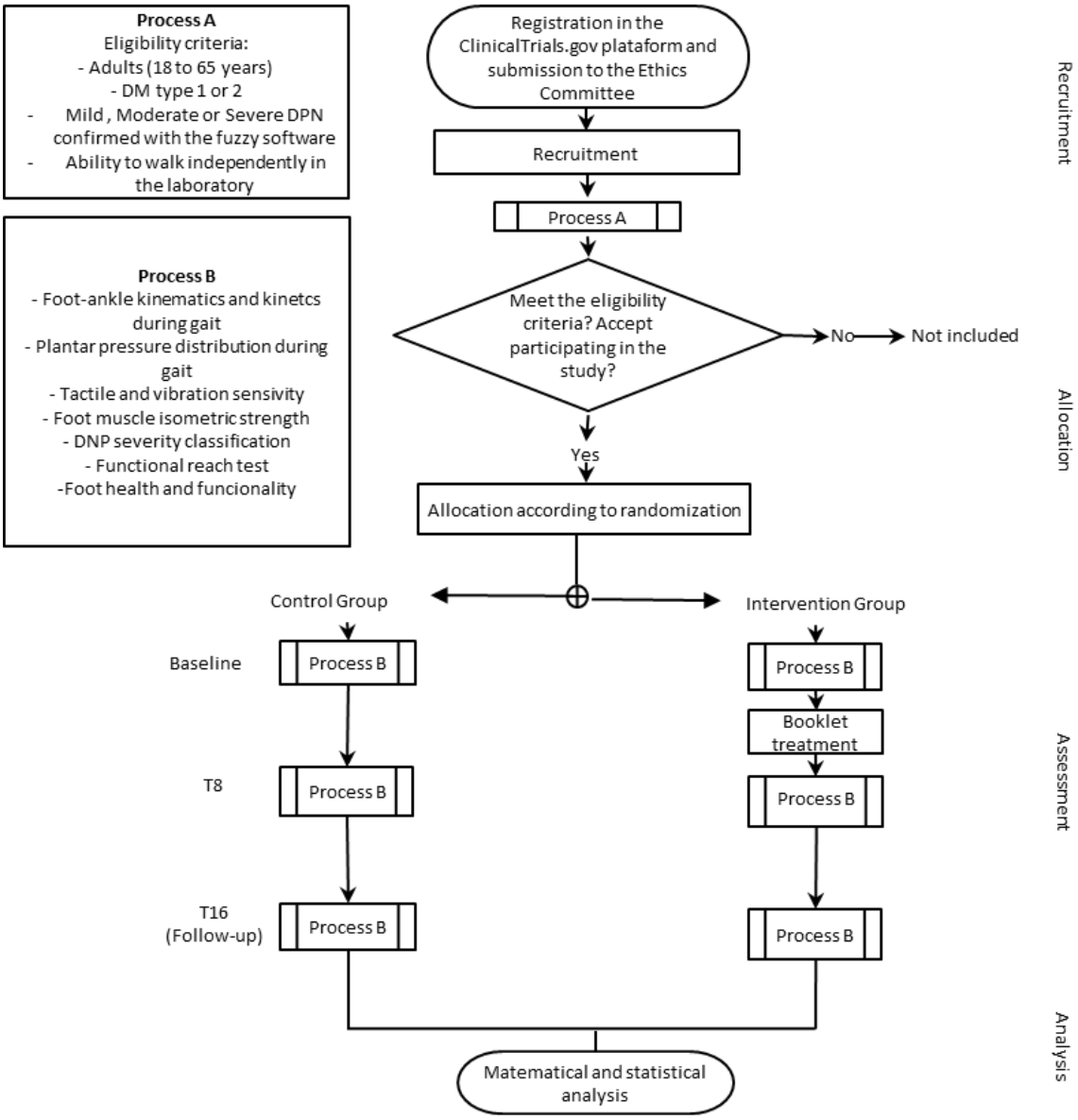

Figure 1 - Consolidated Standards of Reporting Trials (CONSORT) flow diagram illustrating the process of FOCA-II.

Study Setting

The participants allocated to the IG will be treated at their homes, but the first session will take place at the outpatient clinic of the Laboratory of Biomechanics of Human Movement and Posture (LaBiMPH). This clinic is located at the Physical Therapy, Speech and Occupational Therapy department of the School of Medicine of the University of São Paulo and assists all the physical therapy treatments of the laboratory, providing a reliable therapeutic environment for the first intervention. All assessments will be performed at the same laboratory.

Participants and recruitment

This study is currently recruiting patients (study start date: May 1, 2019) with a medical diagnosis of DM and DPN from the Department of Endocrinology of the Hospital das Clínicas of the School of Medicine of the University of São Paulo. Forty-eight participants with DPN will be recruited. The potential subjects will be interviewed by telephone and, once selected, assessed in the laboratory to confirm all eligibility criteria. This first laboratory assessment will represent the baseline condition (blind assessment).

The inclusion criteria are adults up to 65 years of age of either sex diagnosed with DM type 1 or 2 with at least mild DPN confirmed by a fuzzy logic-based system [13], who are able to walk independently for at least 10 m, and who do not have more than one amputated toe (that is not the hallux). The exclusion criteria are the presence of an ulcer not healed for at least 6 months and/or active ulcer; a history of surgical procedure to the knee, ankle, or hip or indication of surgery throughout the intervention period; arthroplasty and/or orthosis of lower limbs or indication of lower limb arthroplasty throughout the intervention period; diagnosis of other

neurological disease outside of DM consequences; dementia or inability to give consistent information; receiving any physiotherapy or offloading devices throughout the intervention period; having major vascular complications and/or severe retinopathy; or having a score of 12–21 (probable depression) on the Hospital Anxiety and Depression Scale (HADS).

Randomization, allocation, and blinding

The randomization schedule will be prepared using Clinstat software (University of York, UK) [50] by an independent researcher (Researcher #1) unaware of the numeric codes for the CG and IG groups. The numerical sequence will be kept in opaque envelopes, numbered sequentially, following an order generated by the software. The randomization procedure will follow the instructions of [51]. This sequence will be kept private and stored in a location inaccessible to blind assessors.

After receiving the patients' informed consent to participate, the random allocation to either the IG or CG will be made by another independent researcher (Researcher #2), who will also be unaware of the codes. Only the main research (Researcher #3) responsible for intervention training will know the group allocation of participants. Patients are aware of the treatment, thus not blind to the allocation. Researcher #3 will also be responsible for monitoring the intervention through weekly telephone calls and by checking the table in the booklet monthly. All patients' personal data will be kept confidential before, during, and after the study by encoding participants' names. Only the main researcher and the person receiving treatment will be aware of the meaning of each code. Patients will be allocated to study groups a maximum of one week after baseline evaluation.

The envelope with the initially generated numerical sequence will then be opened, signed, and dated by the independent researcher, who will make the allocation (Researcher #2). Two other researches (Researchers #4 and #5), which will also be blind to treatment allocation, will be responsible for all clinical, functional, and biomechanical outcome assessments.

To guarantee the blindness of the researchers, before each evaluation, patients will be instructed not to reveal whether they are in the CG or IG; their questions should be asked only for the main researcher (Researcher #3). All researchers will be blind to the block size used in the randomization procedure. The trial statistician will also be blind to treatment allocation until the main treatment analysis has been completed.

Treatment arms

Control

CG patients will not receive any specific intervention other than the treatment recommended by the health care team, which will include pharmacological treatment and self-care guidelines following the International Working Group on the Diabetic Foot guide [52]. These self-care guidelines have been adjusted for our setting in Sao Paulo and include (1) instructing patients to inspect their feet and inside of shoes daily, wash feet daily (with careful drying, particularly between toes), avoid using chemical agents or plasters to remove calluses or corns, avoid cutting calluses or blisters without supervision, use emollients to lubricate dry skin, and cut toe nails straight across; (2) instructing patients to use socks without elastic and sewing; (3) instructing patients to avoid walking barefoot or wearing shoes without socks or slippers and to seek medical assistance whenever identifying problems in their feet; and (4) providing education

aimed at improving footcare knowledge and behavior as well as encouraging the patient to adhere to this footcare advice. These guidelines will be maintained for both groups. Patients in this group will also receive a weekly telephone call to check the adherence to the care recommended by the medical staff and the foot care guidelines and to avoid the nocebo effect.

Intervention

IG patients will receive an educational booklet with two parts. The first part includes educational information to guide the individuals to change their health behavior regarding autonomous footcare, with information about DPN, footwear, and benefits of exercising the foot-ankle. The second part includes a home-based physiotherapeutic foot-related exercise program comprised of six exercises.

Before starting the exercises protocol, the patients will be instructed by the main researcher on how to perform the exercises using the booklet. The first session will be supervised at the outpatient clinic of the Department of Endocrinology of the Hospital das Clínicas, providing a reliable therapeutic environment for the first intervention.

The exercise program includes strengthening of the intrinsic foot muscles and the extrinsic foot-ankle muscles, and it consists of the following steps:

(1) Warm-up: The patients will warm up the foot-ankle with three exercises. They will be instructed to massage their feet, and then use a spiky ball to do a deep tissue massage, and subsequently perform rotating movements in each toe, one by one. Altogether, these exercises should be performed within 2–3 minutes.

(2) A total of six exercises will be performed: four exercises for the intrinsic foot muscles and two for the extrinsic foot-ankle muscles. The exercises will be performed in the order suggested by the booklet using objects such as cotton, pencil, balls, and chairs. The interphalangeal, metatarsophalangeal, and ankle joints are targeted in the protocol. The following muscle groups are targeted in protocol: medial-plantar aspect (abductor hallucis, flexor hallucis brevis, and adductor halluces), lateral-plantar aspect (abductor digiti minimi, flexor digiti minimi brevis, and opponens digiti minimi), middle-plantar aspect (flexor digitorum brevis, quadratus plantae, lumbrical muscles, plantar interosseous, and dorsal interosseous muscles), and dorsal-foot aspect (extensor digitorum brevis and extensor hallucis brevis).

The foot-related exercises will first be performed in the sitting position in one set with 30 repetitions. If the patient finds this too easy, the exercise will then be performed in the standing position, and then standing on one foot. The patient can also increase the number of sets. Patients will follow the exercise program from the booklet with instructions for each exercise prescribed, and after each task, they will fill out a table stating the perceived effort for each exercise (using a Likert scale). At the end of each exercise, patients will define their effort using a visual analogue scale (VAS). If the effort is between 0 and 5, the individual should progress to the next level of the exercise (e.g., from sitting to standing, or using a different object) for the next session. If the effort is between 6 and 8, the same volume and level of difficulty should be maintained. If the effort is between 9 or 10, the amount of repetitions should be decreased or

the position in which the exercise is performed should be modified (e.g., from standing to sitting) (see Additional File 1).

Patients will follow this regime three times a week for 8 weeks, for a total of 24 sessions. The duration of a session should be no longer than 30 minutes. The perceived effort scale will be used to regulate each patient's individual effort for his/her progression to the next session of exercises, and it will be recorded by the participant using the monthly table in the booklet (see Additional File 1).

The discontinuation criteria for the exercises include cramps, moderate to intense pain, fatigue, or any other condition that exposes the patient to any discomfort. The other discontinuation criterion for the intervention is the occurrence of a foot ulcer as assessed by a blinded podiatrist nurse specializing in diabetic feet. The patients will be advised to report any sign of tissue damage to Researcher #3.

Outcomes and measures

Two researchers (Researchers #4 and #5) who are blinded to group allocation will perform all assessments. Participants of both groups will be assessed at baseline (T0), at the end of intervention (T8, 8 weeks after baseline), and at follow-up (T16, 16 weeks after baseline). Table 1 shows the schedule of enrollment, intervention, and assessments according to the SPIRIT guidelines [47].

Table 1 - Schedule of enrollment, intervention, and assessments of the FOCAtrial-II, following SPIRIT guideline

TIMEPOINT	Enrollment	Allocation	Post-allocation		Follow-up
	T-1	T0	T0	T8	T16
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS					
Intervention Group					
Control Group					
ASSESSMENTS					
DPN symptoms			X	X	X
Fuzzy classification of the DPN severity			X	X	X
Foot- ankle kinematics and kinetics during gait			X	X	X
Dynamic plantar pressure distribution during gait			X	X	X
Tactile sensitivity			X	X	X
Vibration sensitivity			X	X	X
Foot health and functionality			X	X	X
Foot isometric strength			X	X	X
Functional balance			X	X	X

An initial anamnesis will be performed to check the eligibility criteria, including clinical, anthropometric, and demographic characteristics of all participants. The classification of DPN severity will be made using the fuzzy score from a web software program [13,53]. Participants with scores equal to or above 2.0, corresponding to mild DPN, will be included in the study. Those who score between 12 and 21 (probable depression) on the Brazilian-Portuguese HADS will not be included [54].

The DPN symptoms and the classification of the DPN severity will be the primary

outcomes. The foot-ankle kinematics and kinetics during gait, plantar pressure distribution during gait, tactile and vibration sensitivities, foot health and functionality, foot strength, and functional balance will be the secondary outcomes.

DPN symptoms

Patients will answer the Brazilian version of the Michigan Neuropathy Screening Instrument (MNSI) [55]. This questionnaire has 15 questions about the sensitivity of the feet and legs and is self-administered. A score of 1 point is given for answers of "yes" for questions 1, 2, 3, 5, 6, 8, 9, 11, 12, 14, and 15 and "no" for questions 7 and 13. Questions 4 and 10 evaluate circulatory deficits and general asthenia, respectively, and neither are included in the final score. The sum of all scores ranges from 0 to 13, and the larger the score, the worse the DPN.

Fuzzy classification of the DPN severity

The classification of the DPN severity will be made using the Decision Support System for Classification of Diabetic Polyneuropathy [13,53] developed by the LaBIMPH and publicly available at: http://www.usp.br/labimph/fuzzy/. This decision will be based on fuzzy logic with the input variables of signs and symptoms extracted from the MNSI as well as tactile sensitivity (through the number of non-touch areas using a 10-g monofilament) and vibration sensitivity (by vibrating a tuning fork at 128 Hz), characterized as absent, present, or diminished. The software gives a score from 0 to 10, with higher scores indicating more severe DPN.

Foot-ankle kinematics and kinetics during gait

Gait kinematics will be assessed by three-dimensional displacements of passive reflective markers (9.5 mm in diameter) tracked by eight infrared cameras at 100 Hz (VERO, Vicon Motion System Ltd., Oxford Metrics, UK) and the NEXUS 2.8 motion capture software (Vicon Motion System Ltd.). Forty-two markers will be placed on both limbs of the subject (pelvis, thigh, leg, ankle, and foot) according to the Plug-In Gait and Oxford Foot Model [56] setup protocols. The laboratory coordinate system will be established at one corner of the force plate, and all initial calculations will be based on it. Each lower-limb segment (shank and thigh) will be modeled based on surface markers as a rigid body with a local coordinate system that coincides with the anatomical axes. Translations and rotations of each segment will be reported relative to the neutral positions defined during the initial static standing trial. All joints will be considered to be spherical (i.e., with three rotational degrees of freedom). Ground reaction forces will be acquired by a force plate (AMTI OR-6-1000, Watertown, MA, USA) embedded in the center of the 10-m walkway at 1 kHz. Force and kinematic data acquisition will be synchronized and sampled by an A/D board (Control Box LOCK VICON, 192 kHz, 24 bits).

Participants will be asked to walk at their comfortable, self-selected speed, with a maximum variation of 5% between measurements, thus ensuring that the same speed is maintained in all assessments (T0, T8, and T16). After a complete habituation to the laboratory environment, 10 valid steps will be acquired on each side during gait.

The automatic digitizing process, 3D reconstruction of the markers' positions, and filtering of kinematic data will be performed using the NEXUS software. Kinematic data will be processed using a zero-lag second-order low-pass filter with cutoff frequency of 6 Hz. Ground reaction force

data will be processed using a zero-lag low-pass Butterworth fourth-order filter with cutoff frequency of 50 Hz.

The bottom-up inverse dynamics method will be used to calculate the ankle moments in the sagittal plane. For the calculation of ankle power, the calculated joint moment and the ankle angular velocity in the sagittal plane will be considered. Calculation of all discrete variables from the time series obtained will be performed using a custom-written MATLAB function (MathWorks, Natick, MA, USA).

The following kinematic variables will be analyzed for the stance phase: (a) sagittal ankle ROM, (b) ankle dorsiflexion at heel strike, (c) ankle plantarflexion at push off, (d) hindfoot to forefoot rotation ROM, (e) transverse plane ROM between first and second metatarsal bones and between second and fifth metatarsal bones, and (f) deformation of the longitudinal medial arch. The ankle kinetic variables to be analyzed are: (a) flexor moment and eccentric power at heel strike and (b) extensor moment and power at approximately 80% of stance phase, corresponding to the propulsion phase.

Plantar pressure distribution during gait

A 700 × 403 × 15.5-mm pressure platform (emed q-100, GmbH, Novel, Munich, Germany) with 6080 sensors (four sensors per cm^2) will be used to acquire plantar pressure data during gait at 100 Hz. Participants will walk barefoot three times over the platform with a self-selected gait speed (same as in the kinematic trials), covering a distance of 4 m. Both feet will be analyzed for each patient. Based on the algorithm by Giacomozzi [57], peak pressure, contact area, and pressure-time integral in seven anatomical plantar regions—heel, midfoot, medial forefoot,

medium forefoot, lateral forefoot, hallux, and toes—will be analyzed. This method relies on the integration of a 3D motion capture system (Vicon system), a pressure measurement device (emed q-100), a multi-segment foot model, and an algorithm to identify regions of interest.

Foot muscle isometric strength

Foot muscle isometric strength of the flexor muscles of the hallux and lesser toes will be measured according to Mickle [58] using a pressure platform (emed q-100). Subjects will stand and push down on the platform as hard as possible with the toes and hallux, controlling for excessive body sway. The plantar regions corresponding to the hallux and the toes will be identified by a standard mask from Novel-win Multimask software v. 9.35. The average of three trials on each foot (left and right) will be used for statistical purposes. The outcomes will be the maximum force under the hallux and toes, normalized by bodyweight.

Tactile sensitivity

Tactile sensory deficits will be assessed by a 10-g monofilament [48] in four plantar areas (plantar surface of the hallux and heads of the first, third, and fifth metatarsals). This instrument has good reliability and validity in elderly individuals [59]. The monofilament will be applied perpendicularly to the skin surface three times on the tested areas with sufficient force to cause the filament to bend or buckle. The sequence of the tested areas will be randomized. The patient will not be able to see the monofilament or where it is being applied. The number of areas in which the patient does not feel pressure will be recorded [60]. The greater the number of areas marked, the greater the impairment of tactile sensitivity.

Vibration sensitivity

Vibration testing will be conducted with the timed method using a 128-Hz tuning fork applied to the dorsal surface of the distal phalanx of the hallux. The time (in seconds) at which vibration sensation diminishes beyond the examiner's perception will then be recorded from both sides on a standardized form [61]. Values less than 10 s will be classified as present vibratory sensitivity, greater than 10 s will be classified as decreased vibratory sensitivity, and no perception will be classified as absent vibratory sensitivity.

Foot health and functionality

The Brazilian-Portuguese version of the Foot-Health Status Questionnaire (FHSQ-BR), which has been translated and validated by [62], will be used. This questionnaire is divided into three domains, and we will use Domains I and II. These domains are comprised of questions with answer options presented in affirmative sentences and corresponding numbers. Domain I evaluates foot health in four dimensions: foot pain, foot function, footwear, and general foot health. Domain II evaluates the general state of health, also in four dimensions: general health, physical activity, social capacity, and vitality. Domain III collects general demographic data. The domain I and II has a score from 0 to 100 points, where 100 is the best condition and 0 is the worst. The scores will be calculated using the FHSQ software version 1.03 (Care Quest, Australia).

Functional balance measure

The functional balance assessment will be performed according to [63] using the

Functional Reach Test (FRT). Subjects will be asked to assume a standing position without shoes or socks. Patients will be asked to stand with their shoulders perpendicular to the reach measurement device (measuring tape), which will be attached to the wall and parallel to the floor at the height of the patient's acromion. The upper extremity should not contact the wall during the task. In order to maintain identical foot placement during all testing conditions, the foot position will be traced on a sheet attached to the surface of the floor. The initial measurement (Position 1) will correspond to the position where the third metacarpal is in the beginning of the measuring tape and end of the measurement is where the third metacarpal achieve in the measuring tape after the forward movement (Position 2). The patient will then be instructed to lean forward as much as possible without losing balance, flexing the hips, or taking a step. Functional reach will be defined as the mean difference between Positions 1 and 2. Three trials will be performed, and the average score will be used for statistical purposes. The greater the distance achieved, the better the functional balance.

Statistical Analysis Plan

The sample size was calculated using the GPower v. 3.1 program [64] based on the following outcomes: MNSI DPN symptoms (primary) and ankle sagittal ROM during gait (secondary). These two outcomes were chosen because they reflect important functional gains for DPN patients. Thus, two sample size calculations were performed, and we selected the one that resulted in the largest number of participants. The effect sizes used for both calculations were based on a study that evaluated the effect of 12 weeks of supervised foot exercise in DM patients [34]. In that study, the improvement in the MNSI symptoms had a medium effect size

(0.52), as did gains in the ankle sagittal ROM during gait (0.46). We chose to use half of the effect size obtained in [34] because the nature of our intervention is home based, whereas Sartor's was face-to-face, which is assumed to be more effective.

The input factors for sample size calculation were a statistical design of F-test with interaction between and within factors with two repeated measures and two study groups, statistical power of 0.80, alpha of 0.05, and effect sizes of 0.26 (MNSI symptoms) and 0.23 (ankle ROM). The resulting sample sizes were 32 and 40 individuals for MNSI and ROM outcomes, respectively. Therefore, we defined our sample size as 40. Assuming a 20% dropout rate during the study, a sample size of 48 patients is needed.

Inferential statistical analyses will be conducted using intention-to-treat and per protocol analyses. The missing data will be treated by imputation methods depending on the type: missing completely at random, missing at random, or not at random [65]. The per-protocol analysis will include only those patients who complete follow-up in the allocated intervention group. Confirmation of normality (Kolmogorov–Smirnov test), homoscedasticity (Levene test), and imputation of the means for the missing data of variables with normal distribution will be conducted. After that, mixed general linear models of analysis of variance for repeated measures will be used to detect treatment–time interactions, followed by Newman–Keuls post hoc test to obtain group effect (intervention and control), time effect (between T0, T8, and T16), and group–time interaction. Significant differences will be considered at $\alpha = 5\%$, but for the description of the effect of the intervention, the effect size (Cohen coefficient) and difference between the means will be calculated with their respective 95% confidence intervals.

Ethics approval and consent to participate

This trial was approved by the Ethics Committee of the School of Medicine of the University of São Paulo (CAAE: 90331718.4.0000.0065), according to the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. The trial was registered at ClinicalTrials.gov (a service of the US National Institutes of Health) with identifier NCT04008745 (2 July 2019) under the brief title " Effect of Educational Booklet for Foot-related Exercises for Prevention and Treatment in People with Diabetic Neuropathy (FOCA-II)". The main researcher will explain to each eligible participant every step of the assessment and follow-up, the possible risks, and the fact that no compensations or benefits are to be expected. When agreeing to participate, participants will be asked for written informed consent, according to the standard forms. On the consent form, participants will be asked if they agree to use their data in the study; if they do not agree, they can choose to withdraw from the trial. Participants will also be asked for permission for the research team to share relevant data with people from the University taking part in the research or from regulatory authorities, where relevant. Any changes made to the protocol will be amended and communicated via a report sent to the sponsor and funder. The ethics committee will also be notified by submission of a form via the national website of the research ethics committee, http://plataformabrasil.saude.gov.br/. Changes will also be included in the clinical trial register (https://clinicaltrials.gov/). This trial does not involve collecting biological specimens for storage.

USP - FACULDADE DE MEDICINA DA UNIVERSIDADE DE SÃO PAULO - FMUSP

Plataforma Brasil

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.

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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 Profa. 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.

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 / /

Witness Signature Date / /

(Only the project leader)

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

Project Leader Signature Date / /