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RELATIONSHIP BETWEEN HEALTH-RELATED QUALITY OF LIFE AND BURDEN OF DISEASE WITH FUNCTIONAL FITNESS IN WOMEN WITH CHRONIC VENOUS DISEASE: a cross-sectional study

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Dissertação apresentada ao Programa de Pós-Graduação em Educação Física da Universidade Federal de Pernambuco, como requisito parcial para a obtenção do título de Mestre em Educação Física.

Área de concentração: Biodinâmica do movimento humano.

Orientador: Profª. Drª. Daniela Karina da Silva Ferreira.

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Dedico esta dissertação à minha mãe. Maria de Fátima Alves Nascimento Lima e meu pai, Dalton Roberto Alves Araújo de Lima. Pois, sem eles, de infinitas formas, eu não chegaria aqui.

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ABSTRACT

Chronic venous disease (CVD) is defined as a visual and functional manifestation of abnormalities in peripheral venous system that either present or not symptoms causing alterations in superficial and deep veins. In addition, the Aberdeen Varicose Vein Questionnaire (AVVQ) is commonly used to verify the burden of CVD and quality of life of the patients with the disease, enhancing information of the patients. Therefore, the functional fitness and the calf muscles in patients with CVD presents itself as one of the pathways to maintain a healthy venous system and better quality of life, or even in some cases, to control and reduce the severity of the disease. The aim of the study was to verify the relationship between quality of life and burden of disease with functional fitness in women with CVD. This is a cross-sectional study comprised of 47 women that present symptoms of CVD. Following recruitment, patients visited the laboratory to answer the AVVQ and sociodemographic questionnaires. The AVVQ measures the quality of life and burden of disease through the pain and dysfunction, extent of varicosities, complications, and overall domains. In the second visit, anthropometric measurements and a familiarization were carried out. Subsequently, for the functional fitness, it was measured endurance, strength, flexibility, agility and dynamic balance, and calf endurance were performed. Multiple linear regression analyzed and adjusted the data for age, body mass index, and monthly income. In the endurance test, a relationship was found for pain and dysfunction in adjusted model (p = 0.032). In the upper- and lower-body strength test, a relationship was found for pain and dysfunction in the crude analysis and after adjustments (p<0.05) as well as for the overall domain (p<0.05). In the upper-body flexibility test, the crude and adjusted models presented significant relationships with pain and dysfunction (p<0.05). For the agility and dynamic balance test, only the adjusted model related with pain and dysfunction and overall domains (p<0.05). In the calf endurance test, a relationship was found for pain and dysfunction in the adjusted model (p = 0.002). Quality of life and burden of disease are related to functional fitness. Pain and dysfunction and overall domains are the most related to functional fitness, presenting relationship with endurance, strength, and agility and dynamic balance. Thereby, since our study has shown the possible influence of functional fitness on women with CVD,

mainly on the pain and dysfunction domain, future controlled and randomized studies should be performed to verify precisely the effect of functional fitness on quality of life and symptoms in CVD patients.

Keywords: Varicose veins. Quality of life. Physical fitness.

RESUMO

Doença venosa crônica (CVD) é definida como manifestações visuais e funcionais de anormalidades no Sistema venoso periférico que podem ou não apresentar sintomas que causam alterações em veias superficiais e profundas. Para verificar essas anormalidades e também a qualidade de vida, podemos usar o questionário de veias varicosas Aberdeen (AVVQ). Dessa forma, como possível fator que pode causar benefício aos pacientes com CVD, a aptidão funcional pode ser um dos caminhos para a manutenção de um sistema venoso saudável e melhora na qualidade de vida, controlando ou até reduzindo a severidade da doença. Verificar a relação entre qualidade de vida e severidade da doença com a aptidão funcional em mulheres com CVD. O estudo é descritivo correlacional, composto por 47 mulheres com sintomas de CVD. Após recrutamento, os pacientes visitaram o laboratório e responderam o AVVQ e o questionário sociodemográfico. O AVVQ mede a qualidade de vida e a severidade da doença através de domínios, esses domínios correspondem a dor de disfunção, extensão das varizes, complicações, e escore total. Na segunda visita, foram realizadas as medidas antropométricas e familiarização dos testes de aptidão funcional. Após a familiarização, os testes mediram a capacidade aeróbia, força, flexibilidade, agilidade e equilíbrio, e resistência muscular da panturrilha. Regressão linear múltipla foi usada para analisar os dados que foram ajustados por idade, índice de massa corporal e renda. Para resistência aeróbia, foi encontrada uma relação com dor e disfunção no modelo ajustado (p = 0.032). Para força de membros superiores e inferiores, houve relação também com o domínio de dor e disfunção na análise bruta e após ajustes (p<0.05). O mesmo aconteceu para o domínio de escore total (p<0.05). Para flexibilidade de membros superiores, foi encontrada relação com dor e disfunção para os modelos bruto e ajustado (p<0.05). O teste de agilidade e equilíbrio apresentou relação apenas após ajustes para os domínios de dor e disfunção e escore total (p<0.05). No teste de resistência muscular da panturrilha, relação foi encontrada apenas para dor e disfunção no modelo ajustado (p = 0.002). Qualidade de vida e severidade da doença tem relação com aptidão funcional. Dor e disfunção e escore total foram os que mais apresentaram relação com a aptidão funcional, especificamente com resistência aeróbia, força, agilidade e equilíbrio. Devido a diversos fatores da aptidão

funcional apresentarem correlação com sintomas da DVC, intervenções que explorem capacidades diversas são recomendadas. Entretanto, estudos controlados e randomizados para verificar o efeito da aptidão funcional na qualidade de vida e sintomas da CVD em pacientes com a doença ainda são necessários para clarificar os efeitos do treinamento.

Palavras chave: Varizes. Qualidade de vida. Aptidão física.

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LIST OF ACRONYMS

CVD	Chronic Venous Disease
AVVQ	Aberdeen Varicose Vein Questionnaire
CEAP	Clinical, etiology, anatomic, pathophysiology

CONTENTS

1 CHAPTER I

1.1 GENERAL INTRODUCTION

Chronic venous disease (CVD) is defined as a visual and functional manifestation of abnormalities in peripheral venous system that either present or not symptoms causing alterations in superficial and deep veins (1). Patients are commonly classified by the CEAP (clinical, etiology, anatomy, and pathophysiology) criteria that range from C0 to C6. Those classes correspond to C0, non-visible and non-palpable signs of venous disease; C1, telangiectasia or reticular veins; C2, varicose veins; C3, edema; C4, changes of skin and subcutaneous tissue (4a pigmentation or eczema; 4b lipodermatosclesrosis or atrophie blanche); C5, healed venous ulcer; and C6, active venous ulcer (2). Moreover, as an advanced stage of CVD, chronic venous insufficiency (CVI) is clinically described as functional abnormalities in the venous system producing changes in subcutaneous tissue and superficial skin that corresponds from the levels C3 to C6 of the disease (2). Regarding CVI, about 5% of the population reach those stages, and 1% might reach the last ones (C5 and C6).

Accordingly, the etiology of CVD is yet not well understood, the main risk factors are age (above 50 years), sex (women), obesity, family history, and number of pregnancy (3,4). Its pathophysiology is divided into reflux, obstruction, or a combination of both that leads to a reduction in the vein ability to empty itself leading to venous hypertension (4). Basically, venous hypertension might lead to valve incompetence, inflammation of the vessel walls, vein wall abnormalities, increased collagen and decreased elastin that are aggravated by dysfunctional pump mechanisms, mainly in the gastrocnemius muscle (5,6).

Regarding epidemiological studies, approximately 60% of the adult population present any level of CVD; nonetheless, those values might reach 80% in industrialized countries (4). In Brazil, those values are similar, 46% of the women aged from 14 to 22 years old present the disease. The cases increase with aging, among women aged 23 to 48 the prevalence of the disease is about 52% and might reach 63% in women aged more than 48 years old. In regard of the symptoms, in young women (14 to 22 years old) symptomatic cases reach only 12%, whereas in women above 48 years old approximately 60% of them have symptoms and prominent veins (7). In fact, despite CVD affects both men and women, due to pregnancy and hormonal function women

are more susceptible to the disease (4). In the last two decades, several epidemiological studies from different populations have shown that patients in C2 level are majority women, its prevalence in women is up to 46%, whereas in men the prevalence is no more than 29% (3,8-10). Also, in the Framingham Study (1988) the incidence of CVD per year is 2,6% in women, whereas in men only 1,9%. Following those facts, women seem to be more vulnerable to CVD than men, indicating strategies must be developed to attend the most impacted population.

In fact, treatments of CVD range from simple leg elevation to surgery. The most conservative ones are elastic stockings, physical therapy, manual lymphatic drainage, and use of medicines known as phlebotonics. Additionally, sclerotherapy is one of the most common types of treatment for patients with CVD. Nevertheless, after 6 years the varicose vein recurrence reaches values as high as 90% (12). Another common method is surgery, most common in patients with CVI that in some cases removes partially or completely the vein. Dwerryhouse and colleagues (1999) evaluated the necessity of reoperation in patients who underwent high ligation with the stripping of the vein, they found 6% of the patients needed surgery in a range of five years. Moreover, surgery is an invasive method and might present complications. Additionally, the cost of treatment is high, in the United States it is estimated in one billion dollars per year, and a single patient might cost about 40 000 dollars in a lifetime (14). However, in the previously cited study, the cost was estimated only in the last stages of the disease (C5 and C6), indicating that the value might be even greater. Thereby, novel and low-cost interventions for preventing, controlling and reducing symptoms of CVD need to be developed.

Although there are several treatment options, maintaining healthy lower limbs is fundamental. The venous return depends on the muscle of the legs up to 90%, the gastrocnemius muscle only is responsible for approximately 65% of venous return, and thigh and foot have an important role on the system as well (15). Moreover, studies in the 90’s started to compare calf muscle pump function in healthy and individuals with CVD (16-18). Those studies showed that healthy individuals have better calf muscle pump function when compared to CVD patients. Thus, healthy gastrocnemius muscle pump might compensate valve incompetence of the vein that maintain or offset CVD symptoms (19), which affect health-related quality of life (20).

Questionnaires were developed to verify the quality of life in patients with CVD. The VEINES questionnaire (21) and the Aberdeen Varicose Vein Questionnaire

(AVVQ) (22,23) are frequently used in studies with CVD patients. However, the AVVQ seems to present an advantage when measuring the burden of CVD, since it divides the burden of disease into five domains, such as pain and dysfunction, aesthetic, extent of varicosities, complications, and overall. Thereby, due to its capacity of enhancing characteristic information of the patients' quality of life concomitant with the burden of disease, the AVVQ is frequently adopted in CVD studies. The questionnaire is composed of pain dysfunction, aesthetic, varicose vein extension, and complication domains that describe the main characteristics of the disease (22).

Importantly, studies have shown that patients with symptoms of CVD might present lower scores of quality of life (24,25) as well as lower functional fitness (26,27). Lima-Junior et al. (2018) observed physical and global domains of quality of life in CVD patients are related to functional fitness. The physical domain presented relationship with chair stand (r = 0,46), arm curl (r = 0,39), and 6-min walk (r = 0,45) as well as the global domain was related to chair stand (r = 0,36). However, psychological, social, and environment domains presented no relationships with any of the investigated functional fitness conditions (chair stand, arm curl, 6-min walk, back scratch, sit-and-reach, up-and-go). Additionally, it is important to highlight the questionnaire used in the study was the WHOQOL-brief, which is not a specific questionnaire for the CVD population. Thus, the AVVQ appears as an interesting tool to evaluate and observe its relations with functional fitness. Thereby, it is important to investigate possible strategies to improve or offset the decrement of quality of life in a disease that impairs people worldwide.

Additionally, in a recent epidemiological study (28), it was found that people who were engaged in physical activity presented slight symptoms of CVD when compared to the inactive ones. Also, van Uden et al. [26] compared walking speed and calf endurance in healthy and patients with active or healed ulcers (C5 and C6). It was observed differences for the preferred walking speed and number of heel rises. However, no difference was observed when subjects performed instructed walking. In another study conducted by Roaldsen et al. [29], differences were observed between healthy and leg ulcer women in the last stages of the disease (C5 and C6) for the ankle range of motion, plantar flexion, dorsiflexion, preferred walking speed, and walking endurance. Healthy patients presented better scores when compared to leg ulcers patients in all measurements. Moreover, Moura et al. [27] observed that healthy patients had a greater gait speed when compared to patients between levels C4 and

C6 of the disease. Furthermore, plantar flexion was performed in an isokinetic dynamometer. The test yielded different values of peak torque and power between healthy and CVD patients. Also, ankle range of motion was greater in healthy patients for plantar flexion and dorsiflexion. Nevertheless, most of the studies only evaluate patients in the last stages of the disease. Only one study has verified the functional fitness throughout the disease's levels performing the heel-rise test. Pieper et al. [30] verified that as long as the level of CVD increases, the lesser is the score in the heel-rise test. However, all the patients in the study are drug users and might acquire the disease by the constant injections of drugs in the vein.

Accordingly, it is common to observe the benefits of improving functional fitness in diseases like hypertension (31), diabetes (32), osteoporosis (33) and Alzheimer's (34). However, the relationship between functional fitness parameters, such as endurance, strength, flexibility, and balance and agility with quality of life and burden of disease in patients with CVD are not clear in the literature. Additionally, the calf muscles are fundamental to the pathophysiology of CVD (15). Thereby, the heel-rise test, a test that measures the calf muscles endurance specifically, might help to understand the effect of calf endurance on the disease. Noteworthy, the Senior Fitness test and the heel-rise test are a valid instrument to measure functional fitness (35,36) and presents a good insertion in the literature. Thus, functional fitness might represent a low-cost and effective way to improve or at least offset the burden of disease and improve quality of life in patients with CVD and studies that might point out the way to treat the disease must be developed.

Therefore, the functional fitness and the calf muscles in patients with CVD presents itself as one of the pathways to maintain a healthy venous system, or even in some cases, to control and reduce the severity of the disease. Since most of the studies only compare healthy with CVD patients in the last stages of the disease (CVI), the impairment caused in other stages of the disease and the effect of functional fitness, in general, remain elusive. The previous study that analyzed the relationship between quality of life and functional fitness (25) used a questionnaire that is not specific for the population and presented no adjustments for the analysis, due to the low number of participants. Hence, more studies are needed to verify the effect of functional fitness on healthy-related quality of life and the burden of disease in CVD patients.

1.1 OBJECTIVE

the aim of the study was to verify the relationship between quality of life and burden of disease with functional fitness in women with CVD.

1.2 HYPOTHESIS

Our hypothesis was the functional fitness of CVD women is related with quality of life

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2 CHAPTER II - RELATIONSHIP BETWEEN HEALTH-RELATED QUALITY OF LIFE AND BURDEN OF DISEASE WITH FUNCTIONAL FITNESS IN WOMEN WITH CHRONIC VENOUS DISEASE: A CROSS-SECTIONAL STUDY

2.1 INTRODUCTION

Chronic venous disease (CVD) is defined as a visual and functional manifestation of abnormalities in peripheral venous system that either present or not symptoms; also, it might cause changes in superficial and deep veins [1]. In fact, approximately 60% of the worldwide adult population present any level of CVD; however, those values might reach 80% in industrialized countries [2]. Moreover, despite CVD affects both men and women, due to pregnancy, women are more susceptible to the disease, leading that population to present higher prevalence and incidence of the disease [2-5]. Additionally, CVD patients are susceptible to thromboembolic events that may lead to pulmonary embolism and post-thrombotic syndrome that might cause death [6]. Thus, CVD might affect negatively several characteristics of patients, such as quality of life and level of physical activity.

Quality of life is an important health indicator, especially in chronic diseases. The Aberdeen Varicose Vein Questionnaire (AVVQ) is commonly used to verify the burden of CVD and quality of life of the patients with the disease [7,8]. Importantly, studies have shown that patients with symptoms of CVD might present lower scores of quality of life [9,10] as well as lower functional fitness [11,12]. Lima-Junior et al. [10] observed functional fitness is related to the physical and global domains of quality of life in CVD patients. The physical domain presented relationship with chair stand (r = 0,46), arm curl (r = 0,39), and 6-min walk (r = 0,45) as well as the global domain was related to chair stand (r = 0,36). However, psychological, social, and environment domains presented no relationships with any of the investigated functional fitness conditions (chair stand, arm curl, 6-min walk, back scratch, sit-and-reach, up-and-go). Additionally, it is important to highlight the questionnaire used in the study of Lima-Junior et al. [10] was the World Health Organization Quality of Life-BREF [13], which is not a specific questionnaire for the CVD population. Thus, the AVVQ appears as an interesting tool to evaluate and observe its relationship with functional fitness. Thereby, it is important to investigate possible strategies to improve or offset the decrement of

quality of life and CVD symptoms in a disease that impairs people worldwide.

In fact, CVD cause impairments in functional fitness. Firstly, in a study conducted by van Uden et al. [11], it was compared preferred and instructed walking speed and calf muscle endurance in healthy and CVD patients. It was found differences in preferred walking speed and calf muscle endurance but not in instructed walking speed. Subsequently, Roaldsen et al. [14] observed differences between healthy and healed and active ulcerations (C5 and C6) woman. The study analyzed functional fitness using the ankle range of motion for plantar flexion and dorsiflexion, preferred walking speed, walking endurance, and physical activity reported by questionnaire were measured. Healthy subjects presented better scores when compared to leg ulcers patients in all measurements, indicating functional impairment caused by CVD. In another study carried out by Moura et al. [12], it was observed that healthy patients had a greater gait speed when compared to patients with CVD. Furthermore, plantar flexion and dorsiflexion were performed in an isokinetic dynamometer. The test yielded different values of peak torque and power between healthy and CVD patients. Also, ankle range of motion was greater in healthy patients.

Moreover, only one study has verified the functional fitness throughout the disease utilizing the heel-rise test. Pieper et al. [15], verified that as long as the level of CVD increases, the lesser is the score in the heel-rise test. However, only calf endurance, and in some cases ankle flexibility, has been investigated and several functional fitness parameters and its relationship with CVD remains unknown. In addition, a complete evaluation of the functional status with a global score and a more robust analysis that allows adjustments in the relationships between physical and health variables in CVD patients lack in the literature. Previous studies have shown patients with CVD present a lower quality of life when compared with the healthy ones, and only one study investigated the effect of functional fitness on quality of life. Nevertheless, none of the previous studies used a specific questionnaire for the CVD population. Also, AVVQ measures the burden of the disease, not only quality of life, it permits a broader analysis of the intervention effects. Thereby, the aim of the study was to verify the relationship between quality of life and burden of disease with functional fitness in women with CVD.

2.2 METHODS

2.2.1 Study design

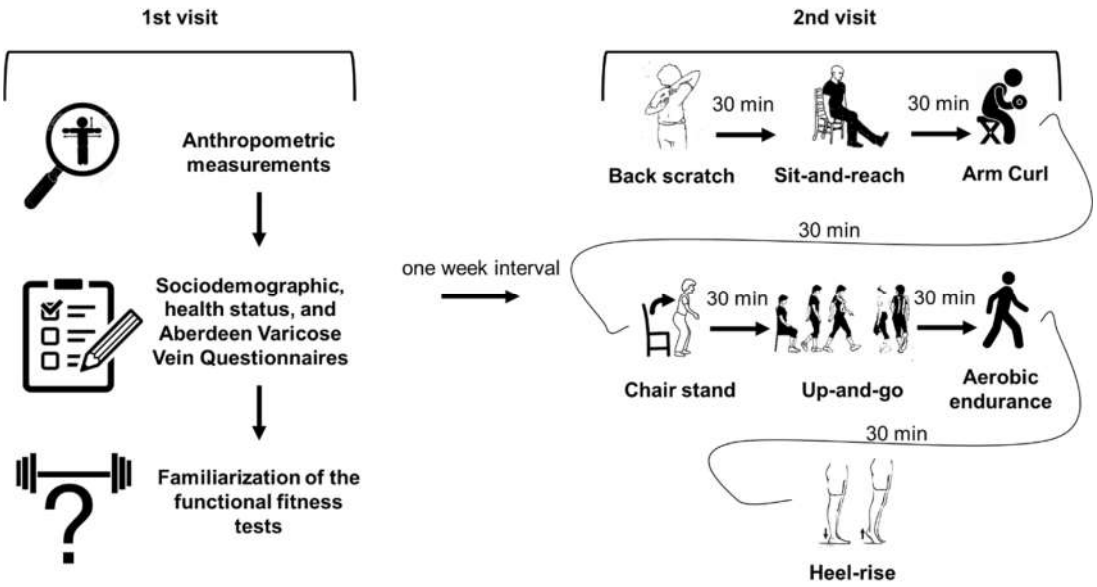
This is a cross-sectional study. The independent variable is functional fitness and as dependent variables, we analyzed quality of life and burden of disease through the Aberdeen Varicose Veins Questionnaire score.

2.2.2 Settings

Patients visited the laboratory twice with at least one week between the two visits. Following recruitment, the patients responded to the AVVQ and a sociodemographic questionnaire. Afterward, we performed the anthropometric measurements and led the patients to the familiarization of the functional fitness battery and the heel-rise tests [16,17]. In the second visit, the patients performed the tests comprised by the 6-minute walk test, chair stand, arm curl, sit-and-reach, back scratch, up-and-go, and heel-rise. Before the tests, a warm-up was performed.

Before the battery of tests, a warm-up was performed. The warm-up consisted of five minutes of marching and swinging arms and was performed before the first test, only. The order of the tests was back scratch (upper-body flexibility), sit-and-reach (lower-body flexibility), arm curl (upper-body strength), chair stand (lower-body strength), up-and-go (agility and dynamic balance), 6-minute walk test (aerobic endurance), and heel-rise (calf endurance). Before each test a brief familiarization was performed to ensure the participants remind the last week familiarization session. Between each test an interval of 30 minutes was given to avoid any detrimental effect (Figure 1). This study was approved by the Ethical Committee in Research of the Federal University of Pernambuco (CAAE: 81178117.8.0000.5208) and was performed according to the Helsinki Declaration.

Figure1 - Study design



Fonte: Author creation

2.2.3 Participants

Women that present symptoms of CVD composed the study. We recruited the patients using the nonprobability convenience sampling technique. The recruitment happened through advertisement, such as bulletin boards, folders fixed nearby and inside the Federal University of Pernambuco, social media, and word of mouth.

As inclusion criteria, the patients had to be women, aged above 40 years old, and non-diabetic. Also, they could not present mental diseases, vascular surgery in the last 6 years, use of any beta-blocker (due to effects on endurance performance), and cardiovascular diseases but hypertension (due to the high prevalence of hypertension in the CVD population). The researchers excluded the patients if they missed any assessment. Before data collecting, all patients were aware of all the procedures and signed in the written informed consent.

2.2.4 Outcomes

2.2.4.1 Aberdeen Varicose Vein Questionnaire (AVVQ). The patients completed the questionnaire composed of 13 questions addressing several characteristics of people with CVD including symptoms, biopsychosocial attributes, daily impact of the disease, and the use of compression stockings. The questionnaire is divided in four domains: pain and dysfunction, aesthetic, extent of varicosities, complications, and overall. The score of the test ranges from 0 to 100, higher scores indicate a greater

burden of the disease. The AVVQ was validated [8], translated, and culturally adapted to the Brazilian Portuguese [18]. The questionnaire was applied in a quiet environment with only the researcher and the patient to avoid any uncomfortable situation.

2.2.5 Predictors

2.2.5.1 Back scratch. To assess upper-body flexibility, the back scratch test was carried out. The test is a valid lower-body flexibility test [16]. The participant remained stood up and put the hand over the same shoulder with the palm down and fingers extended, reaching out the middle of the back as far as possible. The other arm was placed around the back of the waist with the palm up and reaching up the middle of the back as far as possible trying to touch or overlap the other hand. The maximum distance position was held for at least two seconds. The score was the distance (cm) from the middle fingers' tip of one hand to another. It was given a minus score if the fingers did not touch; zero if the fingers barely touched; and positive score if the fingers were overlapped. The test was slowly demonstrated to the patient to ensure high quality of the movement.

2.2.5.2 Sit-and-reach. To assess lower-body flexibility, the sit-and-reach test was carried out. The test is a valid lower-body flexibility test [16]. The test consisted of reaching out or past the toes with the middle fingers seated on the edge of a 43cm chair. The buttocks must be even with the front edge of the chair, the non-dominant leg slightly bent and with the foot flat on the floor. The dominant one was straight with the heel on the floor and the foot flexed at 90º. Using the arms stretched, hands overlapping, and middle fingers even the patient bent forward reaching out as far as possible or past the toes. The maximum distance position was held for at least two seconds. The score was the distance (cm) from the middle fingers' tips to the toes; if the middle fingers touched the toes, the score was zero; if the middle fingers past the toes, the distance between the tips of the middle fingers and the toes was the positive score; if the patient did not touch reach the toe, the distance from the tips of the middle fingers to the toes was the negative score. The test was slowly demonstrated to the patient to ensure the high quality of the movement.

2.2.5.3 Arm Curl. To assess upper-body strength, the arm curl test was carried out. The test is a valid upper-body strength test [16]. The test consisted of 30-seconds of consecutive arm curls in the seated position with the dominant side of the body on the edge of the chair. From the down position, initially with flat arms and neutral grip, the elbow bent and the weight was curled up with the palm gradually rotating to the

supine position as the flexion is completed, following, the arm returned to the initial position. After the “Go!” signal the patient performed as many as possible elbow flexions during 30-seconds. All patients were informed the upper arm should remain still throughout the test. The score was the total number of full motion elbow curl during 30-seconds. The test was slowly demonstrated to the patient to ensure the high quality of the movement.

2.2.5.4 Chair stand. To assess lower-body strength, chair stand test was carried out. The test is a valid lower-body strength test [16]. The test consisted of 30-seconds of consecutive rises and returns to the seated position. In an approximately 43cm chair placed against a wall, the patient started off the test seated in the chair with the arms crossed at the wrists and held against the chest and the back straight. Following the “go!” signal the patient rose to a full stand position and returned to a full seated position. We encouraged the patient to perform as many as full stands were possible for 30 seconds. The score was the number of full stands performed in 30s. The test was slowly demonstrated to the patient to ensure a high quality of the movement.

2.2.5.5 Up-and-go. To assess agility and dynamic balance, the up-and-go test was performed. The test is a valid agility and dynamic balance test (Rikli & Jones, 1999). A chair was placed against a wall facing a cone at 2.4 meters of distance. The patient was instructed to sit in the chair with back straight, hands on the thigh, and feet on the ground. Following the “Go!” signal, the patient got up from the chair, walked as quickly as possible around either side of the cone, and sat back in the chair. The score was the time spent between the “Go!” signal and the patient sit back in the chair to the nearest tenth of a second. The test was slowly demonstrated to the patient to ensure the high quality of the movement.

2.2.5.6 6-minute walk test. To assess aerobic endurance, the 6-minute walk test was carried out. The test is a valid endurance test [16]. The test consisted of walking the maximum distance in six minutes in a 50 meters’ rectangular course. The insider perimeters were marked with cones and every five meters of the course was marked with tapes. The test was performed indoors in a lit area. To keep the track of the walked distance at each lap, the participant informed the number of the current lap to the evaluator. The test initiated at the signal “go”, the researchers instructed the patients to walk as fast as possible (without running) around the rectangle as many times as possible until the 6 minutes is over (measured by a stopwatch). If necessary, the patient might stop and rest in a chair, but the time was running still. The researcher in

charge of the time was inside of the rectangle area after the test started off. To assist with pacing, the elapsed time was called out at each minute. Encouragement phrases as “keep it up!” and “you are doing it really well, let’s go” were utilized all along with the test. At the end of it, participants stopped walking and started marching slowly without moving forward (to avoid any harmful effect of abruptly stopping) until the measurements of the walked distance were made. The score of the test was the total distance (m) performed during the six minutes. The test was slowly demonstrated to the patient to ensure a high quality of the movement.

2.2.5.7 Heel-rise test. To assess specifically calf muscle endurance, the heel-rise test was performed. This protocol was validated and presents good reliability [17]. Both legs were assessed at the same time by the heel-rise test. Prior to the test, a warm-up was performed, consisting of 10 minutes of light to moderate walking and 10 bilateral heel-rises repetitions. The researchers instructed the patients to stand in an upright position, barefoot, and with the balls of the foot on a 10º wedge. The test consisted of touching the heel on the floor and raise them as many times and high as possible until no further repetitions were performed or at least 70% of the maximum angle was not reached. During the test, the patients were allowed to do fingertip support, at the shoulder height, on the wall in front of them to keep balance. Cadence was controlled by a metronome with cycles at 60 per minute keeping the whole body straight. The total number of repetitions and time were recorded. All the participants were given verbal encouragement and posture corrections during the test. In case the participant can no longer maintain the posture, perform a complete heel-rise cycle, lose the pace, or assist performance in any way but the fingerprint on the wall the test will be ceased. At the first visit, an individualized familiarization was performed, so the evaluator provided the corrective feedback to avoid errors during measurement.

2.2.5.8 Global functional score. The scores of the functional fitness tests (back scratch, sit-and-reach, arm curl, chair stand, up-and-go, 6-minute walk, heel-rise) were transformed in Z scores and summed up. It is noteworthy, up-and-go scores had their positive signals converted to negative and vice-versa, since its scores were time and the less the better, they could converge with the other tests.

2.2.6 Potential confounders

2.2.6.1 Anthropometric measurements. We measured body weight and height using an electronic scale with an accuracy of 0,1kg and stadiometer with an accuracy of 0,1cm (Filizola, Brazil). Body mass index was calculated by the formula weight

(kg)/height $(m)^2$.

2.2.6.2 Clinical, etiology, anatomic, pathophysiology (CEAP) criteria. Severity of the disease was also obtained by the CEAP criteria. A trained physiotherapist carried out the CEAP classification. It is composed of seven levels corresponding to C0, no visible or palpable signs of venous disease; C1, telangiectasies or reticular veins; C2, varicose veins, distinguished from reticular veins by a diameter of 3mm or more; C3, edema; C4a, pigmentation or eczema; C4b, lipodermatosclerosis or atrophie blanche; C5, healed venous ulcers; C6, active venous ulcer [19]. It is noteworthy, patients ranged from C5 to C6 stages correspond only to 1% [2], thus, none of them could be recruited. In addition, patients from C0 to C1 are challenging to recruit because they lack signs and symptoms. Since the prevalence of patients in the C2 and C4 levels are higher [2], only patients ranged from C2 to C4 were volunteered in the study.

2.2.6.3 Sociodemographic and health status. Sociodemographic characteristics and health status were collected using a questionnaire. The patients should respond questions about their age, sex, marital status, education, and economic status. In addition, they were asked about diseases, symptoms, smoking status, and medicine taken.

2.3 STATISTICAL ANALYSIS

Initially, an exploratory analysis was performed to describe the characteristics of the variables and its distribution. The relationship between functional fitness and AVVQ domains were assessed by multiple regression. Normality and homoscedasticity of the residual analysis were analyzed by graphics as well as multicollinearity by the variance inflation factor (<5) and tolerance (>0.2) were verified. Standard residuals were above negative two and below positive two. The regression modeling was assessed in two steps; first, the crude analysis and second adjusted by age, body mass index, and monthly income. The model variables were chosen according to a previous study [2] or when added in the model the beta value changed at least 15%. All data were analyzed by the program Statistical Package for the Social Science (SPSS) version 23.0 for Windows and the alpha value adopted was 5%.

2.4 RESULTS

2.4.1 Participants

Sample size calculation was performed by G*Power 3.1.9.2 that yielded a number of 45 participants adopting an effect size of 0,3[10], power of 80%, alpha of 5%, and four independent variables. A total of 54 participants were recruited (20%

above the G*Power calculus), seven missed the second visit and 47 of them completed the study.

2.4.2 Sociodemographic and health status

For social relationships and demographic characteristics, the participants (age 62.65 ± 8.3 years old; height 1.53 ± 0.1 meters; weight 69.55 ± 14.4) reported, education (10.4 ± 3.2 years), marital status (single, married, divorced, widowed), and monthly income (411.94 ± 282.28 U.S. dollar).Health information as obesity (35.4%), dyslipidemia (61.1%), smoking status (1.9%), hypertension (27.7%), body mass index (28.86± 6.9), CEAP criteria (C2-C4, due to recruitment restrictions), and medicines (Indian horse-chestnut 83.3%; angiotensin receptor antagonist 25.9%; statin 11.1%; metformin 7.4%) were collected (Table 1).

Table1 - General characteristics of the participants in the study.

Variables	**Values**
Age (years)	62.65 ± 8.3
Height (m)	1.53 ± 0.1
Weight (kg)	69.55 ± 14.4
Body mass index (kg/m²)	28.86± 6.9
Obesity (%)	35.4
Dyslipidemia (%)	61.1
Smoking (%)	1.9
Hypertension (%)	27.7
Education (years)	10.4 ± 3.2
Monthly income (Minimum wage)	1.75 ± 1.2
Marital Status (%)	
Single	15.4
Married	42.3
Divorced	9.6
Widowed	32.7
CEAP criteria	
C2	29.2
C3	35.4
C4	30.8
Medicine for varicosities(%)	
Indian horse-chestnut	83.3
Other medicines (%)	
Angiotensin receptor antagonist	25.9
Statin	11.1
Metformin	7.4

Data presented as mean and standard deviation or relative frequency. CEAP = clinical, etiology, anatomic, pathophysiology.

2.4.3 Endurance

The crude and adjusted relationship between quality of life and burden of disease scores with aerobic and calf endurance in women with CVD are presented in table 2. In the crude analysis no significant relationship was found ($p > 0.05$) for any endurance test. Nevertheless, a relationship was found between pain and dysfunction and aerobic endurance in adjusted model ($\beta = -0.330$, $p = 0.032$). The same occurred between pain and dysfunction and calf endurance in adjusted model ($\beta = -0.550$, $p = 0.002$). According the aesthetic, extent of varicosities, complications, and overall domains no relationship was found even after adjustments ($p > 0.05$) for any endurance test.

Table2 - Crude and adjusted regression analysis of the relationship between quality of life and burden of disease scores and Aerobic and calf endurance in CVD women.

Dependent variables	**Models**	**β (SE)**	**B**	**r^2**	**p**
Aerobic endurance					
Pain and dysfunction	Crude	-0.010 (0.007)	-0.226	0.030	0.127
	Adjusted	-0.015 (0.007)	-0.330	0.175	0.032
Aesthetic	Crude	-0.001 (0.007)	0.001	-0.022	0.995
	Adjusted	-0.003 (0.007)	-0.075	0.059	0.637
Extent of varicosities	Crude	-0.019 (0.010)	-0.286	0.060	0.057
	Adjusted	-0.016 (0.009)	-0.265	0.140	0.086
Complications	Crude	-0.012 (0.018)	-0.103	-0.012	0.502
	Adjusted	-0.011 (0.021)	-0.092	-0.004	0.593
Overall	Crude	-0.050 (0.029)	-0.257	0.043	0.096
	Adjusted	-0.052 (0.031)	-0.260	0.167	0.100
Calf endurance					
Pain and dysfunction	Crude	-0.012 (0.031)	-0.059	-0.019	0.693
	Adjusted	-0.138 (0.040)	-0.550	0.290	0.002
Aesthetic	Crude	-0.012 (0.031)	-0.060	-0.019	0.687
	Adjusted	-0.005 (0.047)	-0.020	0.054	0.914
Extent of varicosities	Crude	-0.003 (0.045)	-0.011	-0.023	0.945
	Adjusted	-0.038 (0.061)	-0.114	0.074	0.534
Complications	Crude	-0.046 (0.078)	-0.090	-0.015	0.556
	Adjusted	-0.113 (0.127)	-0.173	0.010	0.380
Overall	Crude	-0.051 (0.123)	-0.064	-0.020	0.681
	Adjusted	-0.238 (0.182)	-0.234	0.140	0.200

β (SE) = regression coefficient (standard error); B = standardized regression; r^2 = adjusted coefficient of determination. Adjusted - adjusted for age, body mass index, and monthly income. n = 47; p=??

2.4.4 Strength

The crude and adjusted relationship between quality of life and burden of disease scores and lower-body strength in women with CVD are presented in table 3. In the crude analysis, a relationship was found between pain dysfunction with the lower-body (β = -0.410, *p* = 0.004) and upper-body (β = -0.439, *p* = 0.002) strength. Even following adjusted model, pain and dysfunction remained related to lower-body (β = -0.555, *p* = 0.001) and upper-body (β = -0.496, *p* = 0.001) strength. In regard to aesthetic and the extent of varicosities, the crude and adjusted analyses were not related to lower and upper-body strength (*p*> 0.05). On the other hand, the complications domain was related to the lower-body strength in the crude analysis (β = -0.301, *p* = 0.045). However, in the adjusted model (β = -0.293, *p* = 0.067) the significance was gone. For the overall domain, lower- and upper-body strength presented relationship in the crude (β = -0.321, *p* = 0.036; β = -0.336, *p* = 0.028, respectively) and adjusted (β = -0.334, *p* = 0.029; β = -0.403, *p* = 0.008, respectively) models.

Table3 - Crude and adjusted regression analysis of the relationship between quality of life and burden of disease scores and lower- and upper-body strength in CVD women.

Dependent variables	Models	β (SE)	B	r^2	p
Lower-body strength					
Pain and dysfunction	Crude	-0.425 (0.141)	-0.410	0.149	0.004
	Adjusted	-0.577 (0.127)	-0.555	0.400	0.001
Aesthetic	Crude	-0.049 (0.153)	-0.048	-0.020	0.749
	Adjusted	0.004 (0.160)	0.004	0.054	0.978
Extent of varicosities	Crude	0.036 (0.219)	0.025	-0.023	0.869
	Adjusted	0.001 (0.210)	0.001	0.063	0.999
Complications	Crude	-0.773 (0.373)	-0.301	0.069	0.045
	Adjusted	-0.795 (0.421)	-0.293	0.081	0.067
Overall	Crude	-1.238 (0.571)	-0.321	0.081	0.036
	Adjusted	-1.359 (0.593)	-0.334	0.219	0.029
Upper-body strength					
Pain and dysfunction	Crude	-0.278 (0.085)	-0.439	0.175	0.002
	Adjusted	-0.305 (0.080)	-0.496	0.327	0.001
Aesthetic	Crude	-0.076 (0.093)	-0.121	-0.007	0.416
	Adjusted	-0.120 (0.094)	-0.193	0.094	0.210
Extent of varicosities	Crude	-0.016 (0.132)	-0.019	-0.023	0.983
	Adjusted	-0.048 (0.124)	-0.060	0.067	0.704
Complications	Crude	-0.419 (0.231)	-0.267	0.050	0.076
	Adjusted	-0.500 (0.249)	-0.311	0.092	0.053
Overall	Crude	-0.781 (0.342)	-0.336	0.091	0.028
	Adjusted	-0.955 (0.339)	-0.403	0.271	0.008

β (SE) = regression coefficient (standard error); B = standardized regression; r2 = adjusted coefficient of determination. Adjusted - adjusted for age, body mass index, and monthly income. n = 47 p=??

2.4.5 Flexibility and agility and dynamic balance

The crude and adjusted relationship between quality of life and burden of disease scores and lower-body flexibility in women with CVD presented no relationship with any domain even after adjustments (p> 0.05).

The crude and adjusted relationship between quality of life and burden of disease scores and upper-body flexibility in women with CVD are presented in table 4. In the crude (β = -0.433, p= 0.002), and adjusted (β = -0.439, p= 0.003) models significant relationships were found between pain and dysfunction and the upper-body flexibility. However, no significant relationships were found between upper-body flexibility and aesthetic, extent of varicosities, complications, and overall domains. For the agility and dynamic balance, in the crude analysis, no significant relationship was found (p=>0.05). However, the adjusted model (β = 0.395, p= 0.018) presented a relationship with pain and dysfunction domain. In regard to aesthetic, extent of varicosities, and complication domains no relationship was found (p> 0.05). For the overall domain, no significant relationship was found in the crude analysis (p> 0.05). However, the adjusted model (β = 0.410, p= 0.015) showed significant relationship between the overall domain and agility and dynamic balance.

Table4 - Crude and adjusted regression analysis of the association between quality of life and burden of disease scores and upper-body flexibility and agility and dynamic balance in CVD women.

Dependent variables	Models	β (SE)	B	r^2	p
Upper-body flexibility					
Pain and dysfunction	Crude	-0.163 (0.051)	-0.433	0.170	0.002
	Adjusted	-0.157 (0.049)	-0.439	0.266	0.003
Aesthetic	Crude	-0.043 (0.055)	-0.115	-0.009	0.443
	Adjusted	-0.048 (0.056)	0.133	0.072	0.397
Extent of varicosities	Crude	-0.121 (0.081)	-0.222	0.027	0.142
	Adjusted	-0.075 (0.075)	-0.155	0.089	0.324
Complications	Crude	-0.158 (0.140)	-0.170	0.006	0.265
	Adjusted	-0.118 (0.153)	-0.128	0.005	0.445
Overall	Crude	-0.418 (0.219)	-0.286	0.059	0.063
	Adjusted	-0.288 (0.227)	-0.198	0.137	0.213
Agility and dynamic balance					
Pain and dysfunction	Crude	0.543 (0.407)	0.195	0.017	0.189
	Adjusted	1.051 (0.424)	0.395	0.198	0.018
Aesthetic	Crude	0.092 (0.410)	0.033	-0.021	0.823
	Adjusted	0.499 (0.455)	0.187	0.083	0.280
Extent of varicosities	Crude	0.669 (0.614)	0.164	0.004	0.282
	Adjusted	0.965 (0.599)	0.264	0.128	0.116
Complications	Crude	1.058 (1.185)	0.135	-0.005	0.377
	Adjusted	2.254 (1.461)	0.285	0.052	0.132
Overall	Crude	2.568 (1.970)	0.200	0.016	0.200
	Adjusted	5.311 (2.073)	0.410	0.245	0.015

β (SE) = regression coefficient (standard error); B = standardized regression; r2 = adjusted coefficient of determination. Adjusted - adjusted for age, body mass index, and monthly income. n = 47 p=??

2.4.5 Global functional fitness score

The crude and adjusted relationships between quality of life and burden of disease scores and global functional fitness score in women with CVD are presented in table 5. In the crude analysis, a significant relationship was found between pain and dysfunction and the global functional fitness score (β = -0.400, *p*= 0.005). The results were similar for the adjusted model (β = -0.571, *p*= 0.001). In regard to aesthetic, extent of varicosities, and complication domains no relationship was found (*p*> 0.05). For the overall domain, a significant relationship was found for the crude (β = -0.341, *p*= 0.025) and adjusted (β = -0.390, *p*= 0.011) analyses.

Table5 - Crude and adjusted regression analysis of the association between quality of life and burden of disease scores and global functional fitness in CVD women.

Dependent variables	Models	β (SE)	B	r^2	p
Global functional fitness score					
Pain and dysfunction	Crude	-0.257 (0.088)	-0.400	0.141	0.005
	Adjusted	-0.362 (0.081)	-0.571	0.393	0.001
Aesthetic	Crude	-0.024 (0.095)	-0.038	-0.021	0.802
	Adjusted	-0.049 (0.101)	-0.076	0.060	0.634
Extent of varicosities	Crude	-0.155 (0.140)	-0.166	-0.005	0.276
	Adjusted	-0.189 (0.133)	-0.218	0.114	0.163
Complications	Crude	-0.390 (0.243)	-0.237	0.034	0.116
	Adjusted	-0.451 (0.283)	-0.263	-0.033	0.119
Overall	Crude	-0.892 (0.384)	-0.341	0.095	0.025
	Adjusted	-1.070 (0.395)	-0.390	0.260	0.011

β (SE) = regression coefficient (standard error); B = standardized regression; r2 = adjusted coefficient of determination. Adjusted - adjusted for age, body mass index, and monthly income. n = 47 p=??

2.5 DISCUSSION

This is the first study that analyzed the relationship between quality of life and burden of disease (i.e., pain and dysfunction, aesthetic, extent varicosities, complications, and overall domains) and functional fitness parameters (i.e., flexibility, aerobic and calf endurance, strength and agility and dynamic balance) in patients with CVD. The main findings indicate that pain and dysfunction domain was not related to aerobic and calf endurance in the crude analysis. However, after adjustments a relationship was found. Strength related to the pain and dysfunction and overall domains in the both, crude and adjusted model. even after adjustments. However, for the complications domain, only the lower-body strength presented a relationship in the crude analysis and lost it following adjustments. For lower-body flexibility, no relationship was found for any quality of life and burden of disease domain. All domains of the quality of life and burden of disease were related to the upper-body flexibility independently the models. And finally, agility and dynamic balance presented relationship with pain and dysfunction and overall domain in the adjusted model, only.

It is notable, the literature lacks studies about functional fitness, quality of life, and burden of disease in CVD patients. Thereby, some studies that might corroborate or contradict our results, at least in some degree, were brought up in this session. Aerobic and calf endurance related to pain and dysfunction domain even after adjustments for age, body mass index, and monthly income. It is widely known that CVD affects mainly the lower-body [2] and comprehend how it affect lower-body physically is crucial. Our results corroborate with a previous study [10] that found the patients with greater aerobic endurance presented higher quality of life, specifically in the physical domain. However, our findings indicate a relationship only after adjustments. Moreover, our study was conducted in a developing country where low-income people regularly use public transportation and walk long distances, which might influence walking capacity and endurance. Aerobic and calf endurance presented no relationship with the aesthetic, extent of varicosities, complications and overall domains, which might indicate endurance affects specifically the pain symptom. Thus, an increase in the calf pump function due to walking movement might offset the accumulative blood in the leg veins, increasing venous return and reducing the pain sensation [2, 20]. However, in this study, we did not measure the calf muscle pump.

Strength related to pain and dysfunction and overall domains, the results remained significant even after adjustments. Our study presented similar results to a

previous study [10]; however, the questionnaire adopted in the current study is specific for CVD patients as well as only the physical domain presented a relationship to the lower-body strength. In addition, studies have shown patients with CVD present lower scores of lower-body strength than the healthy ones [12]. Although the lower part of the body is the most affected by the disease, increase of strength in the upper-body improves the cardiovascular system and is associated to arterial stiffness and mortality [21, 22], but its effect on quality of life and burden of disease remains unclear. In addition, strength presented no relationship with the aesthetic and extent of varicosities domains. That is, an improved functional fitness affects quality of life and burden of disease only via the pain and dysfunction and other strategies must be investigated to improve the other domains.

Flexibility related to pain and dysfunction domain in the crude and after adjustments analysis only for the upper-body. Differently, Lima-Junior et al. [10] found no relationship between upper-body flexibility and quality of life. It might have happened due to the specific characteristics of the questionnaire used in our study that focus on CVD symptoms. Although the lack of studies reduces our postulate capacity, other vascular diseases have been improved following upper-body training, such as arm cycle ergometer [23], thus, it is possible that this type of physical activity improves CVD as well. For the lower-body flexibility, our results corroborate with a previous study that showed no relationship between lower-body flexibility and quality of life [10]. However, some studies have found patients with CVD present less flexibility in the ankle when compared to healthy ones, also, the most the burden of disease, the most the impairment of the ankle flexibility [12, 14]. It might have happened due to the specificity of the disease, that might affect mainly the ankle and since the test was developed for the whole limb the influence of the ankle impairment might fade.

Agility and dynamic balance related to pain and dysfunction and overall domains after adjustments. Our data diverges to a previous study, which found no relationship between agility and dynamic balance and quality of life [10]. Differently from the other types of activities analyzed in our study, agility and dynamic balance activity comprise cognitive function, neuromuscular capacity, and endurance [24], revealing the possible influence of a strategy that adds fitness and motor variables and not only strength or endurance. Although those factors play a main role in CVD [2], it is important to know if the effect of agility and dynamic balance training reduce CVD symptoms and future studies are required. For the aesthetic, extent of varicosities, and complications

domains no relationship was found.

Global functional fitness score related to pain and dysfunction and overall domains in the crude and adjusted analyses. It is noteworthy, the general score corroborates with Vuylstek et al. [25] and Lima-Junior et al., [10], indicating patients with high scores of functional fitness present lower scores of burden of disease and higher quality of life scores. Although, it is not possible to infer the effect of functional fitness on CVD patients, the relationship presented in our study encourages other researchers to investigate deeply those variables in others study designs.

This study presents some limitations. Only women were analyzed in our study, thus, inference to men is discouraged. Otherwise, women are the most affected by CVD, reinforcing the significance of the study. Moreover, this is a cross-sectional study that limits the interpretation and impairs causal inferences. Due to sample size, confounding variable were limited to three, constraining more adjustments. Also, the functional fitness tests orders were not randomized, although the time of 30min is enough to fade any fatigue in the patients. Analyses of reflux were not made; thus, physiological responses could not be observed. Thus, our results must be interpreted with caution.

3 CHAPTER III

3.1 CONCLUDING REMARKS

In conclusion, the results indicated functional fitness is related to the quality of life and burden of disease in women with CVD. It is noteworthy, the pain and dysfunction was the domain that related the most with the components of functional fitness, that is, women with higher scores in strength, flexibility, endurance, and agility and dynamic balance presented better scores related to pain. The questions that measured the pain and dysfunction domain were objectively about the time that the patients remained with pain as well as how much it impaired daily and leisure activities. Thereby, since our study has shown the relationship of functional fitness on women with CVD, mainly on the pain and dysfunction domain, future controlled and randomized studies should be performed to verify precisely the effect of functional fitness on quality of life and symptoms in CVD patients. The findings of future studies might elucidate the real effect of different types of exercise on CVD, offsetting or even reducing the symptoms.

4 CHAPTER IV
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APPENDIX A - INFORMED CONSENT

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

(PARA MAIORES DE 18 ANOS OU EMANCIPADOS - Resolução 466/12)

Convidamos o Sr. (a) para participar como voluntário (a) da pesquisa “ARQUITETURA MUSCULAR DO GASTROCNÊMIO, CAPACIDADE FUNCIONAL E PARÂMETROS VENOSOS EM MULHERES COM DOENÇA VENOSA CRÔNICA”, que está sob aresponsabilidade do (a) pesquisador (a) Dalton Roberto Alves Araujo de Lima Junior, Av. Prof. Moraes Rego, s/n, Cidade Universitária, Recife-PE, CEP: 50670-901, Departamento de Educação Física telefone: (81)99696-3352. Também participam desta pesquisa a pesquisadora: Daniela Karina da Silva Ferreira. Telefones para contato: (81)21268506. e-mail limajunior.dalton@gmail.com.

Caso este Termo de Consentimento contenha informações que não lhe sejam compreensíveis, as dúvidas podem ser tiradas com a pessoa que está lhe entrevistando e apenas ao final, quando todos os esclarecimentos forem dados, caso concorde com a realização do estudo pedimos que rubrique as folhas e assine ao final deste documento, que está em duas vias, uma via lhe será entregue e a outra ficará com o pesquisador responsável. Caso não concorde não haverá penalização, bem como será possível retirar o consentimento a qualquer momento, também sem qualquer penalidade.

O projeto tem como objetivo investigar o funcionamento do músculo da panturrilha e suas relações com as varizes, assim como as diferenças funcionais e estruturais do músculo da panturrilha em indivíduos saudáveis e doentes. O senhor(a) será submetido(a) a um teste de capacidade de caminhada e resistência muscular da panturrilha, além de medidas musculares e venosas no ultrassom. Todos os procedimentos serão realizados no Departamento de Educação Física da UFPE. O projeto é composto por apenas 2 visitas. Os riscos para a realização dessa pesquisa podem ser ocasionados pelo fato do senhor(a) sentir desconfortado ou ter constrangimento durante as mensurações antropométricas, ultrassom e durante os protocolos de avaliação que terá o acompanhamento de profissionais de saúde capacitados. Sua participação leva a riscos de lesões ostemioarticulares, mas se

realizadas da forma correta e sob supervisão as chances de lesão serão minimizadas. Além de possíveis efeitos colaterais durante as avaliações como: sensação de queimor ou desconforto nas pernas e falta de ar devido a intensidade da atividade física. Quanto aos benefícios o senhor(a) poderá conhecer o seu tipo físico bem como verificar a sua associação com os principais indicadores de saúde. Além do mapeamento das veias da perna e do músculo da panturrilha. Informamos que o senhor(a) terá toda a liberdade para recusar de participar ou retirar seu consentimento, em qualquer fase da pesquisa, sem penalidade alguma e sem prejuízo. Todas as informações desta pesquisa serão confidenciais e serão divulgadas apenas em eventos ou publicações científicas, não havendo identificação dos voluntários, a não ser entre os responsáveis pelo estudo, sendo assegurado o sigilo sobre a sua participação. Os dados coletados nesta pesquisa: nome, medidas antropométricas, capacidade de caminhada, resistência muscular da panturrilha e as medidas realizadas pelo ultrassom ficarão armazenados em pastas de arquivo e computador dos pesquisadores responsáveis, sob a responsabilidade de Dalton Roberto Alves Araujo de Lima Junior, no Endereço acima informado, pelo período de 5 anos. Nada lhe será pago e nem será cobrado para participar desta pesquisa, pois a aceitação é voluntária, mas fica também garantida a indenização em casos de danos, comprovadamente decorrentes da participação na pesquisa, conforme decisão judicial ou extrajudicial. Se houver necessidade, as despesas para a sua participação serão assumidas pelos pesquisadores (ressarcimento de transporte e alimentação). Em caso de dúvidas relacionadas aos aspectos éticos deste estudo, você poderá consultar o Comitê de Ética em Pesquisa Envolvendo Seres Humanos da UFPE no endereço:(Avenida da Engenharia s/n – 1º Andar, sala 4 - Cidade Universitária, Recife-PE, CEP: 50740- 600, Tel.: (81) 2126.8588 – e-mail: cepccs@ufpe.br).

_____

Assinatura do Pesquisador

CONSENTIMENTO DA PARTICIPAÇÃO DA PESSOA COMO VOLUNTÁRIO (A) Eu, _____,CPF_____, abaixo assinado,

após a leitura (ou a escuta da leitura) deste documento e de ter tido a oportunidade de conversar e ter esclarecido as minhas dúvidas com o pesquisador responsável, concordo em participar do estudo “ARQUITETURA MUSCULAR DO GASTROCNÊMIO, CAPACIDADE FUNCIONAL E PARÂMETROS VENOSOS EM MULHERES COM DOENÇA VENOSA CRÔNICA”, como voluntário(a). Fui devidamente informado(a) e esclarecido(a) pelo(a) pesquisador(a) sobre a pesquisa, os procedimentos nela envolvidos, assim como os possíveis riscos e benefícios decorrentes de minha participação. Foi-me garantido que posso retirar o meu consentimento a qualquer momento, sem que isto leve a qualquer penalidade ou interrupção de meu acompanhamento.

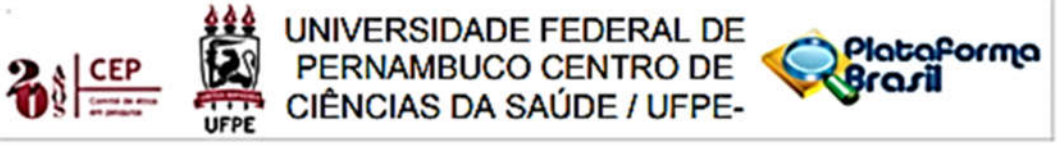
Local e data _____

Assinatura do participante:_____

Presenciamos a solicitação de consentimento, esclarecimentos sobre a pesquisa e o aceite do voluntário em participar. (02 testemunhas não ligadas à equipe de pesquisadores):

Nome:	Nome:
Assinatura:	Assinatura:

APPENDIX B - ETHICAL COMMITEE



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Arquitetura do músculo gastrocnêmio, capacidade funcional e parâmetros venosos em mulheres com doença venosa crônica

Pesquisador: DALTON ROBERTO ALVES ARAUJO DE LIMA JUNIOR

Área Temática:

Versão: 2

CAAE: 81178117.8.0000.5208

Instituição Proponente: Pós-Graduação em Educação Física

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.581.672

Apresentação do Projeto:

Título: ARQUITETURA DO MÚSCULO GASTROCNÊMIO, CAPACIDADE FUNCIONAL E PARÂMETROS VENOSOS EM MULHERES COM DOENÇA VENOSA CRÔNICA

Pesquisador Responsável: Dalton Roberto Alves Araujo

Orientador: Daniela Karina da Silva Ferreira

Programa de Pós-Graduação em Educação física

Desenho do estudo: Estudo descritivo, caso-controle.

Local do estudo: Departamento de Educação Física da UFPE

População-Alvo: 42 mulheres fisicamente inativas com 55 anos ou mais com doença venosa crônica divididas em 3 grupos: Grupo controle, Grupo doença venosa crônica e Grupo insuficiência venosa crônica. Não ficou claro como ocorrerá o recrutamento.

Objetivo da Pesquisa:

Objetivo Geral

Investigar a arquitetura do músculo gastrocêmio, capacidade funcional, e parâmetros venosos em mulheres com doença venosa crônica.

Endereço: Av. da Engenharia s/nº - 1º andar, sala 4, Prédio do Centro de Ciências da Saúde
Bairro: Cidade Universitária **CEP:** 50.740-600
UF: PE **Município:** RECIFE
Telefone: (81)2126-8588 **E-mail:** cepccs@ufpe.br

Avaliação dos Riscos e Benefícios:

As pendências foram atendidas nesse item

Comentários e Considerações sobre a Pesquisa:

Nenhum comentário

Considerações sobre os Termos de apresentação obrigatória:

Termos obrigatórios anexados.

Recomendações:

Sem recomendações

Conclusões ou Pendências e Lista de Inadequações:

As pendências foram atendidas.

Considerações Finais a critério do CEP:

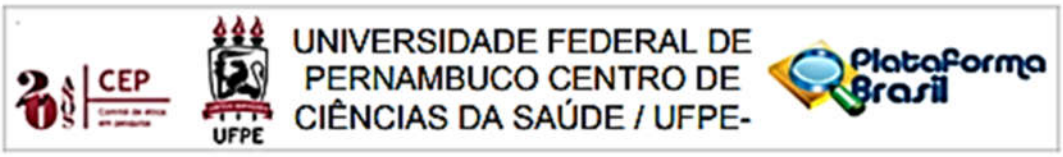
As exigências foram atendidas e o protocolo está APROVADO, sendo liberado para o início da coleta de dados. Informamos que a APROVAÇÃO DEFINITIVA do projeto só será dada após o envio do Relatório Final da pesquisa. O pesquisador deverá fazer o download do modelo de Relatório Final para enviá-lo via "Notificação", pela Plataforma Brasil. Siga as instruções do link "Para enviar Relatório Final", disponível no site do CEP/CCS/UFPE. Após apreciação desse relatório, o CEP emitirá novo Parecer Consubstanciado definitivo pelo sistema Plataforma Brasil.

Informamos, ainda, que o (a) pesquisador (a) deve desenvolver a pesquisa conforme delineada neste protocolo aprovado, exceto quando perceber risco ou dano não previsto ao voluntário participante (item V.3., da Resolução CNS/MS Nº 466/12).

Eventuais modificações nesta pesquisa devem ser solicitadas através de EMENDA ao projeto, identificando a parte do protocolo a ser modificada e suas justificativas.

Para projetos com mais de um ano de execução, é obrigatório que o pesquisador responsável pelo Protocolo de Pesquisa apresente a este Comitê de Ética relatórios parciais das atividades desenvolvidas no período de 12 meses a contar da data de sua aprovação (item X.1.3.b., da Resolução CNS/MS Nº 466/12).

O CEP/CCS/UFPE deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo (item V.5., da Resolução CNS/MS Nº 466/12). É papel do/a pesquisador/a assegurar todas as medidas imediatas e adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e ainda, enviar notificação à ANVISA – Agência Nacional de Vigilância Sanitária, junto com seu posicionamento.



Continuação do Parecer: 2.581.672

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BASICAS_DO_PROJETO_1053199.pdf	02/04/2018 20:52:56		Aceito
Outros	Carta_de_resposta_as_pendencias.docx	02/04/2018 20:51:30	DALTON ROBERTO ALVES ARAUJO DE LIMA JUNIOR	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Dalton151217.docx	02/04/2018 20:46:59	DALTON ROBERTO ALVES ARAUJO DE LIMA JUNIOR	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_CEP_Dalton151217.docx	02/04/2018 20:46:25	DALTON ROBERTO ALVES ARAUJO DE LIMA JUNIOR	Aceito
Folha de Rosto	Folhaderosto_Dalton.pdf	15/12/2017 12:49:18	DALTON ROBERTO ALVES ARAUJO DE LIMA JUNIOR	Aceito
Outros	Cartadeanuencia_Dalton.pdf	15/12/2017 10:12:52	DALTON ROBERTO ALVES ARAUJO DE LIMA JUNIOR	Aceito
Outros	Termo_confidencialidade_Dalton.pdf	14/12/2017 18:37:16	DALTON ROBERTO ALVES ARAUJO DE LIMA JUNIOR	Aceito
Outros	Comprovante_Matricula_Dalton.pdf	14/12/2017 18:27:04	DALTON ROBERTO ALVES ARAUJO DE LIMA JUNIOR	Aceito
Outros	Curriculo_Dalton_Lima.pdf	14/12/2017 18:14:55	DALTON ROBERTO ALVES ARAUJO DE LIMA JUNIOR	Aceito
Outros	Curriculo_Daniela_Ferreira.pdf	14/12/2017 18:14:02	DALTON ROBERTO ALVES ARAUJO DE LIMA JUNIOR	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

RECIFE, 05 de Abril de 2018

Assinado por:
LUCIANO TAVARES MONTENEGRO
(Coordenador)

Endereço: Av. da Engenharia s/nº - 1º andar, sala 4, Prédio do Centro de Ciências da Saúde
Bairro: Cidade Universitária **CEP:** 50.740-600
UF: PE **Município:** RECIFE
Telefone: (81)2126-8588 **E-mail:** cepccs@ufpe.br

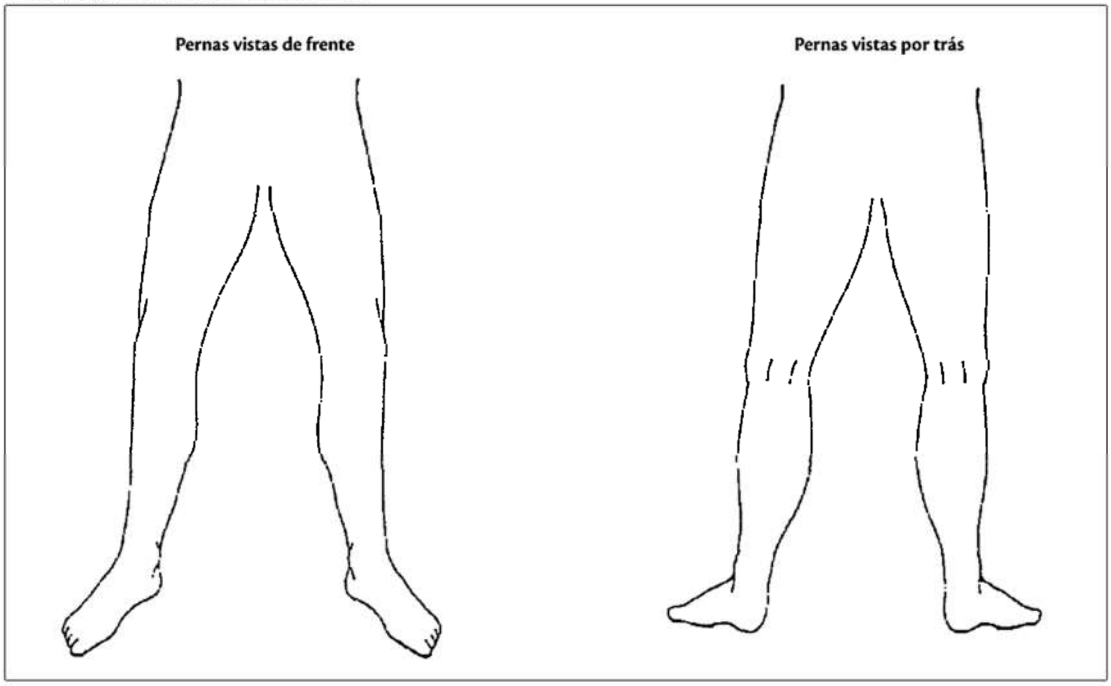
APPENDIX C - DATABASE AND ANALYSES

Link: https://ufpebr0-my.sharepoint.com/:f:/g/personal/dalton_lima_ufpe_br/EgUIN8rsuBVOq5_7ZpNwlUkBfSrI9OP6y0iwA33nlOLmgQ?e=pr1cTc

ANNEX A - ABERDEEN VARICOSE VEIN QUESTIONNAIRE (PORTUGUESE VERSION)

SUAS VARIZES

1. Desenhar, por favor, suas varizes nas figuras abaixo:



2. Nas últimas duas semanas, por quantos dias suas varizes causaram-lhe dor?		
(Por favor marque uma resposta para cada perna)	Perna D	Perna E
De forma alguma		
Entre 1 e 5 dias		
Entre 6 e 10 dias		
Por mais de 10 dias		

3. Durante as últimas duas semanas, em quantos dias você tomou remédio para diminuir a dor de suas varizes?	
(Por favor, marque um quadrado)	
De forma alguma	
Entre 1 e 5 dias	
Entre 6 e 10 dias	
Por mais de 10 dias	

4. Nas últimas duas semanas, quanto inchaço no tornozelo você teve?	
(Por favor, marque um quadrado)	
De forma alguma	
Ligeiro inchaço no tornozelo	
Moderado inchaço no tornozelo (por exemplo, fazendo com que você sente com seus pés levantados sempre que possível)	
Intenso inchaço no tornozelo (por exemplo, causando-lhe dificuldade para por seus sapatos)	

5. Nas últimas duas semanas, você tem usado meias ou ataduras elásticas?		
(Por favor, marque um quadrado para cada perna)	Perna D	Perna E
Não		
Sim, eu mesmo comprei sem prescrição do médico		
Sim, meu médico prescreveu para mim, a qual eu visto de vez em quando		
Sim, meu médico prescreveu para mim, a qual eu visto todo dia		

6. Nas últimas duas semanas, você teve coceira associada com suas varizes?		
(Por favor, marque um quadrado para cada perna)	Perna D	Perna E
Não		
Sim, mas somente acima do joelho		
Sim, mas somente abaixo do joelho		
Acima e abaixo do joelho		

7. Você tem mancha roxa causada por pequeno sangramento de vasos sanguíneos na pele, associado com suas varizes?		
(Por favor, marque um quadrado para cada perna)	Perna D	Perna E
Não		
Sim		

8. Você tem elevações, ressecamento ou manchas de pele na área de seu tornozelo?		
(Por favor, marque um quadrado)	Perna D	Perna E
Não		
Sim, mas não requer tratamento médico ou de enfermagem		
Sim, e requer tratamento médico ou de enfermagem		

9. Você está com uma ferida de pele associada com suas varizes?		
(Por favor, marque um quadrado para cada perna)	Perna D	Perna E
Não		
Sim		

10. A aparência de suas varizes causa-lhe preocupação?	
(Por favor, marque um quadrado)	
Não	
Sim, sua aparência causa-me ligeira preocupação	
Sim, sua aparência causa-me moderada preocupação	
Sim, sua aparência causa-me muita preocupação	

11. A aparência de suas varizes influencia sua escolha de roupa, incluindo meia-calça?	
(Por favor, marque um quadrado)	
Não	
De vez em quando	
Frequentemente	
Sempre	

12. Durante as últimas duas semanas, suas varizes interferiram com seu trabalho doméstico ou outras atividades diárias?	
(Por favor, marque um quadrado)	
Não	
Eu pude trabalhar mas meu trabalho sofreu um ligeiro prejuízo	
Eu pude trabalhar mas meu trabalho sofreu um moderado prejuízo	
Minhas veias impediram que eu trabalhasse um dia ou mais	

13. Durante as últimas duas semanas, suas varizes interferiram com suas atividades de lazer (incluindo esporte, passatempos e vida social)?	
(Por favor, marque um quadrado)	
Não	
Sim, meu divertimento sofreu um ligeiro prejuízo	
Sim, meu divertimento sofreu um moderado prejuízo	
Sim, minhas veias impediram-me de participar em todas as atividades de lazer	

ANNEX B - REGULATORY ACT (ANI # 01_2019)

UNIVERSIDADE FEDERAL DE PERNAMBUCO
PROGRAMA DE PÓS-GRADUAÇÃO *STRICTO SENSU* EM EDUCAÇÃO FÍSICA
MESTRADO ACADÊMICO

Ato Normativo Interno - ANI nº 01/2019

Aprovado pelo Colegiado de Curso na reunião de 14 de junho de 2018 e Substitui o Ato Normativo 03/2016 de 11 de agosto de 2016.

Ementa: Estabelece o formato do projeto de pesquisa e da dissertação que deverão ser apresentados ao Programa de Pós-Graduação em Educação Física da Universidade Federal de Pernambuco (PPGEF-UFPE) para os exames de qualificação, pré-banca e defesa final.

CAPÍTULO I
DAS INFORMAÇÕES PRELIMINARES

Art. 1º - O presente ato normativo apresenta-se em caráter complementar e subordinado ao Regimento do Programa de Pós-Graduação em Educação Física da UFPE, em sua versão mais atual.

Art. 2º - Colaboraram para a conclusão deste ato normativo: Rômulo Fonseca Maia; Vinícius Oliveira Damasceno; Tony Meireles dos Santos; Vilde Menezes e Eduardo Zapaterra Campos; Wallacy Feitosa.

CAPÍTULO II
MODELO DO PROJETO PARA QUALIFICAÇÃO

Art. 3º - O projeto de pesquisa submetido à Qualificação deverá consistir de um documento estruturado no seguinte formato:
I. Parte pré-textual: Capa; Folha de rosto; Lista de Ilustrações (acima de duas); Lista de tabelas (acima de duas); Lista de quadros (acima de dois); Sumário; Resumo.
II. Parte textual: Introdução geral sintetizando uma ampla e completa revisão das principais informações sobre o estado da arte acerca do tema investigado, preferencialmente por meio de ilustrações, tabelas e/ou quadros, que direcione o leitor para a lacuna de conhecimento a ser investigada e, apresentando o(s) documento(s) principal(is) que constitui(em) o projeto de pesquisa; Objetivo geral (obrigatório) e específicos (quando houver); Métodos; Cronograma; Orçamento.
III. Parte pós-textual.
IV. Referências Bibliográficas.
V. Anexos, incluindo o presente ato normativo para consulta e acesso da banca examinadora.
VI. Apêndices.

CAPÍTULO III
MODELO DA DISSERTAÇÃO PARA PRÉ-BANCA E DEFESA

Art. 4º - A dissertação de mestrado submetida à defesa deverá consistir de um documento estruturado em formato inspirado no escandinavo, atendendo à seguinte estrutura:

I. Parte pré-textual: capa, folha de rosto, folha de aprovação e, quando couber, agradecimento, dedicatória e epígrafe; lista de ilustrações, lista de tabelas e quadros; Sumário; resumo; abstract.
II. Parte Textual:
Capítulo I. introdução geral sintetizando uma ampla e completa revisão das principais informações sobre o estado da arte acerca do tema investigado, preferencialmente por meio de ilustrações, tabelas e/ou quadros, que direcione o leitor para a lacuna de conhecimento a ser investigada e, apresentando o(s) documento(s) principal(is) que constitui(em) a dissertação; objetivo geral e específicos (quando houver); referências bibliográficas da introdução.
Capítulo II (até capítulo "n"). No mínimo 01 (um) artigo original, apresentado em capítulo específico, que deve seguir as diretrizes de relatórios para os principais tipos de pesquisa da EQUATOR NETWORK (http://www.equator-network.org).
Capítulo III (ou "n"). Considerações finais com as principais conclusões do(s) artigo(s) apresentado(s) em coerência com o(s) objetivo(s) formulado(s) indicando a direção para investigações futuras e aplicações práticas e que não simplesmente repitam os resultados.
Capítulo IV (ou "n"). Parte pós-textual: referencias, anexos e apêndices (autorização do Comitê de Ética, TCLE, formulários utilizados, detalhamentos complementares sobre os instrumentos, dados brutos e outras informações que se julguem relevantes).

§ 1º - Os demais artigos, apresentado(s) em capítulo(s) específico(s), se existirem, deverão ser apresentados em um único formato e deverá guardar estreita relação e coerência com o primeiro artigo da dissertação.
§ 3º - A padronização para as referências bibliográficas deverá seguir o formato ABNT autor / número (# 6023).
§ 4º - A padronização para as citações deverá seguir o formato ABNT (# 10520) - SISTEMA DE CHAMADA NUMÉRICO.

CAPÍTULO IV
CONSIDERAÇÕES COMPLEMENTARES

Art. 5º - Recomenda-se a impressão em "frente e verso".

Art. 6º - As referências bibliográficas deverão ser geridas, preferencialmente, por *software* específicos para esta função (Endnote, Mendley etc.).

Art. 7º - Os artigos elaborados isoladamente ou a dissertação na íntegra, poderão ser apresentados nas línguas portuguesa ou inglesa.

Art. 8º - O projeto de pesquisa e a dissertação deverão ser impressos em papel branco, formato A4, espaçamento 1,5 entre linhas sem espaçamentos entre parágrafos, margem esquerda com 2,5 cm e demais com 2,0 cm, fonte Times New Roman 12, títulos em negrito e maiúsculas, subtítulos em negrito, itens dos subtítulos em negrito e itálico.
Parágrafo ùnico - O texto deverá ser apresentado em um estilo de redação científico, com revisão gramatical e ortográfica.

Art. 4º - A dissertação de mestrado submetida à defesa deverá consistir de um documento estruturado em formato inspirado no escandinavo, atendendo à seguinte estrutura:

I. Parte pré-textual: capa, folha de rosto, folha de aprovação e, quando couber, agradecimento, dedicatória e epígrafe; lista de ilustrações, lista de tabelas e quadros; Sumário; resumo; abstract.
II. Parte Textual:
Capítulo I. introdução geral sintetizando uma ampla e completa revisão das principais informações sobre o estado da arte acerca do tema investigado, preferencialmente por meio de ilustrações, tabelas e/ou quadros, que direcione o leitor para a lacuna de conhecimento a ser investigada e, apresentando o(s) documento(s) principal(is) que constitui(em) a dissertação; objetivo geral e específicos (quando houver); referências bibliográficas da introdução.
Capítulo II (até capítulo "n"). No mínimo 01 (um) artigo original, apresentado em capítulo específico, que deve seguir as diretrizes de relatórios para os principais tipos de pesquisa da EQUATOR NETWORK (http://www.equator-network.org).
Capítulo III (ou "n"). Considerações finais com as principais conclusões do(s) artigo(s) apresentado(s) em coerência com o(s) objetivo(s) formulado(s) indicando a direção para investigações futuras e aplicações práticas e que não simplesmente repitam os resultados.
Capítulo IV (ou "n"). Parte pós-textual: referencias, anexos e apêndices (autorização do Comitê de Ética, TCLE, formulários utilizados, detalhamentos complementares sobre os instrumentos, dados brutos e outras informações que se julguem relevantes).

§ 1º - Os demais artigos, apresentado(s) em capítulo(s) específico(s), se existirem, deverão ser apresentados em um único formato e deverá guardar estreita relação e coerência com o primeiro artigo da dissertação.
§ 3º - A padronização para as referências bibliográficas deverá seguir o formato ABNT autor / número (# 6023).
§ 4º - A padronização para as citações deverá seguir o formato ABNT (# 10520) - SISTEMA DE CHAMADA NUMÉRICO.

CAPÍTULO IV
CONSIDERAÇÕES COMPLEMENTARES

Art. 5º - Recomenda-se a impressão em "frente e verso".

Art. 6º - As referências bibliográficas deverão ser geridas, preferencialmente, por *software* específicos para esta função (Endnote, Mendley etc.).

Art. 7º - Os artigos elaborados isoladamente ou a dissertação na íntegra, poderão ser apresentados nas línguas portuguesa ou inglesa.

Art. 8º - O projeto de pesquisa e a dissertação deverão ser impressos em papel branco, formato A4, espaçamento 1,5 entre linhas sem espaçamentos entre parágrafos, margem esquerda com 2,5 cm e demais com 2,0 cm, fonte Times New Roman 12, títulos em negrito e maiúsculas, subtítulos em negrito, itens dos subtítulos em negrito e itálico.
Parágrafo ùnico - O texto deverá ser apresentado em um estilo de redação científico, com revisão gramatical e ortográfica.

Art. 9º - As especificações para registro catalográfico da obra, como estabelecidos pela Biblioteca Central da UFPE em sua versão mais atual, deverão ser rigorosamente seguidas.

Art. 10º - As ilustrações (figuras/gráficos), quando necessário, deverão ser elaboradas em software com adequada qualidade (300 dpi), não sendo recomendado o Microsoft Excel ou Power Point.

CAPÍTULO IV
DAS DISPOSIÇÕES GERAIS

Art. 11º - Os casos omissos neste Ato Normativo serão deliberados pelo Colegiado do curso, nos limites de sua competência e, quando devido, pela PROPESQ.

Art. 12º - Aplicam-se, no que couber nos regimes didáticos, disciplinar e outros, as normas constantes dos estatutos e do regime geral da UFPE.

Art. 13º - Este Ato Normativo entrará em vigor a partir da data de sua publicação no *site* do PPGEF-UFPE e substitui disposições anteriores.

Recife, 01 de fevereiro de 2019

Prof. Dr. Tony Meireles dos Santos
Coordenador do PPGEF-UFPE