2024, Retos, 54, 372-380

Jazz Dance in menopause: protocol study for a randomized clinical trial
Danza Jazz en la menopausia: estudio de protocolo para un ensayo clínico aleatorizado

Julia Beatriz Bocchi Martins, Danielly Yani Fausto, Juliana da Silveira, Leonessa Boing, Thuane Huyer da Roza, Adriana Coutinho de Azevedo Guimarães
Universidade do Estado de Santa Catarina

Abstract. Background: Dance as an example of Physical Activity, although not much studied, is shown as a positive non-pharmacological therapy that decreases physical, psychological, and sexual symptoms arisen from menopause. Objective: To provide a Jazz Dance protocol (twice a week / 12 weeks) for menopausal women and compare its effectiveness with the Control Group. Method: This study is a protocol for a randomized clinical trial with menopausal women with two arms: Control Group and Jazz Intervention Group. A 12-week protocol developed for women between the ages of 40 and 59 to analyze the Jazz Dance effect on the primary outcome: Menopause Symptoms (Menopause Rating Scale); and on the secondary outcomes - physical aspects: BMI, body fat percentage (Ultrasound (BX-2000, IntelaMetrix Inc., USA) alongside to Jackson & Pollock's 7 folds equation); fitness cardiorespiratory: (Treadmill (Embramed atl 2000) to lead the submaximal exercise test following the modified Bruce protocol); hormonal aspects: Follicle-stimulating hormone levels (blood sample), and psychological aspects- depressive symptoms and anxiety (Hospital Anxiety and Depression Scale); mood (Brunel Mood Scale) and stress levels (Perceived Stress Scale). Discussion: This study will be the first Jazz Dance protocol offered to support a new randomized clinical trial with menopausal women focused on dancing as a non-medicated treatment.
Keywords: Dancing; exercise; menopause; menopausal symptoms; protocol; Randomized clinical trial.

Resumen. Fundamento: La danza como ejemplo de Actividad Física, aunque poco estudiada, se muestra como una terapia no farmacológica positiva que disminuye los síntomas físicos, psicológicos y sexuales derivados de la menopausia. Objetivo: Proporcionar un protocolo de Danza Jazz (dos veces por semana / 12 semanas) para mujeres menopáusicas y comparar su efectividad con el Grupo Control. Método: Este estudio es un protocolo para un ensayo clínico aleatorizado con mujeres menopáusicas con dos brazos: Grupo Control y Grupo de Intervención Jazz. Se desarrolló un protocolo de 12 semanas para mujeres entre 40 y 59 años para analizar el efecto de la danza jazz en el resultado primario: síntomas de la menopausia (escala de calificación de la menopausia); y en los resultados secundarios: aspectos físicos: IMC, porcentaje de grasa corporal (ultrasonido (BX-2000, IntelaMetrix Inc., EE. UU.) junto con la ecuación de los 7 pliegues de Jackson y Pollock); fitness cardiorrespiratorio: (Cinta de correr (Embramed atl 2000) para conducir la prueba de ejercicio submáximo siguiendo el protocolo de Bruce modificado); aspectos hormonales: niveles de hormona folículo estimulante (muestra de sangre) y aspectos psicológicos: síntomas depresivos y ansiedad (Escala Hospitalaria de Ansiedad y Depresión); estado de ánimo (Brunel Mood Scale) y niveles de estrés (Perceived Stress Scale). Discusión: Este estudio será el primer protocolo de danza jazz ofrecido para respaldar un nuevo ensayo clínico aleatorio con mujeres menopáusicas centrado en la danza como tratamiento no medicado.
Palabras clave: Baile; ejercicio; menopausia; síntomas menopáusicos; protocolo; Ensayo clínico aleatorizado.

Fecha recepción: 27-09-23. Fecha de aceptación: 21-02-24
Julia Beatriz Bocchi Martins
juliabocchi@gmail.com

Introduction

The protocol studies that propose Physical Activity (PA) and physical exercise as a therapeutic form for menopause symptomatology are dated from 2012, in which the first protocol that addressed PA and menopause brought the dance modality in the interactive video format and its effect on cognitive function in postmenopausal women (Jovancevic et al., 2012). To date, this was the first and only study with an intervention protocol design found with the dance modality applied to menopausal women. Furthermore, the last publication to date introduces PA in an interdisciplinary way along with nutrition for reducing the risk of cardiovascular disease in perimenopausal women (Cortés et al., 2021).

These records show a gap in literature along with the need for new studies involving PA and dance with this population. Dance modalities have great relevance as they are determinant practices for positive social aspects development, contributing to the well-being, quality of life, and improvement in the general health of the female population (Altamirano Quevedo et al., 2020; Sheppard & Broughton, 2020). In addition, dance significantly contributes to joint mobility, cardiorespiratory endurance, and balance (Liu et al., 2020), still with the possibility of inducing neuroplasticity, improving cognitive functions (Muiños & Ballesteros, 2020), positive effects on depressive symptoms (Gao et al., 2016), and anxiety (Murillo-Garcia et al., 2020). Moreover, the worsening of psychological conditions is one of the most important associations for sexual dysfunction in menopausal women (del Carmen Carcelén-Fraile et al., 2020).

Beneficial therapies performed with women during this period are important because, during the menopause transition, there is a progressive decrease in the ovarian follicle reserve (Wallace & Kelsey, 2010), with an increase in Follicle-stimulating Hormone (FSH) by the pituitary gland (Saraiva et al., 2010), as well as a reduction of estrogen causing the appearance of menopause characteristic symptoms (Monteleone et al., 2018). Symptoms can be classified as somatovegetative (sweating/hot flashes, sleep disorders, heart problems, joint and muscle complaints); psychological (anxiety and depression, irritability and exhaustion); and urogenital (sexual problems, urinary

complaints, and vaginal dryness) (Heinemann et al., 2003). Therefore, PA and physical exercise are potentially positive non-pharmacological therapeutic options in improving the lipid profile, reducing the values of body mass index (BMI), the percentage of body fat, and increasing or maintaining muscle mass (Duclos, 2021; Park & Kim, 2021), in addition to demonstrating effectiveness for psychological aspects (Nguyen et al., 2020).

After recognizing that dance is a PA capable of contributing to the physical and mental health of practitioners (Sheppard & Broughton, 2020) and observing the gap in studies within the mentioned theme, the development of this study becomes attractive, bringing Jazz Dance in a systematic and planned way for a look aimed at improving physical and psychological aspects and its symptoms resulting from menopause. Classic Jazz Dance is a modality recognized around the world, in addition to bringing the pelvis as a central part of its movements, where the sensuality of the practice brings sexual energy and femininity to the surface (Heiland & Megill, 2018), enabling a woman to reunite with her feminine, aspect so affected in this age group (Khakkar & Kazemi, 2023). This makes it to become a methodological tool for new studies involving this modality and menopause. Therefore, the study aims to provide a Jazz Dance protocol (twice a week/12 weeks) for menopausal women and compare its effectiveness with the control group, with the hypothesis that this may contribute to a positive influence on the physical, hormonal, sexual, and psychological conditions of these women.

Methods

Study design

Protocol study for a randomized clinical trial with two arms developed to analyze the effects of Jazz Dance on the primary outcome of menopausal symptoms and the secondary outcomes: sociodemographic and clinical profile; physical aspects (BMI; percentage of body fat; muscle strength; fitness cardiorespiratory); hormonal aspect (FSH levels); psychological aspects (depressive symptoms, mood and anxiety, and stress levels) and sexual aspects.

Participants will be randomized to a Jazz Dance intervention group and a control group. This study is conducted by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013: Recommended items to address in a clinical trial protocol and related documents (Additional File 1).

Ethical Approval

This study will be carried out under the Declaration of Helsinki (1975) and it was approved by the Committee for Ethics in Research on Human Beings (CEPSH) of the University of the State of Santa Catarina (UDESC) under the protocol No. 4.802.174 on June 24, 2021. The clinical trial was registered in the Brazilian Clinical Trials Registry (REBEC) with the identifier RBR – 87ndrv. Any major deviations or modifications to the protocol will be communicated to CEPSH and the Clinical Trials website for approval, except when necessary to eliminate apparent immediate hazard(s) to the human subjects. In addition, the judgment of participants, trial records, and the newspapers to which the protocol is submitted will be informed.

Participants and Study Environment

Through advertisements in different media communications (radio, television, print media, electronic media, and Universities website), menopausal women aged between 40 and 59 years old from the metropolitan region of Greater Florianópolis (Santa Catarina - Brazil) will be invited to participate in the study. Menopause must have a minimum period of one uninterrupted year without menstruation, starting on the date of the last bleeding that occurred. Following the National Consensus on Menopause of the Portuguese Society of Gynecology (*Consenso Nacional Sobre Menopausa*, 2016), the maximum period of six years after the date of the last menstruation, characterized by an early post-menopause, will be used. Participants will receive an explanation of the study steps, and after providing consent to participate, they will sign an informed consent form and then receive a paper questionnaire for data collection.

The interventions of this study will be carried out in the gym of a Public University located in the state of Santa Catarina, Brazil.

Recruitment and Eligibility Criteria

Participants who demonstrate interest through the disclosure will be contacted by telephone and will receive information about volunteering to participate in the research, along with their general procedural information and citation of approval by the Committee for Ethics in Research on Human Beings of UDESC.

After accepting the invitation and signing the Free and Informed Consent Form (FICF), they will be asked to answer the Menopause Rating Scale (MRS), a validated questionnaire for the Brazilian population by Heinemann et al. (Heinemann et al., 2003), that characterizes the symptoms of menopause. If positive for the symptomatology score, an invitation will be made to carry out a blood collection to verify the FSH levels. Therefore, as an inclusion criterion, women who fit the MRS (Heinemann et al., 2003), and obtain FSH levels ≥ 25 IU/ml, the reference value of the Portuguese Society of Gynecology (*Consenso Nacional Sobre Menopausa*, 2016), indicating menopause, will be selected. In addition to these factors, participants must not have attended Jazz Dance classes in the last three months before the collection and must refrain from practicing other physical exercises than those of the intervention, during its period of occurrence (12 weeks).

Women with a history of neurological and/or musculoskeletal diseases will be excluded from the sample. Figure 1 shows the flowchart of this study:

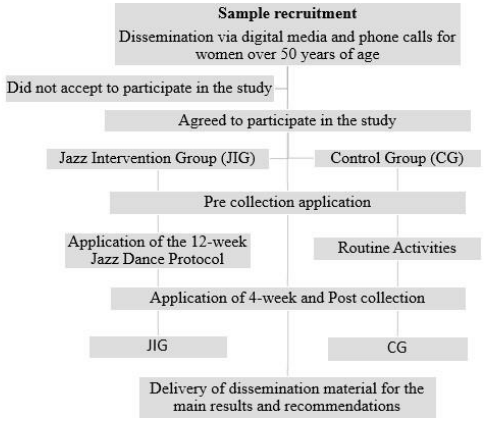

Figure 1. Sample selection flowchart and study steps.

Sample calculation

The G* Power 3.1.9.2 software was used to perform the sample calculation (Faul et al., 2007). The primary outcome was the menopause symptomatology score by the MRS questionnaire, based on a randomized clinical trial carried out with this same population. (Ağıl et al., 2010). This study was chosen because it is a randomized Clinical Trial using PA as an intervention, although not specifically dance, as no other similar studies were found in the literature regarding the practice of this modality and the primary outcome variable chosen. The effect size was $f^2=0.24$, a calculation performed considering the post-intervention average of the experimental and control groups of this study. For the calculation, $\alpha=0.05$, test power of 80% and effect size $f^2=0.24$ were considered, applying in two groups; analyzing the results through the two-way ANOVA test. 30% was added for possible sample losses, resulting in 11 participants per group.

Randomization and blinding

This will be a randomized single-blind study and, therefore, it will not provide information to the participants or the responsible researcher regarding the allocation of the groups, with the need of an invited researcher who had no contact with the previous collections to participate in this process. In this sense, the allocation of the groups will only be conducted after the initial collections to carry out the statistical analysis. In the randomization process, a group of trained researchers from the Leisure and Physical Activity Research Laboratory – LAPLAF/CNPq, will select the participants and a second researcher will randomize the groups through a computer program (www.randomization.com). The two groups that will make up the study (Control Group (CG) and Jazz Intervention Group (JIG)) will be controlled, throughout the process, in different ways: for the CG, monthly contacts will be made by telephone to encourage them to maintain their daily activities, the JIG will undergo the intervention of the Jazz Dance protocol for 12 uninterrupted weeks.

After the first screening, JIG participants will be invited to participate in the Jazz Dance protocol, to be held in the gym of a public university in southern Brazil.

Jazz Dance Protocol

The Jazz Dance was chosen because it is a popular dance modality around the world, which mixes techniques, styles, and aspects of dances from different cultures, highlighting the use of physical abilities, strength, power, and flexibility (Cayou, 1970). In addition, it is a physical activity that presents safety and efficacy within the improvement of physical and psychological aspects, with benefits that are compatible and in some cases even greater than the practice of other types of structured exercises (Fong Yan et al., 2018). Still, the results regarding psychological aspects are identified in the literature, such as the reduction of symptoms related to emotional stress (Duberg et al., 2020) and depressive symptoms (Gao et al., 2016).

The protocol will be carried out over 12 weeks, developed from Jazz Dance and its aspects, at a frequency of two classes per week and a duration of 60 minutes each class, with progressive intensity according to the frequency of beats per minute (bpm) of the songs. There will be three different moments in each class in which the rhythm will be measured based on the songs and their frequency of beats per minute, as well as carried out in the ballroom dance protocol conducted in the study by Braga et al. In this study, songs are categorized into slow (up to 80 bpm), medium (up to 120 bpm) and fast (up to 150 bpm), with Detector Pro application detection.

As the first moment in each class (1), the initial warm-up and stretching will be developed. The songs at this stage will be based on the slow category. Joint movements of the upper and lower limbs, in addition to flexions, extensions, abductions, adductions, and guided rotations from the upper part of the body, until reaching the lower limbs will be conducted. Duration: 10 minutes.

After the initial part, as the main part of the class (2), the objectives and intentions of the class will be exposed and discussed with the group of women, where, depending on the content, brief explanations regarding the theory of dance or some specific step will be related. This moment will be followed by the practical part of teaching the technique. The objective of this moment will be to develop in the participants the movements of the Jazz Dance technique, stimulating motor coordination, rhythm, and body awareness, improving aspects of flexibility and range of motion of the upper and lower limbs. The dynamics of the class can be explored in different directions and formats, being carried out individually, in pairs, or groups, involving movements according to the rhythm of the music, or even by rhythms stipulated by the participants and/or teacher. Still, freedom of movement, body expression, respecting individualities, and allowing the expression of feelings will be provided. The evolution of the technique will be applied as explained in Table 1. For this part of the class, songs with medium and fast rhythms will be used. This class session will last an average of 40 minutes.

To conclude the classes, a moment of relaxation will be developed (3). In this one, slow movements will be appreciated with the same music used at the beginning of the

class. With the heart rate normalization, this part will last 10 minutes. At the end of each class, a brief conversation will be held about the perception of women regarding the contents taught, concerning the objectives discussed at the beginning of the class, and whether these were achieved or not.

Table 1.
Twelve-week Jazz Dance Protocol for menopausal women (Florianópolis, SC, Brazil, 2021)

	Session 1	Session 2
	Slow songs (up to 80bpm) Medium songs (up to 120bpm) Fast songs (up to 150 bpm)	Slow songs (up to 80bpm) Medium songs (up to 120bpm) Fast songs (up to 150 bpm)
1	Presentation of Jazz Dance and its aspects	Presentation of Jazz Dance and its aspects
2	Trunk and hip releases	Displaced torso and hip releases
3	Choreographic sequence based on the torso and hip releases	Choreographic sequence based on the torso and hip releases
4	Petit battement tendú and jeté movements and their possibilities - static / in displacement	Evolution from petit battements to grand battements
5	Floor exercises based on the Contemporary Jazz aspect	Floor exercises based on the Contemporary Jazz aspect
6	Choreographic sequence using solo techniques	Choreographic sequence using solo techniques
7	Setbacks	Displacement setbacks
8	Initiation to turns (two feet) - static and in displacement	Pirouettes performed on one foot
9	Shifts in small jumps (chassé, skip)	Small and big jumps
10	Choreographic sequence in diagonal displacement (combining setbacks, grand battement, releases, and big jumps)	Choreographic sequence in diagonal displacement (combining setbacks, grand battement, releases, and big jumps)
11	Choreographic composition	Review of the movements learned
12	Choreographic sequence using the movements learned	Choreographic sequence using the movements learned

bpm = beat per minute

Control group

The CG will consist of participants who were not randomized to receive the Jazz Dance intervention. These, in turn, will be asked to normally follow their routine activities during the 12 weeks of the intervention. At this stage, monthly calls will be made on the first Fridays of each month by the main researcher and a second researcher, to have a control that daily activities are being followed normally throughout the study.

For data collection, there are no changes concerning the intervention group, being used the same questionnaires with data referring to the sociodemographic profile, psychological and physical aspects, hormonal profile, and sexual function. The collection will be scheduled in advance according to the availability of the participants and in a place of their choice, synchronous to the period of the intervention group, at the pre, at the end of the first 4 weeks, and in the post-intervention period with Jazz Dance, being carried out by the same principal investigator of the study.

At the end of the 12 weeks, participants will be invited to participate in the activities of the "Ritmo e Movimento" extension program at the University of the State of Santa Catarina (Brazil), with the contents of stretching and gymnastics held at Parque de Coqueiros (Florianópolis - SC).

Safety and intensity

The Jazz Dance intervention will be carried out after all the assessment procedures, with the beginning of the 12-week intervention period, increasing volume and intensity, which will be developed by the researchers from LAPLAF/CNPq. The intervention will be given by a Physical Education professional with 12 years of experience in dance. During the protocol, a form of evolution of women will be developed, which should be updated every week by the researchers responsible for the intervention to control the intensity and safety of the protocol practice. To assess the intensity and/or discomfort of the intervention, the Borg Rating of Perceived Exertion Scale of 6-20 points will be used. (Borg, 1998). This 6 to 20 point scale can be used efficiently due to its relationship to heart rate. It should be applied to describe feelings of rest up to situations of maximum physical effort, considering the number six is equivalent to 60 bpm (beats per minute), as well as the number 20 to 200 bpm.

The rhythm of the classes will be governed by the frequency of the soundtracks used, which is a determining factor for controlling the intensity of the movements. The selected songs were divided according to sessions 1 and 2, which were used over the 12 weeks, as shown in supplementary table. Adverse events will be evaluated by the investigators, who will decide to stop the study sooner, and the investigators will take responsibility and provide all care for the women included in the study.

Studied variables

Primary outcome

Menopause symptoms were selected as the primary outcome variables, as they are questions directly linked to specific aspects of the life stage of women who are part of the population under study.

Menopause symptoms - "Menopause Rating Scale", developed in Germany and validated in Brazil by Heinemann et al. [12]. Consisting of 11 questions evaluated on a scale from zero (absence of symptoms) to four (greater severity) and distributed into three domains: somatic symptoms, urogenital symptoms, and psychological symptoms. With the sum of the scores for each domain, the total MRS score is obtained, where the higher the score, the greater the severity of symptoms and the worse the quality of life. With the categorization according to the severity of the symptoms, the general referred intensity will be observed: absent or occasional symptomatology (0-4 points), mild (5-8 points), moderate (9-15 points), or severe (16 points). The variation in the total score is 0

(asymptomatic) and 44 (highest degree of complaints). Linked to symptoms, the minimum/maximum scores can vary across the three dimensions. For psychological symptoms: 0 to 16 points score (4 symptoms: depressed, irritable, anxious, exhausted), for somatovegetative symptoms: 0 to 16 points (4 symptoms: sweating/hot flashes, heart problems, sleep disorders, joint and muscle complaints), for urogenital symptoms: 0 to 12 points (3 symptoms: sexual problems, urinary complaints, vaginal dryness).

Secondary outcomes

As secondary outcomes, there are other variables indirectly related to the results.

1) Sociodemographic and clinical profile: form built by the authors based on studies with a public of women in menopause (Guerra & Prado, 2010; Pedro et al., 2003), addressing the following characteristics: age, marital status, education, economic level, presence of clinically diagnosed diseases, use of medications for hypertension, anxiety, depression, family history, and tobacco use.

Tobacco consumption will follow the model of the question contained in the questionnaire on smoking by the World Health Organization (*Perguntas Sobre Tabaco Para Pesquisas*, 2012), and for the economic level the criterion of the Brazilian Institute of Geography and Statistics - IBGE (*Indicadores Sociodemográficos e de Saúde No Brasil*, 2009) will be used, which classifies the population into economic strata A, B, C, D, and E, based on the minimum wage of 2021, in the amount of R$ 1087.85.2)

Physical aspects: BMI; percentage of body fat and fitness cardiorespiratory (assessments will be performed by trained Physical Education Professionals).

BMI - the division between body mass (Kg) by the square of height (m2); the height will be obtained through a stadiometer with the zero points at ground level, and the body mass through a digital scale. BMI will be classified as normal (up to 24.9 kg/m2), overweight (from 25 kg/m2 to 29.9 kg/m2), and obesity (above 30 kg/m2) following the guidelines of the World Health Organization (Organization, 2016).

Body fat percentage (%F) - Image obtained by a portable ultrasound device (BX-2000, IntelaMetrix Inc., USA). A water-based gel will be used for image acquisition, as it promotes an increase in acoustic contact without the need to put pressure on the skin. Thus, for the calculation of body density, the equation of seven folds (subscapular, triceps, midaxillary, suprailiac, chest/pectoral, abdominal, and thigh) by Jackson & Pollock (Ped et al., 2016), will be used, following the evaluation of its cutoff point for the %F.

Cardiorespiratory fitness - Treadmill (Embramed atl 2000) for conducting the submaximal exercise test, indicated for middle-aged populations, along with the modified Bruce protocol, recommended for middle-aged and elderly sedentary people (Meneghelo et al., 2010). The best-known modification of the Bruce protocol takes place in six stages, where the speed as well as the inclination increase with the end of the test, in this case, when the participant reaches 85% of her estimated maximum heart rate (HRmax), which is identified through an equation specific for women between 20 and 70 years of age (208 - 0.65 × age) (Tanaka et al., 2001).

3) Psychological aspects: Depressive symptoms and anxiety, stress, and mood.

Depressive symptoms and anxiety - The Hospital Anxiety and Depression Scale (HADS), aims to identify (probable or possible) cases of anxiety disorders and/or mild depressive symptoms in non-clinical populations; validated in Brazil by Botega et al. (Botega et al., 1995). Scale composed of 14 items divided into two subscales: HADS-Anxiety (HADS-A), with seven questions for the diagnosis of Anxiety Disorder (odd items) and HADS-Depression (HADS-D), with another seven for Depressive Disorder (even items). The response scale ranges from zero to three points (from absent to very frequent) with a maximum score of 21 points per subscale. The cutoff points obtained in the literature will be ≥9 points for each disorder (0 – 8: no anxiety/no depressive symptoms; ≥9 with anxiety/with depressive symptoms), proposed from theoretical and empirical criteria (Zigmond & Snaith, 1983).

Mood state - Brunel Mood Scale translated into Portuguese by Rohlfs et al. (Provenza et al., 2008). The scale is divided into six subscales (anger, confusion, depression, fatigue, tension, and vigor) that cover 24 simple mood indicators. The score is calculated from specific spreadsheets for each population using the responses of the subjects according to a 5-point scale (from 0 = nothing to 4 = extremely).

Stress - Perceived Stress Scale adapted for Portuguese by Luft et al. (Luft et al., 2007). This scale measures the degree to which individuals perceive situations as stressful and consists of 14 Likert-type questions ranging from 0 to 4 (0= never; 1= almost never; 2= sometimes; 3= fairly often and 4= very often). There are seven questions with a positive connotation (4,5,6,7,9,10 and 13) that are added in an inverted way. The other questions are added directly. The scores of the sum of the 14 questions can range from 0 to 56, and the closer to 56, the higher the stress levels.

4) Sexual function: Female Sexual Function Index (FSFI), built and validated in English by Rosen et al. (Rosen et al., 2000), and translated to Brazil, validated, and culturally adapted by Thiel et al. (Thiel et al., 2008) to assess the Female Sexual Function Index (FSFI) in Brazilian women. This is a brief 19-question questionnaire that assesses 6 aspects: desire, arousal, lubrication, orgasm, satisfaction, and pain. In the FSFI, each domain presents scores, and the answer options are classified from 0 to 5 in ascending order regarding the occurrence of the questioned function. The score is only inverted in questions regarding pain. When the scores of each domain are added, they are multiplied by a factor that homogenizes the influence of each domain, and, in the end, the total score is reached. The higher the final score, the better the sexual function.

5) Hormonal aspect: FSH levels are quantified through blood collection by a professional biochemist. The results must be ≥ 25 IU/ml for the woman to be already in menopause (*Consenso Nacional Sobre Menopausa*, 2016).

Table 2.
Study Assessments according to the studied variables

Outcomes	Instruments	Groups	
		Baseline	Post-intervention
Menopause symptoms	Primary outcome "Menopause Rating Scale" (Heinemann et al., 2003) Other variables	X	X
Sociodemographic and clinical profile	Form built by the authors based on studies with a public of women in menopause (Guerra & Prado, 2010; Pedro et al., 2003)	X	X
	Physical		
BMI	World Health Organization guidelines (Organization, 2016)	X	X
Body fat percentage	Portable ultrasound device (BX-2000, IntelaMetrix Inc., USA) and the 7 folds equation of Jackson & Pollock (Ped et al., 2016)	X	X
Fitness cardiorespiratory	Treadmill (Embramed atl 2000) for conducting the submaximal exercise test with the modified Bruce protocol (Meneghelo et al., 2010)	X	X
	Psychological		
Depressive symptoms and anxiety	Hospital Anxiety and Depression Scale (Botega et al., 1995; Zigmond & Snaith, 1983)	X	X
Mood state	Brunel Mood Scale translated into Portuguese by Rohlfs et al (Provenza et al., 2008)	X	X
Stress	Stress - Perceived Stress Scale adapted for Portuguese by Luft et al. (Provenza et al., 2008)	X	X
	Sexual		
Sexual function	Female Sexual Function Index (FSFI), built and validated in English by Rosen et al. and translated, validated, and culturally adapted to Brazil by Thiel et al. (Thiel et al., 2008)	X	X
	Hormonal		
Hormonal aspect	FSH levels were quantified through blood collection by a professional biochemist. The results must be ≥ 25 IU/ml for the woman to be already in menopause (Consenso Nacional Sobre Menopausa, 2016)	X	X

Data Collect

The JIG and CG data collection will take place in the same period after the invitation is accepted and the FICF is duly filled. This will take place in three moments: pre-intervention, at the end of the first 4 weeks of intervention, and the end of the 12 weeks of intervention, that is, before, during, and after the application of the protocol, as shown in Figure 2. The schedules for the stages will be made in advance according to the availability of each participant and the specific questionnaires for each variable and described in the item above will be self-administered, being answered on the premises of a University located in Santa Catarina (Brazil) with an average time of 45 minutes. The maximal effort test and blood collection will also be scheduled in advance. Data collection will be monitored by three trained researchers from the University, who will ensure that all information is kept confidential and that participants will not have any cost at all stages of the study.

Table 3.
Study evaluation schedule (SPIRIT).

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		
TIMEPOINT**	$-t_1$	0	T_1	T_2	T_3
ENROLMENT					
Eligibility screen	X				
Informed consent	X				
Randomization		X			
INTERVENTIONS					
Jazz Intervention Group					
Control Group					
ASSESSMENTS					
Hormonal aspects			X		X
Lipid profile			X		X
Physical aspects			X		X
Psychological aspects			X		X
Sexual aspects			X		X
Analysis of Study Outcomes					X

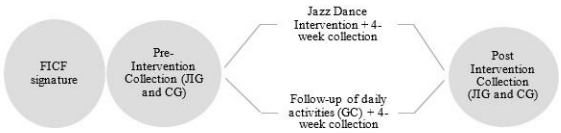

Figure 2. Process for data collection.

Statistical analysis

For the tabulation and organization of the data, Excel® software will be used, together with the SPSS 20.0 statistical package for further analysis. The analysis of descriptive variables will be done through simple frequency (categorical variables) and measures of position and dispersion (numerical variables). The analysis will be performed by intention to treat and by protocol. After the 12 weeks of interventions, a comparative analysis will be carried out between the two groups along with intragroup pre and post-test comparisons, seeking to find possible changes after the intervention from descriptive statistics (average, standard deviation, and percentage) for comprehension of the characteristics of the sample.

The Chi-Square or Fisher's Exact Test will be selected to verify the association between general and health information in the intervention and control groups, and the two-way ANOVA with repeated measures and Sidak Comparison Test will have the purpose to analyze the experimental and control groups in the pre and post-intervention periods. The significance level will be 5%.

Discussion

This randomized clinical trial protocol aims to provide

a Jazz Dance protocol (twice a week/12 weeks) for menopausal women and compare its effectiveness with a control group. To date, protocol studies involving Jazz Dance associated with interventions with menopausal women have not yet been found, so this is the primary protocol in this regard. It is expected, if positive for its effectiveness, an improvement in the severity of symptoms resulting from menopause along with the physical, psychological, and sexual aspects listed in this study, benefiting women during this period.

These results are expected because dance interventions are positive non-pharmacological therapies for the treatment of menopause symptoms (Santos et al., 2020). Although studies within the scope of this modality have only started over the last decade, there are already fine indications in the literature for the applicability of interventions with dance. Within these, an improvement is perceived in fitness cardiorespiratory (Hargan et al., 2020; Teixeira et al., 2021), levels of depression (Gao et al., 2016), anxiety (Santos et al., 2020), in addition to balance (Serrano-Guzmán et al., 2016), motor coordination, and general physical conditioning (Teixeira et al., 2021). However, these already carried out interventions did not propose systematic protocol studies, making it difficult to replicate the methods in intervention with dance, therefore bringing a positive point to the development of this protocol study.

Regarding Jazz Dance specifically, although not yet investigated for this population, it is a modality spread worldwide and with a great influence in different cultures and countries, as it is a dance that was born from social gatherings of Black American roots and it ended up being popularized on large stages around the world (Boross, 2015; Seguin, 2018), which makes it possible for this protocol to be reproduced worldwide. In addition, the methodology of teaching the modality uses movements of large joint range, stretching, and exercises that use physical capabilities such as explosive strength for jumping and kicking movements and proprioceptive and stabilization exercises such as balance and loosening of the trunk and hip (Alpert et al., 2009; Henry & Jenkins, 2019), bringing physical and psychological benefits such as improved balance and an increasing trend for mental health scores (Alpert et al., 2009; Wang et al., 2019). Furthermore, the femininity and sensuality existing in the movements of this dance raise issues related to sexuality, which can be beneficial factors for the psychological and sexual aspects of women in menopause (Henry & Jenkins, 2019; Molinaro et al., 1986).

The scarcity of protocols and studies related to non-pharmacological therapies involving dance, more specifically Jazz Dance related to this population, brings, as well as to identifying the importance of an alignment and systematization of alternative therapies to reduce symptoms for women in this period, the strength and originality of this study. It is considered important to implement a protocol developed through a universal dance such as Jazz Dance, which will bring the opportunity to reproduce it worldwide, in addition to being a modality with benefits registered in the literature (Serrano-Guzmán et al., 2016; Teixeira et al., 2021) and which has a high potential impact to support new randomized clinical trials, bringing evidence for the realization of a PA protocol aimed at dance practices as a non-drug treatment for menopausal women, benefiting not only healthcare professionals, but also the community involved with dance interventions.

Abbreviations

BMI = Body Mass Index
CEPSH = Committee for Ethics in Research on Human Beings
CG = Control Group
FSFI = Female Sexual Function Index
FSH = Follicle-stimulating Hormone
HADS = The Hospital Anxiety and Depression Scale
JIG = Jazz Intervention Group
MRS = Menopause Rating Scale
PA = Physical Activity
UDESC = University of the State of Santa Catarina

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Datos de los autores:

Julia Beatriz Bocchi Martins	juliabocchi@gmail.com	Autor/a
Danielly Yani Fausto	dani.090594@hotmail.com	Autor/a
Juliana da Silveira	judasilveira88@gmail.com	Autor/a
Leonessa Boing	leonessaboing@gmail.com	Autor/a
Thuane da Roza	thuaneroza@yahoo.com.br	Autor/a
Adriana Coutinho de Azevedo Guimarães	adriana.guimaraes@udesc.br	Autor/a