*Acute and Chronic Effects of Exercise in Health*

# Dance therapy as an alternative for cardiac rehabilitation in women population: autonomic and hemodynamic acute responses - a crossover clinical trial protocol

Maria Júlia Lopez Laurino[1], João Pedro Lucas Neves Silva[1], Natacha de Lima Gervazoni[1], Júlio César de Ávila Soares[1], Bruna Izadora Spinardi Alves[1], Luiz Carlos Marques Vanderlei[1], Roselene Modolo Regueiro Lorençoni[1]

[1]*Universidade Estadual Paulista "Júlio de Mesquita Filho", Faculdade de Ciências e Tecnologia, Departamento de Fisioterapia, Laboratório de Fisiologia do Estresse, Presidente Prudente, SP, Brazil.*

Associate Editor: Angelina Zanesco. Universidade Metropolitana de Santos, Faculdade de Medicina, Santos, SP, Brazil; [2]Universidade Estadual Paulista "Júlio de Mesquita Filho", Departamento de Educação Física, Instituto de Biociências, Rio Claro, SP, Brazil. E-mail: angelina.zanesco@unesp.br.

**Abstract - Aim:** The objective of this study is to 1. Investigate in women with cardiac risk factors the acute responses of cardiac autonomic modulation and hemodynamic parameters during and after a dance-based cardiac rehabilitation session and II. Compare these responses with a conventional exercise-based cardiac rehabilitation session. **Methods:** This will be a crossover-clinical trial that will enroll women with at least one cardiac risk factor. The interventions consist of one dance-based (DB) and one traditional exercise-based (EB) session of cardiac rehabilitation, both composed of initial rest, warm-up, moderate-intensity physical exercise, fast recovery evaluation in orthostatic position, and slow recovery evaluation. The main outcomes are 1. Autonomic modulation, evaluated through heart rate variability linear and non-linear methods, and II. Hemodynamic parameters (heart rate, blood pressure, peripheral oxygen saturation, and respiratory rate). All measures will be evaluated in specific moments during the initial rest, physical exercise, and recovery. **Conclusion:** The results will allow the safe inclusion of dance-based sessions in cardiac rehabilitation programs opening an important field of research to investigate the long-term effects on physical fitness and cardiac risk factors, as well as adherence and motivation to attend cardiac rehabilitation in the women population.

**Keywords:** alternative therapy, exercise, autonomic nervous system, cardiac rehabilitation, post-exercise recovery.

## Introduction

Cardiac rehabilitation (CR) is a well-established and highly recommended model of care for primary and secondary prevention of cardiovascular diseases worldwide. However, despite the CR benefits it is globally under-utilized[1], especially by the female population, who are less likely referred and enrolled and have lower adherence and higher dropout rates[2].

Among the various barriers related to women's under-utilization of conventional exercise-based CR are the lack of awareness, motivation, and enjoyment to attend the traditional aerobic activities and the predominant male presence in the program, as reported by Vidal-Almela et al.[3] in a recent literature review. Thus, to address these barriers some alternative therapies have been suggested and studied in the CR scenario in the past years.

To date, DT proved to be efficient in improving functional capacity and lowering blood pressure, as long-term outcomes[4,5], however, to our knowledge, only Kokubo et al.[6] and Belardinelli et al.[7] investigated the acute hemodynamic and cardiopulmonary responses of this intervention in a population with cardiovascular disease. Although, these studies did not consider the autonomic modulation responses during exercise and did not evaluate the acute post-exercise recovery, which is of increasing interest in the literature due to its important prognostic value and correlation with acute events[8]. Also, most of the available studies regarding DT included both male and female populations, which reinforces the relevance of studies specifically targeting the female population, as women are under-represented in the cardiovascular science research field[9].

Therefore, this study became relevant as it will add novel information regarding the acute autonomic and hemodynamic responses during and after a dance-based CR session, an innovative approach that may be useful to

enhance the woman's adherence to regular physical exercise in CR programs, and in addition, this study will provide specific information to the female population, contributing to expand the actual knowledge in this field.

The objective of the study is to: I. Investigate in women with cardiac risk factors the acute responses of cardiac autonomic modulation and hemodynamic parameters during and after a dance-based cardiac rehabilitation session and II. Compare these responses with a conventional exercise-based cardiac rehabilitation session.

We hypothesize that dance-based cardiac rehabilitation will produce physiological acute responses like those observed in conventional exercise-based cardiac rehabilitation, acting as a safe strategy to treat and enhance the adherence of women with cardiac risk factors in supervised exercise programs.

## Methods

### *Study design*

This is a non-randomized crossover clinical trial, registered at clinicaltrials.gov (NCT04967235) and reported accordingly with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[10].

The study will be carried out at the São Paulo State University (UNESP) Faculty of Sciences and Technology, Presidente Prudente, Brazil. The experimental procedure consists of two phases: I. Conventional Exercise-based Session (ES), and II. Dance-based Session (DS). Both are preceded by a familiarization session. The sessions will not be randomized due to the study's organizational and logistical aspects.

### *Ethical aspects*

All procedures were approved by the Committee for Ethics and Research of the Faculty of Science and Technology FCT/ UNESP (CAAE: 79786017.5.0000.5402) and followed the Helsinki declaration. All volunteers will be asked to sign a consent form.

### *Eligibility criteria and recruitment*

The recruitment will be performed by independent researchers that will evaluate the medical records of all women enrolled in the cardiac rehabilitation program offered at the Center for Physical Therapy and Rehabilitation Studies and Treatment of UNESP, and simultaneously attend dance classes offered in the same Institution.

The inclusion criteria are I. Woman ≥ 18 years old; II. Hemodynamically stable; III. Previously attending exercise-based cardiac rehabilitation and dance classes for at least 3 months; IV. To be previously diagnosed with at least one of the cardiac risk factors, defined by the American College of Sports Medicine[11]. Will be excluded from the study from those volunteers who do not attend all study phases.

An interview and a physical evaluation will be conducted, to obtain the following information: I. Age; II. Work occupation; III. Medications of daily use; IV. Heigh (Sanny, Brazil); V. Body mass (Welmy R/I 200, Brazil); and VI. Body mass index.

### *Interventions*

All interventions will be performed between 1:00-6:00 pm in a room with temperature and humidity controlled (21-23 °C and 40-60%)[12]. The ES and DS will occur with a minimal interval of 48 h to allow for the volunteers' recovery. All volunteers will perform the DS before the ES, and both experimental sessions will be preceded by a familiarization session. The study phases are summarized in Figure 1.

Volunteers will be oriented to, during the 24 h that will precede the data collection, avoid high-intensity physical activities, and not consume stimulant substances to ensure the reliability of the autonomic and hemodynamic measures[12].

#### Exercise intensity prescription

The exercise intensity for both protocols will be set at 60-80% of the heart rate reserve (HRR), however, for those volunteers diagnosed with diabetes mellitus, the intensity will be set at 40-70% of the HRR[11]. During both experimental sessions, the exercise intensity will be monitored through an HR monitor (Polar Electro, Kempele, Finland).

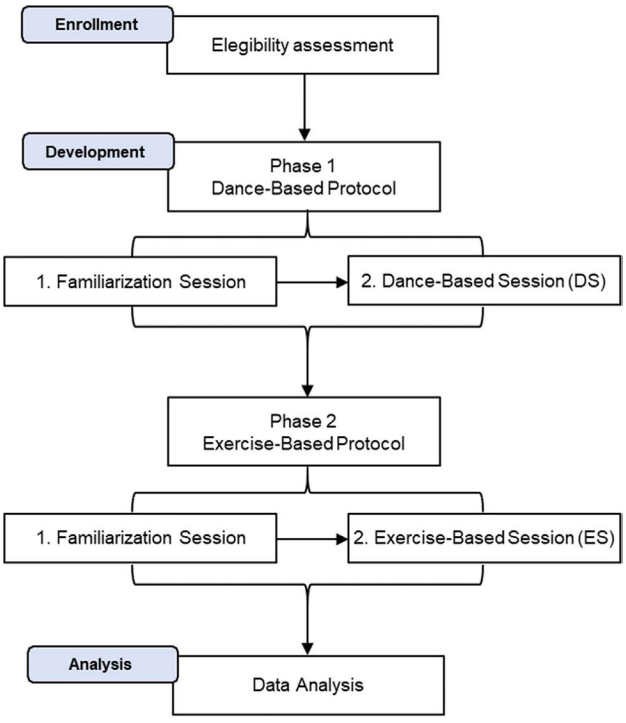


**Figure 1** - Protocol design.

Conventional Exercise-based Session (ES) and Dance-based Session (DS)

Both sessions will be composed of the same phases (Figure 2):

1. Initial rest: supine position and spontaneous breath for 10 min.
2. Warming up: 15 min of stretching and global exercises.
3. Resistance: 30 min of treadmill exercise for ES and dance therapy for DS.
4. Fast phase recovery: after exercise interruption, volunteers will remain in an orthostatic position in rest for 60 s for the evaluation of HR recovery and vagal reactivation.
5. Slow phase recovery: supine position and spontaneously breathe for 30 min.

The resistance phase in the ES will be carried out on a treadmill (Super ATL®, Inbrasport, Brazil) with a constant load, individually defined during the familiarization.

In the DS, the resistance phase will consist of a standardized sequence of dance movements, elaborated by experienced choreographers. The choreography was defined based on the study of Braga et al.[13] and consists of constant and dynamic leg movements including anterior, posterior, lateral, and diagonal body displacements, high knee marching, and little jumps, the arms are engaged with elevation movements and clapping, and in determined moments body turns are performed. Were selected 10 songs from traditional Brazilian music genres ("sertanejo", "axé", "pop", and "funk").

Familiarization sessions

Although volunteers are already familiar with dance classes and exercise-based cardiac rehabilitation, the familiarization sessions will be necessary to establish the treadmill load that will be used in ES, and for training the choreographing and dance movements that will be used in the DS, to ensure that all volunteers will be able to perform the whole choreography and avoid hemodynamic and autonomic alterations related to the intermittence of the dance activities due to the volunteer not being able to keep up with the choreography.

*Outcomes*

Cardiac autonomic modulation: Heart Rate Variability (HRV)

The autonomic modulation will be assessed through the HRV, considering the linear and non-linear methods. For this purpose, the HR will be recorded beat by beat by the Polar RS800CX® (Polar Electro, Kempele, Finland).

The RR interval series will be digitally filtered (Polar Pro Trainer Software - version 5.0, Polar Inc., Kempele, Finland), and visually inspected by a blinded and experienced researcher. Only the series with less than 5% of error will be included[12].

Will be considered the linear [time (rMSSD and SDNN) and frequency domains (LF and HF), geometric indices (TINN and RRtri), and Poincaré plot (SD1 and SD2)] and non-linear [recurrence plot (recurrence rate, determinism), sample entropy, approximate entropy, detrended fluctuation analysis (alpha-1, alpha-2, and DFA-total), symbolic analysis (0V, 1V, 2LV, 2ULV, and Shannon Entropy)] methods of HRV[14].

As primary outcomes, the HRV will be analyzed in five-minute epochs (Figure 3): 5th to 10th min of initial rest (REST), from the 5th to the 25th min of resistance phase (EX1 to EX4), and from the beginning to the end of the slow recovery phase (REC1 to REC6). Each epoch must contain at least 256 consecutive RR intervals[12].

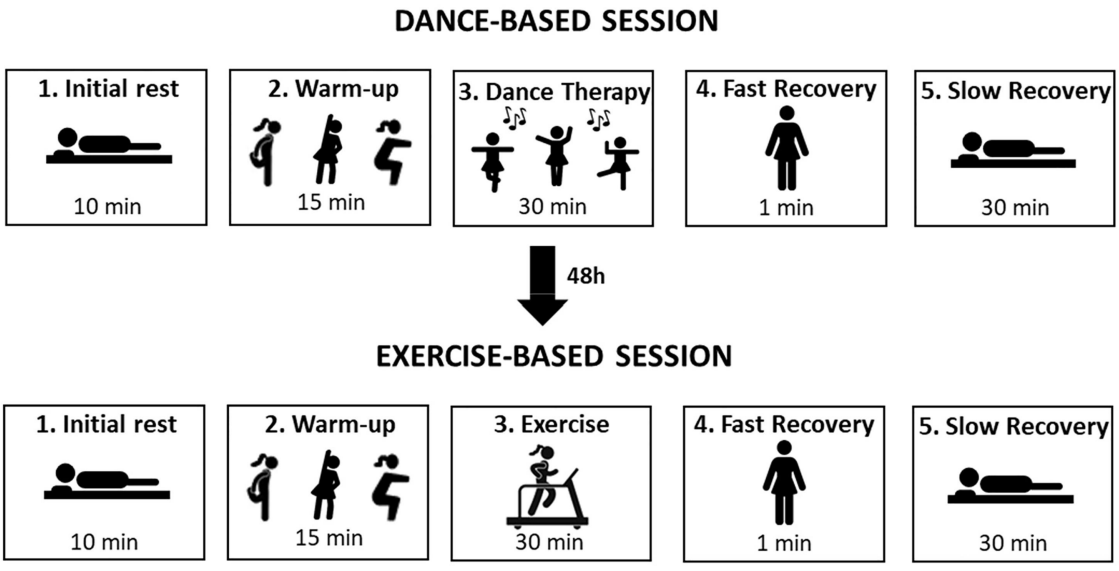


**Figure 2** - Experimental procedure.

Additionally, as a secondary outcome, the fast phase of the autonomic recovery will be evaluated. For this purpose, the vagal reactivation will be assessed by the rMSSD index analyzed in 30-seconds epochs (rMSSD30)[15]. This index will be calculated in the last 30 s of the resistance phase (EX30), and during the one minute of orthostatic passive recovery after the resistance phase (R0-30 and R30-60).

The linear indices, the SampEn, ApEn, and those extracted from the recurrence plot will be calculated at the Kubios HRV software - version 2.0 software. The DFA indices will be calculated at the software "Detrended fluctuation analysis" available in the PhysioNet repository. The symbolic analysis will be performed using the software Symbolic Analysis fast version - version 4.0 Universita'Degli Studi di Milano, Itália, 2005.

Hemodynamic parameters

As primary outcomes, the hemodynamic response during and after the experimental sessions will be evaluated by the following variables: HR, SBP, DBP, peripheral oxygen saturation (SpO2), and respiratory rate (f). These parameters will be analyzed in the following moments: the 5th min of initial rest, and the 1st, 2nd, 3rd, 5th, 10th, 20th, and 30th min of slow recovery.

The HR will be recorded beat by beat during all phases of experimental sessions by the Polar RS800CX® (Polar Electro, Kempele, Finland). In addition, the HR recorded during the 30 min of resistance phase will be also considered in the analysis, to quantify the periods in which volunteers remained above, within, and under the HRR prescribed during both experimental sessions.

The SBP and DBP will be indirectly measured by an experienced and independent researcher. The SpO2 will be evaluated through a pulse oximeter (Mindray PM-50 Pulse Oximeter, China). The f will correspond to the number of respiratory incursions counted within one minute, without the volunteer noticing it.

As a secondary outcome, the fast recovery phase will be evaluated by the heart recovery[15], assessed after one min of passive recovery in the orthostatic position (HRR1).

*Blinding, randomization, and allocation*

Due to the study design, the assessors and participants cannot be blinded, however, the researcher responsible for the HRV data filtering, HRR1 calculation, and all data analysis will be blinded. All datasheets will be codded ensuring the confidentiality of the data.

The randomization and secret allocation will not be performed due to the study's organizational and logistical aspects, which is a limitation of our design. However, to minimize this bias, we established as inclusion criteria the participation in exercise-based cardiac rehabilitation and dance classes for at least 3 months, to ensure that all volunteers have previous experience with the interventions applied in the experimental sessions, avoiding possible confounding effects, as the acute cardiovascular, autonomic, and emotional effects of initiating a new activity.

Additionally, to allow the full volunteers´ recovery after a bout of exercise we included a 48 h washout period between DS and ES, to avoid any carry-over effect related to the acute effects of exercise.

*Sample size*

The required sample size was calculated (GPower - version 3.1), considering the rMSSD index obtained in a pilot study. The mean difference assumed was 5.6 ms, and the standard deviation was 6.0 ms. The alpha and beta risks were 5% and 80%, respectively. The sample size resulted in 14 volunteers. Accounting for possible sample losses, we added 10% to the calculated sample size, totalling 16 volunteers.

*Statistical methods*

All analysis will be performed at IBM SPSS Statistics Software - version 22.0 by a blinded researcher using a coded datasheet. The sample profile data will be presented as mean, standard deviation, 95% confidence interval, and absolute and relative values.

For the main outcomes, the normality of the data will be checked by Shapiro-Wilk´s test. To compare the experimental sessions (ES and DS) and the time effect

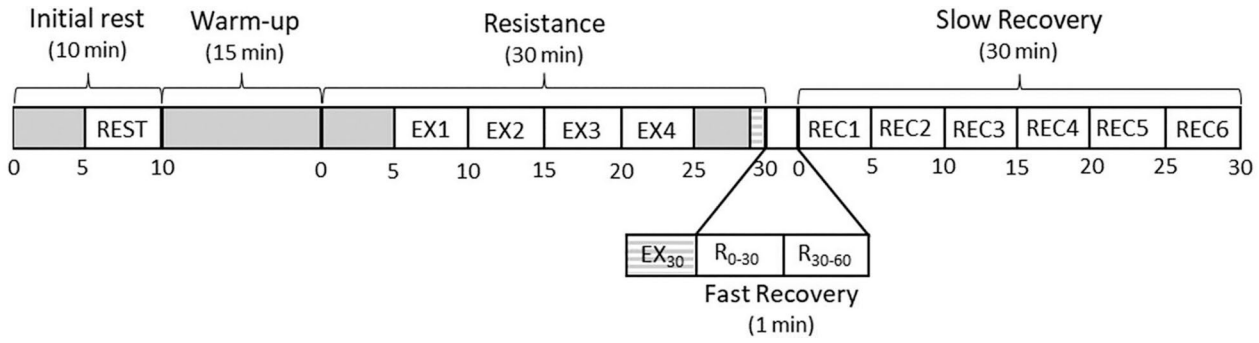


**Figure 3** - Heart rate variability analysis moments.

(rest vs recovery and rest vs exercise), the two-way repeated-measures ANOVA with Bonferroni or Dunn post-hoc test will be used, accordingly to the data normality. The data sphericity will be checked by Mauchly´s test, and if it is violated the Greenhouse-Geisser correction will be considered. If differences between sessions are found, they will be assessed moment by moment by the student´s t-test for unpaired data or the Mann-Whitney test, accordingly to the data normality.

For the heart rate recovery analysis, the comparison of HRR1 between sessions will be performed by the Student´s t-test for unpaired data or the Mann-Whitney test, and the comparison between the HRpeak and HRR1 in the same session will be performed by the Student´s t-test for paired data or Wilcoxon test.

To analyse the periods in which volunteers remained above, within, and under the HRR prescribed, the total time spent in each category will be summed and presented as percentage values concerning the total of 30 min of the resistance phase. The statistical difference will be set at 5%.

## Conclusions

This clinical trial protocol will allow the investigation of the acute autonomic and hemodynamic responses during and after a dance-based cardiac rehabilitation session compared to a conventional exercise-based cardiac rehabilitation session in women with cardiac risk factors. If the results prove that dance therapy promotes similar responses to those observed in conventional exercise-based cardiac rehabilitation, it will open an important field of research to investigate the long-term effects on physical fitness and cardiac risk factors, as well as adherence and motivation to attend cardiac rehabilitation.

## References


1. Franklin BA, Brinks J. Cardiac rehabilitation: underrecognized/underutilized. Curr Treat Options Cardiovasc Med. 2015;17(12):62. doi
2. Bittner V. Cardiac rehabilitation for women. In: Advances in experimental medicine and biology. New York, Springer LLC; 2018. p. 565-77. doi
3. Vidal-Almela S, Czajkowski B, Prince SA, Chirico D, Way KL, Pipe AL, et al. Lessons learned from community-and home-based physical activity programs: a narrative review of factors influencing women's participation in cardiac rehabilitation. Eur J Prevent Cardiol. 2021;28:761-78. doi
4. Cugusi L, Manca A, Bergamin M, di Blasio A, Yeo TJ, Crisafulli A, et al. Zumba fitness and women's cardiovascular health: a systematic review. J Cardiopulmon Rehab Prevent. 2019;39:153-60. doi
5. Conceição LSR, Neto MG, do Amaral MAS, Martins-Filho PRS, Carvalho VO. Effect of dance therapy on blood pressure and exercise capacity of individuals with hypertension: a systematic review and meta-analysis. Int J Cardiol. 2016;220:553-7. doi
6. Kokubo T, Tajima A, Miyazawa A, Maruyama Y. Validity of the low-impact dance for an exercise-based cardiac rehabilitation program. Phys Ther Res. 2018;21(1):9-15. doi
7. Belardinelli R, Lacalaprice F, Ventrella C, Volpe L, Faccenda E. Waltz dancing in patients with chronic heart failure: a new form of exercise training. Circ Heart Fail. 2008;1 (2):107-14. doi
8. Qiu S, Cai X, Sun Z, Li L, Zuegel M, Steinacker JM, et al. Heart rate recovery and risk of cardiovascular events and all-cause mortality: a meta-analysis of prospective cohort studies. J Am Heart Assoc. 2017;6(5):e005505. doi PMID
9. Melloni C, Berger JS, Wang TY, Gunes F, Stebbins A, Pieper KS, et al. Representation of women in randomized clinical trials of cardiovascular disease prevention. Circ: Cardiovasc Qual Outcomes. 2010;3(2):135-42. doi
10. Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleza-Jeric K, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials development of the spirit 2013 statement. Ann Intern Med. 2013;158:200-07. doi
11. Pescatello LS, Arena R, Riebe D, Thompson PD. ACSM'S guidelines for exercise testing and prescription. Baltimore, Wolters Kluwer; 2013.
12. Catai AM, Pastre CM, Godoy MF de, Silva E, Takahashi ACM, Vanderlei LCM. Heart rate variability: are you using it properly? Standardisation checklist of procedures. Braz J PhysTher. 2020;24:91-102. doi
13. Braga HO, Gonzáles AI, Sties SW, de Carvalho GMD, Netto AS, Campos OA, et al. The Brasilian samba protocol for cardiac rehabilitation. Rev Bras Med Esporte. 2015;21 (5):395-9. doi
14. Shaffer F, Ginsberg JP. An overview of heart rate variability metrics and norms. Front Public Health. 2017;5:258. doi
15. Peçanha T, Bartels R, Brito LC, Paula-Ribeiro M, Oliveira RS, Goldberger JJ. Methods of assessment of the post-exercise cardiac autonomic recovery: a methodological review. Int J Cardiol. 2017;227:795-802. doi



*Corresponding author*

Maria Júlia Lopez Laurino, Universidade Estadual Paulista "Júlio de Mesquita Filho", Faculdade de Ciências e Tecnologia, Programa de Pós-Graduação em Fisioterapia, Presidente Prudente, SP, Brazil.
E-mail: majulaurino@hotmail.com.



*Manuscript received on August 22, 2022*
*Manuscript accepted on September 11, 2022*