

Cardiovascular health program with university students based on e-TEORISC: protocol for a clinical trial

Programa em saúde cardiovascular baseado no e-TEORISC com estudantes universitários: protocolo de um ensaio clínico

Programa de salud cardiovascular basado en e-TEORISC con estudiantes universitarios: protocolo para un ensayo clínico

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How to cite this article:

Cruz Neto J, Cavalcante TF, Félix NDC, Moreira RP. Cardiovascular health program with university students based on e-TEORISC: protocol for a clinical trial. Rev Gaúcha Enferm. 2024;45(spe1):e20240160. <https://doi.org/10.1590/1983-1447.2024.20240160.en>

ABSTRACT

Aim: To describe a study protocol to compare the difference between the risk of impaired cardiovascular function (00311) among university students as mediated by standard nursing consultation, when compared with nursing consultations mediated by the e-TEORISC.

Method: Randomized, controlled and blinded clinical trial protocol. People with the NANDA-I nursing diagnosis of risk of impaired cardiovascular function (00311) will be included. Participants will be distributed, according to paired randomization by gender and number of etiological factors in nursing diagnosis 00311, into an intervention group (consultation and software based on the nursing theory studied) and a control group (standard nursing consultation). The main outcome will be the reduction of two or more etiological factors of the nursing diagnosis. The proposal was registered with the Brazilian Registry of Clinical Trials under number RBR-8y3qx39.

Expected results: The implementation of the care program through e-TEORISC is expected to encourage the target audience to adhere to health services and allow care plans to be drawn up that reduce the etiological factors of the nursing diagnosis.

Descriptors: Nursing theory. Heart disease risk factors. Standardized nursing terminology. Software. Clinical trial.

RESUMO

Objetivo: Descrever um protocolo de estudo para comparar a diferença entre o Risco de função cardiovascular prejudicada (00311) entre estudantes universitários, mediada por consulta de enfermagem padrão versus consulta de enfermagem mediada pelo e-TEORISC.

Método: Protocolo de ensaio clínico randomizado, controlado e cego. Serão incluídas pessoas com o diagnóstico de enfermagem de Risco de função cardiovascular prejudicada (00311) da NANDA-I. Os participantes serão distribuídos conforme randomização pareada por sexo e quantidade de fatores etiológicos do diagnóstico de enfermagem 00311, em grupo intervenção (consulta e software embasado na teoria de enfermagem estudada) e controle (consulta padrão de enfermagem). The main outcome will be the reduction of two or more etiological factors in the nursing diagnosis. A proposta foi registrada no Registro Brasileiro de Ensaios Clínicos sob nº RBR-8y3qx39.

Resultados esperados: Espera-se que a implementação do programa de cuidados por meio do e-TEORISC favoreça a adesão do público-alvo aos serviços de saúde e permita conduzir planos de cuidado que reduzam os fatores etiológicos do diagnóstico de enfermagem.

Descritores: Teoria de enfermagem. Fatores de risco para doenças cardíacas. Terminologia padronizada em enfermagem. Software. Ensaio clínico.

RESUMEN

Objetivo: Describir un protocolo de estudio para comparar la diferencia entre el riesgo de deterioro de la función cardiovascular (00311) entre estudiantes universitarios, mediado por la consulta de enfermería estándar, comparado con la consulta de enfermería mediada por e-TEORISC.

Método: Protocolo de ensayo clínico aleatorizado, controlado y ciego. Se incluirán personas con el diagnóstico de enfermería NANDA-I de Riesgo de deterioro de la función cardiovascular (00311). Los participantes se distribuirán según una aleatorización emparejada por sexo y número de factores etiológicos en el diagnóstico de enfermería 00311, en un grupo de intervención (consulta y programas informáticos basados en la teoría de enfermería estudiada) y un grupo de control (consulta de enfermería estándar). El resultado principal será la reducción de dos o más factores etiológicos del diagnóstico de enfermería. La propuesta fue registrada en el Registro Brasileño de Ensayos Clínicos con el número RBR-8y3qx39.

Resultados esperados: Se espera que la aplicación del programa de cuidados a través de e-TEORISC anime al público destinatario a adherir a los servicios sanitarios y permita elaborar planes de cuidados que reduzcan los factores etiológicos del diagnóstico de enfermería.

Descriptores: Teoría de Enfermería. Factores de Riesgo de Enfermedad Cardíaca. Terminología Normalizada de Enfermería. Software. Ensayo Clínico.

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INTRODUCTION

Cardiovascular risk is related with a context of health and care that allows identifying modifiable and non-modifiable risk factors that predispose one to disease. These can be biological, cardiometabolic, behavioral, psychosocial, cultural, and work-related, and all of them indicate processes that make the individual vulnerable⁽¹⁾. In the international setting, care for cardiovascular risk classifies it using scales and scores such as Framingham, The HEARTS, Global Score, SCORE, QRISK, and Reynolds⁽²⁻⁵⁾. However, these strategies cannot correctly help care, but merely warn about the potential presence of a health issue in the midst of a set of factors⁽⁶⁾.

Six in every ten people do not go through adequate training for cardiac disease. Furthermore, the risk is veiled and hardly ever stratified⁽⁷⁾. Usually, cardiovascular risk stratification in Brazil takes place in primary care. It is regulated by primary health care booklet No. 37 and performed by physicians and nurses using Framingham score as a guidance⁽⁸⁾. A setting seldom studied to stratify the risk are universities whose public is exposed to several cardiovascular risk factors due to the routine and university adaptations, such as stress, anxiety, depression, sleep deprivation, and metabolic changes⁽⁹⁾.

A way to implement nursing care in the university environment is through nursing consultations. A nursing consultation is a private activity of the nurse which comprises five well-established, interrelated, recurrent, interdependent, and cyclical stages, which are: nursing evaluation (objective and subjective data identified using several techniques); nursing diagnosis (evaluation of the conditions that make a person, family, community, or a special group vulnerable); nursing planning (care plan and decision-making); implementation (standards of care); and evolution (evaluation of results)⁽¹⁰⁾. A nursing consultation is a private nurse activity which comprises five well-established, interrelated, recurrent, interdependent, and cyclical stages, which are: nursing evaluation (objective and subjective data identified using several techniques); nursing diagnosis (evaluation of the conditions that make a person, family, community, or a special group vulnerable); nursing planning (care plan and decision-making); implementation (standards of care); and evolution (evaluation of results)⁽¹⁰⁾. One important step in improving the health care provided is to find out which characteristics and related factors are present in an individual due to health conditions that would allow inferring nursing diagnoses.

The NANDA-I defines the nursing diagnosis "risk for impaired cardiovascular function" (00311) as "Susceptibility to disorders in the transport of substances, body homeostasis, removal of metabolic tissue residue, and organic function"⁽¹¹⁾. When the heart function impairment increases, it requires

innovative strategies that can reduce clinical indicators which harm people's health and have an impact on nursing care⁽¹¹⁾.

Due to the epidemiological importance of cardiovascular risks and of the work of the nurse in promoting cardiovascular health care, outpatient nursing consultations to evaluate the nursing diagnosis "risk for impaired cardiovascular function" (00311) and the prescription of actions to promote health and reduce the risk associated with individual factors and phenomena are necessary.

The use of nursing theories in clinical practice can favor cardiovascular risk-related care. Once the phenomena responsible for the disease of an individual are identified, the use of the theory can foster articulations between different sets of factors as a way to organize the care provided, thus maximizing the possibilities of improving plans of care and directing guidance, reducing gaps in the identification, stratification, monitoring, implementation, and evaluating care⁽¹²⁾.

The grouping of data, assumptions, and factors within nursing theories, foster and guide practice through the praxis of care, in addition to being a way to test and operationalize. This study is guided by philosophical precepts from the Theory of Care in the Context of Cardiovascular Risk (TEORISC). Its concepts regarding the factors, cardiovascular risk phenomena, and the 00311 diagnosis from NANDA-I are articulated to the software e-TEORISC⁽¹²⁻¹³⁾.

This is a perspective from nursing science according to which nursing consultations should be structured according to classification systems and guided by theories⁽¹⁴⁾. This attitude can improve the quality of nursing care, effecting the leadership of this professional and promoting better conditions for therapeutic adherence, while reducing rehospitalizations related with cardiovascular diseases⁽¹⁵⁾.

Although cardiovascular disease care programs may have an impact in risk factors⁽¹⁶⁾, it is necessary to improve nursing and health knowledge with a method that can evaluate, monitor, and intervene in individuals with no comorbidities. This raises the question: What is the impact of a cardiovascular health program in university students using the e-TEORISC?

The gap in knowledge that originated this study lies in the need to expand the scope of nursing practices in the assistance to patients who are under the risk of having an impaired cardiac function, as adapted to a care program led by a nurse using the e-TEORISC. Clinical trials must be encouraged in order to test technologies focused on supporting professional practice. It is necessary to improve the quality of nursing care and health care in the context of cardiovascular risks, using a technological tool in the university public, which is a justification for this study. When this tool is in place, the nurse will be able to determine strategies to manage plans of care to prevent cardiovascular risk.

As a result, this research seeks to describe a study protocol to compare the differences between the risk of impaired cardiovascular function (00311) among university students when mediated by standard nursing consultations, and the same risk when mediated by nursing consultations that use the e-TEORISC. The clinical trial will be randomized, controlled, triple blind, parallel, and exploratory.

■ METHOD

This study follows the Standard Protocol Items: Recommendations for Interventional Trial (SPIRIT) guidelines⁽¹⁷⁾, as a way to report the RCT. Additionally, it followed the Consolidated Standards of Reporting Trials (CONSORT), which guides the construction and execution of an RCT⁽¹⁸⁾. The trial was registered in the Brazilian Registry of Clinical Trials (REBEC), under No. RBR-8y3qx39. This study is part of an MS dissertation developed in partnership with two federal universities inland Brazilian northeast, in the states of Ceará and Bahia.

1. Participants, interventions, and outcomes

Site of the study

This study will be conducted in the cardiovascular health outpatient clinic associated with a higher education institution in inland Ceará, which attends not only the academic population, including its workers and subcontractors, but also the population of thirteen municipalities in the health microregion of Ceará.

Eligibility criteria

The study will include university students from 18 to 59 years old, diagnosed with risk of impaired cardiovascular function (00311), who show interest to receive clinical follow up. Will be ineligible pregnant women, people with cardiac diseases, as well as those with physical, visual, or auditory disabilities, and those who, for any reason, are prevented from taking anthropometric measures and/or whose specific needs is not included in the instruments used.

In order to provide a diagnostic definition and verify whether a factor is present, we will use the operational definition from Silva⁽¹⁹⁾, in addition to scales to measure etiological factors and their corresponding thresholds. To evaluate the outcomes, we will apply the same instruments and compare them with the baseline stage. Etiological factors evaluated will include: family history of cardiovascular diseases, sedentary lifestyles, alcohol use/abuse, dyslipidemia, lack of knowledge about cardiovascular risk factors, being overweight, obese, smoking, unhealthy diet, anxiety, stress, diabetes, use of illegal

drugs, depression, and metabolic syndrome, according to the 2021-2023 version of NANDA-I. This version was chosen to structure the project and carry out its stages as it is the current edition. The presence of two or more etiological factors will define the presence of the nursing diagnosis.

Interventions

The descriptions of the interventions to be applied in this study are in Chart 1.

The e-TEORISC is a software produced by a team of authorities in the field of health, nursing, and computer sciences. It is comprised of sets of activities, divided into cardiometabolic, behavioral, psychosocial, affective, therapeutic, and work-related factors. The nursing diagnosis results are focused in a terminological subset of CIPE^{®(12-13)}, in addition to the 00311 diagnosis of NANDA-I⁽¹¹⁾. For each patient, the main researcher will list care plans with diagnoses, interventions, and outcomes that correspond to the needs found, using the options available in the software.

To minimize potential CG biases, the three nurses used the same standard protocol to guide the care in the consultations. This protocol, not validated, is the only one used in the service for the triage of cardiovascular risk patients. The difference with the software is especially in the management of the tool and the plans of care, longitudinal follow up of diet, and information feedback, in addition to using standardized language that is not well articulated with the real needs of the public.

The study will be interrupted or discontinued if any individual stops following clinical evaluation recommendations prescribed in the consultations, at any time and regardless of their reason to do so, in order to ensure that the research is reliable. To improve the adherence to protocols, both the intervention and the control group will be evaluated by a lab, regardless of locus and with no cost. This will allow evaluating their state of health and the continuation of their care. During the trial, they will be allowed to undergo simultaneous treatments, as long as they involve lifestyle changes and are implemented during the consultation, in an agreement between nurse and patient.

Outcomes and measurement variables

We will compare the difference between the risk of impaired cardiovascular function in people monitored using the standard nursing consultation and those under e-TEORISC mediated nursing consultations. The clinical variables measured include etiological factors of the nursing diagnosis of risk of impaired cardiovascular function⁽¹⁹⁾. They will also include anthropometric measures: weight (kg); height (m); waist, neck, hip, and thigh circumferences (cm); body mass index (Kg/m²); and vital signs using certified instruments,

Chart 1 – Interventions applied in the study locus. Redenção, Ceará, Brazil, 2024.

	Intervention Group (IG)	Control Group CG
Profile of those included	Students with, at least, two factors from diagnosis 00311	Students with, at least, two factors from diagnosis 00311
Intervention strategy	Nursing consultation using the e-TEORISC Software ⁽¹²⁾	Nursing consultation using the standard operational protocol of the service
Who will carry out the consultations	Nurse that proposed the study	Three nurse professors who work in the service
Main variables evaluated in the strategies	Sociodemographic and anthropometric data; Laboratory and clinical; Nursing diagnoses, outcomes, and nursing interventions; Structural organization based on TEORISC; Use of CIPE® and NANDA-I systems.	Sociodemographic data; Reason for seeking care (signs and symptoms); Diseases and medications used; Non-standardized nursing diagnosis to interventions and outcomes
Number of consultations	1	1
Number of reinforcements	1	0
Time between first consultation and outcome evaluation	90 days	90 days

according with national guidelines⁽²⁰⁻²¹⁾. The evaluation will use portable calibrated electronic scales, in addition to flexible, and inelastic Coscorf® portable stadiometers with an accuracy of 0.1 cm.

The clinical signs examined are: arterial pressure (mmHg), as measured by the research team according to the oscillometric method, using a logicare 19-J-0098 olidef multiparametric monitor, calibrated according to the Brazilian Society of Cardiology and international recommendations⁽²⁰⁾; heart rate (bpm); respiratory rate (irpm); temperature (°C); and oxygen saturation (SpO₂). The latter by means of a portable Multilaser OX-06 HC261 oximeter.

The necessary exams to identify risk factors are: total HDL-c cholesterol, VLDL triglycerides, and glycemia, collected after 12-hour fasting and analyzed using specialized laboratory methods⁽²⁾. It is worth noting that these exams will be funded by a universal project associated with the research, at no cost to participants. The materials will be collected by the company that is associated with the research, and reports will be delivered to the main researcher.

The main outcome will be the reduction of two or more etiological factors in the nursing diagnosis. A secondary outcome is the biochemical change of total cholesterol, HDL-c,

LDL, and non-HDL (VLDL), in addition to triglycerides and glycemia. The reduction, equivalence, or increase in these markers will be observed. Independent variables will be the sociodemographic, clinical and, and laboratory factors analyzed. The outcome variables will be the reduction, elimination, or the control of etiological factors of the nursing diagnosis 00311.

The time between the intervention and the evaluation of the outcomes will be 90 days. The time stipulated considers the minimum time to establish a nursing led care program⁽²²⁾.

Participant history

The schedule of protocol procedures related to the locus of the study is described in steps, according to Chart 2.

Sample size

The study population will include adults, followed up in an outpatient clinic for cardiovascular health, who undergo a baseline exam and attend to inclusion criteria. Sample calculation will consider a predictability of 80% and a significance level of 5% (α) with power of 20% (β) and an increase of 20% to compensate potential losses and refusals, thus forming the final sample. Thus, for a sample calculation, we will use the difference model for two groups⁽²³⁾. Considering

Chart 2 – Schedule of protocol procedures related to the locus of the study. Redenção, Ceará, Brazil, 2024.

Atividade Evaluation			-1	0	T1	T2	T3	T4
	Research member	Approximate time to complete	Pre-study consent	Triage	Randomization	Consultation	Follow up (45 days after T1)	Outcome (90 days after T1)
Pre-selection consent (invitation).	Research team	30 days*	X					
Triage records	Main researcher	15 days*	X					
Consent form/questionnaire	Research team	15 days*	X					
Inclusion/exclusion form	Main researcher	15 days [†]	X	X				
Group allocation	External researcher	15 days [‡]			X			
IG consultation (simultaneous with CG consultation)	Main researcher	90 days [§]				X	X	
CG consultation (simultaneous with IG consultation)	Nursing professors	30 days [§]				X		
Outcome assessment	Research team	30 days						X
Data analysis	Statistician	30 days						X

Caption: *Happens in sequence, adding up to 60 days; [†]Happens simultaneous, adding up to 15 days; [‡] happens over 15 days; [§] happens simultaneously, adding up to 90 days. Source: Data prepared by the author, 2024.

an initial prevalence of 0.8 (p1) and a secondary prevalence of 0.5 (p2) for cardiovascular risk (24), in addition to losses, the sample will include 19 patients in each group. Any losses or withdrawals will be recorded carefully.

Recruitment

The invitation will be made in three ways: via telephone, using the records available in the service (registered patients), manifestation of interest using a Google Forms form (made available to undergraduate student from the institution via WhatsApp), and spontaneous demand, that is, including patients who were waiting for a consultation. Eligible participants will be invited to a consultation where a clinical triage will be carried out in order to identify the criteria of the diagnosis "risk of impaired cardiovascular function" (00311), according with the intervention protocol. These will be included after the participant and the researcher sign two copies of the informed consent.

2. Intervention administration

Allocation and sequence generation

An equal number of participants will be allocated to the IG and IC. A researcher that is not part of the team will be responsible for randomizing the participants. This collaborator will not take part in any other activity aimed at implementing the intervention and the evaluation of the outcome. He generated the allocation sequence using the software <https://www.meta-calculator.com/statistics-calculator.php>(25). Thus, the researcher and members of the team did not have access to this early list, being blinded.

Randomization was blocked, in a 1:1 ratio. To ensure the equitable distribution at baseline, the variable "number of cardiovascular etiological factors" will be designated, in addition to the stratification factor of the two sets of participants, considering, for each pair, the similarity of this variable. When pairing each block, we also considered the variable sex, in order to homogenize the participants in each branch of the experiment. Thus, participants had the same chance of being allocated to the IG or the CG.

Blinding

Participants, scholarship beneficiaries who collaborate (outcome evaluators), and the statistician responsible for data analysis will be blinded (no access to details from the groups), thus characterizing a triple-blind study. To do so, the database will be coded, and only the main researcher will have access to the caption of the variables and to information regarding which group they belong to. This ensures the feasibility and robustness of a possible RCT, when there

is a nursing intervention. This process will ensure adequacy and reduce biases that may occur. In this trial, breaching blinding will not be allowed.

3. Data collection, management, and analysis

Data collection methods

Data collection will have three stages: stage I – baseline, the presentation of the research and recruiting (carried out by the research team); stage II – application (carried out by the nurse researcher for IG and nurse professor for the CG); and stage III – evaluation of the outcomes (carried out by the research team) (with a 45-day interval after the last consultation for both groups. For the IG, the second moment includes two consultations, one of which is the software mediated consultation, while the second is a follow up on the previous consultation, with 45 days between them. Research assistants will help in the baseline stage and in the evaluation of the outcomes. At that time, considering the presence of the factors according with the team, the researcher will validate or not the 00311 diagnosis.

The research team is formed by the main researcher, undergraduates receiving a scholarship, and a supervisor. The undergraduate nursing students will be previously trained in two sections, in order to learn how to handle the study instruments via clinical cases, after having already finished the adult health discipline, which is mandatory in the nursing course. They will be blinded for the application of the interventions and the outcome, being unaware of which group each patient evaluated belongs to.

Data collection instruments to identify each etiological factor include many scales, presented in the operational definition⁽¹⁹⁾. We will use a sociodemographic instrument made exclusively for this research to characterize the participants including anthropometric variables, vital signs, and clinical variables. The Mini-Mental State Examination will also be applied in the triage, with a cutoff point of 23/24⁽²⁶⁾, for the continuity of the research process, according to the eligibility criteria established.

Participants who do not continue their treatment will have their data collected and stored by the researcher, and in case they undergo any exams, these will be given to them. The sample will not be complemented after the losses, since the RCT will last as long as the MS of the main researcher.

Data management

The main researcher is responsible for storing all data, records, instruments, scales, exams, terms, and samples for a minimum period of five years after the research is finished. Any changes necessary to the research protocol will be formally

communicated to the research ethics committee and to the REBEC. Any doubts will be clarified before the study, and any later questions can be asked through the contact information in the form. Data collected will be stored, double-checked, and undergo a paired verification of the information.

Statistical methods

Analyses will be carried out based on the intention to treat, with individuals being followed up until the end, with their data stored for analysis. The data collected will be stored and blinded using the Microsoft 365 software, and analyzed using the Statistical Package for Social Sciences, version 24, considering a significance level of $\alpha < 0.05$. At first, normality (Kolmogorov-Smirnov) and homoscedasticity (Levene test) will be evaluated. Then, we will calculate the frequency distribution (mean) and standard deviation (SD) of the sociodemographic, clinical, and general health profile. For the inferential analysis of the categorical data, we will use Fisher's exact, and the logistic regression technique with odds ratio, 95% confidence interval (CI) and p-value using the forward technique, adjusting the model to the Wald test to verify its significance. In regard to numerical data, we will apply parametric statistical tests to compare means (Student's t-test or ANOVA), or medians (Mann-Whitney's), in the case of non-parametric distributions. Data will be disposed in tables, figures, and models.

4. Ethics and dissemination

Damage and confidentiality of the research

This research will follow all ethical precepts from Resolution 466/2012 of the National Council of Health, in addition to minimizing damage/risks (fatigue, impotence, or discomfort due to the need to adapt to a new self-care routine). The fatigue caused by the number of consultations was reduced with scheduling and planning, which will be made so consultations can take place in the most comfortable days and times for the patient. Feelings of impotence, caused by the feeling that they cannot perform any of the activities or because they actually are unable to do them properly; discomfort due to being in front of "strangers" and fear of any repercussions on their health. To do so, an individual consultation will be conducted in a private room, an office for individualized care, with requests for relatives or companions when needed, ensuring that the information will be used only for scientific research purposes and the patient will have access to it whenever they wish.

Benefits will be maximized (cardiovascular health promotion, exams to determine a biochemical profile, and the

creation of an objective, free-of-charge, and widely accessible care program), to ensure human dignity and protect study participants. Individuals could interrupt their participation by requesting it, in which case any personal information collected will be kept for analysis, unless the participant states otherwise.

Regarding data confidentiality, the research team will have access to the participants' medical records after they are randomized, since at this point they will only have a coded number to be used in data spreadsheets. After this process, the main investigator will be responsible for storing the material.

Ethical approval of the research

The RCT was submitted to an evaluation of the outpatient clinic management through a consent form and forwarded by the university's Research Ethics Committee being approved under CAAE 69626223.0.0000.5576. Participation will be voluntary, free of charge and days and times will be scheduled. Participant data will be coded according to their medical record numbers, which will ensure anonymity and preserve individuals from any embarrassment.

Disclosure Policy

Data from the dissertation will be disseminated to the scientific community and to health professionals, patients and other interested parties through relevant scientific means (papers in journals, books, and national and international events). Access to the final set of data will be restricted to the main researcher. Linguistic and/or statistical reviewers will not be considered authors for texts related to this work.

■ EXPECTED RESULTS

We expect this study to contribute with research and in the care provided by nurses for people at cardiovascular risk, especially university students, allowing the scientific advancement of the profession through the use of taxonomies in clinical trials. Furthermore, implementing the e-TEORISC will show the impact of the software-based cardiovascular health program when compared to traditional consultations, while also showing the adherence of its participants to reduce etiological factors of the nursing diagnosis under study. We believe that including the e-TEORISC will allow managing and continuously improving this tool, which is easy to expand into other health services, showing potential to be used by all primary/secondary care ones.

We expected that, using the e-TEORISC, university students will be better identified and stratified, helping the process of longitudinal health care, and horizontal care practices in the Single Health System to ensure universal access,

providing integral and equal care by designing a specific plan for each individual's health. Finally, nurses will have the opportunity of designing strategies for their public with a holistic, interactive, adaptive, and multi-focused perspective, by establishing goals, developing their clinical-diagnostic reasoning, clarifying the basis for the interaction between health care systems, and expanding nursing research.

Study status

This research is in the data collection stage, respecting the conclusion date in table 1. It will be made available to the scientific community.

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■ Acknowledgment

To the support from the Coordination for the Improvement of Higher Education Personnel – Brazil (CAPES) – Financing Code 001.

■ Funding

National Council for Scientific and Technological Development – Brazil (CNPq) – Universal Call process 406424/2021-7.

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The authors declare that there is no conflict of interest

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Associate editor:

Taline Bavaresco

Editor-in-chief:

João Lucas Campos de Oliveira

Received: 05.19.2024

Approved: 09.04.2024

