



FEDERAL UNIVERSITY OF DOS
JEQUITINHONHA E VALLEYS
MUCURI



CONSUBSTANTIATED OPINION OF THE CEP

AMENDMENT DATA

Search Title: PHYSICAL AND FUNCTIONAL PROFILE OF INDIVIDUALS WITH OBESITY AND ASSOCIATION WITH CARDIOVASCULAR AND METABOLIC DISEASES

Researcher: VANESSA AMARAL MENDONÇA

Thematic Area:

Version: 7

CAAE: 34095720.0.0000.5108

Proposing Institution: Federal University of the Jequitinhonha and Mucuri Valleys

Primary Sponsor: Own Financing

OPINION DATA

Opinion Number: 5,331,784

Project presentation:

Amendment to the project: "PHYSICAL AND FUNCTIONAL PROFILE OF INDIVIDUALS WITH OBESITY AND ASSOCIATION WITH CARDIOVASCULAR AND METABOLIC DISEASES"

Research Objective:

Add the assessment of food consumption of research volunteers, according to the recommendations of the Food Guide for the Brazilian population.

Assessment of Risks and Benefits:

Not applicable

Comments and Considerations about the Research:

This amendment aims to add the assessment of the food consumption of research volunteers, according to the recommendations of the Food Guide for the Brazilian population, as, according to recent literature, excessive caloric intake and the intense deterioration in the quality of diets, with increased consumption of so-called "ultra-processed" foods, is associated with an increased risk of several diseases, especially obesity, diabetes, cardiovascular diseases and several other chronic non-communicable diseases of great epidemiological relevance. This amendment is pertinent due to what was justified in the project. It will not result in a significant change in the participation of volunteers, this being an increase of 15 minutes of participation, using an already existing and standardized questionnaire. The number

The sample size still needs to be changed: 369.

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Proposed Methodology:

Data collection will begin after the Research Ethics Committee approves the project. Scheduling will occur depending on the participant's availability, and they are advised to attend the study location with all pre-test recommendations sent by phone or email: Wear light clothing, do not use metallic objects, and attend fasting. An interview/anamnesis based on a Data Collection Instrument will be applied to verify the health status, characterize the profile of individuals with obesity in Diamantina, and compose the database that will be part of the analysis in the future.

Statistics will be used in association with the other tests that will be carried out. The experimental stage of the present study

will be carried out at the Exercise Physiology Laboratory (LAFIEX), at the Inflammation and Metabolism Laboratory (LIM) and will have the participation of the Exercise Biology Laboratory (BioEx), located at the Integrated Research and Postgraduate Center - Graduation in Health (CIPq - Health) and at the UFVJM School of Physiotherapy clinic. The laboratories have all the necessary infrastructure for the development of research. The experimental design will take place entirely on a single day, with measurements to be carried out in the morning and afternoon shifts, which means that after recruitment, each volunteer will undergo all assessments once. The researchers involved will be previously trained, and intra-examiner reliability analysis will be conducted to apply all functional clinical tests.

After the participant has been selected and has consented to participate in the project, the day will be scheduled for them to carry out all the assessments. The assessment day, morning shift: signing the informed consent form and anamnesis based on filling out the data collection instrument. The body composition of the participants will then be investigated. To this end, Dual Energy Radiological Absorptometry (DEXA) and Single Electrical Frequency Bioelectrical Impedance Analysis (BIA) equipment will be used. Finally, a researcher from the Exercise Biology Laboratory (BioEx) located in the same building as CIPq Saúde - Campus JK, UFVJM, will collect a blood sample from the volunteers (08 ml of which: 3 ml of blood in a tube with fluoride anticoagulant for glucose; 5 ml of blood in a tube without anticoagulant for the lipid profile) for subsequent analysis of serum concentrations of glucose, total cholesterol, HDL, LDL and triglycerides. The assessment day, afternoon shift: THIS SHIFT WILL BE DESIGNED FOR THE ASSESSMENT OF ANTHROPOMETRIC MEASURES, THE APPLICATION OF QUESTIONNAIRE ASSESSMENTS OF FOOD CONSUMPTION, AND the FUNCTIONAL PERFORMANCE OF INDIVIDUALS. Body

weight, height, waist circumference, and hip circumference will be measured. Body mass index (BMI) will be calculated based on the volunteers' weight and height results. IN SEQUENCE, THEY WILL BE

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FOOD CONSUMPTION EVALUATION QUESTIONNAIRES USED THROUGH THE EATING PRACTICES SCALE ACCORDING TO THE FOOD GUIDE FOR THE BRAZILIAN POPULATION - GAPB AND THE 24-HOUR FOOD RECORD, and the assessment of handgrip strength (HGS) and the Short Physical functional clinical tests were carried out Performance Battery (SPPB) and Physical Performance Test (PPT). Before and after each stage of the application of clinical-functional tests, blood pressure (BP) will be measured (two measurements), heart rate (HR) and subjective perception of exertion will be assessed (modified Borg scale). Additional information: The Federal University of Vales do Jequitinhonha and Mucuri has all the physical (DEXA and BIA), personal, and financial structure necessary to conduct this research, making the project feasible and viable. Sample Calculation: According to data from the Ministry of Health, the prevalence of obesity in Brazil is 19.8% (Brazil, 2019). In the city of Diamantina-MG, which has 47,617 inhabitants, this percentage represents 9428 inhabitants with obesity. Using the G power program, consider

Considerations about Mandatory Submission Terms:

Not applicable

Recommendations:

Not applicable

Conclusions or pending issues and list of inadequacies:

Amendment approved

Final Considerations at the discretion of the CEP:

This opinion was prepared based on the documents listed below:

Document Type	File PB_INFORMATION	Post	Author	Situation
Brochure Investigator TCLE / Terms of Assent / Justification of Absence	MAÇÕES_BÁSICAS_191081 Basic Project Information 1_E4.pdf Detailed Project / Project.docx	03/10/2022 12:26:37		Accepted
Schedule		03/10/2022 11:54:04	VANESSA AMARAL MENDONÇA	Accepted
	TCLE.docx	03/10/2022 11:37:15	VANESSA AMARAL MENDONÇA	Accepted
	SCHEDULE.docx	08/17/2021 12:17:10	VANESSA AMARAL MENDONÇA	Accepted

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Declaration of agreement	concordancia_LAFIEX_BIOEX_LIM.pdf 06/07/2020 14:50:37	23/06/2020	Jacqueline de Paula Chaves Freitas	Accepted
Others	INVITATION_LETTER.docx	18:40:13 23/06/2020	VANESSA AMARAL MENDONÇA	Accepted
Others	INSTRUMENTO_DE_COLETA_DE_DA DOS.docx	18:39:02 23/06/2020	VANESSA AMARAL MENDONÇA	Accepted
Title Page	FolhaDeRosto.pdf	18:17:00	VANESSA AMARAL MENDONÇA	Accepted

Status of the Opinion:

Approved

Requires CONEP Appraisal:

No

DIAMANTINA, April 5, 2022

Signed by:

FABIO LUIZ MENDONÇA MARTINS
(Coordinator)

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