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## Protocol Registration and Results System (PRS)

**ClinicalTrials.gov ID: [Not yet assigned]**

**Last review date: October 13th, 2023.**

**Study Identification Unique Protocol ID: 023-005-OMI(CEI-05022)**

**Brief Title:** Improving Lifestyle Behavior by "Joven, Fuerte y Saludable" Multidisciplinary Program. Official Title: Efecto de Una intervención Multidisciplinaria de Estilo de Vida Sobre el Exposoma de Pacientes premenopáusicas Con cáncer de Mama Estadios I-III.

Mexico City, on ____of _____ of 20__ ____

# Informed consent

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| **Study title** | "Efecto de una intervención multidisciplinaria de estilo de vida sobre el exposoma de pacientes premenopáusicas con cáncer de mama estadios I-III, así como su impacto en la calidad de vida y desenlaces oncológicos." Versión 2, español, 06 de octubre de 2022 |
| | |
| **Participant name** | |

1. **Application**

   You have been invited to participate in the research entitled "Effect of a multidisciplinary lifestyle intervention on the exposome of premenopausal patients with breast cancer I-III stages, impact on the quality of life and oncological outcomes."

   A multidisciplinary intervention is performed by a health team specialized in different disciplines, for the purposes of this protocol, this team will be composed by specialists in oncology, nutrition, rehabilitation, psychology and mindfulness.
   The purpose of this health team is to work with young women who have not yet presented their menopause and who have been recently diagnosed with breast cancer in localized stages, (localized tumor in the breast or nodes only near the breast). The intention of this project is to provide an intervention that supports you implementing or maintaining a healthy lifestyle. Lifestyle is also known as personal exposome. This study aims to evaluate how our intervention can generate changes in blood test components, known as metabolites, biochemical and cellular parameters that are part of the internal exposome. As part of this protocol, the intervention, lifestyle (personal habits) and internal changes (internal exposome) will also be measured as well as how they impact quality of life and the evolution of cancer disease (clinical outcome).
   For the realization of the present research study, you are invited to read carefully the following information, feel free to ask any questions or aspect that you do not understand. In order for you to make an informed decision about your participation in this research project, this document describes the objective of the study, acquired rights and commitments, the necessary procedures for the study and the possible benefits or risks.

2. **Objective of the study**

   To assess the effect of lifestyle intervention on the exposome of premenopausal women with stages I-III of breast cancer.

3. **Purpose of the study**

   This study aims to determine the effect of multidisciplinary intervention (nutritional guidance, psychological therapy, physical activity recommendations, and mindfulness). This intervention will be delivered through face-to-face sessions and virtual

accompaniment (hybrid) with phone calls, text messages, email, website or zoom, to facilitate understanding and carrying out the activities planned for this protocol. This project will help you learn or reinforce what a healthy lifestyle is. Lifestyle includes elements such as diet, physical activity, sleep hygiene and stress management through relaxation techniques; all of the above is known as a personal exposome.

The term exposome considers everything our body has been exposed to from conception to death, showing how the human body (cells, genes, proteins, metabolites) is related to lifestyle and the environment and how our body responds to this exposure. Understanding all these mechanisms and their consequences will give us the keys to understand how the regulation of your body is affected by the exposure to personal factors (lifestyle) and how this is related to cancer disease and the tolerance to the medical treatments that you will receive.

That is to say, this study aims to guide you about the ideal activities you should realize to have a healthy lifestyle and how to implement them in your daily life. Another expected benefit of this healthy lifestyle intervention is the improvement of your quality of life, addressing specific symptoms such as depression, anxiety, fatigue, sleep disturbances, nutritional problems; as well as encouraging you to have physical activity based on your possibilities during your cancer treatment. In addition, it is expected that this lifestyle will be maintained during your survival stage.

If you decide to participate in this study, you may be included in one of the following groups: a lifestyle education group with support from a multidisciplinary team that includes expert professionals in oncology, nutrition, psychology, oncology rehabilitation, and mindfulness. This education program has a duration of 48 weeks, where in addition to virtual support, you will have individual follow-up with telephone or video calls by the specialists. You could also be included in a second group, which includes the previously described educational intervention, accompanied by a face-to-face personalized intervention based on your needs. The intention of having these two groups is to know how much each of these strategies can support you in acquiring a healthy lifestyle. Inclusion in one group or another is based on a well-designed procedure, which includes the assignment of participants considering their clinical characteristics and score in validated questionnaires that allow us to detect any risk parameter. Both interventions will be managed and supervised by the multidisciplinary team. It is important for you to know that the proposed interventions in both groups have been independently tested in other clinical studies, and have shown benefits for breast cancer patients. Therefore, it is expected that you will improve your lifestyle by participating in any of the study groups.

As part of this protocol, the effects of the proposed interventions will be analyzed through questionnaires on quality of life, sleep hygiene, physical activity, mindfulness, and lifestyle. Likewise, measurements of your weight, height, percentage of fat and muscle (known as anthropometric measurements), will be measured by well-trained specialists, with a non-invasive technique for your body, called bioimpedance. Additionally, blood samples will be taken by puncture of one of your arm veins, which will allow us to analyze your levels of glucose, insulin, triglycerides, cholesterol, as well as proteins called interleukins and adipokines (for inflammation assessment), and

substances called metabolites. All of the above will allow us to know how these parameters that we call anthropometric, biochemical, inflammatory and metabolomic are modified, with the proposed interventions. This gives us a reflection of how your body is responding to acquiring a healthy lifestyle.

4. **Relevance of the research**

   This research is important, because of the high prevalence of overweight and obesity observed in patients with breast cancer; this could be presented from diagnosis or during treatment, affecting people's quality of life. Interventions that include several health professionals, such as those proposed in this study, have been previously applied in other clinical studies to support women with breast cancer, with beneficial results as weight improvement and greater anthropometric parameters as body fat percentage and muscle mass, better biochemical or inflammatory response, in addition to a positive effect in the quality of life of these patients, also improving tolerance to medical treatments. This study will provide new information, including how the metabolites produced by your body are changed by these interventions. Metabolites are the final substances produced by chemical reactions carried out by your cells, and can be use to understand the changes your body may experience with the food you eat, the exercise you take, and the degree of emotional well-being that you present. Upon completion of this study, the research team will be able to generate future lifestyle interventions to be included in the routine of the Breast Tumor service at our Institution.

5. **Learning to the participants**

   Your participation in this project will allow you to learn more about aspects of a healthy lifestyle and how these changes in your daily life activities can improve your quality of life and your tolerance to the treatments that you will receive for the management of your disease. You will also receive education through workshops, printed material, support by health professionals, easy-to-prepare recipes in your day-to-day life, as well as examples of physical activity appropriate to your stage of treatment.

6. **Institution**

   This study will be carried out at the facilities of the National Institute of Cancerology, specifically in nutrition and research offices, located at Av. San Fernando 22, Belisario Domínguez Secc 16, Tlalpan, 14080 Mexico City, CDMX. It is possible that a follow-up will be given via telephone or video call.

7. **Procedures to be followed for sample collection**

   Your participation will consist of a lifestyle intervention, depending on the group in which you participate, this intervention may consist of an educational intervention with virtual support by health professionals or a virtual educational intervention plus a personalized intervention based on your nutritional needs with virtual and face-to-face hybrid accompaniment by specialized health personnel. Both interventions include education on different aspects of lifestyle such as nutrition, physical activity, sleep hygiene, and quality of life. In the same way, measurements will be taken such as waist circumference, hip circumference, weight and height; body composition data using specialized equipment (bioimpedance) and blood analysis. The blood sampling will be carried out by a professional expert in sampling, a member of the research team,

following all the safety measures required for this procedure, causing minimal discomfort, such as mild pain at the puncture site or itching, and less frequently bruising or infection at the puncture site. After the collection, the samples will be stored in the Tissue Bank of this institution, following the institutional established measures for their preservation, until further analyzes are carried out (cellular, biochemical, cytokine and metabolite analyses), proposed in this study. As part of the protocol, comparisons will be made at 0, 3, 6, 12 and 18 months, and nutritional evaluation will be carried out every 3 weeks.

8. **Scientific publication and confidentiality**

   All of your sensitive personal data will be treated confidentially to preserve your right to privacy and protection, derived from the Federal Law on Protection of Personal Data Held by Private Parties (hereinafter the "Law"). In this act, you give your consent for the processing of your personal data and/or sensitive personal data for the study, with the understanding that you will not be identified by name, address, telephone number or any other direct personal identifier, except when the Law and/or any other applicable regulations so require.

   Your information, such as study records, information about your general health status, your questionnaires responses, as well as the results obtained from your blood samples during the study, will be collected by any of the researchers in this study. You will be uniquely identified by a participant number and the information will be stored in a secure location with limited access to research study staff. You have the right to request updated information to request that errors be corrected.

   At any time during or after the study, the competent authorities (eg Federal Commission for the Protection against Sanitary Risks, the Ministry of Health in Mexico or other governmental, regulatory or surveillance organizations) will have direct access to the data resulting from this study, so that they can confirm that the information collected is accurate. In these circumstances, your identity will remain absolutely confidential. Representatives of the Institute's Research Ethics Committee/Research Committee may also have access to your data.

   The scientific information obtained with this protocol will be used anonymously by the research group, to be published in scientific research journals or may be presented in congresses, as well as in related research projects, with prior review and approval by the Research and Ethics Committees of the National Institute of Cancerology and the Universidad Anahuac México.

9. **Data storage**

   Your data will be used and stored only for the purposes of this study, any other subsequent use will require that you sign a new Informed Consent.

10. **Risks**

    In accordance with the regulations of the General Health Law on clinical research, article 96 establishes that the present research represents minimal risk, due to common procedures such as physical examination, application of validated questionnaires for the patient with breast cancer. The medical treatments that you receive will be indicated by your oncologists, and are not modified by this research team. The blood collection will be carried out on the days that you go to your routine laboratories. This procedure

is safe and is performed by a trained health professional, in accordance with the OFFICIAL MEXICAN STANDARD NOM-253-SSA1-2012, (For the disposal of human blood and its components for therapeutic purposes).

It is necessary for you to inform your oncologist and the research team about any medication you take while on the study (including alternative medicine). Since drug-nutrient interactions may occur and increase the risk of presenting undesirable effects.

**11. Benefits**

Your participation in this project will allow you to recognize your lifestyle before starting the proposed intervention, and how this lifestyle affects the body on a physical, mental and internal level (personal and internal exposome, which was previously explained). With the measurements that are made throughout the study, we will be able to know how these parameters change over time, while improving your lifestyle. The educational program will give you valuable information for yourself that you can also share with your family and friends. The virtual intervention will allow us to know how much lifestyle education is useful for the patients who participate in this group. This will allow us to design future interventions for patients who do not live near our institution or who, due to personal or work reasons, cannot frequently attend to the hospital. In addition, you will have a health team specialized in lifestyle and breast cancer, who will follow-up and motivate you to keep this healthy lifestyle, receiving support, doubts and problem solving through-out the intervention, receiving specialized guidance. This study will not have economic remuneration for any of the participants included in the study groups, nor is the payment of per diem or extra studies to those consigned in the study considered, therefore, your participation will be voluntary, without expecting economic remuneration. This applies to both study groups. The care you will receive under this protocol will be additional to your medical treatment and will not affect it.

**12. Voluntary acceptance and revocation of consent**

You are informed that you have the right not to participate or leave the study at any time and without the need to give any explanation. This will not have any consequence on the quality of care/treatment you receive from our institution, there will not be prejudices to continue with your treatment or with the attention that, as a patient, the National Institute of Cancerology guarantees. All that is required is a notice to the research group of your decision.

There are some cases in which your participation in the research can be suspended, such as: not attending consultations, educational activities or taking anthropometric, biochemical, inflammatory or metabolomic parameters, losing follow-up by not answering the questionnaires, and having an incomplete file.

**13. Costs**

You will not have any expenses related to the procedures and materials necessary for the extraction and storage of your samples. The expenses related to this research from the moment you voluntarily agree to participate in it, will not be paid by you. All additional expenses originated from this investigation will be covered by the budget of this project. Your participation will not grant you any monetary compensation. This investigation does not include hospital transfer costs.

14. **Confidentiality and privacy**

    The information and personal data registered are confidential; neither your identity nor the personal details of the clinical history will be disclosed to third parties outside the investigation, except to the investigator, auditor(s) or other regulatory agency that inspected and/or recorded the results to ensure the quality and analysis of the results. The data (including the patient's file) to verify the accuracy and veracity of the clinical research of this trial will be preserved without violating the confidentiality, according to COFEPRIS regulations and the Institute of Cancerology Research Ethics Committee guidelines.

    In all the documentation collected during the study, including the follow-up period, your data will be storage with your initials and with an identification number that will be assigned to you. However, the sponsor, or its representatives, or any other appropriate regulatory authority may observe your medical records at the hospital. All individuals who will have access to your medical records are professionals and are required to keep the information as confidential.

15. **Patient rights and contact**

    Any question you may have regarding the study and/or specifically regarding sample extraction will be answered by the responsible investigator. You are informed that this Letter of Informed Consent is prepared and signed in two original copies, one original will be given to you and the other will be kept by the principal investigator.

16. **Committee**

    This study has been reviewed and approved by the Research Committee and the Research Ethics Committee of the National Institute of Cancerology and the Anahuac University, which are independent from the group of researchers, to protect their interests. The information obtained in this investigation, used to identify each participant, will be kept strictly confidential, in accordance with the provisions of the Federal Transparency and Access to Public Information, General Transparency and Access to Public Information, and General Protection Laws of Personal Data in Possession of Obligated Subjects and other applicable regulations on the matter.

You can contact your doctor about any doubts or questions you have about the study.

If you have any questions about your rights while participating in this research study, please contact the National Cancer Institute Research Ethics Committee.

**INFORMED CONSENT**

I have received a copy of this form after it was signed and dated. I reviewed and/or had the information explained to me about this research study. I understand the information and all my questions have been answered. **I agree to participate in this research study as described above and authorize the use of the data generated in this research as previously described in this Informed Consent Form.**

**I authorize providing my contact information for scheduling visits and other issues related to the research protocol. I authorize to be contacted for future investigations.**

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| Patient signature | Printed Name (Name(s), Last Name) | Signature date (dd/mm/yyyy) |

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| Investigator/Designee signature | Printed Name (Name(s), Last Name) | Signature date (dd/mm/yyyy) |

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|---|---|---|
| Signature of First Witness | Printed name (First name(s), last name) | Date signed (dd/mm/yyyy) |
| Witness Address | Street and number:<br>Colonia: Delegation/Municipality: | |
| Relationship to subject | | |

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|---|---|---|
| Signature of Second Witness | Printed name (First name(s), last name) | Date signed (dd/mm/yyyy) |
| Witness Address | Street and number:<br>Colonia: Delegation/Municipality: | |
| Relationship to subject | | |