

Effects of a Physical Exercise Program on Cardiovascular, Metabolic, Physical Fitness and Quality of Life in Cancer Survivors' Adult Women

Date: December 27th, 2024

INFORMATION ON THE RESEARCH PROJECT TO WHICH I AM **INVITED**

PARTICIPANT INFORMATION DOCUMENT AND INFORMED CONSENT FORM

This Informed Consent Form is intended for adult women interested in participating in a 3-month PHYSICAL EXERCISE PROGRAM in the city of Concepción, Bio Bio Region, Chile. The name of this project in which you are invited to participate is entitled:

EFFECTS OF A PHYSICAL EXERCISE PROGRAM ON CARDIOVASCULAR, METABOLIC, FITNESS AND QUALITY OF LIFE IN FEMALE CANCER SURVIVORS

Responsible Investigators:

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Msc. Carolina Andrea Fuentes Hidalgo

PhD. Lissé Angarita Dávila

Universidad Andrés Bello

My name is **Cristian Alvarez**, I work as a teacher and researcher for the Universidad Andrés Bello, Concepción, and I am the researcher responsible for the project. We are investigating the topic of how physical exercise produces cardiovascular adaptations beneficial to your health. I will give you the information and invite you to participate in this research.

You do not have to decide today whether to participate or not. Before you decide, you can talk to me or someone from my team (see emails and phone numbers below) to clarify questions about the research. There may be some words you do not understand. Please stop me as I inform you to give me time to explain very pleasantly. If you have questions later, you can ask me or a member of the research team.

OBJECTIVE OF THE RESEARCH:

“The objective is to determine the effects of suggested traditional post-treatment breast cancer therapy added to a 12-week physical exercise program on cardio-vascular, metabolic, and fitness levels in female breast cancer survivors.”

TYPE OF RESEARCH INTERVENTION:

This is an experimental type of research. We will apply a quality of life questionnaire and we will measure your weight, height, waist circumference and body composition with a weight called bio-impedanciometer, a fast, safe, painless and non-invasive control equipment, which in 30 seconds allows us to know also information such as the percentage of body fat, as well as measure blood pressure, using an electronic device in your arm, which similarly, is fast, safe, painless and non-invasive control, which in 30 seconds allows us to know this information. We will measure some vascular parameters, using computer type equipment called Ultrasound, where you lie on a stretcher and we will take a picture of your artery. We will also generate an occlusion in your forearm for 5 minutes to know your arterial stiffness with a blood pressure cuff to see how healthy your arterial vasodilation is. We will know your glycemia, total cholesterol, triglycerides and lactate levels through a rapid capillary blood sample test on a finger. We will evaluate their cardiorespiratory capacity in a bicycle test and their arm and leg muscle strength capacity. The research considers that people interested in participating should meet different inclusion criteria such as: a) (>30 years to 64.9 years), b) Associated co-morbidities and current therapy (diabetes, arterial hypertension, or metabolic syndrome, fatty liver), c) With or without overweight/obesity situation BMI 25.0 to 39.9 kg/m². Likewise, we have some exclusion criteria: (a) Abnormal ECG, (b) Disability situation (use of wheelchair, canes, other), c) Symptomatic cardiovascular disease, (d) Diagnosis of cardiomyopathy, or type 1 diabetes, (e) Musculoskeletal and/or neuromuscular disorders and/or injuries that prevent exercise, (f) Pulmonary disease type (Chronic Obstructive Pulmonary Disease), (g) Renal disease, (h) Pregnancy, and (i) Smoking behavior or dependence on other substances.

“.....This offer to participate in this research, will be made publicly (signs will be placed in public places, universities, health centers, and **IN ANY CASE WILL IT BE CARRIED OUT, IF; YOU DO NOT MEET ANY OF THESE CRITERIA....**”

SELECTION OF PARTICIPANTS:

We are inviting to participate any adult person who is in condition of HAVING SUFFERED BREAST CANCER AND FINISHED FORMAL TREATMENTS, who is interested in participating in a PROGRAM OF PHYSICAL EXERCISE GUIDED by professional researchers in the enclosure “Exercise Laboratory” of the Institute of Exercise Science and Rehabilitation ICER-UNAB”, Located in the Brisas del Sol sector, on the 1st floor of the Andrés Bello University.

DURATION:

The research considers 3 months (12 weeks) to carry out the physical exercise program, but, in its entirety, the project will last 9 months be considering all stages of development and the work and commitments of the research team.

VOLUNTARY PARTICIPATION:

Your participation in this research is completely voluntary. You may choose to participate or not. Whether you choose to participate or not, all services you receive or have access to at Universidad Andres Bello Concepcion, or at your Family Health Center, Health Center, or cancer group where you participate will continue under the same conditions as before the study. You can change your mind later and stop participating even if you have accepted before.

BENEFITS OF THE RESEARCH:

You will get the following benefits as remuneration for participating in this research,

- Service of weight, height and BMI calculation, in addition to the service of body composition evaluation of fat and muscle mass: Your result will be delivered in 1 printed sheet.
- Vascular evaluation service with Ultrasound: Your result is delivered in 1 printed sheet.
- Blood pressure evaluation service: Your result is delivered in 1 printed sheet.
- Upper and lower body muscle strength measurement service. Your result is delivered in 1 printed sheet.

- Glycemia, total cholesterol, triglycerides and lactate level evaluation service: Your result is delivered in 1 printed sheet.
- Service of physical exercise program to improve physical condition and health of 36 sessions.
- Delivery of a hand wipe and a cup to store water for hydration.

Other benefits:

- Benefits in terms of physical and mental health:
- Improve mental health in a socially distracting space such as the exercise room.
- Receive fitness and disease condition education on an ongoing basis.
- Improve personal well-being and thus quality of life, as we have previously reported in these types of guided physical exercise programs.

RESEARCH RISKS:

Muscle soreness after exercise: muscle soreness is reported primarily in the first few days after exercise. It will be minimized by education at each exercise session to participants. Recommendations will be given for cold baths immediately following the exercise session and pharmacological analgesia if necessary.

Muscle sprains and injuries: In the case of this exercise program, the risk of sprains will be controlled because the exercise will not be done running or walking where there is a greater risk of sprains but will be done on a stationary bicycle. It is also suggested to perform a muscle stretching/flexibility exercise at the end of the cycling exercise.

Hypoglycemia: Regular reminders will be given about the importance of carbohydrate intake, hydration, as well as the respective rest and sleep hours to be able to exercise.

RESEARCH COSTS:

There will be **NO COST** for you to participate in this research.

CONFIDENTIALITY OF INFORMATION:

Information obtained in the research will be kept strictly confidential. Only a code will be used and not your name.

SHARING THE RESULTS:

The knowledge we gain from conducting this research will be shared with you. It is also possible that the results obtained will be presented later at congresses and conferences and published in journals and conferences, but always keeping your identity confidential.

RIGHT TO WITHDRAW FROM THE RESEARCH:

Your participation in this research is completely voluntary and you have the right to withdraw your consent - and to withdraw from the research - at any time you deem appropriate.

If you withdraw from the research, you will not lose any rights. Should you withdraw from the research, the information obtained will not be used.

How can I withdraw from the investigation?

Very easy, just give written or verbal notice to any of the following means of communication:

OPTION 1: Cell phone and whatsapp of the principal investigator	+569-81702216
OPTION 2: Principal Investigator's e-mail address	cristian.alvarez@unab.cl
OPTION 3: Telephone or cell phone of the secretary of the School of Rehabilitation Sciences (Mrs. Mónica Herrera):	+41- +569-63161894
OPTION 4: E-mail from the secretary of the Faculty of Rehabilitation Sciences (Mrs. Mónica Herrera):	monica.herrera@unab.cl

INFORMED CONSENT FORM

Patient's statement:

I have been invited to participate in the research on "EFFECTS OF A PHYSICAL EXERCISE PROGRAM ON CARDIOVASCULAR, METABOLIC, FITNESS AND QUALITY IN WOMEN SURVIVORS OF CANCER.

- The investigator has personally given me full information about the purpose of this document and about the objectives, procedures, benefits, costs, and risks of this research.
- Confidential use will be made of my name and the information collected.
- I am not waiving any rights I have.
- I know that there may be no benefits to me personally and that I will not be financially rewarded, other than the provision of a hand wipe and a portable cup for hydration during exercise.
- I have been provided with the names of researchers who can be easily contacted using the name and address given to me.
- I have read the information provided or it has been read to me.
- I have had the opportunity to ask questions about the research and have answered the questions I have asked answered to my satisfaction.
- I voluntarily consent to participate in this research as a participant and understand that I have the right to withdraw from the research at any time without being affected in any way by the care received at the exercise facility, Family Health Center, or Health Center I attend.

Participant's Name _____

Participant's Signature _____

Date _____ Month/Day/year _____