

**MY BODY, MY RHYTHM, MY VOICE
PROMOTION OF PHYSICAL ACTIVITY IN BREAST CANCER SURVIVORS IN
COLOMBIA**

INFORMED CONSENTS

FEBRUARY 2019

My body, my rhythm, my voice Promotion of physical activity in breast cancer survivors in Colombia

Participant ID

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INFORMED CONSENT

On behalf of the Universidad de los Andes, we extend a cordial invitation to participate in the study: "Mybody, my rhythm, my voice: Promotion of physical activity in breast cancer survivors in Colombia". If you decide to participate, your participation in the study will consist of attending rumba sessions (musicalized physical activity) and allowing the collection of data that will be detailed in this document.

This is a study coordinated by Dr. Olga Lucía Sarmiento and her group of researchers; It has the support of the Faculty of Medicine of the Universidad de los Andes, in partnership with researchers from the Manuela Beltrán University, Stanford University, the League Against Cancer, the Ministry of Health, the District Institute of Recreation and Sports of Bogotá and the SIMMON Foundation.

This document explains the different aspects of the research study: its purpose, the procedures to be performed, the risks of the procedures, and the potential benefits. Once you know what the study is about, you will be asked if you wish to participate, and if so, you will be asked to sign this written authorization.

Purpose of the study: The purpose of this study is to see what the motivations and barriers are to attending physical activity sessions and what changes in physical and mental health occur as a result of the practice of physical activity. It also identifies barriers to ensuring the permanence of a program to promote physical activity in breast cancer survivors.

Study Procedures: If you choose to participate, an appointment will be scheduled with you to assess your current health status by taking body composition and physical activity data. These measurements, which will be described below, will be carried out in the same institution where the physical activity sessions will be carried out.

Body composition is assessed by a bio-impedanceometry test. This test is performed on special scales that have metal plates that conduct a type of weak electric current that passes through the entire body. Thanks to this current, these scales can calculate the amount of muscle, fat, and water in the body.

To measure physical activity, you will be asked to use a portable motion meter (accelerometer); which is a device that gives objectively the amount of movement you perform during the day. The use of this meter does not alter your daily activities or generate discomfort or pain. The monitoring with this device will last twenty-four (24) hours during seven (7) consecutive days.

To measure your functional capacity, we will perform a test called a 6-minute walk, which consists of measuring the maximum distance you can walk for 6 minutes without stopping. This measurement will be performed twice (during the first measurement, and 8 weeks later). This test will be carried out in a flat space, delimited by cones and without any obstacles. In addition to this, we will use a device called Polar (similar to a watch), which will be placed on your wrist, to measure your heart rate during the test.

In this first measurement, you will also be asked to answer an initial survey on sociodemographic data, quality of life, anxiety, perception of fatigue and other health indicators. Likewise, you will be invited to a meeting with the other participants to discuss the main motivations for the practice of physical activity.

After this, you will be invited to participate for 8 weeks in physical activity classes offered three times a week and led by trained staff. Some sessions will be accompanied by workshops of manual arts and healthy habits to be carried out in the same space of the physical activity sessions. Additionally, psychosocial support will be provided to strengthen behavioral change, through a pedagogical primer. Once the intervention is finished, measurements similar to the initial

one will be made again to determine if you had any change in your health condition as an effect of the rumba classes. Finally, a meeting will be held to learn about your experience in physical activity classes; you will have an audio record of those meetings. Your family members can also participate in the directed physical activity classes, workshops, and the meeting with the research group.

Study Risks: During physical activity sessions there are risks of falls and injuries. To minimize these risks, physical activity classes have been adapted to their needs and limitations given by their underlying pathology. There will be the permanent accompaniment of personnel trained in life support during the physical activity classes, who in case you require urgent medical attention, will immediately call the emergency service of the Health Institution, will provide you with the necessary life support measures while you are referred to the attention by the emergency doctor. To be included in this study you must have affiliation to the health system and carry your membership card during all physical activity sessions.

Benefits of the study: This study seeks to contribute to the quality of life of women survivors of breast cancer, motivating them to practice physical activity through rumba sessions of an approximate duration of one hour each. The sessions have been designed and will be offered by experts who have knowledge of the limitations that breast cancer patients present as a result of chemotherapy, radiotherapy or surgery treatment.

Through your participation in this study, we want to make you aware of the multiple benefits that result from the habitual practice of physical activity. Just as we hope to understand and make visible your perceptions and your family's in the face of the establishment of a program of direct physical activity linked to the care of your health. Refreshments will be delivered in each of the classes or workshops and other gifts will also be given as a thank you for your participation.

Cost to you: None.

Confidentiality: No person outside the research group will have access to the processing of the information collected, but this information will be used for research purposes. Additionally, the data will be stored anonymously in such a way that its results are not related to personal or family information. The audios of the meetings to be held at the beginning and end of the intervention will be destroyed after 5 years of the conclusion of the project. Moreover, because the information collected during each meeting may be shared by other study participants, we will ask each of you to sign a confidentiality report at the beginning of each session.

Participation is voluntary: Participation in the study is completely voluntary. If you do not wish to participate or withdraw after starting the study, this will not affect your relationship with researchers, or with health personnel in any way now or in the future.

Delivery of results: After the bio-impedance measurements, the participants will be given a report of their body composition including general recommendations of healthy habits and if necessary, the assessment by a doctor of their health insurer.

Questions: Please ask anything you don't understand. Take the time to decide whether or not to participate in the study. If you have any questions or wish to have access to the results of the study you can contact the researcher Dr. Olga Sarmiento on the phone 3394949 ext. 3785. If you have additional questions about the study or about your rights as a participant in it, you can call the ethics committee of the Universidad de los Andes at 3394949 ext. 5339 and request to be communicated with the Research Ethics Committee or you can write to the email: comité-etica-investigaciones@uniandes.edu.co.



Project title: My body, my rhythm, my voice. Promotion of physical activity in breast cancer survivors in Colombia.

INFORMED CONSENT

Consent: By means of this consent I _____ declare that the objective of this project has been clarified to me. I also declare that I have been offered the opportunity to resolve all my doubts regarding the study. I declare that I do not have any heart disease diagnosed so far. In addition, I place on record that I read and understood the contents of this document.

Date: _____ Place: _____

	Yes	No
I authorize audio recording and use for research purposes	<input type="checkbox"/>	<input type="checkbox"/>
I authorize audio transcription and use for knowledge dissemination	<input type="checkbox"/>	<input type="checkbox"/>
I authorize the taking of photos and their use for research purposes	<input type="checkbox"/>	<input type="checkbox"/>
I authorize the taking of photos and their use for dissemination of knowledge	<input type="checkbox"/>	<input type="checkbox"/>

Signatures:

Name	Signature or Fingerprint*	Date	CC
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Residence address	City	Phone
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Witness 1	CC	Date
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Witness2	CC	Date
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Who applies the informed consent	CC	Date
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*The fingerprint of the participants is requested in case they do not know how to read and / or write

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My body, my rhythm, my voice
Promotion of physical activity in breast cancer survivors in Colombia

INFORMED CONSENT CONTROL GROUP

On behalf of the Universidad de los Andes, we extend a cordial invitation to participate in the study: "Mybody, my rhythm, my voice: Promotion of physical activity in breast cancer survivors in Colombia". If you decide to participate, your participation will consist of allowing the collection of data that will be detailed in this document and subsequently attend sessions of musicalized physical activity.

This is a study coordinated by Dr. Olga Lucía Sarmiento and her group of researchers; It has the support of the Faculty of Medicine of the Universidad de los Andes, in partnership with researchers from the Manuela Beltrán University, Stanford University, the League Against Cancer, the Ministry of Health, the District Institute of Recreation and Sports of Bogotá and the SIMMON Foundation.

This document explains the different aspects of the research study: its purpose, the procedures to be performed, the risks of the procedures, and the potential benefits. Once you know what the study is about, you will be asked if you wish to participate, and if so, you will be asked to sign this written authorization.

Purpose of the study: The purpose of this study is to see what the motivations and barriers are to attending physical activity sessions, and what changes in physical and mental health occur as a result of the practice of physical activity. Also, the identification of factors to ensure the permanence of a program of promotion of physical activity in breast cancer survivors.

Study Procedures: If you choose to participate, an appointment will be scheduled with you to assess your current health status by taking body composition and physical activity data. These measurements, which will be described below, will be carried out in the same institution that has invited you to participate in the study.

Body composition is assessed by a bio-impedanceometry test. This test is performed on special scales that have metal plates that conduct a type of weak electric current that passes through the entire body. Thanks to this current, these scales can calculate the amount of muscle, fat, and water in the body.

To measure physical activity, you will be asked to use a portable motion meter (accelerometer); which is a device that gives objectively the amount of movement you perform during the day. The use of this meter does not alter your daily activities or generate discomfort or pain. The monitoring with this device will last twenty-four (24) hours during seven (7) consecutive days.

To measure your functional capacity, we will perform a test called a 6-minute walk, which consists of measuring the maximum distance you can walk for 6 minutes without stopping. This measurement will be performed twice (during the first measurement, and 8 weeks later). This test will be carried out in a flat space, delimited by cones and without any obstacles. In addition to this, we will use a device called Polar (similar to a watch), which will be placed on your wrist, to measure your heart rate during the test.

In this first measurement, you will also be asked to answer an initial survey on sociodemographic data, quality of life, anxiety, perception of fatigue and other health indicators. Likewise, you will be invited to a meeting with the other participants to discuss the main motivations for the practice of physical activity. An audio record of these conversations will be kept.

After eight weeks, a data collection similar to the initial one will be carried out again to identify if there are changes in your overall health. After these measurements, you will be invited to participate in music-based physical activity

sessions designed specifically for breast cancer survivors. Your family members can also participate in directed physical activity classes, workshops and the meeting with the research group.

Risks of the study: The taking of data to assess your health status does not pose risks to your health. During physical activity sessions there are risks of falls and injuries. To minimize these risks, physical activity classes have been adapted to their needs and limitations given by their underlying pathology. There will be the permanent accompaniment of personnel trained in life support during the physical activity classes, who in case you require urgent medical attention, will immediately call the emergency service of the Health Institution, will provide you with the necessary life support measures while you are referred to the attention by the emergency doctor. To be included in this study you must have affiliation to the health system and carry your membership card during all physical activity sessions.

Benefits of the study: This study seeks to contribute to the quality of life of women survivors of breast cancer, motivating them to practice physical activity. Through your participation in the study, we want to make you aware of the multiple benefits that result from the habitual practice of physical activity. Just as we hope to understand and make visible your perceptions and your family's in the face of the establishment of a program of direct physical activity, linked to the care of your health. The rumba sessions have been designed and will be offered by experts who have knowledge of the limitations that breast cancer patients present as a result of chemotherapy, radiotherapy or surgery treatment. Refreshments will be delivered in each of the activities and a gift will also be given as a thank you for your participation.

Cost to you: None.

Confidentiality: No person outside the research group will have access to the processing of the information collected, but this information will be used for research purposes. Additionally, the data will be stored anonymously in such a way that its results are not related to personal or family information. The audios of the workshops will be destroyed after 5 years of the conclusion of the project. Moreover, because the information collected during each workshop may be shared by other study participants, we will ask each of you to sign a confidentiality certificate at the beginning of each session.

Participation is voluntary: Participation in the study is completely voluntary. If you do not wish to participate or withdraw after starting the study, this will not affect your relationship with researchers, or with health personnel in anyway now or in the future.

Delivery of results: After the bio-impedance measurements, the participants will be given a report of their body composition including general recommendations of healthy habits and it will be indicated if the assessment by a doctor of their health insurer is necessary.

Questions: Please ask anything you don't understand. Take the time to decide whether or not to participate in the study. If you have any questions or wish to have access to the results of the study you can contact the researcher Dr. Olga Sarmiento on the phone 3394949 ext. 3785. If you have additional questions about the study or about your rights as a participant in it, you can call the ethics committee of the Universidad de los Andes at 3394949 ext. 5339 and request to be communicated with the Research Ethics Committee or you can write to the email: comité-etica-investigaciones@uniandes.edu.co.



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I authorize the taking of photos and their use for dissemination of knowledge	<input type="checkbox"/>	<input type="checkbox"/>

Signatures:

Name	Signature or Fingerprint*	Date	CC
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Residence address	City	Date	Phone
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Witness 1	CC	Date	
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Witness2	CC	Date	
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Who applies the informed consent	CC	Date	
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