

**Distribution of Pulmonary Ventilation With the modified Pachon's incentive vs. Another  
Branded Respiratory Incentive, Through Electrical Impedance Tomography, in a Healthy  
Volunteers of the City of Cali**

NCT ID not yet assigned

June 10, 2022

## Distribution of Pulmonary Ventilation With the modified Pachon's incentive vs. Another Branded Respiratory Incentive, Through Electrical Impedance Tomography, in a Healthy Volunteers of the City of Cali

Participating institution Universidad del Valle

### STUDY INFORMATION

Dear participant, you are invited to participate in a research led by the Exercise and Cardiopulmonary Health Research Group of the School of Human Rehabilitation. This study aims to Validate the Incentivo Modificado de Pachón, a device made in an artisanal way, by which deep air is taken through the mouth helping to inflate the lungs and comparing it with a branded incentive that serves to improve lung capacity, and for this, an equipment called Electrical Impedance Tomography (EIT) will be used to evaluate how the air is distributed in the lungs.

The results of this research will provide valuable information for the treatment of people who for economic reasons cannot have access to the benefits of the branded device, can have the same benefits through the use of a handmade device, this will optimize the rehabilitation process. and is justified because it will strengthen clinical decision making.

The results obtained with this research will be presented in a document that will be published as the Degree Project of the Master's Degree in Physiotherapy at the Universidad del Valle.

If you accept and approve your participation in the research by signing the consent, you will participate with 17 other healthy adults who will initially undergo a simple pulmonary spirometry, a procedure that serves to confirm good respiratory function, which consists of performing a maneuver deep breathing, followed by a forced expiration maneuver through a tube that goes directly to the mouth, this test will be performed at the Hospital Universitario del Valle, and lasts approximately 30 minutes, that same day a questionnaire, and a series of anthropometric measurements such as weight and height measurement, and clinical measurements will be taken that will be recorded on a form; and the application of 2 scales will be carried out to evaluate their clinical stability and their level of physical activity, these activities will also last 30 minutes.

In the days after the spirometry, a session will be held for the application of either of the two incentives while it is measured with the EIT, the EIT is an exam where a belt with electrodes will be attached around the chest that will allow you to see in time real your breaths on a monitor, this exam will be carried out in the facilities of the SERH of the Universidad del Valle. The session time with the incentive and the tomography measurement is around 30 minutes.

Lastly, a week later he will be summoned again for the application of the other incentive, at the same time that it is measured with the EIT in the facilities of the SERH of the Universidad del Valle. The session time with the incentive and the tomography measurement is around 30 minutes.

During the performance of the procedures, photographic and/or video recording will be made for academic and quality control purposes for the procedures performed.

Your responsibility in the study is to allow the measurements and follow the instructions during the measurement session and the IMP technique and the branded incentive, which last approximately 30 minutes each. you must bear the cost of transportation

“This study is considered minimal risk research according to standard 008430 of the Ministry of Health (currently the Ministry of Social Protection). Among the risks during the application of the incentive could be: dizziness and increased heart rate. To control these risks, heart rate, oxygen saturation, and respiratory rate will be continuously monitored.

If you decide to participate in this study you will not receive any financial compensation. Consider that, thanks to your participation in this study, it will be possible to identify if the IMP performs the same function as a branded flow incentive, favoring its validation and making available to health personnel an affordable device that can be used in people who have some difficulty getting enough air into the lungs

With this study you will be able to know the current status of your lung function through spirometry and EIT.

You may withdraw from the study when you consider it expressed verbally or in writing.

Participation in this study is completely voluntary and you will not incur any additional costs.

The information generated by this study is strictly confidential, privacy will be maintained and you will not be identified, for this a numerical code will be used in the study formats and the data will only be known by the researchers and used for academic purposes such as publications or for the development of subsequent projects if the participant authorizes it.

If you have any questions, you can contact the researchers, you will receive a copy of this informed consent. The information, results and data of the study may be made known to you and may be used by the authors for future research, subject to approval by the Ethics Committee of Universidad del Valle.

The right to withdraw from the study without prior notice and on the day you wish will be guaranteed.

## PARTICIPANT'S DECLARATION

I declare that I am of legal age, I am in full use of my mental capacities and my participation is voluntary. The nature and purpose of this research has been explained to me and I understand it. I have been informed that the project will be carried out by the physiotherapist and currently a master's student in Physiotherapy Noraelena Mera Quintero under the supervision of the Physiotherapist Esther Cecilia Wilches Luna. This research was endorsed by the Health Research Ethics Committee of the Universidad del Valle; In the event of any disagreement or if I have any additional questions about my rights as a study participant, you can contact the researcher Noraelena Mera at 3187983544 or by email at nora.elena.mera@correounivalle.edu.co, or with the Committee of Ethics of the Universidad del Valle by phone: 5185677 or email eticasalud@correounivalle.edu.co.

I have read this consent and clarified any doubts regarding the study, and I have also received a copy of it. I agree to participate in this study and as proof of the foregoing I sign in agreement.

Participant Name	Signature	Identification card	Telephone	Date	Hour

Name of Witness 1	Signature	Identification card	Telephone	Relationship with the participant	Date	Hour

Name of Witness 2	Signature	Identification card	Telephone	Relationship with the participant	Date	Hour

I authorize the use of data, photographs and videos in future studies and publications prior approval of a Research Ethics Committee.

YES \_\_\_\_ NO \_\_\_\_

### STATEMENT OF THE SUPERVISOR AND STUDENT RESEARCHER.

We have informed the participant of the purpose and nature of the procedure described above, its possible risks and the use of the results thereof.

#### Researcher data:

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Identification card: \_\_\_\_\_

Telephone: \_\_\_\_\_

Date: \_\_\_\_\_