

# Effect on the incidence of exacerbations of a programme of physical activity encouragement using pedometers in patients with chronic obstructive pulmonary disease

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<b>Registration date</b> 02/07/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/07/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Chronic Obstructive Pulmonary Disease (COPD) is the most common long-term respiratory illness in adults and is a major cause of death and disability. In Chile, COPD is the leading respiratory disease in terms of its impact on health. One of the national health goals for this decade is to reduce the illness and deaths caused by COPD.

COPD causes long-term blockage of airflow, leading to breathing difficulties, especially during physical activity. This condition lowers a person's ability to exercise, causes them to be less active, and worsens their overall health and quality of life. Patients with COPD experience worsening symptoms, called acute exacerbations, about twice a year on average. These exacerbations are marked by a sudden increase in breathing difficulty, coughing, and mucus production, often requiring urgent medical visits and sometimes hospital stays. About 40% of patients who have an exacerbation need to be hospitalized, which is costly and associated with a lower chance of survival.

Research shows that physical activity is crucial for people with COPD. More active patients experience fewer symptoms, enjoy a better quality of life, and, regardless of lung function, sex, or other illnesses, have fewer hospitalizations and lower mortality rates than those who are less active.

Our team conducted a 3-month clinical trial where patients with COPD used step counters to encourage physical activity.

### Who can participate?

Patients aged 40 years and older, with COPD.

### What does the study involve?

Participants are randomly assigned to the experimental or the control group.

**Experimental Group:** Patients use step counters and logs, with goals to increase steps based on baseline and monthly check-ups.

**Control Group:** Patients attend monthly physical therapist visits, recording symptoms and treatments in a logbook reviewed only by the physician.

The study involves attending hospitals regularly once a month until the follow-up is completed. The visits are brief, about 20 to 30 minutes, and they are helped with the cost of their travel. For the evaluations, they should allow more time (approximately 2 hours).

**What are the possible benefits and risks of participating?**

This study does not contemplate a direct benefit for patients except that all patients who complete the study are given a step counter. For patients in the experimental group, the step counter is given to them at the beginning of the follow-up; for patients in the control group, it is given to them at the end of their follow-up after the last evaluation.

Since the intervention consists only of walking supported by the step counter, it does not imply any risks for patients. Nor do the evaluations include any significant risk for patients.

**Where is the study run from?**

Agencia Nacional de Investigación y Desarrollo (Chile)

**When is the study starting and how long is it expected to run for?**

March 2019 to December 2023

**Who is funding the study?**

Agencia Nacional de Investigación y Desarrollo (Chile)

**Who is the main contact?**

Dr Laura Mendoza, lmendoza@hcuch.cl

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Laura Mendoza

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

FONIS SA19AI0179

## Study information

### Scientific Title

Effect on the incidence of exacerbations of a programme of physical activity encouragement using pedometers in patients with Chronic Obstructive Pulmonary Disease: A randomized multicenter clinical trial

### Acronym

PedometersAECOPD

### Study objectives

A program of physical activity encouragement using pedometers in COPD patients reduces the incidence of exacerbations

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 20/11/2019, Comité Ético Científico o de Investigación del Hospital Clínico de la Universidad de Chile (Dr. Carlos Lorca 999 Independencia, Santiago, 8380420, Chile; +56 229788409; comitetetica@hcuch.cl), ref: 072

### Study design

Interventional randomized controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Exacerbations in patients with Chronic Obstructive Pulmonary Disease

### Interventions

Experimental Group (EG):

Patients assigned to the EG will receive the physical activity incentive program supported by step counters, where the kinesiology professional will teach them how to use the step counter, give each patient the step counter and give them goals for increasing the number of steps taken per day, initially based on the baseline measurement of the number of steps taken per day, and then in successive monthly check-ups, based on the average number of steps taken in the week prior to each visit, obtained from the information on the step counter and the logbook. Patients

will be instructed to always attend visits with their step counter.

The guideline that will be used to encourage an increase in the number of steps taken per day in patients in the experimental group will be the same as that used in a previous project (Mendoza et al ERJ 2015), which is why it is validated in terms of safety (there were no adverse effects attributed to the use of the step counter) and efficacy, and which is as follows:

Steps walked per day at baseline or monthly visits:

< 6000 = asked to increase by 3000

6000 to 9000 = asked to reach 9000

> 9000 = asked to maintain or increase

Patients in the GE will receive two logs:

1. Step log: in this log they must write down every night the number of steps they have walked throughout the day, obtained from the information on the step counter.
2. Acute exacerbation log: in this log they will be asked to record any symptoms that attract their attention and whether they have been treated for worsening of their symptoms at their respective care centers and the medications that have been prescribed to them at said centers.

Control Group (CG):

Patients in the control group will also be scheduled to see a physical therapist on a monthly basis and will also be given a logbook to record any symptoms that attract their attention and whether they have been treated for worsening of their symptoms at their respective care centers and the medications prescribed to them at said centers. This logbook will not be reviewed by the physical therapist, only by the physician who will remain blind to the patient's assignment and who will be in charge of evaluating all patients in the study on a monthly basis during the year of intervention.

The information obtained at each visit by the physical therapist will be recorded on forms specifically designed for the follow-up of patients in the EG or CG.

Participants provide data once per month, for 3 months.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Baseline, 6-month, and 12-month (final) assessments include the following measurements:

1. Anthropometric measurements: Weight, height, determination of body mass index (BMI).
2. Pre- and post-bronchodilator spirometry
3. Quality of life assessment using the Saint George Quality of Life Questionnaire (SGRQ) and the abbreviated questionnaire: COPD Assessment Test (CAT)
4. Dyspnea assessment using the modified Medical Research Council (mMRC) scale

## **Key secondary outcome(s)**

Measured at baseline, 6-month, and 12-month (final) assessments:

1. Determination of physical activity level by:
  - 1.1. Delivery of an accelerometer that will be indicated to be used during the day for a full week, which determines average hours per day with light, moderate, and vigorous physical activity levels.
  - 1.2. Determination of the number of steps walked per day obtained by averaging the results in 1 week using the step counter with a screen sealed with masking tape. The step counter that will be used in the study has a memory of 7 previous days.
  - 1.3. Proactive Questionnaire

2. Determination of exercise capacity by determining the distance traveled in 6 minutes (DR6) in the six-minute walk (C6M) and the 1-minute "sit to stand" test.

**Completion date**

13/12/2023

## Eligibility

**Key inclusion criteria**

1. COPD patients
2. 40 years old and older
3. Ex smokers

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

40 years

**Upper age limit**

90 years

**Sex**

All

**Total final enrolment**

22

**Key exclusion criteria**

1. Exacerbations until 2 months before recruitment
2. Not able to walk

**Date of first enrolment**

29/08/2022

**Date of final enrolment**

08/05/2023

## Locations

**Countries of recruitment**

Chile

**Study participating centre**  
**Hospital Universidad de Chile**  
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Santiago  
Chile  
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**Study participating centre**  
**Universidad de Concepción**  
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4030000

## **Sponsor information**

**Organisation**  
Agencia Nacional de Investigación y Desarrollo

**ROR**  
<https://ror.org/02ap3w078>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Agencia Nacional de Investigación y Desarrollo

**Alternative Name(s)**  
Agencia Nacional de Investigación y Desarrollo de Chile, National Agency for Research and Development, Government of Chile, Chilean National Agency for Research and Development, Agencia Nacional de Investigación y Desarrollo de Chile (ANID), ANID

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**

Chile

**Results and Publications****Individual participant data (IPD) sharing plan**

The datasets will be available upon request

Laura Mendoza [lmendoza@hcuch.cl](mailto:lmendoza@hcuch.cl)

**IPD sharing plan summary**

Available on request