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

Submission date
31/05/2024

Recruitment status
No longer recruiting

Registration date
02/07/2024

Overall study status
Completed

Last Edited
01/07/2024

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

ORCID ID
https://orcid.org/0000-0001-5426-0439

Contact details
Dr. Carlos Lorca 999 Independencia
Santiago
Chile
8380000
+56 229788409
lmendoza@hcuch.cl

Additional identifiers

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 Cientifico 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

Primary study design
Interventional

Study design
Interventional randomized controlled trial

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 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
Dr. Carlos Lorca 999

Santiago
Chile
8384020

Study participating centre
Universidad de Concepción
Facultad de Medicina
Chacabuco esquina Janequeo sin. número
Concepción
Chile
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

IPD sharing plan summary
Available on request