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Strengthening muscles involved in breathing to improve cough effectiveness, speaking and swallowing in people with Parkinson's disease

Submission date
29/05/2018

Recruitment status
No longer recruiting

Registration date
31/05/2018

Overall study status
Completed

Last Edited
23/08/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
In Parkinson's disease, parts of the brain become progressively damaged over many years. In patients with Parkinson’s disease, the main cause of death is lung inflammation caused by bronchial secretions or food that enters the lungs. This is thought to be because people with Parkinson's disease can have problems with breathing and swallowing that are caused by weakness and slowness of the muscles involved in breathing. A strong cough response is needed to remove food and mucus from the passageways to the lungs. To cough properly, you need to breathe in enough air and then be able to expel it quickly and with force. Strengthening inspiratory (breathing in) and expiratory (breathing out) muscles, as well as breath stacking techniques, can make the cough stronger and more able to clear the passages into the lungs. The aims of this study is to investigate the effects of air stacking in addition to an inspiratory and an expiratory-muscle training program to improve lung function, cough strength, speaking and swallowing in patients with Parkinson's disease.

Who can participate?
People with active Parkinson's disease, who have some disability, are in a stable stage of the disease and are receiving stable treatment for Parkinson's disease.

What does the study involve?
Participants will be allocated randomly to use inspiratory or expiratory muscle training devices in addition to using breath stacking techniques or to use minimum expiratory muscle training only. They will be trained in how to do the exercises and then will do the exercises at home for 2 months.

What are the possible benefits and risks of participating?
Possible benefits include a stronger and more effective cough to remove food and mucus from the passageways to the lungs, improved voice volume, and receiving comprehensive assessments of breathing, voice and swallowing functions. Possible risks include respiratory

muscle soreness and fatigue. The risks associated with the respiratory muscle training are low, but to minimize them the training is tailored to each participant and the necessary resting time is provided to avoid fatigue.

Where is the study run from?
Universidad Andres Bello

When is the study starting and how long is it expected to run for?
April 2018 to October 2018 (as of 04/10/2018)

Who is funding the study?
Chilean National Fund for Scientific and Technological Development

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11160419

Study information

Scientific Title
The effects of respiratory muscle training and air-stacking on pulmonary function, phonatory measures and swallowing function in patients with Parkinson's disease

Study objectives

The use of air stacking and an expiratory muscle training program would be more effective than the use of air stacking and an inspiratory muscle training program to improve peak cough flow, phonation and swallowing function in patients with Parkinson's disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics Commitee of the Rehabilitation Sciences Faculty at Andres Bello University, 17/05 /2018, #A059

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Idiopathic Parkinson's disease

Interventions
39 patients with Parkinson's disease will be divided into 3 groups using the block randomization method. 13 participants will be assigned to perform home-based expiratory muscle training and air stacking, 13 will be assigned to perform home-based inspiratory muscle training and air stacking, and 13 participants will be assigned to receive home-based expiratory muscle training only at minimum and fixed load (control group).
Inspiratory muscle training protocol will consist on 5 sets of 5 inspiratory efforts using a Threshold® Inspiratory Muscle Trainer (HS730-010. Phillips Respironics, USA). Expiratory muscle training protocol will consist on 5 sets of 5 efforts using an expiratory muscle trainer (EMST150. Aspire Products, LLC). Both training will be performed at a resistance equal to 75% of each participants maximum inspiratory pressure and maximum expiratory pressure, which will be calculated based on maximum inspiratory pressure and maximum expiratory pressure baseline measurements. The air-stacking program for both groups will consist of 10 series of 3-4 consecutive lung insufflations by air-stacking 6 times a week for 2 months. Inspiratory and expiratory muscle training will be performed 6 times a week for 2 months.
The control group will perform home-based expiratory muscle training at minimum and fixed load (9 cm H2O) using the same protocol of training groups.

Intervention Type
Device

Primary outcome measure
Voluntary and reflex peak cough flow, measured using a pneumotachograph (MLT 1000; ADInstruments, Inc) coupled to a data acquisitions system (PowerLab 8/35, ADInstruments, Inc.), before and after 2 months of respiratory muscle training and air stacking

Secondary outcome measures
1. Maximum inspiratory and expiratory pressure, measured using a pressure manometer (Micro RPM, Micro Medical-Care Fusion, Kent, UK) before and after 2 months of respiratory muscle training and air stacking
2. Slow vital capacity, forced vital capacity and forced expiratory volume in 1s, measured using a digital spirometer (FE141, ADInstruments, Inc.) coupled to a data acquisitions system (PowerLab 8/35, ADInstruments, Inc.) before and after 2 months of respiratory muscle training and air stacking
3. Phonatory measures subglottic pressure (SGP) and phonation threshold pressure (PTP) were measured during the production of plosives and recorded using a handled battery-operated device (PG-100E, Glottal Enterprises, Canada) connected to a 0.5 inches (inner diameter) silicon tubing and a standard Luer-connector. The opposite end of the silicon tubing was placed between each participant's lips preventing them from biting the tip of the tubing. Participants were instructed to repeat the syllable /pa/ at a rate of 1.5 to 2 seconds until the pressure tachometer inside the device (PG-100E), reached a 3-second plateau. SGP and PTP measurements were performed at three voice intensities: conversational, lowest possible intensity, and highest possible intensity. SGP and PTP were repeated at least 3 times for each voice intensity. The highest value of each voice intensity record was used for further analysis. Voice production intensity during SGP and PTP measurements were recorded using a portable digital recorder (Tascam DR40) sampling rate 44kHz/16-bit, placed at 45° and 20 cm from participants' lips. Voice recordings were further analyzed using Praat software (Phonetic Sciences, University of Amsterdam. The Netherlands). The mean and maximum sound pressure level (SPL) in decibels were extracted for further analysis. For maximum phonation time (MPT) participants were instructed to produce a sustained vowel /a/ sound for as long as possible after a deep inspiration. Three consecutive measures were performed and the highest value was considered for further analysis. MPT was measured with a stopwatch and participants were verbally encouraged during their vocalization. All phonatory measures were performed with participants in the seated position and in a noiseless room. All phonatory measures were assessed at baseline and after 2 months of respiratory muscle training and air stacking.

Overall study start date
16/04/2018

Completion date
08/10/2018

Eligibility

Key inclusion criteria
1. Idiopathic Parkinson's disease confirmed by a neurologist and in the "on" stage of the disease with a moderate level of disability (stage II and III Hoehn and Yahr scale)

2. Ability to understand and respond to the instructions given in the study
3. Stable dose and type of antiparkinsonian medication
4. Stable disease at the moment of inclusion in this study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
39 in three groups of 13

Total final enrolment
31

Key exclusion criteria
1. Other concomitant neurological disease
2. Current smoker
3. History of cardiovascular pathology, lung disease or the presence of respiratory symptoms such as cough, phlegm, wheezing or dyspnoea at the time of assessment
4. Difficulty in maintaining a proper mouth seal or unable to avoid air leakage during pulmonary function testing

Date of first enrolment
23/05/2018

Date of final enrolment
13/08/2018

Locations

Countries of recruitment
Chile

Study participating centre
Chilean League Against Parkinson's disease
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Sponsor information

Organisation
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University/education

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Funder(s)

Funder type
Not defined

Funder Name
National Fund for Scientific and Technological Development

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal in mid-2019

Intention to publish date
08/10/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because the informed consent does not allow the dissemination of personal information of the participants.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	27/09/2019	Yes	No
Protocol file			23/08/2022	No	No