ISRCTN10301406 https://doi.org/10.1186/ISRCTN10301406

Respiratory muscle training in patients with Parkinson's disease

Submission date
03/01/2018

Recruitment status
No longer recruiting

Registration date
16/01/2018

Overall study status
Completed

Last Edited
05/10/2022

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
Parkinson's disease is a condition in which parts of the brain become progressively damaged over many years. In patients with Parkinson’s disease, the main cause of death is a lung inflammation produced by the entrance of bronchial secretions or other foreign materials into the lungs. The high incidence of this complication has been attributed to deglutition (swallowing) and pulmonary (breathing) problems such as reduced respiratory muscle strength and respiratory muscle slowness. Cough is an important defence mechanism that removes foreign material from the bronchus (the main passageway into the lungs). To produce an effective cough, it is necessary to breathe in an adequate volume of air before coughing, to then expel an adequate volume of air while coughing to push the foreign material out of the bronchus. Strengthening inspiratory (breathing in) and expiratory (breathing out) muscles may lead the muscles to produce a greater expiratory airflow and velocity and therefore a cough able to clean the bronchus efficiently. The aims of this study are to compare the effects of an inspiratory versus an expiratory muscle-training program on the amount of airflow produced during cough, and to determine which training (inspiratory or expiratory), produces greater improvements in the amount of cough airflow in patients with Parkinson’s disease.

Who can participate?
Patients with Parkinson's disease

What does the study involve?
Participants are randomly allocated into three groups. The first group receives home-based inspiratory muscle training, the second group receives home-based expiratory muscle training, and the third group receives home-based expiratory muscle training at a minimum and fixed load. Respiratory muscle training involves performing 25 inspiratory or expiratory efforts, from Monday to Saturday, using a specific, personal and transportable device provided by the researchers of the study. The training period lasts 2 months, and each training session takes about 15-20 minutes. Participants undergo lung assessments before and after the training. They also were also contacted every two weeks to check the progress of the training. Participants also receive phone calls and/or text messages as reminders to perform the breathing exercises and arrange appointments.

What are the possible benefits and risks of participating?
Possible benefits include improved cough effectiveness by increasing the volume of air during coughing, improved safety during deglutition and decreased risk of bronchial secretions or food getting into the airway, improved voice volume, and receiving comprehensive assessments of breathing, voice and deglutition 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?
Chilean League Against Parkinson's Disease (Chile)

When is the study starting and how long is it expected to run for?
December 2016 to November 2017

Who is funding the study?
Fondo Nacional de Desarrollo Científico y Tecnológico (Chile)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11160419

Study information

Scientific Title
The effects of respiratory muscle training on peak cough flow in patients with Parkinson's disease

Study objectives
An expiratory muscle-training program is more effective than an inspiratory muscle-training program to improve voluntary and reflex peak cough flow in patients with Parkinson's disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pontificia Universidad Católica de Chile (Pontifical Catholic University of Chile) ethics committee, 18/05/2017, ID number: 16-292

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The study employed a 3 (groups) x 2 (measure times: baseline and 2 months) repeated measures design. Forty participants completed all baseline measurements and then were randomly divided into three groups using the randomisation block method. Thirteen participants were assigned to receive home-based inspiratory muscle training, 13 participants were assigned to receive home-based expiratory muscle training, and 14 participants were assigned to receive home-based expiratory muscle training at minimum and fixed load (control group). Thirty-one participants completed the study protocol. The intervention lasted 2 months for all study groups. Allocation concealment was implemented using sequential sealed envelopes prepared by an independent research assistant. The assessors were not blinded to patients allocation group.

Participants in the inspiratory training group performed a home-based inspiratory (5 sets of 5 repetitions) muscle-training program using a Threshold® Inspiratory Muscle Trainer (HS730-010. Phillips Respironics, USA).

Participants in the expiratory training group performed a home-based expiratory (5 sets of 5 repetitions) muscle-training program using an Expiratory Muscle Trainer (EMST150. Aspire Products, LLC). Both groups trained 6 times a week for 2 months. These training parameters were chosen because previous studies have shown significant improvements in pulmonary function in patients with Parkinson’s disease using a similar protocol.

Participants in both groups started training at a resistance equal to 50% of their maximum inspiratory pressure and maximum expiratory pressure, which was calculated based during baseline measurements described below. The resistance was adjusted every two weeks to reach a training intensity of 75% during the last 2 weeks of training.

Participants in the control group used a Threshold® PEP (HS-735-010. Phillips Respironics, USA) for expiratory muscle training because this device provides lower resistance for expiratory flows than those devices used by the training groups. They trained using the same protocol of the participants in the training groups for the same number of repetitions, frequency and duration, but the intensity was fixed at the minimum load of the device (9 cmH20) throughout the training period.

All participants were asked to mark on the provided training diary when a training session was completed. All participants were contacted every two weeks, to ensure that they were training and to adjust the resistance of the training devices. Phone calls or messages throughout the study period were sent to remind participants to perform the training as instructed.

Intervention Type
Device

Primary outcome(s)
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 inspiratory or expiratory muscle training

Key secondary outcome(s))
Current secondary outcome measures as of 23/05/2018:
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 inspiratory or expiratory muscle training
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 inspiratory or expiratory muscle training
3. 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. Phonatory measures were assessed at baseline and after 2 months of respiratory muscle training.

Previous 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 inspiratory or expiratory muscle training
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 inspiratory or expiratory muscle training

Completion date
27/11/2017

Eligibility

Key inclusion criteria
Participants of both genders with diagnosis of idiopathic Parkinson's disease (stage I-III Hoehn and Yahr scale) in the “on dopaminergic” state were initially recruited in the study. Inclusion criteria were:
1. Diagnosis of idiopathic Parkinson's disease confirmed by a neurologist
2. Participants with the ability to understand and respond to the instructions given in the study
3. Unaltered dose and type of antiparkinsonian medication
4. Stable disease at the moment of inclusion in this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Other concomitant neurological disease
2. Current smokers
3. Participants with a 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. Participants with difficulties in maintaining a proper mouth seal or unable to avoid air leakage during pulmonary function testing

Date of first enrolment
03/04/2017

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
Chile

Study participating centre
Chilean League Against Parkinson's Disease
Chile
8360376

Sponsor information

Organisation
Universidad Andres Bello

ROR
https://ror.org/01qq57711

Funder(s)

Funder type
Government

Funder Name
Fondo Nacional de Desarrollo Científico y Tecnológico

Alternative Name(s)
National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

Individual participant data (IPD) sharing plan

The dataset will not be made available because the informed consent document that all participants signed for this study states that “the information obtained from this investigation will be kept strictly confidential. The results of this investigation will be presented in scientific journals and/or conferences; however, your name will not be revealed”. All printed documents used to collect data are kept and secured in a locked drawer placed in the principal investigator office. Digital information is kept in a desktop computer located in the principal investigator office of the sponsoring institution (Andres Bello University). The desktop computer is password locked.

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	01/10/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			05/10/2022	No	No
Protocol file			05/10/2022	No	No
Protocol file			05/10/2022	No	No