The effects of an exercise intervention on pulmonary function, respiratory muscle strength, aerobic capacity and perception of breathlessness in a representative population of patients with Idiopathic Parkinson's Disease

Submission date	Recruitment status No longer recruiting	Prospectively registered			
03/10/2012		Protocol			
Registration date	Overall study status Completed	Statistical analysis plan			
05/10/2012		[X] Results			
Last Edited 06/08/2020	Condition category Nervous System Diseases	Individual participant data			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Ailish O'Callaghan

Contact details

North Tyneside General Hospital Rake Lane North Shields United Kingdom NE29 8NH

Additional identifiers

Protocol serial number 12407

Study information

Scientific Title

The effects of an exercise intervention on pulmonary function, respiratory muscle strength, aerobic capacity and perception of breathlessness in a representative population of patients with Idiopathic Parkinson's Disease

Study objectives

Many people with Idiopathic Parkinson's disease (IPD) suffer from respiratory symptoms including shortness of breath on exertion, cough and sputum production. Respiratory complications with IPD are a common reason for hospital admission and a higher proportion of people with IPD die from pneumonia than in the general population. Studies looking at lung function in IPD have produced varied, conflicting results. High quality research examining the effect of exercise on lung function is lacking.

We plan to undertake the largest study to date, of 100 participants, to look at the lung function, breathing muscle strength, perception of breathlessness and blood gas levels in people with IPD. We will subsequently recruit 30 of the participants to a trial that looks at the effect of a 12 week exercise programme on the above measurements. We will also evaluate the effect of the exercise intervention on the amount of oxygen the body can use during exercise, the distance walked in 6 minutes and a selection of quality of life and well being measures.

Blood tests will also be done to quantify the effect exercise has on the bodys secretion of brain derived neurotrophic factor, a protein secreted in response to activity that has the ability to signal neurons, the core components of the brain and spinal cord, to survive, become more specialised and grow. Exercise in IPD may also improve the brains ability to adapt to environmental change, respond to injury and obtain new information.

Ethics approval required

Old ethics approval format

Ethics approval(s)

12/NE/0188

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Parkinsons Disease; Disease: Parkinson's disease

Interventions

Exercise Programme, 30 participants randomised 1:1 control:intervention groups. The 15 in the intervention group will have a 3x weekly structured exercise intervention for 12 weeks.

Intervention Type

Behavioural

Primary outcome(s)

Aerobic Capacity at baseline and end of 12 weeks

Key secondary outcome(s))

Pulmonary Function at baseline and end of 12 weeks

Completion date

08/05/2015

Eligibility

Key inclusion criteria

- 1. Idiopathic Parkinsons Disease by the UK PD Society Brain Bank Criteria
- 2. Hoehn and Yahr Stage I-IV (I-III for RCT)
- 3. Ability to provide written informed consent
- 4. Aged 18 years or over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Other forms of Parkinsonism e.g. drug induced
- 2. Significant medical conditions which would preclude lung function testing
- 3. Significant medical conditions which would preclude exercise (RCT group)
- 4. Pregnancy
- 5. Recent diagnosis of a blood clot, deep vein thrombosis, pulmonary embolism or myocardial infarction
- 6. Unstable cardiac status, haemoptysis, pneumothorax, thoracic, abdominal or cerebral aneurysm
- 7. Recent eye, thoracic or abdominal surgery

Date of first enrolment

15/08/2012

Date of final enrolment

08/05/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
North Tyneside General Hospital
North Shields
United Kingdom
NE29 8NH

Sponsor information

Organisation

Northumbria Healthcare NHS Foundation Trust (UK)

ROR

https://ror.org/01gfeyd95

Funder(s)

Funder type

Charity

Funder Name

British Geriatrics Society (UK)

Alternative Name(s)

The British Geriatrics Society, The British Geriatrics Society (BGS), GeriSoc, BGS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Parkinson's UK (UK)

Alternative Name(s)

Parkinson's Disease Society

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	06/08/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes