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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)

Treatment

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

### 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 particpants 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 measure
Aerobic Capacity at baseline and end of 12 weeks

### Secondary outcome measures
Pulmonary Function at baseline and end of 12 weeks

### Overall study start date
15/08/2012

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants

Planned Sample Size: 100; UK Sample Size: 100

### 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
England

United Kingdom

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

## Sponsor information

### Organisation
Northumbria Healthcare NHS Foundation Trust (UK)

### Sponsor details
North Tyneside General Hospital
Rake Lane
North Shields
England
United Kingdom
NE29 8NH

### Sponsor type

Hospital/treatment centre

**ROR**
https://ror.org/01gfeyd95

# Funder(s)

**Funder type**
Charity

**Funder Name**
British Geriatrics Society (UK)

**Alternative Name(s)**
BGS

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Associations and societies (private and public)

**Location**
United Kingdom

**Funder Name**
Parkinson's UK (UK)

**Alternative Name(s)**

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Associations and societies (private and public)

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/09/2020 | 06/08/2020 | Yes | No |