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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