ISRCTN52284448 https://doi.org/10.1186/ISRCTN52284448

Parkinson's disease, exercise and cognitive training

Submission date	Recruitment status	[X] Prospectively registered
23/03/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/04/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/01/2018	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a long-term medical condition which is caused by the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing abnormal movements such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia). As well as the issues with movement, many patients with PD also experience problems with cognitive function (thinking, reasoning and memory). In the early stages of the disease medications can help to reduce the physical symptoms, but the effects of these drugs on cognitive function are not fully understood. Several studies have suggested that a combination of both physical exercise and cognitive training can help to improve cognitive function in PD patients more efficiently than cognitive training alone, however further research is needed in order to find out how effective this really is. The aim of this study is to find out whether a programme involving both physical exercise and cognitive training is more effective at improving cognitive function than cognitive training alone.

Who can participate?
Adults aged between 40 and 80 who have Parkinson's disease with mild to moderate disability.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the second group take part in cognitive training alone. This involves completing a number of mental tasks on a computer of increasing difficulty. The difficulty levels are adapted for each patient. Those in the second group take part in cognitive training with exercise. This involves completing the cognitive training on a touch screen computer while walking on a treadmill. Two weeks before and after the training and again two months later, participants in both groups complete a number of assessments and questionnaires to test their cognitive and physical performance.

What are the possible benefits and risks of participating?
Participants may benefit from being able to improve their cognitive function. There are no notable risks involved with taking part in this study.

Where is the study run from?
University Hospital Complex of A Coruña (Spain)

When is the study starting and how long is it expected to run for?
December 2014 to February 2018

Who is funding the study?
Ministry of Economy and Competitiveness (Spain)

Who is the main contact?
Professor Miguel Fernández del Olmo
mafo@udc.es

Contact information

Type(s)
Scientific

Contact name
Prof Miguel Fernández del Olmo

ORCID ID
http://orcid.org/0000-0001-5325-503X

Contact details
Departamento de Educación Física e Deportiva
Facultade de Ciencias do Deporte e a Educación Física (INEF Galicia)
Avd. Ernesto Che Guevara 121, Pazos-Liáns
A Coruña
Spain
15179
+34 981167000
mafo@udc.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DEP2014-53896-R

Study information

Scientific Title
Effects of the combination of physical exercise and cognitive training on cognitive functions in patients with Parkinson's disease

Acronym
EFECEP

Study objectives
Multimodal intervention of physical exercise and cognitive training will induce greater cognitive improvements compared with the unimodal intervention of cognitive training in Parkinson's disease patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of University of A Coruña, 30/12/2015, ref: 20/2014

Study design
Single-centre randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

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

Interventions
Patients will be allocated randomly in two groups, a group of multimodal intervention (physical exercise + cognitive training) and a group of unimodal intervention (cognitive training).

Group 1: Participants complete cognitive training alone. This involves completing computer tasks, individualized for the cognitive capacity, using the software SmartBrain (http://www.smartbrain.net/). Participants complete three sessions a weeks for eight weeks, lasting for around 64 minutes per session.

Group 2: Participants complete the cognitive training whiles walking on a treadmill, by using touch screen technology. Participants complete three sessions a weeks for eight weeks, lasting for around 64 minutes per session.

Two weeks before and after the training programs, clinical, motor, neuropsychogical and neurophysiological evaluations will be conducted. A two month follow up will also be performed.

Intervention Type
Behavioural

Primary outcome measure
1. Cognitive performance is measured using CDS (Cognitive Difficulties Scale), WAIS-III (Wechsler Adult Intelligence Scale-III), Digital Span Forward and backwards, Trail Making Test A and B, Stroop Test, Corsi Block, Verbal Fluency (FAS), Tower of London and Wilcoxin Card Sorting Test at 2 month before intervention, 2 weeks before intervention (baseline), 2 weeks post-intervention and two months post-intervention (follow-up)
2. Motor performance is measured using walk at comfortable speed, Time Up & Go and walk with dual-task at 2 month before intervention, 2 weeks before intervention (baseline), 2 weeks post-intervention and two months post-intervention (follow-up)
3. Quality of life is measured using ADLS (Activities of Dayly Living Scale), QOLS (Quality Of Life Scale) and IPAQ (International Physical Activity Questionnaire) at 2 month before intervention, 2 weeks before intervention (baseline), 2 weeks post-intervention and two months post-intervention (follow-up)

Secondary outcome measures
1. Functional connectivity is measured using evoked related potentials at 2 weeks before intervention (baseline) and 2 weeks post-intervention
2. White matter is measured using diffusion tensor imaging at 2 weeks before intervention (baseline) and 2 weeks post-intervention

Overall study start date
01/12/2014

Completion date
15/01/2018

Eligibility

Key inclusion criteria
1. Aged 40–80 years
2. Diagnosed with PD according to UK PD Society Brain Bank Criteria.26
3. Disease severity of Hoehn and Yahr (H&Y) stages I–III

Participant type(s)
Patient

Age group
Mixed

Sex

Both

Target number of participants
60

Key exclusion criteria
1. Significant cognitive impairment (Mini-Mental State Examination < 23)
2. Below average premorbid intelligence (vocabulary subtest, Wechsler Adult Intelligence Scale-III [WAIS-III] typical score < 40)
3. Major depression (GDS-15 > 10)
4. Severe auditory or visual deficits
5. Another psychiatric/neurological condition

Date of first enrolment
01/06/2016

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
Spain

Study participating centre
University Hospital Complex of A Coruña (Complexo Hospitalario Universitario de A Coruña)
As Xubias, 84
A Coruña
Spain
15179

Sponsor information

Organisation
University of A Coruña

Sponsor details
Rúa da Maestranza, 9
A Coruña
Spain
15001
+34 981167000
reitor@udc.es

Sponsor type

University/education

Website
www.udc.es

ROR
https://ror.org/01qckj285

Funder(s)

Funder type
Government

Funder Name
Ministerio de Economía y Competitividad

Alternative Name(s)
Ministry of Economy and Competitiveness, MINECO, MEC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication of study results in peer reviewed journals.

Intention to publish date
06/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request