ISRCTN17452402 https://doi.org/10.1186/ISRCTN17452402

# Randomised controlled trial to assess the clinical- and cost-effectiveness of physiotherapy and occupational therapy in Parkinson's disease

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| **Submission date**<br>21/08/2008 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>01/09/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>02/09/2016 | **Condition category**<br>Nervous System Diseases | |

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

**Study website**
www.pdrehab.bham.ac.uk/

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

### ClinicalTrials.gov number

### Secondary identifying numbers
HTA 07/01/07

# Study information

### Scientific Title
Randomised controlled trial to assess the clinical- and cost-effectiveness of physiotherapy and occupational therapy in Parkinson's disease

### Acronym
PD REHAB

### Study objectives
Parkinson's disease (PD) is a progressive neurological disorder caused by the loss of pigmented dopaminergic neurones in the brain and the consequent depletion of the neurotransmitter dopamine. This leads to increasing problems with movement, including tremor, rigidity, slowness, postural disturbance and loss of balance. PD is one of the commonest causes of disability in older people. It is estimated that about 8,000 new cases of PD are diagnosed in the UK each year. Average life expectancy is about 15 years, leading to a minimum prevalence of 100,000 cases. Incidence increases rapidly with age, with most patients developing the initial symptoms of PD between 50 and 70 years of age. There is currently no curative therapy for PD, and treatment is directed towards the alleviation of symptoms.

The objective of this randomised controlled trial (RCT) is to evaluate the clinical and cost-effectiveness of combined domiciliary physiotherapy (PT) and occupational therapy (OP) in patients with PD. The results of the trial will inform future decisions by patients, clinicians, commissioners, the National Institute for Health and Clinical Excellence (NICE) and Government regarding the use of these rehabilitation therapies in PD. Patients and carers, along with the Parkinson's Disease Society, will be involved in translating the trial findings into a patient/carer leaflet to support their decision making in therapy up-take and will ensure the patient/carer voice is embedded within all recommendations for clinical practice.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/070107
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/51736/PRO-07-01-07.pdf

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
MREC approval on 17/12/2008

### Study design
Multicentre randomised controlled trial

### Primary study design
Interventional

### Secondary study design

Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## 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
The participants will be randomly allocated to either immediate OT and PT versus no treatment for the duration of the trial.

Treatment arm: Physiotherapy and occupational therapy will be delivered in the patient's home by a trained therapist. The framework for the content of the therapy has been developed and it will be further agreed in advance by expert groups based on our previous work on standard NHS OT and PT and European guidelines. It will meet the requirements of patient-centred care as therapists will work towards the patients agreed goals within the framework. In that way therapy will be tailored to the individual patient's requirements. We have allowed for 8 visits by both the occupational therapist and physiotherapist to each patient in line with standard NHS practice as documented in the Physiotherapy Evaluation Project and our survey of occupational therapy services in the UK.

Control arm: The control patients will consent to have OT and PT deferred until the end of their 15 months participation in the trial. Since there is insufficient evidence to prove or disprove the benefit of OT and PT in PD, equipoise still exists. Therefore, it is ethical to randomise between immediate versus no therapy. We anticipate that patients will try to be fully compliant. However, some may have one or both therapies arranged by health or social care providers not associated with the trial (e.g., social services). Since this may lead to a dilution of the intervention effect, at each assessment, we will ask control arm patients whether they have received such therapy. To reduce the possibility of control arm patients receiving therapy, we will devise a clear short leaflet about the importance of the control arm and why utilising other therapies may impact on their participation in the study. This will be developed by the patient and carer involvement group.

Total duration of intervention: 3 months (if allocated the treatment arm)
Total duration of follow-up: 12 months (therefore, total duration of trial: 15 months)

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure

Instrumental activities of daily living (NEADL; patient completed). NEADL specifically assesses aspects of patient function to which OT and PT are directed. NEADL was originally developed for stroke trials, but has now been used more widely as a generic outcome measure, such as in intervention studies for older people with general frailty and in those with specific problems (e. g. visual impairment and respiratory disease). NEADL questionnaires will be completed at baseline, 3, 9 and 15 months)

### Secondary outcome measures
1. Health-related quality of life, assessed by the Parkinson's Disease Questionnaire 39 (PDQ 39) and EuroQol-5D (EQ-5D), both to be completed by the patient at baseline, 3, 9 and 15 months
2. Cost-effectiveness: cost per quality adjusted life year (EQ-5D; see first secondary outcome measure), patient-completed health economics questionnaire at 9 and 15 months
3. Hoehn and Yahr scale at entry/baseline (investigator completed)
4. Serious adverse events throughout trial (investigator completed)
5. Carer quality of life, assessed by the Short Form 12 (SF-12) (carer completed) at baseline, 3, 9 and 15 months

### Overall study start date
01/01/2009

### Completion date
31/12/2013

## Eligibility

### Key inclusion criteria
1. Both males and females, no age limit
2. Idiopathic PD defined by the UK Parkinson's Disease Society Brain Bank Criteria. These criteria are in standard use throughout the NHS in the UK and were supported by the NICE guidelines.
3. PD patients who report limitations in activities of daily living (ADL). We will stratify patients according to their baseline Nottingham Extended Activities of Daily Living (NEADL) score which means we will be able to examine the efficacy of these interventions at different levels of ADL disability.

### Participant type(s)
Patient

### Age group
All

### Sex
Both

### Target number of participants
750

### Key exclusion criteria
Current information as of 02/09/2009:
1. Dementia, as usually defined clinically by the patient's physician. From our experience in another trial, some patients with moderate to severe dementia have difficulty in completing self-

assessment forms.
2. Received occupational therapy or physiotherapy in the last 1 year

Initial information at time of registration:
1. Dementia, as usually defined clinically by the patient's physician. From our experience in another trial, some patients with moderate to severe dementia have difficulty in completing self-assessment forms.
2. Received occupational therapy in the last 2 years or physiotherapy in the last 1 year

### Date of first enrolment
01/01/2009

### Date of final enrolment
31/12/2013

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**City Hospital Birmingham**
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## Sponsor information

### Organisation
University of Birmingham (UK)

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### Sponsor type
University/education

**Website**
http://www.bham.ac.uk/

**ROR**
https://ror.org/03angcq70

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**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 | 01/03/2016 | | Yes | No |
| Results article | results | 01/08/2016 | | Yes | No |