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

Submission date
21/08/2008

Recruitment status
No longer recruiting

Registration date
01/09/2008

Overall study status
Completed

Last Edited
02/09/2016

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
All

Sex
All

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
United Kingdom

England

Study participating centre
City Hospital Birmingham
Birmingham
United Kingdom
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Sponsor information

Organisation
University of Birmingham (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, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	01/03/2016		Yes	No
Results article	results	01/08/2016		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes