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A pilot study of a sleep hygiene education program in Parkinsons disease sufferers: effect on carer well-being

Submission date
08/09/2005

Recruitment status
No longer recruiting

Registration date
14/09/2005

Overall study status
Completed

Last Edited
04/03/2013

Condition category
Nervous System Diseases

[_] 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
3

Study information

Scientific Title

Study objectives
By managing sleep disturbance in PD sufferers, we will significantly enhance quality of life in carers of PD sufferers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

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

Interventions
Behavioural intervention (a sleep hygiene education program) versus a placebo intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Change in overall carer well-being as measured by the General Health Questionnaire (GHQ). This is a well-established and well-validated measure of general physical and mental well being.
2. Change in overall carer burden as measured by the Burden Interview. This is a well-established and well-validated measure of feelings of burden of caregivers in caring for an older person with dementia.

Key secondary outcome(s)
1. Sleep disturbance in carers/sufferers (Epworth Sleepiness Scale & sleep diary)
2. Quality of life in PD sufferers (PD-QOL, a quality of life scale)
3. Psychiatric/behavioural functioning in sufferers/carers (Geriatric Depression Scale, & Neuropsychiatric Inventory/NPI carer distress scale (NPI).
4. Parkinsonian motor symptoms in PD sufferers (Unified Parkinsons Disease Rating Scale, subscore (UPDRS- motor) & the Hoehn-Yahr Scale (HYS) for stage of motor severity in PD).

Completion date

01/01/2006

Eligibility

Key inclusion criteria
1. Diagnosis of Parkinsons disease (based on UK Brain Bank Criteria) in the mild-moderate stage (Hoehn-Yahr rating <4)
2. Men and women between the ages of 35 and 90
3. Sleep disturbance in the PD sufferer, as determined by screening sleep questionnaire
4. PD sufferer has a live-in carer who is willing to participate in the study
5. Good general physical health or stable medical condition
6. Able to give consent and willing to participate in the study
7. Mini-mental State Examination (MMSE) score of <27 in the PD participant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Dementia or severe psychiatric disturbances which would render them unable to participate with study procedures
2. Severe, unstable medical conditions
3. Those unable to give their own consent

Date of first enrolment
01/07/2005

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Park House
Manchester

United Kingdom
M8 5RB

Sponsor information

Organisation
Manchester Mental Health and Social Care Trust (UK)

Funder(s)

Funder type
Not defined

Funder Name
No funding

Results and Publications

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	01/10/2010		Yes	No