

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	<input type="checkbox"/> Prospectively registered
Registration date 14/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/03/2013	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Iracema Leroi

Contact details
Park House
North Manchester General Hospital
Delaunay's Road
Crumpsall
Manchester
United Kingdom
M8 5RB
+44 (0)161 720 2497
ILeroi2002@yahoo.co.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

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 measure

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.

Secondary outcome measures

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).

Overall study start date

01/07/2005

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

Age group

Adult

Sex

Both

Target number of participants

15 patient-carer pairs (30 in total)

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

England

United Kingdom

Study participating centre

Park House

Manchester

United Kingdom

M8 5RB

Sponsor information

Organisation

Manchester Mental Health and Social Care Trust (UK)

Sponsor details

Chorlton House

70, Manchester Road

Chorlton

Manchester

England

United Kingdom

M21 9UN

+44 (0)161 882 1138

stephanie.burns@mhsc.manchester.nhs.uk

Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Not defined

Funder Name

No funding

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	01/10/2010		Yes	No