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

Submission date	Recruitment status	Prospectively registered		
08/09/2005	No longer recruiting	☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
14/09/2005		[X] Results		
Last Edited	Condition category	Individual participant data		
04/03/2013	Nervous System Diseases			

# 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

## 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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## 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

# **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

# 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