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# Caring for carers of people with Parkinson's disease

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 27/05/2009 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 21/07/2009 | Stopped | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 07/08/2020 | Nervous System Diseases | [ ] Record updated in last year |

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

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Richard Brown

**Contact details**
King's College London
Institute of Psychiatry
Department of Psychology (PO77)
De Crespigny Park
London
United Kingdom
SE5 8AF

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
CSA/07/017

# Study information

### Scientific Title
Caring for carers of people with Parkinson's disease (C4C-PD): a multicentre randomised controlled trial of the development and evaluation of a nurse-led group-based psychological intervention for caregiver stress and distress

### Acronym
C4C-PD

### Study objectives
Is a psychological group intervention effective in reducing the level of stress and distress experienced by carers of patients with Parkinson's disease?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Joint South London and Maudsley and Institute of Psychiatry NHS Research Ethics Committee, 05/02/2009, ref: 09/H0807/6

### Study design
Interventional multicentre randomised controlled trial (delayed treatment)

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Quality of life

### 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
Carer stress; Parkinson's disease

### Interventions
1. Cognitive behavioural therapy nurse-led group intervention: 6 - 9 carers per group, 8 x 2 hour sessions at weekly intervals over 2 - 3 months. Intervention guided by trial manual and supporting materials.
2. Waiting list group: The waiting list group will be offered treatment after 3 months.

### Intervention Type

Other

### Phase
Not Applicable

### Primary outcome measure
28-item General Health Questionnaire (GHQ-28): score at the end of treatment for the immediate treatment group compared to score of the delayed treatment group at the same timepoint. Measured at pre-randomisation and end of treatment (for active arm) or at 3 months (for control arm). All will be assessed again at 3 months post-treatment to assess uncontrolled delayed effects.

### Secondary outcome measures
1. Zarit Caregiver Burden Interview
2. Caregiver Strain Index
3. Geriatric Depression Scale (GDS-15)

In addition to the analysis at the primary endpoint, (uncontrolled) treatment effects at the end of follow-up relative to baseline and end of treatment will be analysed as a secondary endpoint. All measured at pre-randomisation and end of treatment (for active arm) or at 3 months (for control arm). All will be assessed again at 3 months post-treatment to assess uncontrolled delayed effects.

### Overall study start date
01/08/2009

### Completion date
31/12/2010

### Reason abandoned (if study stopped)
Participant recruitment issue

## Eligibility

### Key inclusion criteria
Participants must:
1. Be the primary caregiver for the person with Parkinson's disease and either live in the same home and/or have at least 12 hours direct care-related contact per week
2. Be able to provide informed consent
3. Be willing and able to attend 8 weekly or fortnightly sessions
4. Score 5 or more ('case' level problems) using binary (0/1) scoring on the 28-item General Health Questionnaire (GHQ-28)
5. Be aged 18 years or older (no upper age limit), males or females

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
146

### Key exclusion criteria
Participants will be excluded if they:
1. Lack sufficient spoken language skills and literacy to meaningfully engage with the sessions or complete treatment related activities between sessions
2. Are felt unlikely to comply with the 'rules' that typically apply to participants in group-based interventions (e.g. maintaining confidentiality, allowing others to speak)
3. They have received psychological therapy or a course of counselling in the past year, are currently receiving treatment or counselling, or plan to start in the next year

### Date of first enrolment
01/08/2009

### Date of final enrolment
31/12/2010

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**King's College London**
London
United Kingdom
SE5 8AF

## Sponsor information

### Organisation
King's College London (UK)

### Sponsor details
Research Governance/Clinical Trials Facilitator
R&D Office PO05

De Crespigny Park
London
England
United Kingdom
SE5 8AF

**Sponsor type**
University/education

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

**ROR**
https://ror.org/0220mzb33

# Funder(s)

**Funder type**
Charity

**Funder Name**
Parkinson's Disease Society

**Funder Name**
Edmund J Safra Philanthropic Foundation

# 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