

# Caring for carers of people with Parkinson's disease

|                                        |                                                      |                                                              |
|----------------------------------------|------------------------------------------------------|--------------------------------------------------------------|
| <b>Submission date</b><br>27/05/2009   | <b>Recruitment status</b><br>No longer recruiting    | <input checked="" type="checkbox"/> Prospectively registered |
|                                        |                                                      | <input type="checkbox"/> Protocol                            |
| <b>Registration date</b><br>21/07/2009 | <b>Overall study status</b><br>Stopped               | <input type="checkbox"/> Statistical analysis plan           |
|                                        |                                                      | <input type="checkbox"/> Results                             |
| <b>Last Edited</b><br>07/08/2020       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Individual participant data         |
|                                        |                                                      | <input type="checkbox"/> Record updated in last year         |

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

**Primary study design**

Interventional

**Study design**

Interventional multicentre randomised controlled trial (delayed treatment)

**Study type(s)**

Quality of life

**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(s)**

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.

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

King's College London

London

United Kingdom

SE5 8AF

## Sponsor information

**Organisation**

King's College London (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

Individual participant data (IPD) sharing plan

## **IPD sharing plan summary**

Not provided at time of registration