# 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

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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

#### Study design

Interventional multicentre randomised controlled trial (delayed treatment)

#### Primary study design

Interventional

#### 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

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes