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Caring for carers of people with Parkinson's disease

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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