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Reducing distress in carers of patients receiving specialist palliative care: a randomised controlled trial

Submission date
08/09/2005

Recruitment status
No longer recruiting

Registration date
17/10/2005

Overall study status
Completed

Last Edited
21/12/2011

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRUK reference C1432/A4179

Study information

Scientific Title

Study objectives
A two-armed randomised controlled trial of the effectiveness of a 6 week intervention designed to reduce informal carer distress. Specifically, we aimed to evaluate the effects of an intervention for distressed informal carers of patients receiving specialist palliative care on:
1. Carer well-being (primary outcome)
2. Carer strain
3. Carer quality of life
4. Carer bereavement outcome
5. The proportion of patients dying at home

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Informal carers of patients receiving specialist palliative care

Interventions
Six weekly visits from a carer advisor versus usual care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Change in carer distress as measured by General Health Questionnaire 28 (Goldberg & Williams 1988) 4, 9 and 12 weeks after randomisation.

Secondary outcome measures
1. Caregiver Strain Index: 4, 9 and 12 weeks after randomisation
2. Care-Giver Quality of Life Index (Cancer): 4, 9 and 12 weeks after randomisation
3. Carer Bereavement: 4 months after the patients death

Overall study start date
01/10/2000

Completion date
31/10/2003

Eligibility

Key inclusion criteria
1. Informal carers of patients receiving specialist palliative care
2. Able to give informed consent
3. No organic brain disease
4. over 18 years.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
280

Key exclusion criteria
1. Unable to understand English
2. Unable to give informed consent
3. Organic brain disease or dementia
4. Under 18 years of age.

Date of first enrolment
01/10/2000

Date of final enrolment
31/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept Mental Health Sciences
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref:C1432/A4179)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2007		Yes	No