ISRCTN86241808 https://doi.org/10.1186/ISRCTN86241808

A short-term group intervention for informal carers of palliative care patients: feasibility and pilot study of a randomised controlled trial

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 07/01/2010	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Irene Higginson

Contact details
Department of Palliative Care and Policy
Guy's, King's and St Thomas' School of Medicine
King's College London
Cutcombe Road
London
United Kingdom
SE5 9RJ
+44 (0)20 7848 5584
irene.higginson@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RDC01028

Study information

Scientific Title

Study objectives
This study is investigating the needs of carers of patients with advanced illness. It will determine whether a support group for carers is feasible, acceptable and accessible and will develop and pilot methods for its evaluation in a randomised controlled trial. Such a support group was found to be effective in one study in the US; it improved patient and carer outcomes and increased time at home. However, such a service has not been tested in this country in any rigorous evaluation. The study is based in two specialist palliative care services, both of which offer multi-professional specialist palliative home care support.

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)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Pain; palliative care

Interventions
Standard care vs short-term intervention

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
1. Zarit Burden Inventory
2. GHQ-12
3. 6-item State-Trait-Anxiety Inventory
4. Index of coping responses
5. Palliative Outcome Scale
6. Eastern Cooperative Oncology Group Performance Scale

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/1999

Completion date
01/02/2001

Eligibility

Key inclusion criteria
Nearest carers of patients with advanced and terminal disease (mainly cancer patients but some will have other progressive diseases such as neurological or cardiovascular disease's) in the care of palliative care services at the Camden and Islington Palliative Care Centre, London and St Christopher's Hospice, London. Patients will usually be in the last months of life - average time in care of the services is 12-18 weeks. Patients and carers from a wide range of ethnic and social backgrounds. 75% are 65 years of age or older.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Younger than 18 years
2. Lack of fluent english
3. Prognosis less than 3 weeks

Date of first enrolment
01/02/1999

Date of final enrolment

01/02/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Palliative Care and Policy
London
United Kingdom
SE5 9RJ

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name

NHS Executive London (UK)

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	01/11/2002		Yes	No