

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/01/2010	Condition category Other	<input type="checkbox"/> 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

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

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