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(TRIAL TERMINATED - problems with recruitment) Effects of guiding informal caregivers of terminal cancer patients who stay at home, by district nurses who are specialised in palliative care/oncology

Submission date 20/12/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/12/2005	**Overall study status** Stopped	
Last Edited 10/08/2009	**Condition category** Cancer	

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
25073; NTR157

Study information

Scientific Title

Acronym
Gids-project (Guidance of informal carers by district nurses)

Study objectives
Informal caregivers in the experimental group are expected to be more satisfied with the care provided to them and the patient they take care of, to experience a less heavy burden, and to have a better health compared to the informal caregivers who are assigned to the control group and will receive standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Terminal cancer

Interventions
Four one-hour home visits by district nurses who are specialised in palliative care/oncology over a period of six weeks, in order to support informal caregivers in handling problems they are faced with when taking care of a terminally ill cancer patient.

Next to the visits of the district nurses, informal caregivers in the experimental group receive written information about self-care for informal caregivers and contact with other informal caregivers. They also receive information about national and local organizations involved in the care for informal caregivers.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Satisfaction of the informal caregivers with the care provided to them and the patient they take care of. Measured at baseline and eight weeks later, with the Maastricht measuring-Instrument Satisfaction Terminal Care (in Dutch: Maastrichts meetInstrument Tevredenheid Terminale Zorg - MITTZ).
2. Burden perceived by the informal caregivers, measured at baseline and eight weeks later, with the Caregiver Reaction Assessment-Dutch (CRA-D)
3. Health of the informal caregivers, measured at baseline and eight weeks later, with the MOS 36-item Short Form Health Survey (SF-36)

Secondary outcome measures
The use of health care facilities by both the informal caregivers and the patients, measured over a period of eight weeks, by means of a care diary.

Overall study start date
15/04/2005

Completion date
28/02/2006

Reason abandoned (if study stopped)
Problems with recruitment

Eligibility

Key inclusion criteria
Informal caregivers can enter the study if they take care of a patient who has been diagnosed with cancer and has a life expectancy of less than four months. Next to these criteria, the patient has to spend his last months largely at home and has to be at least 18 years old. Informal caregivers can also take part in the study if they are not involved in the care for the patient at the moment, but are expected to be in the near future.

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
Informal caregivers who take care of a cancer patient with a life expectancy of less than two months, because this interferes with the post-measurement eight weeks after inclusion

Date of first enrolment
15/04/2005

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Integraal Kankercentrum Limburg
Maastricht
Netherlands
6201 HA

Sponsor information

Organisation
Comprehensive Cancer Centre Limburg (The Netherlands)

Sponsor details
P.O. Box 2208
Maastricht
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Sponsor type
Charity

Funder(s)

Funder type
Government

Funder Name
Province of Limburg (Netherlands)

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