

(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
Registration date 20/12/2005	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 10/08/2009	Condition category Cancer	☐ 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
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

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

Study type(s)

Quality of life

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(s)

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)

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

Funder(s)

Funder type

Government

Funder Name

Province of Limburg (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration