Optimization of complex palliative care at home by means of expert consultation via telemedicine.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23729

Source
Nationaal Trial Register

Brief title
FRONTIDA

Health condition

The symptom burden of palliative patients and the palliative trajectory in oncological patients. Further, the experienced continuity of care by the patients will be studied, as well as the burden of care of the family caregiver.

Keywords English: Palliative care, symptom burden, teleconsultation, teleconferencing, continuity of care.

Dutch: palliatieve zorg, symptoomlast, teleconsultatie, videobellen, continuiteit van zorg

Sponsors and support

Primary sponsor: UMC St Radboud, department Anesthesiology, pain and palliative care.

Source(s) of monetary or material Support: ZZG-zorggroep (home care organization)

Intervention

Outcome measures

Primary outcome

The multidimensional symptom burden of the patient (ESAS; HADS) at baseline and then every week.

Secondary outcome

1. Level of identification of problems and needs (PNPC - sv) at baseline and after every 4 weeks;

2. Experienced quality of care (questionnaire ‘continuity of care’, developed by the St Radboud Medical Center) at baseline and after every 4 weeks;

3. Satisfaction with the teleconsultation for patient, GP and member of the palliative consultation team (PSQ) just after the first two teleconsultations;

4. Burden of care of the informal caregiver (EDIZ) at baseline and after every two weeks;

5. Number and indication of hospital admissions at the end of the inclusion period.

Study description

Background summary

Objective:

The aging population in Western society is a great challenge for palliative care. Many people, particularly elderly, eventually dying of cancer or non-oncological diseases prefer to die at home. However, 30-40% of palliative patients in Belgium and the Netherlands is being transferred to a hospital or health care institution in the last week of life. Good palliative care at home is necessary to guarantee quality of dying. Telemedicine has the potential to deliver high quality of palliative care at home and therefore possibly decreases the symptom burden of the patient. The primary goal of this study is to evaluate the effectiveness of telemedicine in reducing the symptom burden of the palliative patient at home.

Subjects:

Dutch-speaking adult patients, with a progressive oncological disease in an advanced stage, that have a life expectancy of 3 months or less will participate in a cluster randomized controlled clinical trial (n=100).

Primary outcome measure:

The symptom burden of palliative patients at home, measured at baseline and then weekly (ESAS; HADS).

Methods:

Patients will be included via the GP. GP's in the area of Nijmegen will be invited to participate in this study. A telemedicine device will be installed in the homes of the patients in the intervention group. Besides the usual care, these patients have a weekly teleconsultation with a member of the palliative consultation team. The GP will join the consult when medical decision-making is on the agenda. During this study, the GP continues to be the coordinator of medical care of the patient. The nurse practitioner, in cooperation with the palliative care specialist of the palliative consultation team, will advise the GP. The control group will receive care as usual, and will not make use of the telemedicine device.

Hypotheses:

Teleconsultation will decrease the symptom burden of the patient and the burden of the family caregiver. Besides, teleconsultation will lead to less hospital admissions and improves the continuity of care. It is also hypothesized that the patient, GP and the members of the palliative consultation team are satisfied with the teleconsultations.

Study objective

Palliative care is a growing need in Western society. The improved quality of healthcare makes people live longer and chronic diseases are increasing. Evidence shows that many elderly, eventually dying of cancer or non-oncological diseases, prefer to die at home. However, 30-40% of palliative patients in Belgium and the Netherlands is being transferred to a hospital or health care institution in the last week of life. The transfer of the patient is an immense burden for patient and family caregiver and leads to increased health care costs. Early recognition and anticipation at the patient's worsening situation is necessary to prevent this heavy burden and can subsequently decrease the number of hospital admissions.

The delivery of palliative care at home is necessary to enable patients to die at their

preferred place of death and to improve the quality of the last phase of life.

Teleconsultation has the potential to support good palliative care at home and is therefore hypothesized to decrease the symptom burden of the patient and the burden of the family caregiver. Besides, it will be considered whether telemedicine will decrease the number of hospital admissions and will lead to improved continuity of care.

Study design

1. Primary outcome: At baseline and after every week;

2. Secondary outcomes: At baseline and after every 4 weeks. Exceptions: The burden of care of the informal caregiver (every two weeks) and the satisfaction with the teleconsultations (just after the first two consultations).

Intervention

The intervention consists of a weekly teleconsultation palliative care. A telemedicine computer will be installed at the patient's home. The first teleconsultation will be between the patient and a Nurse Practitioner of the palliative consultation team. During this first consult, the NP checks for problems in palliative care (e.g. physical problems, social problems, coordination of care). Next, there will be a weekly teleconsultation between the patient and a member of the palliative consultation team. The GP will join the consult when medical decision-making is on the agenda. During this study, the GP continues to be the coordinator of medical care of the patient. The nurse practitioner, in cooperation with the palliative care specialist of the palliative consultation team, will advise the GP on treatment policy of the patient.

The control group will receive care as usual, and will not make use of the telemedicine device.

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Eligibility criteria

Inclusion criteria

Dutch-speaking patients, aged 18 years or older, with a progressive oncological disease in an advanced stage, that have a life expectancy of 3 months or less (Karnofsky-score <= 60).

On the moment of inclusion, the patients stay at home with a GP as coordinator of medical care.

Exclusion criteria

1. Patients unable to give informed consent;

2. Patients with an active psychotic disorder or a serious cognitive disorder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2011

Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion
Date: 21-03-2011
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34360
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2688
NTR-old	NTR2817
CCMO	NL34426.091.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34360

Study results

Summary results
N/A