Pain in Cancer Patients.

No registrations found.

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

Summary

ID

NL-OMON21593

Source
NTR

Brief title
Pijnsein

Health condition

aandoening: patients with cancer and pain (kanker en pijn)

The incidence and prevalence of cancer is high, and many cancer patients have pain. The next decade, the prevalence of patients with cancer and oncological pain will still increase, so knowledge of barriers and misbeliefs of caregivers and patients about pain reporting, diagnosing and treating pain, together with improved communication is of upmost importance.

Sponsors and support

Primary sponsor: Universitair Medisch Centrum St Radboud te Nijmegen
Source(s) of monetary or material Support: Bergh in het zadel

Intervention

Outcome measures

Primary outcome

1. Percentage of all patients that visit the medical oncology outpatient clinic with adequate

pain therapy/medication with the Pain Management Index (PMI);

2. Mean pain intensity of those cancer patients with pain (NRS).

Secondary outcome

1. Percentage of medical records of new patients in the outpatients oncology clinic, in which pain is registered with NRS;

2. Quality of life of patients with pain (EORTC QLQ-C30);

3. Knowledge of doctors of content of the guideline (questionnaire and Vignette);

4. Prospective descriptive study of pain intensity of the group of patients that will be monitored via sms-alerts and SMS pain reporting;

5. Process evaluation of the intervention study.

Study description

Background summary

Background:

The prevalence of pain in patients with cancer is high. In 2007, nearly one out of two patients with cancer pain was undertreated. Inadequate pain control still remains an important problem. Therefore, in 2008 a national, evidence-based multidisciplinary guideline "pain in patients with cancer" has been developed. Yet, publishing a guideline is not enough. Implementation of guidelines is needed to improve pain reporting and pain management. This study aims to implement the Dutch guideline pain in patients with cancer. This implementation will improve pain reporting, pain measurement and hence pain control in newly diagnosed patients with cancer in pain. As an innovative tool the interactive voice control is used to improve the pain reporting and to improve the training of medical oncologists, nurses and general practitioners.

Methods/design:

A randomised controlled trial with two arms will be performed in six oncology outpatient clinics of hospitals in the Southeastern part of the Netherlands, with three hospitals in the intervention condition and three in the control condition. Follow-up measurements will be conducted in all hospitals, to study the long-term effect of the intervention. The intervention includes training of professionals (medical oncologists, nurses and general practitioners) and

Short Message Service with Interactive Voice Response SMS alert to report pain in patients with cancer. Besides, in both conditions a patient leaflet of the Dutch Cancer Society on cancer pain as well as a pain diary will be used.

Study objective

Publishing a guideline is not enough. An implementation strategy is needed to improve pain reporting, pain measurement and adequate pain therapy.

Study design

1. Knowledge questionnaire Vignette medical professionals: At baseline and after 12 months;

2. Knowledge questionnaire for GPs: At baseline, 6 weeks after web-based training and after 12 months;

3. Patients with cancer measurements: Quality of life, PMI at baseline, after three months. NRS (SMS-alerts) and pain diary once a week for three months.

Intervention

Multifaceted intervention:

1. In-person training in the most important aspects of the guideline (including 2 repeating sessions) (in total three sessions of one hour- few hours) of medical oncologists and nurses at the medical oncology outpatient clinincs;

2. Interactive computer-based training (once) in the most important aspects of the guideline will be offered to general praticitioners;

3. Pateints recieve SMS-alerts once a week to ask for their pain (NRS score). If patients have an NRS score of 5 of higher a nurse will contact the patient and the patient will recieve a personal advice how to reduce his/her pain.

Control:

Training will not be offered to medical professionals in the control group and patients with cancer recieve a KWF-leaflet on cancer pain.

Contacts

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Eligibility criteria

Inclusion criteria

Participants:

Via the hospital boards, professional caregivers, oncologists and nurses involved in cancer care of the six participating hospitals will be invited to take part. Patients who visit the oncology outpatient clinic will be screened for possible inclusion. Patients will be invited to take part by their medical oncologist or research nurse if they experience pain for the first time caused by cancer.

Overall inclusion criteria for patients are:

1. Diagnosed with cancer;

2. Aged 18 years or older;

3. Pain intensity of 3 or more on an numeric rating scale (NRS) for the worst pain experienced in the last 24 hours;

4. Having and being familiar with the use of a mobile phone.

Exclusion criteria

1. Dementia and other severe cognitive disorders;

2. No informed consent;

3. Not Dutch speaking and writing.

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):	15-12-2010
Enrollment:	210
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-02-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2611
NTR-old	NTR2739
Other	METC UMC St Radboud : 2011/020
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A