Effects of a multifaceted teleguided pain care programs in patients with cancer * pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON36949

Source
ToetsingOnline

Brief title
Self-management support in cancer pain * pilot study

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
cancer pain, oncologic pain

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: cancer pain, outpatients, self management, telemonitoring

Outcome measures

Primary outcome

The primary outcomes of the pilot study is to provide insight into the technical functioning, usability, acceptability, comprehensiveness, and feasibility of the telemonitoring intervention and care organisation, for both patients as well as participating health professionals. Technical functioning will be measured by recoding the number of errors, technical failures, defects and their causes in a logbook. Information regarding the usability, acceptability, comprehensiveness, and feasibility of the system will be collected during semi-structured interviews with the research in in logbooks that the nurses will keep in the web based application.

Secondary outcome

Not applicable.

Study description

Background summary

The prevalence of pain in patients with cancer is high (59% in patients on active treatment, 64% in patients with advanced disease, 33% in patients who had been cured). Pain has an enormous impact on functioning of patients and may results in anxiety and depression. According to the three step WHO pain ladder and national guidelines, adequate symptom relief should be accomplished in 70-90% of patients with cancer. At present though, adequate pain control is not being realized in 50% of the patients. Factors related to ineffective pain management in the outpatient situation are identified on the level of the organization, the health professional and the patient. Shortcomings in current pain control, together with developments in demographics and health care,

necessarily imply that outpatients have to be involved more closely in their own pain management.

Study objective

The aim of this pilot study is to provide insight into the technical functioning, usability, acceptability, comprehensiveness, and feasibility of the telemonitoring intervention and care organisation, for both patients as well as participating health professionals (nurses, treating physicians and the multidisciplinary team). Based on the findings from the pilot study the telemonitoring intervention and care organisation will be further improved. After the pilot study and subsequent adjustments a large scale intervention study is planned.

The eventual aim of the intervention and large evaluation study is to support patients in self-management of their cancer (treatment) related pain. The intended result of monitoring, feedback information, education and interaction is more self management and eventually lower pain intensity scores.

Study design

This pilot study will be carried out in the regions of Maastricht Heuvelland and Oostelijk Zuid Limburg, surrounding the MUMC+ and Atrium MC. Patients will participate in the study for four week. At baseline, the nurse and researcher will visit the patient at home to carry out a pain anamnesis and to explain how the tablet-pc should be used. Halfway and after finishing data collection, the researcher visits each patient once more for a semi-structured interview.

Intervention

The system consists of 1) a web-application or the pharmacist to enter and change medication prescriptions; 2) a tablet-pc-application for the patient in order to monitor pain, symptoms and medication use; 3) a web-application for the nurse to monitor and analyse patient data; and 4) a web-application for the treating physician to provide insight into the monitored data of their own patients and to interact and exchange information with the nurse. This system is embedded in a health care organisation in which health professionals involved communicate and cooperate to established optimal pain treatment for their patients. In this pilot study only the tablet-pc-application for the patients as well as the web-application for the nurse will be tested.

Patient application: By means of a tablet-pc patients fill out twice daily a number of questions about their pain (pain at this moment, number of pain attacks, worst pain), other symptoms (including nausea, dizziness and constipation), satisfaction with pain treatment, changes in prescription and activity/sleep. In addition patients are requested to tick off medication that

is presented in an overview per point in time. The monitored data are sent secured to the server. From that point the patient is provided with feedback information (graphs) that provides them insight in their own situation. Education is part of the intervention as well. During participation in the study the patient receives education topics several times about: causes of pain, treatment of pain, medication facts and fiction, recognition of symptoms that require action, and methods that patients themselves can implement to control their pain and other symptoms. The education is based on and tested during previous studies (ref). Patients might pose questions or remarks for the nurse, a kind of e-consult.

Nurse application: The nurse receives a translation of the data as well. He or she will enter the web-application by use of a log in name and password once a day to monitor and analyse the pain and medication data. With help of a decision support system, by orderly presenting and the use of collared flags, nurses have quick insight into which patients need their attention and action or posed a question or remark. When needed nurse interventions can be applied (feedback and advise by means of the tablet-pc, consultation by telephone, consultation with pain doctors or advise to the treating physician to switch medication). In the pilot study the nurse is responsible for keeping the medication overview of the patient.

Study burden and risks

The risk that is associated with participation is minimal because the current situation of the patient will be starting point for fine tuning the pain treatment. The daily monitoring of patients could result in patients being focused and possibly anxious by getting insight into their own situation. The nurse will take care of this. The benefit that opposes the burden mentioned above is that participants possibly get a detailed insight into their own course of pain and the relation between this course of pain, their medication use and their sleep / activity patterns. By means of the intervention, eventually patients are better able to cope with their pain and other symptoms more adequately. Furthermore pain treatment can be fine-tuned better and faster, by daily monitoring and assessment. Eventually pain intensity scores should be lowered.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Diagnosis of cancer
- Patients who are under (palliative) anti-tumour treatment in a day clinic or outpatient clinic, or patients who have no treatment options available anymore
- Cancer (treatment related) pain > 2 weeks when patients are not currently treated with opioids or < 2 weeks when patients are already treated with opioids
- Pain is defined as a patient reported pain score * 4 on a numerical rating scale (NRS, scale 0-10)
- Living at home (independent or in a home for the elderly)

Exclusion criteria

- Expected life expectancy < 3 months
- Chronic non-cancer pain
- Known cognitive impairments
- Participation in other studies that interfere with this study
- Not being able to read and understand the Dutch language
- Reduced vision which complicates screen reading on the tablet-pc
- Non-reachable by phone

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	26-09-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
CCMO	NL41821.096.12