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

Published: 18-11-2013
Last updated: 24-04-2024

The aim of this study is to evaluate the effect of the intervention regarding pain intensity and quality of life as compared to care as usual. Secondary outcomes of the effect evaluation are self-efficacy, knowledge, depression and anxiety, and...

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

Summary

ID

NL-OMON38991

Source
ToetsingOnline

Brief title
Self management support in cancer pain * effect evaluation

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
cancer pain, oncologic pain

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit 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 effect evaluation are pain intensity and quality of life.

- Pain intensity is measured with the Brief Pain Inventory (BPI), an instrument frequently used to monitor pain in the clinical and research setting (Cleeland 1994; Jensen, 2003).
- Quality of life is measured with the EORTC Quality of Life Questionnaire (EORTC-QLQ-C30 version 3). This instrument is cancer specific, multi-dimensional and appropriate for self-administration. The EORTC-QLQ-C30 has shown acceptable levels of reliability and validity (Aaronson et al., 1993).

Secondary outcome

Secondary outcomes measures for the effect evaluation include self-efficacy, knowledge, anxiety and depression, and medication use.

- Self-efficacy is measured with the Chronic Pain Self-efficacy Scale (CPSS-DLV). The Dutch language version of the CPSS has two subscales (pain and symptom management and physical functioning), each consisting of 10 items. Patients score the items on a 10-100 scale, 10 representing very unsecure and 100 very secure. Reliability and validity have been demonstrated for different

pain conditions (Köke, unpublished).

- Ferrell*s Patient Pain Knowledge Questionnaire (PKQ-DLV) will be used to measure knowledge. The questionnaire includes eight items that will be transformed to a 0-100 scale (0 is the lowest knowledge score; 100 is the highest knowledge score). The PKQ-DLV has an acceptable reliability and validity (De Wit, 1999).
- Anxiety and depression will be measured with the Hospital Anxiety and Depression Scale (HADS). The HADS showed good performance to assess symptom severity, anxiety disorders (alpha 0.67-0.90) and depression (0.67-0.90) in somatic, psychiatric and primary care patients, with a sensitivity and specificity of approximately 0.80 (Bjelland et al., 2002; Spinhoven et al., 1997)
- Information about medication use will be derived from the regular patient passport of the pharmacist. Other demographic and medical data will be collected at the first measurement and retrieved from the medical record.

The outcome measure for the economic evaluation is costs per QALY.

- Cost utility will be measured with the EuroQol (EQ-5D-5L). This is a self-administered questionnaire which consists of five dimensions of health-related quality of life (mobility, self-care, daily activity, pain/discomfort and anxiety/depression). These dimensions can be added to comprise an overall health state that will be translated to a utility. Utility rates, derived from the Doran algorithm, will be used to compute QALY*s (EuroQol Group, 2011).

- Cost-effectiveness evaluation includes costs of the intervention, healthcare costs (referral to the hospital, outpatient clinic visits, visits to GP and other physicians, contact with paramedics, psychologists), patient and family costs (time, informal care, travel costs) and costs outside the health care sector. Existing questionnaires will be combined to identify all relevant costs. Valuation of costs will be based on the Dutch manual for cost analysis in health care research (Oostenbrink et al., 2004).

The outcome measures for the summative process evaluation are use of the intervention, satisfaction with the intervention, and the occurrence of nurse interventions. These items will be discussed in semi-structured interviews with intervention patients and health professionals.

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 have been cured). Pain has an enormous impact on functioning of patients and may result 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. 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. Technological possibilities might provide a solution.

In the first phase of the project a telemonitoring intervention has been developed during which patient and professionals were closely involved. The intervention aims at supporting patients in self-managing their pain by means of pain and medication monitoring, feedback information, education and contact with a specialized nurse. The pilot study (December 2012 * March 2013; 13

patients and 3 specialized nurses) provided insight into technical functioning, usability, acceptability, comprehensiveness and feasibility of the intervention. Accordingly, the intervention has been optimized.

Study objective

The aim of this study is to evaluate the effect of the intervention regarding pain intensity and quality of life as compared to care as usual. Secondary outcomes of the effect evaluation are self-efficacy, knowledge, depression and anxiety, and medication use. Besides a cost evaluation and summative process evaluation will be performed.

Study design

This study will be carried out in the regions of Maastricht Heuvelland and Oostelijk Zuid Limburg, surrounding the MUMC+ and Atrium MC. The duration of the study is twelve weeks for each individual patient. Randomisation will assign patients to the intervention or control condition. The intervention group receives the intervention. At the start, the nurse will visit these patients at home to carry out a pain anamnesis and gives instructions about the use of the iPad application. After the study the researcher visits the intervention patients once more for a semi-structured interview. The control group receives care as usual. Measurements for both groups will be carried out at T0 (baseline), T1 (4 weeks), T2 (12 weeks) and consist of written questionnaires.

Intervention

The system consists of an iPad application for the patient and a web-application for the health professional (nurse and treating physician). The applications are embedded in a health care organisation in which health professionals involved cooperate to establish optimal pain treatment for their patients. When a new patient is included in the intervention group the pharmacist is informed and requested to provide a medication passport. The pain medication from this passport is entered into the webbased application by the nurse, which is checked by a second nurse. These data are translated into the medication overview that is visible for patients in the iPad application. Changes in pain medication during the study period are processed in the same way.

Application patient: By means of an iPad application 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 insight into his or her 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 (De Wit et al., 1997; Van der Peet, 2009). Patients are able to leave a message for the nurse.

Application health professional: 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 message. When needed nurse interventions can be applied (feedback and advise via the iPad application, consultation by telephone, a home visit, consultation with the pain specialist, discuss the patient*s situation in the multidisciplinary team or advise to the treating physician to change medication). When needed, the nurse discusses the patient with the pain specialist. Accordingly, the nurse contacts the treating physician to report the discussed advise. The treating physician decides on whether or not to take the advice and therefore on follow-up. Via login data the treating physician has access into the web-application and insight into the data of own patients.

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. Feelings of anxiety and focus on pain, as a result of using the intervention, have not emerged in the pilot study. Evaluations were mostly positive.

The benefit that opposes the burden mentioned above is that participants 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

Public
Universiteit Maastricht

Duboisdomein 30
Maastricht 6229 GT
NL
Scientific
Universiteit Maastricht

Duboisdomein 30
Maastricht 6229 GT
NL

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
- Pain is defined as a patient reported pain score * 4 on a numerical rating scale (NRS, scale 0-10)
- Living at home

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
- Non-reachable by phone

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2014
Enrollment:	174
Type:	Actual

Ethics review

Approved WMO

Date:	18-11-2013
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	NL46552.096.13