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COMBAT study – Computer based assessment and treatment – A clinical trial evaluating impact of a computerized clinical decision support tool on pain in cancer patients

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HIGHLIGHTS

- Pain in cancer patients is not managed adequately and must be improved.
- Modern information technology is widely used at many health care institutions.
- This study examines utilization of information technology in pain management.
- Modern information technology did not improve pain management in this study.
- Lack of efficacy is probably related to insufficient implementation strategies.

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ABSTRACT

Background and aims: The prevalence of pain in cancer patients are relatively high and indicate inadequate pain management strategies. Therefore, it is necessary to develop new methods and to improve implementation of guidelines to assess and treat pain. The vast improvement in information technology facilitated development of a computerized symptom assessment and decision support system (CCDS) – the Combat system – which was implemented in an outpatient cancer clinic to evaluate improvement in pain management.
Methods: We conducted a controlled before-and-after study between patient cohorts in two consecutive study periods: before ($n = 80$) and after ($n = 134$) implementation of the Combat system. Patients in the first cohort completed questionnaires with the paper-and-pencil method and this data was not shown to physicians. Patients in the latter cohort completed an electronic questionnaire by using an iPad and the data were automatically transferred and presented to physicians at point of care. Additionally, the system provided computerized decision support at point of care for the physician based on the electronic questionnaires completed by the patients, an electronic CRF completed by physicians and clinical guidelines.
Results: The Combat system did not improve pain intensity and there were no significant alterations in the prescribed dose of opiates compared to the cohort of patients managed without the Combat system.
Conclusion: The Combat system did not improve pain management. This may be explained by several factors, however, we consider lack of proper implementation of the CCDS in the clinic to be the most important factor. As a result, we did not manage to change the behaviour of the physicians in the clinic.
Implications: There is a need to conduct larger prospective studies to evaluate the efficacy of modern information technology to improve pain management in cancer patients. Before introducing new information technology in the clinics, it is important to have a well thought out implementation strategy.
The trial is registered at Clinialtrials.gov, number NCT01795157.

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1. Introduction

Cancer pain affects the health related quality of life (HRQOL) of patients and their families [1] and approximately 50% of cancer outpatients reports inadequate pain control [2,3].

Several trials indicate the presence of insufficient pain assessments. In a study by Cohen et al. pain assessment was documented in the medical records of 57% of cancer outpatients and reassessment after treatment was documented in 34% [4]. Several studies have also reported a lack of agreement between physicians' observer ratings and cancer patients' self-reports of symptoms [5,6] and this disagreement contribute to poor pain outcomes [7]. Therefore, it is recommended to employ patient reported outcome measures (PROMs), which are various type of patient data reported by the patients and collected without modification from clinicians or other health care personal, for assessment, classification and follow up of pain [8].

It has been shown that pain can be alleviated in 88% of the patients by adhering to WHO guidelines for treatment of cancer pain [9] and implementation of pain guidelines in routine clinical practice improves pain control according to a randomized clinical trial [10], but adherence to cancer pain guidelines is relatively poor [11].

The main purpose of information technology systems at hospitals is to record, store and retrieve patient data. A more complex health related computer system is a computerized clinical decision support systems (CCDS). CCDS provide decision support for patient management by integrating patient data from different sources [12]. Various subtypes of CCDS have been investigated like alerts and reminders system [13,14], computerized provider order entry systems [15] and expert systems [16,17] and several systematic reviews from other areas than cancer pain management have supported the effectiveness of CCDS in patient management [18–20].

For cancer patients, a CCDS could include both PROMs and computerized algorithms using PROMs to provide advice for clinicians. Patients can use a computer system, for instance a tablet, in order to collect PROMs and assure that the results are presented to the physician at point of care, which may improve patient–physician communication [21], cancer pain treatment and potentially patients' HRQOL [22].

We developed the COMBAT (**Com**puter **B**ased **A**ssessment and **T**reatment) system which includes the following procedures: (i) A computer based collection of PROMs, (ii) an immediate wireless transfer of PROMs to the oncologist computer at point-of-care and (iii) a CCDS system designed for cancer pain management. We have hypothesized that pain management in an outpatient oncology clinic could be improved by applying the COMBAT system and conducted a controlled before-and-after study by comparing two cohorts of patients, before and after implementation of the COMBAT system, to answer the following research questions:

- Is there an improvement in pain control, measured as average pain last 24 h, within the first three weeks of treatment after implementing the COMBAT system?
- Is there an improvement in pain control, measured as worst pain last 24 h, within the first three weeks of treatment after implementing the COMBAT system?
- Are prescribed opioid doses modified after implementing the COMBAT system?

2. Method

2.1. Study design

The Combat study is designed as a controlled before-and-after study comparing data between patient cohorts in two consecutive study periods: Before implementation of the COMBAT system (the pre-intervention period) and after implementation of the COMBAT system (intervention period).

2.2. Patients

Patients were recruited from the outpatient department at the Cancer Clinic, St. Olavs University Hospital, between March 2010 and February 2013. All potentially eligible patients with an appointment with the physician at the outpatient department during the study period were approached by phone by a research assistant the day before an appointment with a physician and invited to participate in the study if they fulfilled the inclusion criteria (Fig. 1).

The inclusion criteria were: Histologically verified malignancy, age 18 years or above, pain intensity (any of current pain, average pain last 24 h or worst pain last 24 h) of at least 4 on a 0–10 point numerical rating scale (NRS), physical and cognitive function appropriate to follow study instructions.

Eligibility screening data was collected in 33 of 39 intervention weeks. Hundred-and-seventy-six patients were eligible for inclusion of which 141 (80%) were included in the study during these 33 weeks. The main reason for exclusion was low pain intensity.

2.3. Pre-intervention period

In the pre-intervention period (Fig. 1) the patients completed a questionnaire by paper-and-pen method about 30 min prior to consultation with the clinician. This data was not presented for the physician.

2.4. Intervention period

The intervention consisted of applying the COMBAT system which involved three main facets (Fig. 1). (1) Collection of data on PROMs. Patients completed an electronic questionnaire and an electronic body map by using an iPad2 [23] about 30 min prior to consultation with their physician. Selected items among the electronic questionnaire were screening questions on pain, breakthrough pain (BTP), neuropathic pain, depression and pain medication. An affirmative response or a response above a predefined threshold to these screening questions resulted in additional follow up questions. (2) Transfer of PROMs to the physician as a part of the consultation: Data on PROMs were immediately and wirelessly transferred to the desktop computer employed by the physician. The data was available for physician before the consultation, both as an overview of the most important symptoms including the electronic body map, and as a structured digital output of the entire set of questionnaires. At the end of the consultation the physician completed an electronic CRF (Case Report Form) on diagnosis, tumour directed treatment, sites of metastasis and pain medication. (3) Computerized decision support: The electronic questionnaire and electronic CRF completed by the patients and the physician, respectively, were subsequently processed by the CCDS engine providing decision support for the clinician at point of care. The decision support presented for the clinician employed mathematical algorithms according to international guidelines [24,25] and involved four topics: Pain, BTP, neuropathic pain and depression. The decision support algorithm was based on responses to a limited amount of questions. For instance, if the patient responded with a value of at least 4 on a numerical rating scale on current pain, average pain last 24 h or worst pain last 24 h and answered "no" if he/she used strong opioids, then the following text was conveyed to the physician as decision support: "The patient has pain with pain intensity of at least 4 on a numerical rating scale (NRS), which may be current pain, average pain last 24 h or worst pain the last 24 h. The patient does not use opioids. If the pain is caused by

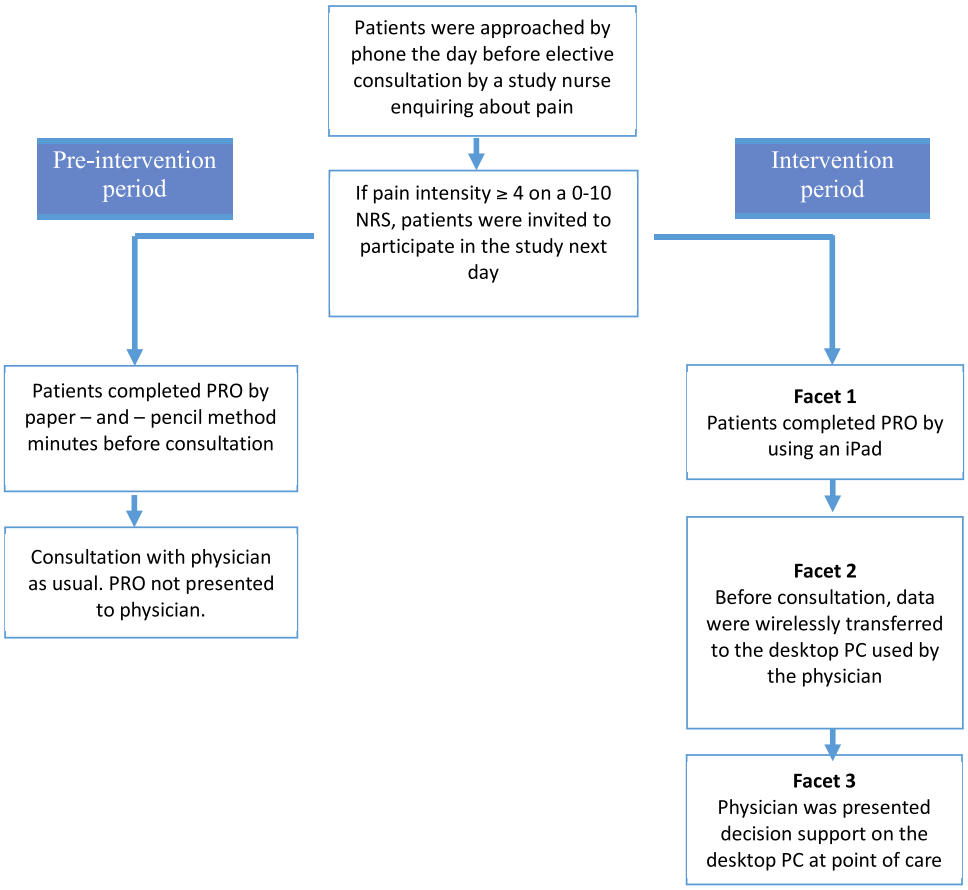

Fig. 1. Differences in procedures and assessment in pre-intervention and intervention period.

cancer, please consider to prescribe Dolcontin tablets 10 mg twice a day (a long acting opiate) and Morphine tablets 10 mg as rescue medication.

Physicians participated in an introductory lecture on how to use the software and written instructions were also provided. Physicians could ask for service from a study nurse stationed at the outpatient department if they needed assistance in terms of logging into the software, basic navigation within the software, completing the electronic CRF or other issues regarding the technical aspects of the CCDS.

2.5. Assessment

Assessments were performed at baseline, 1 week and 3 weeks after inclusion. At baseline patients completed questionnaires on current pain medication, education and ethnicity. Data on cancer diagnosis, metastatic sites, tumour directed treatment, aim of treatment (curative, life-prolonging, symptomatic) pain aetiology and changes in pain medication were completed by the physicians by using an electronic CFR during the consultation. Is cases where the physician did not complete such information, this information was completed by the first author (SXR) from the electronic medical record. We also recorded the aetiology of pain and classified this as either pain due to malignant invasion, pain due to cancer treatment or pain due to other conditions and diseases than cancer or cancer treatment. Patients completed data on pain medication through questionnaires which was subsequently verified by checking the medical records and electronic prescriptions.

Pain intensity was measured using the Brief Pain Inventory (BPI) [26], which is a pain self-assessment tool thoroughly validated and translated into different languages, including Norwegian [27]. For this analysis data from two questions were used ("average pain intensity last 24 h" and "worst pain intensity last 24 h", both assessed on a 0–10 NRS). Additionally, the presence of BTP were assessed by a single screening question on breakthrough pain ("Have you experienced breakthrough pain past 24 h?"). The pre-intervention questionnaire was the same as the intervention questionnaire.

Patients in both study periods were followed up by phone by a study nurse 1 and 3 weeks after consultation and completed the same set of questionnaires as baseline. If the patient were unable to reply phone calls at the day of follow up, the study nurse approached the patient by phone once a day for three consecutive days excluding weekends. If still unable to reach the patient, the follow up were defined as missing.

A total of 30 physicians were involved in the Combat study. Three physicians included 14 patients each, two physicians included nine patients each, one physicians included 8 patients, two physicians included seven patients and three physicians included 6 patients. The remaining 50 patients were included by 19 physicians.

2.6. Study endpoints

The three primary endpoints were average pain intensity last 24 h (as the mean of 1 and 3 weeks follow up assessments), worst pain intensity last 24 h (as the mean of 1 and 3 weeks follow up assessments) and prescribed opioid doses (oral Morphine equivalents in mg/24 h, as the mean of 1 and 3 weeks follow up dosages).

2.7. Statistical analyses

We considered a pain reduction of 1.5 on a 0–10 point NRS as clinical significant [28] and hypothesized a standard deviation

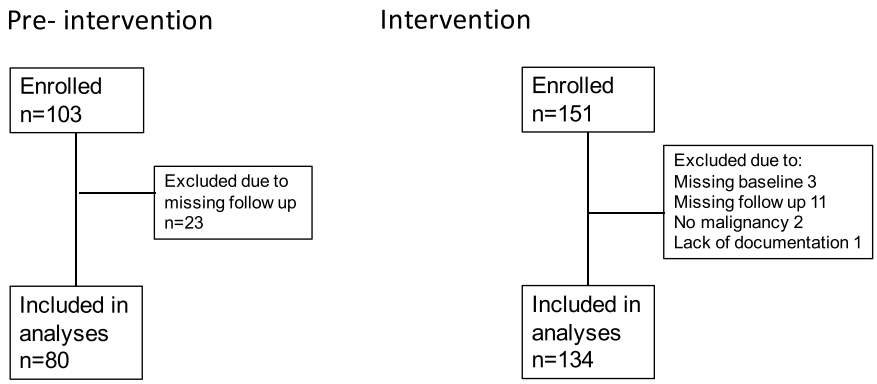

Fig. 2. Consort diagram. Patients included and excluded in the study.

of 2.5 based on an earlier study at our institution [29] which resulted in an effect size of 1.5/2.5 = 0.6. Due to multiple outcomes, we decided upon an alpha value of 0.01. In the hypothesis of a detectable effect size of 0.6 in the three primary outcome measures using a *t*-test for the difference between two independent means, an alpha level of 0.01 and a power of 0.9 we estimated the requirement of at least 85 patients in each study period, 170 in total. To account for 20% lost to follow up we decided to include at least 102 patients in each study period. We scheduled a fixed time frame of 12 months for inclusion in both study periods, but due to delayed accrual we extended the inclusion period to 18 months in the pre-intervention period. We included more patients than planned in the intervention period to increase the power when analyzing multiple outcomes and to compensate for lost to follow up, which was an issue in the pre-intervention period.

Patients demographics and pain characteristics were summarized by applying means, proportions and standard deviations (SD). Repeated follow-up assessments of the three main outcomes were analyzed using the summary measure approach as suggested by Frison and Pockok [30]. This method involves averaging the follow-up assessments on each patient and then applying this as dependent variable in an ANCOVA model with baseline data as covariate to measure the effect of the study period adjusting for baseline imbalance. In a second stage of analyses the effect of potentially confounding variables (age, gender, presence of cancer related pain, presence of rheumatic disease) were also tested in ANCOVA models.

In the evaluation of pain and opioid prescription we included patients with at least one follow up examination, thus, patients who had completed only the baseline examination were excluded from this analysis. Opioid dose was converted to oral morphine equivalents (mg/24 h) [31]. Further on, we defined cancer related pain as pain due to malignant invasion and/or pain due to cancer treatment. This sub-classification of pain was done in order to examine the influence of the CCDS on patients with cancer related pain. Thus, we had to define cancer related pain which we defined as pain due to malignant invasion and/or pain due to cancer treatment.

The trial is registered at Clinialtrials.gov, number NCT01795157.

3. Results

3.1. Study sample

A total of 247 patients were included from March 2010 to February 2013, a total of 103 and 151 patients in the pre-intervention period and intervention period, respectively. Patients with at least one follow up interview after inclusion were included in the final analyses. This led to the exclusion of 23 patients in the pre-intervention period and 17 patients in the intervention period (Fig. 2).

3.2. Demographics

Patients main demographic and clinical characteristics (Table 1) were well balanced between the pre-intervention and intervention periods except a higher frequency of rheumatic disease in the intervention period and higher frequency of cancer related pain and patients taking opioid medication in the pre-intervention period.

3.3. Pain intensity

Fig. 3 shows that pain intensity scores are very similar both at baseline and at follow up between patients in the pre-intervention and intervention period without any significant differences.

The mean of pain intensity scores of 1 and 3 weeks follow up were 3.6 and 3.3 for average pain intensity last 24 h in the pre-intervention period and intervention period, respectively, with a between group difference of 0.12 (95% CI – 0.33–0.58) after adjusting for baseline pain intensity (Table 2). For worst pain last 24 h the mean of pain intensity scores at 1 and 3 weeks follow up were 4.6 and 4.8 in the pre-intervention period and intervention period, respectively, with a between group difference of 0.32 (95% CI – 0.27–0.91) after adjusting for baseline pain intensity (Table 2). This indicates no differences in pain intensity scores after introducing the Combat system when adjusting for baseline pain intensity. Adjusting for potential confounding predictor variables such as age, gender, opioid consumption, the presence of rheumatic disease, presence of BTP, pain medication and cancer related pain, intervention with the Combat system did not improve the results significantly (Table 2). It is worth noting that 75% of the patients in the pre-intervention period and 42% of the patients in the intervention period had cancer-related pain ($p \leq 0.001$). However, this imbalance did not alter the lack of efficacy of the intervention as shown in the regression analyses when adjusted for cancer related pain (Table 2, the far-right column).

3.4. Opioid prescription

The mean of opioid doses at 1 and 3 weeks follow up were 48 mg and 59 mg in the pre-intervention and intervention periods, respectively, with a between group difference of 8.4 mg (95% CI – 11.3–28.0) after adjusting for baseline opioid dose (Table 2). This indicates no differences in opioid prescription after introducing the Combat system when adjusting for baseline opioid dose. Adjusting for potential confounding variables such as age, gender, presence of rheumatic disease, presence of BTP, use of pain medication and presence of cancer related pain did not alter the results (Table 2).

Table 1
Baseline characteristics.

	Preintervention $N = 80$ n (%)	Intervention $N = 134$ n (%)	p-value
Age (years ± SD[a])	58.6 ± 13.25	61 ± 12.2	0.91
Male gender	41 (51.3)	70 (52.2)	0.89
Diagnosis			0.78
Breast	20 (25)	32 (23.9)	
Prostate cancer	13 (16.3)	21 (15.7)	
Colorectal cancer	8 (10)	18 (13.4)	
Lymphoma	7 (8.8)	19 (14.2)	
Lung cancer	8 (10)	11 (8.2)	
Testicular cancer	4 (5)	5 (3.7)	
Anal	3 (3.8)	4 (3)	
Upper GI cancer	0	6 (4.5)	
Other	17 (21)	18 (13.4)	
Disease extent			0.06
Localized	15 (19.2)	16 (11.9)	
Metastatic	37 (46.1)	44 (32.8)	
Cancer absent	24 (29.5)	63 (47.0)	
Not relevant[b]	4 (5.1)	11 (8.2)	
Treatment			0.33
Chemotherapy	9 (11.2)	25 (18.7)	
Radiation therapy	2 (2.5)	10 (7.5)	
Radiochemotherapy	3 (3.8)	2 (1.5)	
Hormone therapy	20 (25.0)	28 (20.9)	
Targeted therapy	4 (5.0)	4 (3.0)	
Chemotherapy and targeted therapy	3 (3.8)	9 (6.7)	
No treatment	37 (46.2)	52 (38.8)	
Missing	2 (2.5)	4 (2.9)	
Treatment intention			0.07
Curative	38 (47.5)	84 (62.7)	
Life-prolonging	39 (48.8)	44 (32.8)	
Symptomatic	3 (3.8)	6 (4.5)	
Comorbidity			
Rheumatological disease	5 (6.3)	35 (26.1)	<0.001
COPD	5 (6.3)	2 (1.5)	0.06
Diabetes[c]	6 (7.5)	10 (7.5)	0.99
Vascular disease[d]	22 (27.5)	49 (36.8)	0.17
Myocardial infarction	7 (8.8)	5 (3.7)	0.12
Presence of BTP[e]	49 (63)	74 (55)	0.23
Presence of cancer related pain[f]	60 (75)	56 (42)	<0.001
Pain medication			0.007
No pain medication	14 (18)	32 (24)	
Non-opioid pain medication	13 (16)	46 (34)	
Opioid pain medication	43 (54)	48 (36)	
Missing	10 (12.5)	8 (6)	

[a] SD = standard deviance.
[b] Patients with active cancer where TNM staging is not applicable (lymphoma, CNS tumour, myeloma).
[c] Diabetes without organ complication.
[d] Peripheral vascular disease excluding coronary artery disease and cerebrovasuclar disease.
[e] BTP = breakthrough pain.
[f] Cancer related pain = pain due to tumour invasion and/or cancer treatment.

The proportion of patients starting new opioid medication were 8.8% and 10.5% (Pearsons Chi square = 0.16, $p = 0.69$) in the pre-intervention and intervention period, respectively. In the pre-intervention period physicians changed the dose of opioids in 18.8% of the patients compared to 21.6% of the patients in the intervention period (Pearsons Chi square = 0.26, $p = 0.61$).

4. Discussion

The primary aim of this study was to evaluate the efficacy of the Combat system on pain management. The study did not demonstrate improved pain control or an alternation in the prescribed opioid dose.

Previous systematic reviews and meta-analyses on CCDS have provided information of the effects CCDS systems on clinical outcomes. Kawamoto et al. [32] conducted a meta analyses of 71 trials where the following factors were associated with improved practice: (i) Automatic treatment suggestions presented to the physician at point of care as opposed to treatment suggestions which was not available during consultation. (ii) CCDS which generated a treatment recommendation as opposed to only an assessment. (iii) A computer generated decision support as opposed to systems depending on manual procedures. Evidence that treatment suggestions at point of care is essential for successful CCDS has also been shown by others [33]. A recent meta-analysis [20] of 162 trials demonstrated that standalone CCDS were more likely to improve care than CCDS within an electronic charting or order entry systems. Additionally, CCDS systems providing advice to both clinician and patients and systems where clinician had to provide a reason for not accommodating to advice were shown to improve patient care.

The CCDS used in our study provided decision support at point of care which is important for successful CCDS as shown in meta-analyses [32,33]. The CCDS provided a recommendation (rather than a simple assessment) and generated a computerized decision support to start opioid medication, prompting the presence of, and advising on treatment, of neuropathic pain as well as depression, issues which are crucial for efficient CCDS [32]. Further on, we employed a CCDS as a stand-alone product, which is a prognostic factor for improving care according to Roshanov [20]. However, our CCDS did not provide decision support for the patients. It was not compulsory for the clinicians to provide a reason for not following an advice. Both of these issues may have reduced the efficacy of the CCDS.

Further limitations in our study may be related to lack of a proper implementation strategy of the CCDS. A well-planned implementation strategy is essential when introducing new technology in health care [34]. In the current study, we attempted to implement the CCDS through an introductory lecture for the physicians providing instructions on how to use the software and the decision support system as well as written information as a leaflet. When evaluating our efforts in retrospect we did not put enough emphasis into identifying barriers and solutions for a major change in routine clinical practice, hence, our method of implementing the CCDS was insufficient and not powerful enough to change the behaviour of the physicians. For future trials, we would recommend profound implementation strategies. Implementation strategies at the organization level in the context of this study could involve curtained areas in the clinic where patients could complete questionnaires with a tablet PC and a more thorough engagement of the nurse staff. In the present study patients completed questionnaires applying a tablet in the ordinary waiting room and the nurse staff was not involved in the study. Implementation strategies involving health care professionals in the context of this study could imply regularly audit and feedback sessions [35], a tighter collaboration between study nurse and physicians and encouraging communication between physicians and patients on the basis of the completed questionnaires. Follow up lectures, certification procedures or individual follow up are methods which may have facilitated behaviour changes and improved implementation of the CCDS [36]. A basic barrier at an oncology outpatient department, where the primary focus is to treat the tumour and not symptoms, is to change the attention and clinical behaviour towards symptom diagnosis and treatment including pain diagnosis and treatment. Therefore, the interventions need to be well planned, repetitive and with a meticulous attention to observe if the new technology is used as intended. It is our opinion that a well-founded implementation strategy may have changed the behaviour of physicians [37] and improved correct utilization of the Combat system in this study.

Another limitation was that the software was not integrated with the electronic medical record. Even though Roshanov et al. argue that a stand-alone CCDS system may be beneficial, Miriovsky

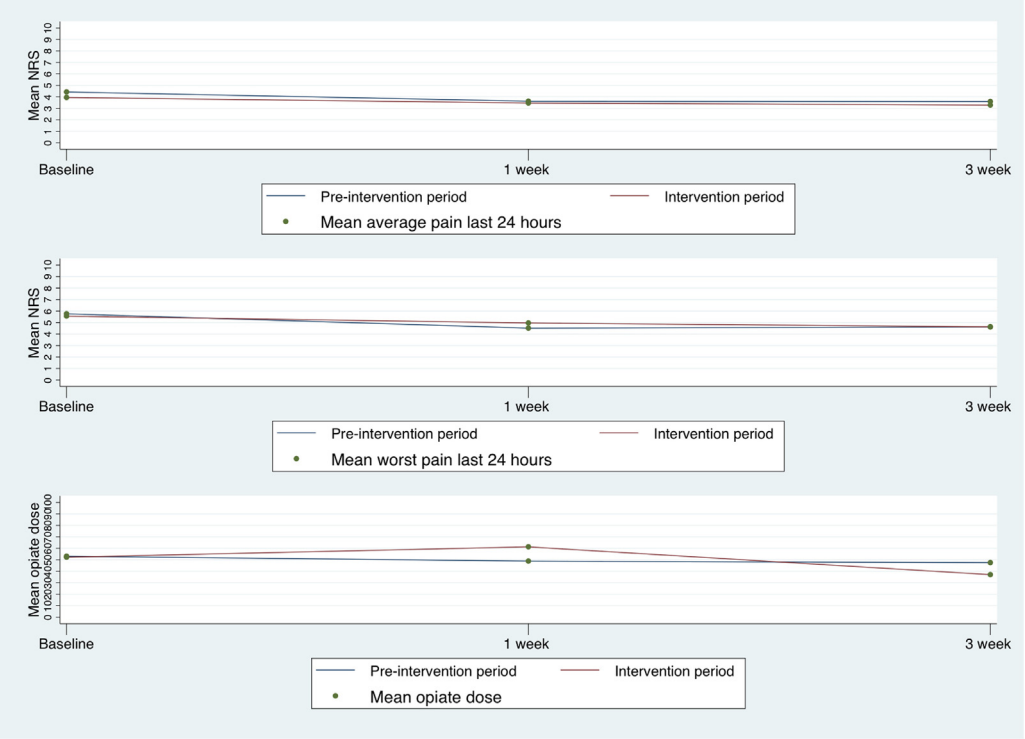

Fig. 3. Pain intensities and opioid dose at baseline, follow up 1 week and follow up 3 weeks in the pre-intervention and intervention period.

Table 2
Pain intensity and opioid consumption in pre-intervention and intervention period.

	Pre-intervention period	Intervention period	Between group difference (95% CI)	
	Mean (95% CI)	Mean (95% CI)	Adjusted for baseline	Adjusted for other variables (*)
Pain intensity	*N* = 80	*N* = 134		
Baseline *average pain* intensity[a] last 24 h	4.4 (4.0–4.8)	4.0 (3.7–4.2)		
Mean pain intensity[a] of 1 and 3 weeks follow up on *average pain* last 24 h	3.6 (3.1–4.1)	3.3 (3.0–3.7)	0.12 (−0.33 to 0.58)	0.86 (−0.41 to 0.58)
Baseline *worst pain* intensity[a] last 24 h	5.8 (5.4–6.2)	5.6 (5.3–5.9)		
Mean pain intensity[a] of 1 and 3 weeks follow up on *worst pain* last 24 h	4.6 (4.0–5.1)	4.8 (4.4–5.2)	0.32 (−0.27 to 0.91)	0.18 (−0.46 to 0.81)
Opioid dosages	*N* = 72	*N* = 125		
Baseline opioid dose[b]	53 (32–74)	52 (20–85)		
Mean opioid dose of 1 and 3 weeks follow up	48 (24–72)	59 (22–96)	8.4 (−11.3 to 28)	8.0 (−14.1 to 30.2)

[a] Pain intensity measured on 10-point numerical rating scale from 0 to 10.
[b] Oral morphine equivalent in mg.
[*] Adjusted for the following variables at baseline: Age, gender, presence of breakthrough pain, presence of cancer related pain, presence of rheumatological disease and use of pain medication.

et al. [38] endorse that various IT systems used in hospital medicine, such as electronic radiological and laboratory data, may be presented alongside of other clinical data collected from the patient and presented to the physician in an integrated manner. However, this approach has not been, to our knowledge, tested in comparative clinical trials.

An individual follow up may have been used to collect data on how the physicians applied the software at point-of-care. Such a data collection could have been applied as a part of the intervention itself, but also as background information to better understand the lack of clinical measurable effects in this study. Only 10.4% and 12% of the patients started with new pain medication and changed existing medication, respectively, among patients in the intervention period which is not significantly different compared to the pre-intervention period. This indicates that physicians did not take advantage of the information conveyed through the Combat system.

We did not collect information on how often the physicians accessed or acknowledged recommendations from the CCDS at point of care, which is a limitation in the study. This would have provided valuable insight on the impact of this CCDS system. In future trials involving implementation of new technology such as CCDS, a thorough assessment of how the physicians utilize recommendations from CCDS systems is crucial to develop successful systems [39].

The content and the structure of the software applied in this study may have been another limitation. The software was developed with an emphasis on the electronic PROMs completed by the patients. The presentation of PROMs to the physician was less emphasized and may not have been as mature as the electronic PROMs. Additionally, the decision support was founded on very simple algorithms, hence, the advices may have been perceived as too superficial by the oncologists.

We did not examine how the patients experienced the usefulness and the implementation of the CCDS system. Hence, we do not have information about limitations of the system from the patients point of view. One way of obtaining such information is to organize focus groups of patients and providers, which we aim to do in future trials.

Twenty-five and 58% of the patients had non-malignant pain in the pre-intervention and intervention periods, respectively. The higher prevalence in the intervention period may be explained by a high number of patients with rheumatic disease. Others have reported a prevalence of non-malignant pain in 25% of cancer outpatients with pain [40,41]. These findings illustrate the importance of non-malignant pain also in a cancer population. The influence from non-malignant pain may be one of the factors that is different between relatively healthy patients at an out-patient cancer clinic and in cohorts with patients with advanced cancer disease. In this study, the decision support algorithm was not programmed to account for non-malignant pain, which may have influenced how the physician interacted with the software. The treatment of non-malignant pain is complex, often difficult to treat and not commonly managed by oncologists. Therefore, the finding of a high number of patients in an out-patient clinic with non-malignant pain may explain some of the lack of efficacy of a decision support defined with the purpose of treating cancer pain.

The disadvantage of the controlled before-and-after study approach was organizational changes at our department during the pre-intervention period. This may have resulted in slightly imbalance of patient demographic as shown in Table 1. We omitted a randomized study with a parallel group design due to the risk that physicians in the control group could improve their pain management skills and thus biasing the results. A parallel group design may have been conducted by recruiting patients at other cancer outpatient departments in a cluster randomized trial in order to reduce potential bias. Further on, the study design did not distinguish between the effects of the PROMs and the decision support system.

The amount of missing data was higher in the pre-intervention period. This may have biased the treatment effect estimates (differences between two study groups), especially if we hypothesize that patients excluded from the analysis due to missing follow-up assessment had a different pain outcome.

5. Conclusion

Even though the current trial did not provide significant results of employing a CCDS to improve pain management, we believe that CCDS have a potential to improve management of cancer patients if correctly designed and carefully implemented as shown in clinical trials [16,18,19].

6. Implications

There is a need to conduct larger prospective studies to improve pain management by using modern information technology. However, such trials must be carefully planned in order to secure a proper implementation of new technology as well as paying close attention to how health care providers utilize modern information technology. It is also necessary to improve the CCDS software by utilizing existing information technology, for instance by facilitating electronic feedback from the patients to the physician about the efficacy of various pain management strategies and supporting automatic referral to a pain specialist when the aim of pain management is not achieved.

Ethical issues

The study was approved by the Regional Committees for Medical and Health Research Ethics in Norway and all patients provided written informed consent to participate in the study before inclusion.

Conflict of interest

The authors declare no conflict of interest. Cinzia Brunelli has provided consultancy for Mundipharma Pharmaceurticals. The main author has full control of all primary data and will allow the journal to review the data if requested.

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