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Improvement of pain-related self-management for cancer patients through a modular transitional nursing intervention: A cluster-randomized multicenter trial

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ABSTRACT

Patients' self-management skills are affected by their knowledge, activities, and attitudes toward pain management. This trial aimed to test the Self Care Improvement through Oncology Nursing (SCION)-PAIN program, a multimodular structured intervention to reduce patients' barriers to self-management of cancer pain. Two hundred sixty-three patients with diagnosed malignancy, pain > 3 days, and average pain ⩾ 3/10 participated in a cluster-randomized trial on 18 wards in 2 German university hospitals. Patients on the intervention wards received, in addition to standard pain treatment, the SCION-PAIN program consisting of 3 modules: pharmacologic, nonpharmacologic pain management, and discharge management. The intervention was conducted by specially trained cancer nurses and included components of patient education, skills training, and counseling. Starting with admission, patients received booster sessions every third day and one follow-up telephone counseling session within 2 to 3 days after discharge. Patients in the control group received standard care. Primary end point was the group difference in patient-related barriers to self-management of cancer pain (Barriers Questionnaire – BQ II) 7 days after discharge. The SCION-PAIN program resulted in a significant reduction of patient-related barriers to pain management 1 week after discharge from the hospital: mean difference on BQ II was −0.49 points (95% confidence interval −0.87 points to −0.12 points; $P = 0.02$). Furthermore, patients showed improved adherence to pain medication; odds ratio 8.58 (95% confidence interval 1.66–44.40; $P = 0.02$). A post hoc analysis indicated reduced average and worst pain intensity as well as improved quality of life. This trial reveals the positive impact of a nursing intervention to improve patients' self-management of cancer pain.

1. Introduction

Pain is still one of the most frequent and distressing symptoms in cancer patients, particularly in advanced stages of disease [6,7,19,33,55]. A survey on symptom prevalence in more than 1300 cancer patients with various malignancies showed that almost 85% of the patients suffered from pain [13]. Pain was not only a frequent symptom, but also had high intensity, with a mean score of 5.0 (P25–P75 interquartile range 2.0–7.0 on a 0–10 numeric rating scale [NRS]). Untreated or treated inadequately persisting pain interferes with patients' activities of daily living and reduces health-related quality of life (HRQoL) [24,40].

For more than 10 years it has been known that up to 90% of patients can obtain sufficient pain relief if adequate guideline-based treatment is provided [38], that is, using the World Health Organization step scheme, adhering to medication plan (dose and time) and application type (most common oral route) [45]. However, pain often remains undertreated due to patient-related, institutional, or health care professional barriers [29]. Therefore, sufficient treatment of pain and associated symptoms must be based on receptive attitudes and effective self-management of the

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patient, facilitated through patient education and counseling. These factors gain importance after discharge, and studies show that pain management becomes even more difficult in outpatient settings [8,59].

Patient-related cognitive barriers include attitudes and beliefs about pain treatment in 4 dimensions: firstly, misconceptions of physical effects of pain medication, for example, medication should be saved in case the pain gets worse; secondly, fatalism, for example, beliefs that the pain is untreatable or treatment is ineffective; thirdly, communication-related barriers, for example, not annoying the professionals by complaining about pain; fourthly, worries about harmful effects of pain medication, for example, that pain medication is very addictive. These attitudes and beliefs are held by almost all patients and build barriers for adequate pain control [27,57].

The evidence on educational interventions to reduce patient-related barriers is limited. A systematic review from Bennett et al. (2009) [8] identified 13 trials evaluating the influence of patient knowledge and cognitive barriers with moderate effects on pain intensity and adherence [4,5,12,18,36,37,40,49,52,54,56–58]. Due to different health care systems and professional roles and competences of nurses within the counseling programs, the generalizability of the results is limited.

Although there is growing evidence for the importance of care transition interventions [16,47,48], the effectiveness of educational interventions using the inpatient period to prepare cancer pain patients for care transition remains unacknowledged.

Therefore, the aim of this study was the evaluation of Self Care Improvement through Oncology Nursing, SCION-PAIN, a nursing-administered program to reduce patients' barriers and improve pain management and pain-related discharge management.

2. Methods

We compared the effectiveness of the intervention on a trans-institutional path, starting with an inpatient setting and continuing after discharge with standard care. To avoid contamination, the study had been designed as a cluster-randomized clinical trial and the intervention had been applied at ward level.

We included 18 oncological wards from 2 German university hospitals in Saxony-Anhalt and Bavaria. The eligibility criterions for wards were frequent treatment of oncological patients ($\geqslant$10% of all annually treated patients) and consent to trial participation. Patients were included if they were aged 18 to 80 years, had a cancer diagnosis, a moderate average pain intensity score on the moderate level ($\geqslant$3.0 on a 0–10 NRS) [46], persisting pain for more than 3 days, and signed written informed consent. Consent was sought on the individual patient level after their allocation to a trial participating ward.

Patients were excluded if they had a limited performance status (Eastern Cooperative Oncology Group [ECOG] 4), documented ongoing alcohol or drug abuse, surgery within the last 3 days, showing signs of disorientation, and were not able to read, write, and understand German.

The study was performed according to the International Conference on Harmonisation-Good Clinical Practice principles and has been approved by the ethics committees of Martin-Luther-University Halle-Wittenberg and Technical University Munich. The trial was registered at ClinicalTrials NCT00779597.

2.1. Intervention

The intervention consisted of a nurse-led counseling program to improve pain management and pain-related discharge management. The SCION-PAIN intervention mainly focused on reducing patient-related cognitive barriers, such as misconceptions about opioid use, because they crucially interfere with establishing and maintaining proper pain-related self-management [30]. In the intervention group, the SCION-PAIN program was administered by specially trained ward nurses in cooperation with a study nurse.

Counseling sessions were carried out in 3 modules, supplemented by a teaching booklet for patients tailored to meet patients' needs, a pain diary, a discharge preparation checklist for patients, and a compact disc with progressive muscle relaxation (PMR) exercises [34].

The first module, "Pharmacologic pain management," addressed reliable pain assessment, effective communication about pain, and administration of pain medication. The second module, "Non-pharmacologic pain management," included information on the effectiveness of complementary pain treatment methods, and patients were given a compact disc with instructions to carry out PMR independently.

The third module, "Pain related discharge management," aimed to prepare patients to appropriately counteract potential problems in pain-related self-management during transition to outpatient care. Advice on how to maintain the self-management strategies learned in modules one and two after discharge was provided, and a checklist to ensure adequate discharge management was administered. This checklist contained 7 essential questions to be answered during hospitalization, for example, who will prescribe pain medication after discharge or who will provide advice in case of inappropriate pain management. The study nurse checked the list for completeness 1 day before discharge.

The content of all 3 modules was summarized within the 33-page patient education booklet, "Leaving the pain behind," which had been developed by some of the authors based on a literature review and approved by an institutional advisory panel of pain experts. Each pain-related topic was specially enriched with information regarding patient-related barriers to pain management, according to the domains identified by Ward et al. [56] and Gunnarsdottir et al. [27]. For example, the importance of communicating pain openly in order to provide the best possible pain management was explained to overcome reluctance to report pain in order to be a "good patient" as one frequent patient-related barrier.

According to the structure of the SCION-PAIN program as presented in Fig. 1, the basic counseling included standardized information for all patients across all 3 modules. The follow-up counseling was tailored to the patients' individual needs, thus, content and frequency varied algorithm-based. The algorithms were part of the intervention book handed out to each SCION-PAIN intervention ward. The book was developed by some of the authors and approved by an institutional advisory panel of pain experts.

To ensure counseling tailored to patients' individual needs but standardized according to the basic model, we provided assessment of patients' resources regarding knowledge, skills, and attitudes or perceptions, with indication questions, for example, "Do you know your pain medication plan?"; for the assessment of *knowledge* in the pharmacological pain treatment module. Each question was related to an intervention, for example, provide information of the pain medication plan and type of application. High levels of resources were indicated if each question were answered with "yes."

Patients from the control group received care as usual. Care as usual included standard pharmacological pain treatment, but neither standardized teaching or application of written materials, nor other evidence-based treatment protocols were given.

2.2. Intervention timeline

The basic session, held by the study nurse within 24 hours after trial inclusion, contained an overall introduction on