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Results of a randomized controlled pilot study of a self-management intervention for cancer pain

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A B S T R A C T

Purpose of the research: This paper reports findings from a randomized controlled pilot study evaluating the PRO-SELF© Plus Pain Control Program, a U.S.-developed cancer pain self-management intervention, regarding feasibility and effect sizes in a German patient sample.
Methods and sample: Thirty-nine German oncology outpatients were randomized to intervention ($n = 19$) and control ($n = 20$) groups. The intervention group received the PRO-SELF© Plus Pain Control Program in 6 visits and 4 phone calls a 10-week period. The control group received standard education and care. The intervention employed three key strategies: information provision, skills building, and nurse coaching. Primary outcomes were changes in average and worst pain intensity. Secondary outcomes included changes in pain-related knowledge, opioid intake, and self-efficacy. Data were collected at enrollment, then at 6, 10, 14, and 22 weeks.
Key results: The group-by-time effect showed a statistically significant increase in knowledge (week 10: $p = 0.04$; week 22: $p < 0.01$). Despite slight reductions in average and worst pain, no statistically significant changes were found for pain, opioid intake, or self-efficacy.
Conclusions: This study is the first to evaluate and demonstrate the feasibility of a U.S.-developed cancer pain self-management intervention in a German patient population. Pain self-management related knowledge improved significantly and effect sizes for pain reduction were determined. Findings from this pilot RCT provide the basis for planning a larger RCT.
Clinical trial registration number: NCT00920504.

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Introduction

Even with effective treatment options available, over 40% of cancer pain patients lack the resources to manage their pain effectively (Breivik et al., 2009; Mercadante, 2007; Spichiger et al., 2011). In addition to inadequate assessment and treatment, several patient-related barriers impede optimal pain management (Jacobsen et al., 2009a). These include cognitive (e.g., concerns about analgesic use), affective (e.g., stress, depression), sensory (e.g., side effects), and practical components (Jacobsen et al., 2009b). Of these, the cognitive components, such as oncology patients' common misconceptions regarding analgesic medications (e.g., fear of addiction, tolerance, fatalism), are most strongly associated with undertreatment (Ferrell et al., 1993a; Valeberg et al., 2008a; Ward et al., 1993). Furthermore, because the implementation of pain self-management strategies into daily practice is a complex process, patients may experience insufficient pain relief (Schumacher et al., 2002). Oncology patients and their family caregivers (FCs) must acquire knowledge and skills on how to obtain, take, and titrate analgesic regimens, deal with side-effects, and know what to do if pain is not relieved (Schumacher et al., 2002). Finally, patients' lack of adherence to the analgesic regimens is a main contributor to inadequate pain control (Valeberg et al., 2008b).

Effects of interventions that support cancer pain self-management were examined in systematic reviews by Allard et al. (2001), Bennett et al. (2009), Devine (2003). Findings from these reviews suggest that, while such interventions have gained increasing attention, they remain understudied. While all three reviews noted reductions in pain, effects were of moderate size. In

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the most recent meta-analysis of 21 experimental studies on pain self-management interventions (Bennett et al., 2009), a weighted mean difference of −1.1 (95% confidence interval [CI]: −1.8 to −0.41) was found on a numeric rating scale (NRS) of 0 (no pain) to 10 (worst imaginable pain) for average pain, and a difference of −0.78 (−1.21 to −0.35) for worst pain intensity. In addition, significant heterogeneity in study designs, methods, and types of interventions may have weakened the findings. Additional studies are therefore warranted.

The pilot study described in this paper is based on the PRO-SELF© Pain Control Program (PCP; West et al., 2003). This Program was adapted for use in a German population because it was found to be effective in a large RCT in the United States (U.S.; Miaskowski et al., 2004), and because published adaptations, based on extensive qualitative and quantitative analyses, indicated that the revised version might show improved effects (Miaskowski et al., 2007; Schumacher et al., 2002). In addition, the Program's authors agreed to collaborate for its implementation in a German-speaking population.

In the randomized controlled trial (RCT) in the U.S., 174 patients ($n = 81$ control group; $n = 93$ intervention group) participated either alone (55%) or with FCs (45%). In the intervention group, specially trained nurses conducted three home visits and three phone calls with patients and FCs over 6 weeks. The PRO-SELF© PCP was based on three key strategies: provision of information, skills building, and ongoing nurse coaching, and consisted of structured and tailored components.

Information was provided using academic detailing, an educational strategy found to be effective in changing physicians' prescribing behaviors (Soumerai and Avorn, 1990). It is based on adult learning principles and includes establishing baseline knowledge, defining clear objectives, giving unbiased sources of information, presenting both sides of controversial issues, stimulating active participation, using educational materials, and providing reinforcement in follow-up visits (Soumerai and Avorn, 1990). While average pain (weighted mean difference = −0.98 [95% CI: −1.56/−0.40]) and worst pain (weighted mean difference = −1.1 [95% CI: −1.81/−0.39]) intensity scores decreased significantly (Bennett et al., 2009; Miaskowski et al., 2004), a more detailed evaluation revealed that only 50% of patients in the intervention group indicated complete responses (decrease of pain intensity scores > 30%), 25% indicated partial responses (decrease of pain intensity scores between 1% and 29%), and 25% showed no response to the intervention (Miaskowski et al., 2007). These three groups did not differ on any demographic or clinical characteristics. However, a qualitative analysis of audio-taped interactions between patients, FCs, and intervention nurses revealed numerous difficulties putting pain management regimens into practice at home. In fact, at the time of the final home visit, the majority of the intervention patients were still actively involved in problem-solving to achieve better pain control (Schumacher et al., 2002).

Both the quantitative and qualitative analyses provided the basis for the refinements that resulted in the PRO-SELF© Plus PCP. For example, it was noted that patients needed additional time in the coaching/problem-solving process to achieve optimal pain control. Hence, the Program was extended to ten weeks. To assess the sustainability of the intervention's effects, the follow-up period was extended to 22 weeks after enrollment. Currently, the "second generation" PRO-SELF© Plus PCP is currently being tested in a U.S. RCT.

To our knowledge, until the current study, no intervention designed to support oncology patients' pain self-management was tested in the German speaking population. The PRO-SELF© Plus PCP served as the foundation for this pilot study, which was conducted in Germany. The overall framework for both the U.S. and the German studies was adapted from symptom management theory (Dodd et al., 2001; Humphreys et al., 2008), which was developed at the University of California in San Francisco. This theory contextualizes the patient's experience of symptom management in relation to the person, their health and illness, and their environment. In addition, the underlying theoretical foundation for the intervention is taken from Bandura's social cognitive theory, an adult learning theory established on the principle that human behavior influences and is affected by the individual, behavior, and environment. One product of social cognitive theory is the concept of self-efficacy (i.e., one's belief in one's ability to succeed in specific situations; Bandura, 1989).

The purpose of this paper is to report findings from a pilot RCT of the adapted German PRO-SELF© Plus PCP in oncology outpatients and their FCs. Focusing primarily on feasibility and effect sizes for the outcome variables of worst and average pain intensity, the results are intended for use in subsequent power calculations. Findings for secondary outcomes (i.e., pain management related knowledge and opioid intake) are also reported.

Methods

Design

In this single-center pilot RCT, the PRO-SELF© Plus PCP was modified by translating and adapting study instruments and the intervention for the German healthcare system. During the translation process, various adaptations were made to the original PRO-SELF© Plus PCP, including the addition of a baseline cognitive assessment; personalized, reachable goal setting; and the stepwise engagement of FCs and home nurses for patients who were unable to implement the pain and side effect management plan. Details of the study and intervention procedures are reported elsewhere (Koller et al., 2013).

Sample and setting

Oncology outpatients were recruited consecutively from a large Comprehensive Cancer Center in Freiburg, Germany. Inclusion and exclusion criteria are listed in Table 1. The study was approved by the local ethics committee.

Study procedures

Patients were approached during routine clinic visits and invited to participate in the study. If FCs were involved, they were also invited. After providing written informed consent, patients and FCs were stratified by cancer diagnosis (i.e., breast, lung, or other)

Table 1
Inclusion and exclusion criteria of patients during the pilot study.

Inclusion criteria:	• Cancer pain ≥3 on a 0 (no pain) to 10 (worst pain imaginable) numeric rating scale • ≥18 years • Ability to read, write and understand German • Estimated life expectancy of more than 6 months • Access to a telephone • Living within a 1 h car ride from the clinics
Exclusion criteria:	• Patients with a family caregiver who was involved substantially in their pain self-management and who was not willing to participate in the study (Patients who did not have a family caregiver who was involved substantially in their pain self-management could participate as individuals) • Hospitalization for >2 weeks during the 10-week intervention period

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