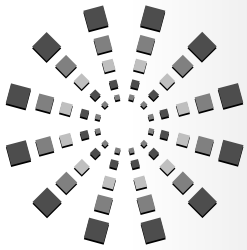

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Testing the Implementation of a Pain Self-management Support Intervention for Oncology Patients in Clinical Practice

A Randomized Controlled Pilot Study (ANtiPain)

KEY WORDS
Neoplasm
Pain
Patient education
Pilot randomized controlled trial
Self-management

Background: In oncology, pain control is a persistent problem. Significant barriers to cancer pain management are patient related. Pain self-management support interventions have shown to reduce pain intensity and patient-related barriers. Comparative effectiveness research is a suitable approach to test whether effects are sustained in clinical practice. **Objective:** In this pilot randomized controlled trial, the implementation of the ANtiPain intervention into clinical practice was tested to assess the effects on pain intensity, function-related outcomes, self-efficacy, and patient-related barriers to pain management to prepare a larger effectiveness trial. **Methods:** Within 14 months, 39 adult oncology patients with pain scores of 3 or higher on a 10-point numeric rating scale were recruited in an academic comprehensive cancer center in Southern Germany. Patients in the control group (n=19) received standard care. Patients in the intervention group (n=20) received ANtiPain, a cancer pain self-management support intervention based on 3 key strategies: provision of information, skill building, and nurse coaching. An intervention session was performed in-hospital. After discharge, follow-up was provided via telephone calls. Data were collected at baseline and 1 and 6 weeks

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after discharge. Effect sizes were calculated for all outcomes. **Results:** Large effects were found for activity hindrance (Cohen d=0.90), barriers (d=0.91), and self-efficacy (d=0.90). Small to moderate effects were found for average and worst pain (Cohen d=0.17-0.45). **Conclusions:** Key findings of this study involved function-related outcomes and self-efficacy. **Implications for Practice:** Because these outcomes are particularly meaningful for patients, the integration of ANtiPain to routine clinical practice may be substantial. A larger study will be based on these findings.

■ Background

The Problem

Depending on type and stage of the illness, 30% to 75% of oncology patients experience pain.[1] Despite highly effective therapies,[2,3] pain control is a persistent problem in cancer patients.[4] Significant barriers to cancer pain management are patient related.[5,6] Common patient issues arise from a lack of information and fears related to pain medication that are deeply rooted in modern society.[5] Indeed, concerns over drug tolerance and addiction are 2 frequently named examples.[5] Furthermore, patients may lack skills and knowledge to carry out appropriate cancer pain self-management.[6] These challenges are compounded by the fact that cancer treatment is increasingly being shifted to the outpatient setting, leaving patients in charge of their pain management at home. Thus, patients' self-management is of growing importance for a successful pain treatment.

Pain Self-management Support

Pain self-management support interventions are known not only to have significant and clinically relevant effects on patient-related barriers to cancer pain management[7,8] but also to increase pain-related self-efficacy[7,9] and to decrease pain intensity moderately.[10–14] The effect of these interventions on pain intensity (mean 1.1 reduction on an 11-point numeric rating scale [NRS] from 0 = no pain to 10 = worst imaginable pain) is slightly higher than some analgesic agents, like paracetamol or gabapentin, that are frequently added to opioid therapy for pain management.[11] Notably, such a reduction is higher than the commonly accepted threshold for the "minimal clinically important difference" in pain management.[15] These effects are even seen if pain treatment is prescribed by specialized pain physicians, which guarantees that patients have optimal medical pain therapy available.[16] It can thus be assumed that self-management support interventions significantly add to the effect of state of the art pharmacological pain management. Considering the absence of toxicity, cancer pain self-management support interventions may become an important component of cancer pain management routines.[14]

However, the clinical applicability of cancer pain self-management support interventions in routine clinical care has not yet been the focus of research,[10–13] as these have mostly been tested in highly controlled settings (ie, randomized controlled trials [RCTs]), with rather rigid inclusion and exclusion criteria, that do not fully reflect the variability in patients, providers, and practice patterns in various settings.

Moreover, cancer pain self-management support interventions are so-called "complex interventions" that target behavior change of oncology patients with pain. Complex interventions are interventions that consist of several interacting components.[17] Complexity is increased by a high number of interacting intervention components as well as other factors, such as the number and difficulty of behaviors required by those delivering or receiving the intervention, as well as the degree of flexibility or tailoring of the intervention permitted.[17] In the past, the quality of reporting complex interventions that target behavior change has been low. Therefore, Michie et al[18] provided a taxonomy to describe behavior change interventions, such as cancer pain self-management support interventions. It is known that complex interventions are highly sensitive to local contextual features such as staff morale and competence as well as available resources.[17] Therefore, comparative effectiveness research is a useful approach to assess the effectiveness of cancer pain self-management support interventions in clinical practice.[17]

Target Outcomes for Pain Self-management Support Intervention Research

In the past, most trials focused mainly on traditional outcome measures such as pain intensity.[14] However, it is known that patients may consider other outcomes more important, such as the interference of pain with other dimensions of life (eg, interpersonal relationships).[19] Because pain self-management support interventions target these outcomes of interest, it has been recommended to integrate function-related outcomes in pain self-management research.[19,20]

Development of the ANtiPain Intervention

In German-speaking countries, interventions to support cancer pain self-management are largely unknown. Therefore, we translated and adapted the PRO-Self Plus Pain Control Program (PCP) by Miaskowski et al[7] that was successfully tested in the United States for the German context. The 10-week PRO-Self Plus PCP was based on 3 key strategies (information, skill building, and nurse coaching). It was implemented by

master's-prepared oncology nurses in the outpatient setting during face-to-face home visits (biweekly) and telephone calls (every other week). Information was provided using academic detailing, an educational strategy that allows tailoring the information to the participants.[21] In addition, the PRO-Self Plus PCP included core principles like assessing baseline knowledge, defining goals, providing correct medical information, discussing controversial issues, encouraging active participation, using educational materials, and providing reinforcement in follow-up sessions.[22]

The German version of the 10-week program was pilot tested at the Tumorzentrum Ludwig Heilmeyer–Comprehensive Cancer Center Freiburg.[22–24] To implement complex interventions, usually, adaptations are required to ensure a proper fit with the individual setting in routine clinical care. For this, interventions can be conceptualized as having 'core components' (ie, indispensable elements of the intervention) and an "adaptable periphery" (eg, structures and systems).[25] Results of the pilot RCT provided the information to adapt the PRO-Self Plus PCP. The changes that were made to the PRO-Self Plus PCP were of a structural kind while the core of the PRO-Self Plus PCP intervention was maintained (eg, 3 key strategies). The adapted intervention was called ANtiPain and is described in detail in Table 1. ANtiPain is a clinically, more feasible, and cost-effective intervention in the local German context.[26] To be a good fit for as many practice settings as possible, ANtiPain was conceptualized so that the first contact with the patients could be made in both the inpatient and outpatient setting. In addition, as master's-prepared oncology nurses are scarce in Germany, ANtiPain was designed to be implemented by experienced bachelor-prepared oncology nurses who work in the clinical setting. For this study, the first contact was made during an in-hospital stay with the patients. Follow-up telephone calls were chosen instead of home visits after discharge in view of the costs. In addition, the option for visits with the intervention nurse during outpatient or inpatient routine follow-up (eg, with their treating physician) was provided.

Objectives

The main objective of this pilot RCT was to test the effect of the implementation of the ANtiPain intervention in the clinical setting on pain intensity, function-related outcomes, self-efficacy, health-related quality of life (HRQoL), and patient-related barriers to pain management to prepare a larger effectiveness trial.

■ Methods

Setting and Sample

In a randomized controlled pilot study of adult oncology, inpatients of a palliative care consultation service at the University Medical Center Freiburg, Germany, were recruited. The inclusion criteria were that patients had pain scores of 3 or higher out of 10, they needed to self-manage their pain after discharge, had a life expectancy greater than 3 months as assessed by the treating physicians, and could understand, read, and write German. Patients were excluded if the treating physician perceived severe cognitive deficits that would prevent patients from participating actively in self-management support.

Interventions

CONTROL GROUP

The hospital's palliative care consultation service or the acute pain management service recommended treatment following state of the art guidelines.[2] In addition, patients in the control group (CG) received routine cancer care that did not include any standardized cancer pain self-management support. After the 6-week study period, patients in the CG were offered pain self-management support by one of the intervention nurses.

INTERVENTION GROUP

Patients in the intervention group (IG) also received a recommendation for state-of-the-art pain treatment by either the hospital's palliative care consultation service or the acute pain management service. In addition, patients in the IG participated in the ANtiPain intervention, which is described in detail following the taxonomy of Michie et al[18] in Table 1. If family caregivers were involved in pain self-management, they were invited to take part in the intervention. The ANtiPain intervention included structured and tailored components and was based on 3 key strategies: information, skill building, and nurse coaching. It was performed following a detailed intervention protocol by at least bachelor-prepared oncology nurses who were part of the clinical team in the oncology department. The intervention consisted of an in-hospital visit before discharge and telephone calls after discharge. In-person visits after discharge were scheduled only if patients had routine follow-up visits due to their cancer treatment. Laminated cards were used to visualize the intervention's content for the patients. Patients received a corresponding booklet that summarized the information from the intervention session and a pillbox to organize their oral medication. Time and duration of the follow-up phone-calls were tailored individually according to a standardized clinical algorithm that was based on patient-reported pain intensity, satisfaction with pain management, and adherence to the analgesic regimen (see Table 1).

QUALITY ASSURANCE OF THE INTERVENTION

In 2 one-to-one sessions, the intervention nurses were trained by the first author (A.K.) to perform the intervention by following a detailed intervention protocol. Ongoing quality assurance of fidelity with the intervention protocol was performed by peer review of the intervention nurses. The first intervention session of each intervention nurse was audio recorded and a second intervention nurse checked the audio file for protocol fidelity. With this method, at least 95% protocol fidelity was reached as assessed by the intervention nurses. In addition, the intervention nurses noted timing, duration, and content of each intervention session and kept field notes in which they noted all relevant

Table 1 • Literature-Based Description of ANtiPain Intervention With 3 Key Strategies (Information, Skill Building, Nurse Coaching) Following the Taxonomy of Michie et al[18] Derived From Koller et al[26]

Cluster Label of Michie et al[18]	Techniques of Michie et al[18]	ANtiPain Intervention Component Example[26]	Time Point of Intervention
(3) Repetition and substitution	Generalization of target behavior [8.6]	*Information* about individual analgesic prescription and co-medication including optimal time points of prescribed analgesics during 24 h Information about side effects and side effect management *Information* printed in corresponding booklet for patients	IH, Tf-u
	Habit formation [8.3]	*Skill building and nurse coaching:* Supporting the implementation of analgesic intake into daily routine	IH, Tf-u
	Habit reversal [8.4]	*Skill building and nurse coaching:* Correcting analgesic intake time-points during the day	Tf-u
	Behavioral rehearsal/ practice [8.1]	*Skill building and nurse coaching:* Checking and correcting daily practice of analgesic intake	Tf-u
(4) Antecedents	Restructuring the physical environment [12.1]	*Skill building:* Implementing weekly medical pillboxes	IH
	Restructuring the social environment [12.2]	*Information:* Addressing barriers to pain management of family caregivers	IH, Tf-u
	Distraction [12.4]	*Nurse coaching:* Addressing nonadherence with recommendations and considering solutions with participants	Tf-u
(7) Natural consequences	Health consequences [5.1]	*Information:* Health consequences if pain is persistently high *Skill building:* Self-monitoring of pain and side effects	IH, Tf-u
(8) Feedback and monitoring	Feedback on behavior [2.2]	*Nurse coaching:* Giving feedback on analgesic intake	Tf-u
	Other(s) monitoring with awareness [2.1; 2.5]	*Skill building:* Family caregivers are invited to give feedback	IH, Tf-u
	Self-monitoring of behavior [2.3]	*Skill building:* Patients are asked to self-monitor their analgesic intake	IH, Tf-u
	Self-monitoring of outcome of behavior [2.4]	*Skill building:* Patients are asked to self-monitor the effects of their analgesic intake on pain and side effects	Tf-u
(9) Goals and planning	Action planning (including implementation intentions) [1.4]	*Information and nurse coaching:* Discussion about cancer pain self-management techniques that may be implemented into daily practice	IH, Tf-u
	Problem solving/coping planning [1.2]	*Nurse coaching:* Supporting patients to find solutions to everyday problems with pain management	Tf-u
	Goal setting (behavior and outcome) [1.3]	*Information and nurse coaching:* Setting a maximum pain level as target outcome for cancer pain self-management	IH, Tf-u
	Discrepancy between current behavior and goal [1.6]	*Nurse coaching:* Relating achieved or not achieved target pain level with pain management behavior in a discussion with patient *Algorithm to stop intervention:* Stopping intervention if patient is satisfied with pain management *and* pain level ≤3 *and* patient adheres with pain management recommendations	Tf-u
	Review behavior and outcome goal(s) [1.5; 1.7]	*Nurse coaching:* Reflecting with patient implemented and not implemented daily pain management behavior *Nurse coaching:* Clinical algorithm to tailor timing of intervention sessions (patients are asked at the beginning of each telephone call whether pain was <3; if they were satisfied with the pain management; and if they were able to adhere to the analgesic prescription. If 1 question is answered with "no," the next telephone call is scheduled. If all questions are answered with "yes" for 2 wk in a row, the intervention is ended)	Tf-u
(10) Social support	Practical, general, and emotional social support [3.1–3.3]	*Nurse coaching:* Inclusion of family caregivers	IH, Tf-u
(12) Self-belief	Verbal persuasion and role modeling [15.1]	*Information and nurse coaching:* The intervention nurse uses academic detailing technique[21] and model-patient examples from intervention protocol underlined with her practical experience to address patient-related barriers to cancer pain management.	IH, Tf-u

(continues)

Table 1 • Literature-Based Description of ANtiPain Intervention With 3 Key Strategies (Information, Skill Building, Nurse Coaching) Following the Taxonomy of Michie et al[18] Derived From Koller et al[26], Continued

Cluster Label of Michie et al[18]	Techniques of Michie et al[18]	ANtiPain Intervention Component Example[26]	Time Point of Intervention
(16) Regulation	Regulate negative emotions [11.2] Pharmacological support [11.1]	*Information:* The intervention nurse uses academic detailing technique[21] to address patient-related cognitive barriers to cancer pain management. *Information:* Individualized correct medical information is given the patients about their analgesic prescription and patients are given a detailed written analgesic medication plan.	IHIH, Tf-u

Abbreviations: IH, in-hospital (shortly before discharge); Tf-u, telephone follow-up (following a clinical algorithm that was triggered by patient satisfaction with cancer pain self-management, pain level, and patient adherence; telephone call is scheduled if 1 of the questions is answered unsatisfactorily, and the intervention is stopped when for 2 weeks in a row, all questions are answered satisfactorily).

issues regarding study procedures. The latter were discussed in monthly research meetings with the study coordinator (S.W.).

Measurements

The objective of this study was to assess the intervention's effect on relevant outcomes such as pain intensity, function-related outcomes (ie, pain interference with daily activities and pain-related activity hindrance), pain-related self-efficacy, HRQoL, and patient-related barriers to cancer pain management. Figure 1 shows the research model that underlies the measurement plan of this pilot study. A more detailed description of the psychometric properties of the listed instruments can be found elsewhere.[26] Demographic and clinical data, functional status, depression, daily opioid intake, as well as the dose of the intervention were measured as covariates.

For *pain intensity*, 9 items from the Brief Pain Inventory (BPI) were used to measure average and worst pain intensity

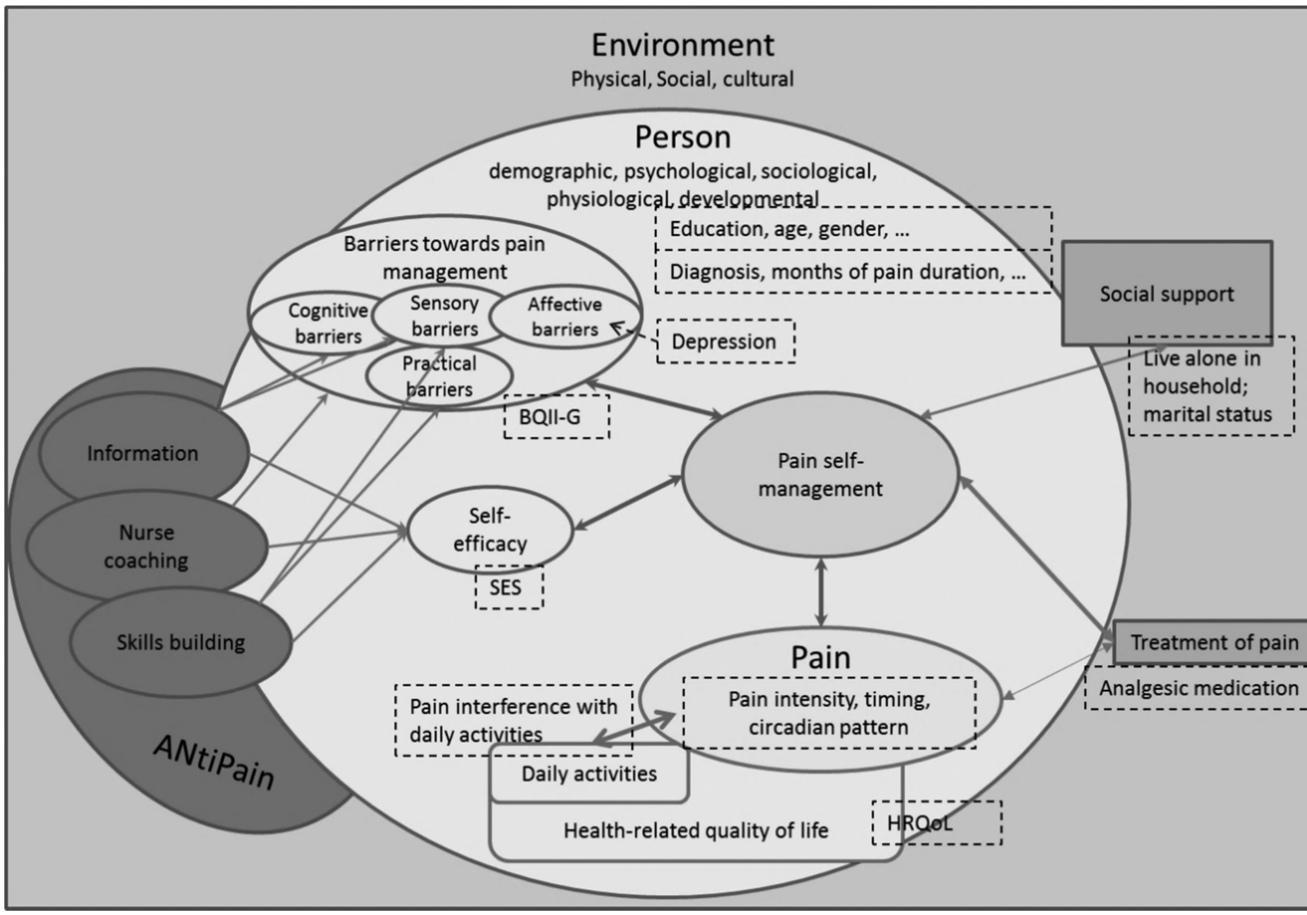

Figure 1 ■ Research model that illustrates the proposed relationships tested in the ANtiPain pilot study. Study measurements are noted in boxes with dashed lines; BQII-G: German version of the Barriers Questionnaire II; HRQoL: Health-related quality of life; SES: Self-efficacy scale.

and pain interference with daily activities.[27] In the BPI, *worst and average pain intensities* are measured with an 11-point NRS: 0 (no pain) to 10 (worst pain imaginable).

For *function-related outcomes*, pain interference with daily activities is a 7-item scale within the BPI in which patients are asked to evaluate on 11 point NRS (0 = no interference and 10 = complete interference) with 7 daily activities such as sleep or walking ability. In addition, the self-developed item from a previous study was used to measure pain-related activity hindrance,[22] by asking the patients to rate "The pain hindered me to do things that I wanted to do today" on a 0 (not at all) to 10 (completely) NRS.

Pain-related self-efficacy was measured with the German version of the Pain Self-efficacy Questionnaire.[28] Patients rated each of the 10 items regarding their self-confidence to manage a number of aspects of their pain on a 7-point NRS (0 = very uncertain to 6 = very certain).

Health-related quality of life was measured with the Medical Outcome Study Short-Form, a 12-item self-report tool that is commonly used and well validated.[29,30] Items are scored on 3- and 5-point Likert scales and summed up to 2 subscales (physical and mental).

Patient-related barriers to cancer pain management were measured with the German version of the Barriers Questionnaire II, which is a self-report questionnaire with 27 items addressing 8 common barriers (eg, concerns about addiction).[31,32] Items are recorded on 6-point Likert scales with 0 (do not agree at all) and 5 (agree very much).

Functional status was rated by the patients with the German version of the Eastern Cooperative Oncology Group Performance Status (ECOG-PS), which measures the patient's capacity to perform a variety of activities that are normal for most people.[33,34]

Depression was measured with the Patient Health Questionnaire, a 2-item screening tool[35] that assesses decrease of interest and dejectedness each on a 0 (never) to 3 (almost every day) NRS. For *analgesic medication*, within the BPI, patients listed their around-the-clock and as needed analgesic medication. Daily opioid intake was calculated as the daily dose equivalent of oral morphine, according to opioid conversion ratio tables. The *dose of intervention* was measured as the time that was spent with the patient and was noted in hours and minutes by the intervention nurses at each session and telephone call.

Data Collection Procedures

Patients were approached during their routine hospital stay and invited to participate if inclusion criteria applied. After providing written informed consent, patients were first asked to complete the baseline questionnaire (T0) to obtain unbiased data with regard to group allocation. Then, patients were randomized 1:1 into the IG and CG by using a computer-generated list with randomly permuting block lengths. Opaque envelops were prepared by an uncommitted study nurse (was not involved in recruitment or intervention) who arranged them in a box accessible to recruiting personnel. Therefore, recruiting personnel was blinded to group allocation. Follow-up data collection was performed via mail with patient self-report questionnaires 1 (T1) and 6 (T2) weeks after discharge. It was organized by study nurses who were blinded to group allocation. For T1, patients were given the questionnaires and prestamped and addressed envelopes at discharge. Four to 6 days after hospital discharge, a study nurse contacted the patients via telephone as a reminder to return the completed questionnaires. For T2, questionnaires were sent together with a prestamped and addressed envelope. A study nurse contacted the patients via telephone first, to announce the third questionnaire, before sending them, and second, to remind them to send back the completed questionnaires at T2.

Data Analysis

Descriptive statistics were applied as appropriate. Line diagrams were drawn for all outcomes.

EFFECT SIZES

To assess the magnitude and clinical significance of the effects, 2 different measures for effect sizes were applied. The linear mixed model (LMM) that is applied in this study for longitudinal data analysis does not yield information on the sizes of found effects. Therefore, we calculated within-group changes over time (change scores) and then compared these change scores between groups. This means that Cohen *d* was calculated for between-group differences of the change score for those patients who completed the baseline, and at least 1 more questionnaire (T1 or T2) for the respective time point. Cohen *d* was calculated for primary and secondary outcomes (for ΔT1 to T0 and ΔT2 to T0, respectively), with $d = 0.2$ representing a small, $d = 0.5$ a moderate, and $d = 0.8$ a large effect in favor of the IG. In addition, to assess clinically meaningful differences in the 2 groups, we calculated the proportion of patients who achieved the clinically important difference of 30% improvement for each group for each outcome to compare them between the IG and the CG.[15]

STATISTICAL SIGNIFICANCE

We also applied an LMM to determine statistical differences between the 2 groups, regarding the outcomes with treatment as binary and time as continuous covariate, their interaction as fixed effects and the intercept and time as random effects. Significance of treatment effects were assessed by testing the interaction term. The level of significance was set at .05.

■ Results

Between December 2013 and January 2015, 39 patients (44% women) were recruited (Figure 2). The 2 groups did not differ in baseline characteristics (Table 2). The mean (SD) age of patients was 57 (10.6) years and a median school education of 10 years (25/75 percentile = 9/13). At inclusion, the mean functional status (ECOG) was 2.8, which means that, on average, patients were not able to leave their bed for more than 50% of daytime. Mean (SD) baseline average pain intensity was 4.4 (1.5), and mean (SD) baseline worst pain intensity was 7.9 (1.4). Over the time of the study, the daily opioid dose of patients in the IG decreased slightly compared to the patients in

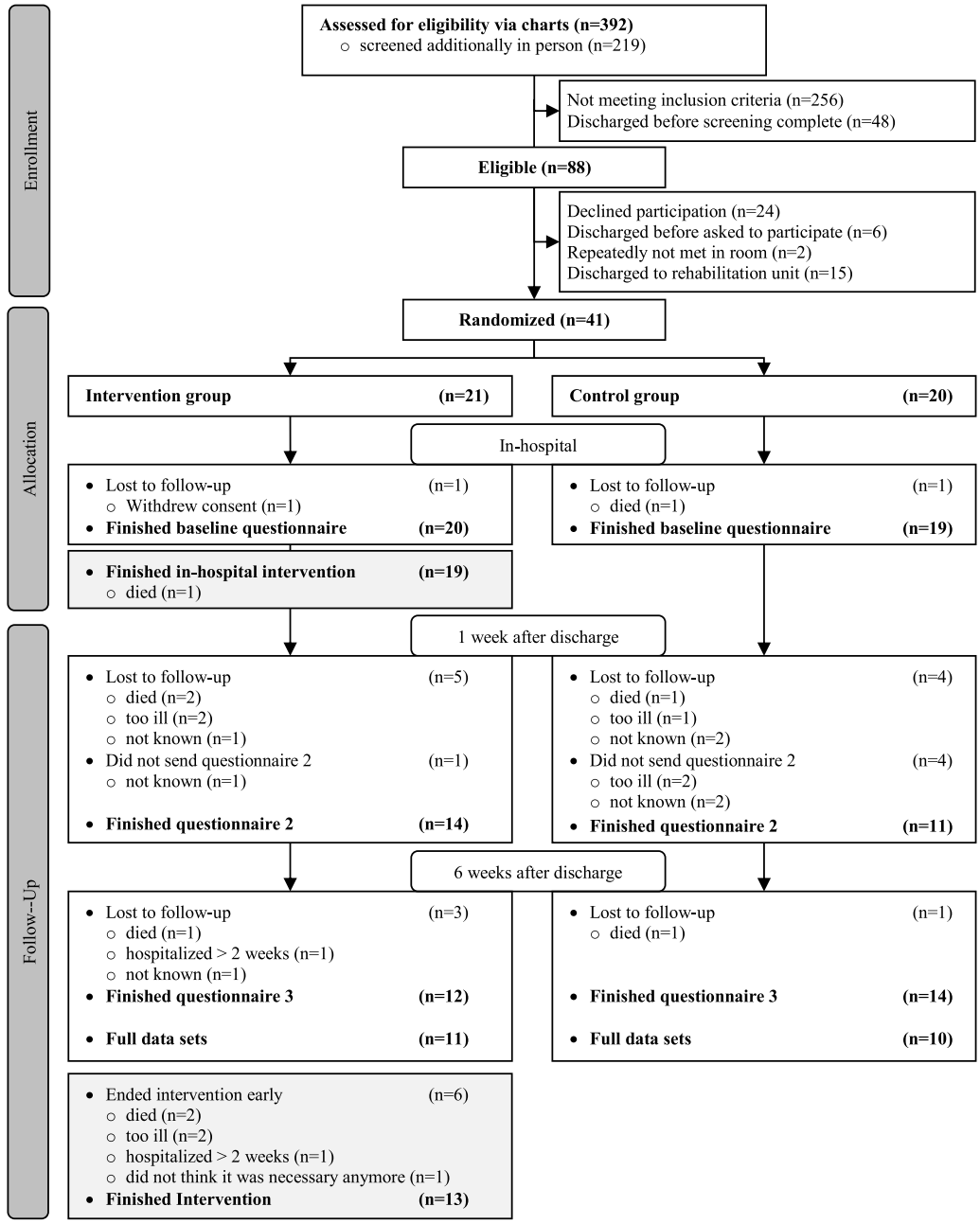

Figure 2 ■ Flow of participants during the course of the study.

the CG (T1 $d=-0.28$; T2 $d=-0.38$). Whereas for all patients, the functional status decreased over the course of the study, it decreased slightly more in the IG (ECOG T0 IG: 2.95, CG: 2.59; T1 IG: 2.36, CG: 2.11; T2 IG: 1.59, CG: 2.14).

Effect Sizes

COHEN *d*

Line diagrams of all outcomes over the course of the study are shown in Figure 3. Cohen *d* of average and worst pain intensity ranged between 0.17 (T1 average pain) and 0.45 (T2 average pain), representing small to moderate effects (Table 3). Large effects ($d>0.8$) were found for the function-related outcome "pain-related activity hindrance" at T2 ($d=0.9$), for patient-related barriers to pain management ($d=1.62$ at T1 and $d=0.91$ at T2), and self-efficacy at T2 ($d=0.92$; Table 3). Patients in the IG also reported moderately lower interference with daily activities (T1, $d=0.6$; T2, $d=0.77$) and moderately increased physical/mental HRQoL (T1, $d=0.32/0.54$; T2, $d=0.57/0.38$) compared with patients in the CG.

CLINICALLY IMPORTANT DIFFERENCE

The proportion of patients who reported an improvement in average pain of 30% or greater at T2 was 84.8% in the IG versus 64.3% in the CG (ΔIG-CG: 20.5%; Table 4). For worst pain intensity, the proportion with an improvement of

Table 2 • Demographic and Clinical Baseline Characteristics of Patients

Variable		IG	CG	Total	*P*
Number of participants	n	20	19	39	
Age in years	Mean (SD)	55.3 (10.2)	58.1 (11.2)	56.6 (10.6)	.4
Female sex	% (n)	60.0 (12)	36.8 (7)	48.7 (19)	.21
Live alone in household	% (n)	30.0 (6)	31.6 (6)	30.8 (12)	
Marital status, % (n)	Married	60.0 (12)	47.4 (9)	53.8 (21)	.71
	Widowed	5.0 (1)	15.8 (3)	10.3 (4)	
	Separated	15.0 (3)	15.8 (3)	15.4 (6)	
	Unmarried	20.0 (4)	21.1 (4)	20.5 (8)	
Years of school education	Median (quartiles)	11 (9/13)	10 (9/13)	10 (9/13)	.53
Months since diagnosis	Median (quartiles)	6 (3/34)	9 (1/36)	8 (2/34.5)	.77
Diagnosis, % (n)	Gastrointestinal	30.0 (6)	36.8 (7)	33.3 (13)	.28
	Breast and gynecological	45.0 (9)	21.0 (4)	33.3 (13)	
	Other (including lung, Multiple Myeloma, etc.)	25.0 (5)	42.1 (8)	33.3 (13)	
Therapeutic goal, % (n)	Curative	50.0 (10)	52.6 (10)	51.3 (20)	.59
	Palliative	35.0 (7)	42.1 (8)	38.4 (15)	
	Missing	15.0 (3)	5.3 (1)	10.3 (4)	
Months of pain duration	Median (quartiles)	10 (2/35.3)	3.5 (1/12.3)	5.0 (1.8/23.3)	.19
Pain pattern, % (n)	Permanent pain with little fluctuation	5.0 (1)	26.2 (5)	15.4 (6)	.12
	Permanent pain with strong fluctuation	50.0 (10)	47.4 (9)	48.7 (19)	
	No permanent but breakthrough pain	45.0 (9)	21.1 (4)	33.3 (13)	
	Missing		5.3 (1)	2.6 (1)	
ECOG	Mean (SD)	2.95 (0.91)	2.59 (0.87)	2.78 (0.90)	.24
Depression score (PHQ2)	Mean (SD)	3.05 (1.88)	2.61 (1.24)	2.84 1.86	.5
Patient preference, % (n)	Strongly preferred IG	45.0 (9)	52.6 (10)	48.7 (19)	.88
	Strongly preferred CG	5.0 (1)	5.3 (1)	5.1 (2)	
	No preference	50.0 (10)	42.1 (8)	46.2 (18)	
Patients who dropped out	% (n)	40.0 (8)	26.0 (5)	33.3 (13)	.5
Baseline questionnaire only	% (n)	25.0 (5)	21.1 (4)	23.1 (9)	.77
Average pain T0	Mean (SD)	4.0 (1.56)	4.9 (1.41)	4.4 (1.54)	.15
Worst pain T0	Mean (SD)	7.6 (1.39)	8.2 (1.43)	7.9 (1.42)	.07
Pain interference with function T0	Mean (SD)	6.0 (2.10)	5.6 (2.00)	5.8 (2.03)	.32
Pain-related activity hindrance T0	Mean (SD)	5.2 (4.05)	5.9 (3.49)	5.5 (3.78)	.74
QoL physical health T0	Mean (SD)	27.1 (8.61)	26.3 (6.05)	26.7 (7.39)	.73
QoL mental health T0	Mean (SD)	42.9 (12.02)	45.9 (7.91)	44.3 (10.21)	.22
Patient-related barriers to pain management T0	Mean (SD)	3.2 (0.84)	2.8 (0.46)	3.04 (0.70)	.14
Self-efficacy scale T0	Mean (SD)	3.1 (1.48)	3.1 (1.01)	3.1 (1.26)	.76

$P = .05$.
Abbreviations: IG, intervention group; CG, control group; ECOG, Eastern Cooperative Oncology Group Performance Status; PHQ2, Patient Health Questionnaire-2; T0, measured at baseline; QoL, quality of life.

30% or greater was 54.5% in the IG, compared with 50.0% in the CG at T2 (ΔIG-CG: 4.5%). For pain interference with daily activities, 40.4% more patients in the IG reported an improvement of more than 30%, compared with patients in the CG (83.3% in the IG vs 43.9% in the CG). The proportion of patients with an improvement in patient-related barriers of 30% or greater was higher in the IG than in the CG (58.3% in the IG vs 0% in the CG at T2).

Statistical Significance

Applying the LMM, a significant effect on patient-related barriers toward pain management ($P = .03$) was found, which means that barriers decreased statistically more in patients from the IG than for patients in the CG. The effects on the other outcomes were statistically not significant (Table 3).

■ Discussion

To our knowledge, this is the first study to pilot test the implementation of a cancer pain self-management support intervention into clinical practice. Results indicate that the intervention may have highly valuable effects, particularly on outcomes that are essential from a patient perspective (eg, pain interference with daily activities, self-efficacy, patient-related barriers). However, although study and intervention procedures were feasible in

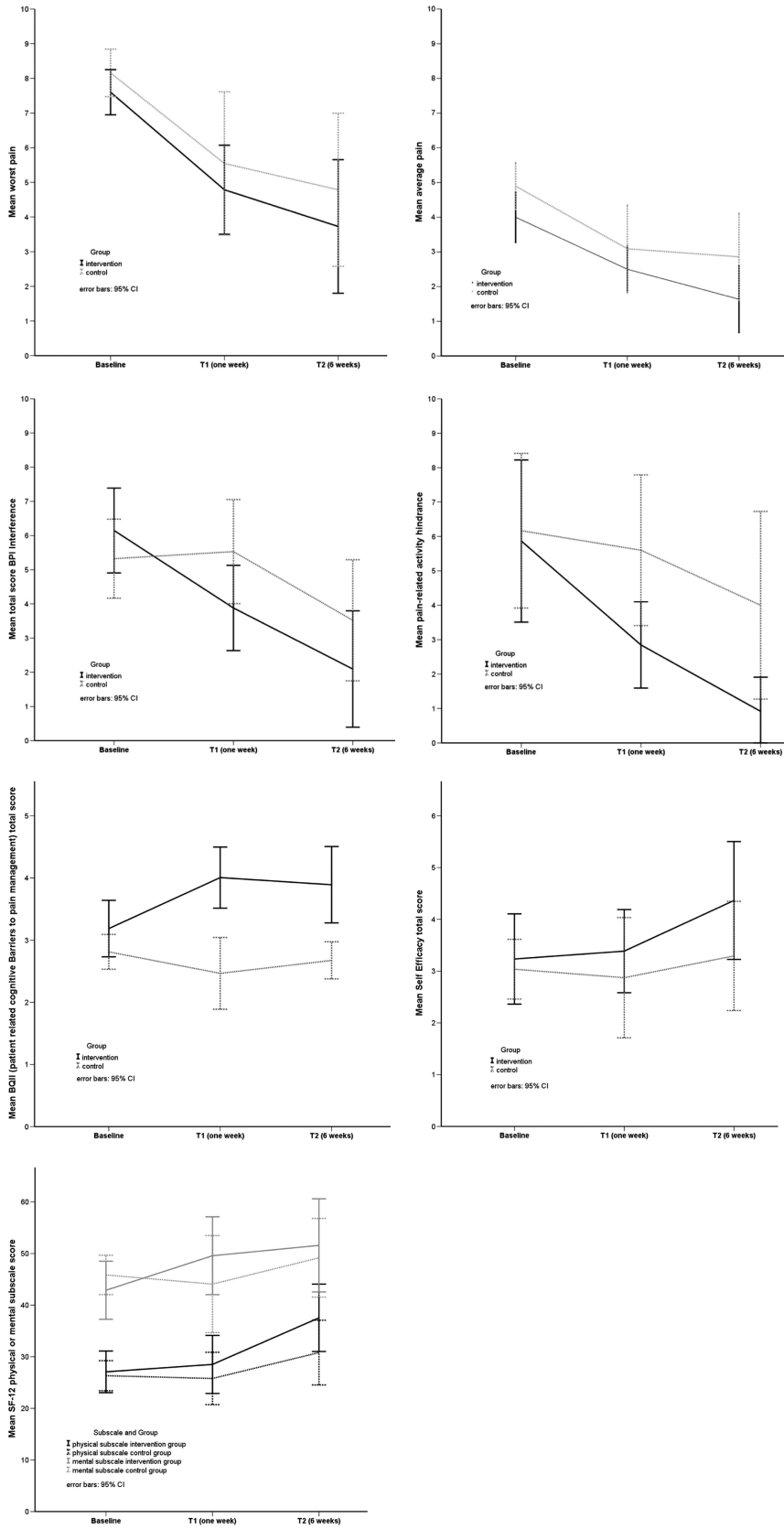

Figure 3 ■ Line diagrams of outcome variables over the course of the study for patients who completed at least baseline and 1 more questionnaire.

general, some aspects (eg, optimizing the recruitment of patients with cancer-related pain) may need additional consideration for the planning of future trials.

When asked to participate, 37% of patients declined participation. This rate was low compared with other studies on cancer pain self-management support,[8,36,37] even though patients in our study

Table 3 • Cohen *d* and Change Scores of Outcomes (Pain, Function, and Health-related Quality of Life) and Covariates (Self-efficacy and Patient-related Barriers Toward Pain Management) as well as *P* Values of the LMM

		IG			CG			
	Cohen *d*[a]	n	Mean	SD	n	Mean	SD	*P* LMM[b]
Average pain T1	0.17	14	−1.43	1.95	11	−1.09	1.97	
Average pain T2	0.45	11	−2.45	1.51	14	−1.71	1.77	.55
Worst pain T1	0.23	14	−2.86	2.35	11	−2.09	4.06	
Worst pain T2	0.34	11	−4.27	2.41	14	−3.14	4.00	.36
Pain interference with function T1	0.60	14	−2.12	2.35	12	−0.22	3.79	
Pain interference with function T2	0.77	11	−4.05	2.79	14	−1.70	3.29	.08
Pain-related activity hindrance T1	0.32	13	−3.15	3.69	12	−2.14	2.41	
Pain-related activity hindrance T2	0.90	7	−5.17	4.84	11	−0.73	5.06	.15
QoL physical health T1	0.32	13	1.04	6.01	11	−0.58	3.91	
QoL physical health T2	0.57	12	9.46	13.03	14	3.39	7.52	.16
QoL mental health T1	0.54	13	7.35	18.04	11	−1.46	14.70	
QoL mental health T2	0.38	12	9.48	15.16	14	4.11	13.38	.39
Patient-related barriers toward pain management T1	1.62	14	−0.91	0.78	11	0.25	0.64	
Patient-related barriers toward pain management T2	0.91	11	−0.50	0.84	14	0.13	0.51	.03[c]
Self-efficacy scale T1	0.51	14	0.14	2.25	11	−0.86	1.59	
Self-efficacy scale T2	0.92	11	1.57	1.44	14	0.20	1.53	.23

Abbreviations: LMM, linear mixed model; IG, intervention group; CG, control group; T1, data collection time point 1, 1 week after discharge; T2, data collection time point 2, 6 weeks after discharge; QoL, quality of life.
[a]$d = 0.2$, small effect; $d = 0.5$, medium effect; $d = 0.8$, large effect.
[b]The *P* value is given for the group-by-time interaction effect of the LMM.
[c]Statistically significant at the .05 level.

had a low baseline functional status (mean ECOG, 2.8). This may indicate that from the perspective of a large proportion of cancer patients, the intervention targeted a relevant issue but may not be applicable or valued by all patients.

In this study, the retention of participants was exceptionally challenging (dropout rates were quite high [23% at T1 and 33% at T2]). These dropout rates, however, are comparable with those in other studies with palliative care patients who oftentimes present with a permanently decreasing health status.[38] The high mortality rate in this study was surprising given the fact that the expected 3-month longevity was an inclusion criterion. However, it is known that even when researchers do

Table 4 • Number and Proportion of Patients With More Than 30% Improvement in Pain, Function-related Outcomes, Health-related Quality of Life, Self-efficacy, and Patient-related Barriers Toward Pain Management

	IG		CG	
		Improvement≥30%		Improvement≥30%
	n	% (n)	n	% (n)
Average pain intensity T1	13	46.2 (6)	11	54.5 (6)
Average pain intensity T2	11	81.8 (9)	14	64.3 (9)
Worst pain intensity T1	13	46.2 (6)	11	81.8 (9)
Worst pain intensity T2	11	54.5 (6)	14	50.0 (7)
Pain interference with daily function T1	14	35.7 (5)	11	27.3 (3)
Pain interference with daily function T2	12	83.3 (10)	14	42.9 (6)
Pain-related activity hindrance T1	13	61.5 (8)	7	42.9 (3)
Pain-related activity hindrance T2	12	66.7 (8)	11	36.4 (4)
Health-related quality of life physical subscale T1	13	23.1 (3)	11	0
Health-related quality of life physical subscale T2	12	50.0 (6)	14	21.4 (3)
Health-related quality of life mental subscale T1	13	46.2 (6)	11	9.1 (1)
Health-related quality of life mental subscale T2	12	58.3 (7)	14	21.4 (3)
Patient-related barriers toward pain management T1	14	71.4 (10)	11	9.1 (1)
Patient-related barriers toward pain management T2	12	58.3 (7)	14	0.0 (0)
Self-efficacy T1	14	35.7 (5)	11	36.4 (4)
Self-efficacy T2	11	45.5 (5)	14	35.7 (5)

Abbreviations: CG, control group; IG, intervention group; T1, data collection time point 1, 1 week after discharge; T2, data collection time point 2, 6 weeks after discharge.

put a limit on life expectancy, estimates are often inaccurate.[38] High dropout rates are probable in studies with oncology patients with cancer pain. Therefore, we chose a statistical analysis that allowed for the inclusion of all completed questionnaires irrespective of the patient's participation at subsequent data collection time points. In future studies, the use of clinically estimated life expectancy may be reconsidered. In patients with advanced disease, low retention is particularly unfavorable because these patients are potentially in special need of cancer pain self-management support. Apart from a steadily decreasing functional status that may prevent even highly motivated study participants from proceeding with participation, study burden may be a compounding factor. For these patients, the completion of self-report questionnaires and additional meetings with intervention nurses may present an extra challenge. With our pilot study, we aimed at reducing study burden first, by using telephone calls for follow-up, hence avoiding extra clinic visits for pain management. Still, in a future study, measures will be undertaken to integrate the intervention even more into routine clinical practice. For example, bachelor-prepared ward nurses will be trained to deliver the intervention and will be supported in peer review meetings to integrate visits and telephone calls into routine clinical care. Second, we determined meaningful outcomes and covariates and ruled out more unimportant ones.[39,40] For example, we will aim at shortening the German version of the Barriers Questionnaire II in a future study. One-scale instruments may be used instead of the long versions.[41] In addition, a minimally necessary data set may be defined (eg, main outcome and only the most important demographic variables) if patients cannot complete all questionnaires; data collection may be performed via telephone if the completion of questionnaires is not possible for the patients. This pilot study provided the basis for the compilation of short and valid questionnaires for a larger RCT.

Another challenge is that the pain etiology in a large number of cancer patients is not chronic cancer–related but rather transient treatment-related pain, for example, because of surgical interventions. However, these patients are in need of pain-management support for days to weeks. In fact, a subanalysis of our data showed that surgical patients needed the follow-up telephone calls as long as other patients did. In clinical practice, strategies to address all kinds of cancer- and treatment-related pain are needed. The ANtiPain intervention adequately addressed these patients' needs.

Effect Sizes

The effect sizes for worst and average pain intensity remained in the small to moderate range, which is plausible when compared with effect sizes from previous meta-analyses.[11,14] However, effect sizes for function-related outcomes in our study were large (eg, "pain-related activity hindrance"). This is even more significant in the light of an overall decrease of the objectively measured functional status (ECOG) over the course of the study. Importantly, differences in functional outcomes between the IG and the CG also appeared to be clinically important, which means that testing the effect in a larger study seems to be worthwhile. Previous studies show that function-related outcomes may be more important for patients than pain intensity.[16,19,42] This means that the improvement of outcomes like pain-related function and self-efficacy is a highly valuable contribution of the ANtiPain intervention to cancer pain treatment. The lack of statistical significance on functional outcomes is most probably due to the small sample size and will be established when doing a larger effectiveness study. These results will build the basis for the statistical planning of a larger effectiveness study in which pain intensity may still remain a secondary outcome. However, the larger study may be powered for assessing pain-related function as primary outcome as well as pain-related self-efficacy.

Opioid Intake

It has previously been supposed that the increase of opioid intake is a key benchmark for adequate cancer pain treatment.[2] Notably, in this study, effects were achieved even though over the course of the study, opioid doses of patients in the IG decreased compared to patients in the CG.[11,14,43] This is surprising at first sight. However, it could be explained that in our patient population with a high proportion of patients suffering from potentially transient treatment-related cancer pain (ie postoperative pain), patients were empowered by active self-management to reasonably adapt opioid doses to the actual need by active self-surveillance and focused patient-physician communication. The fact that patients in the IG used less opioids over time may also reflect that strategies beyond knowledge transfer of biomedical and pharmaceutical aspects of pain are extremely important in cancer pain management.[14,44]

■ Implications and Conclusions

Despite low functional status, 2 of 3 eligible patients were willing to participate in the study. The core effects of the interventions seem to involve function-related outcomes as well as self-efficacy. Because these effects are most meaningful for patients with cancer-related pain, the contribution of ANtiPain to physician-based pharmaceutical cancer pain management may be exceptionally valuable. Therefore, ANtiPain may be a promising intervention to improve cancer pain management when integrated into clinical practice. A larger clinical effectiveness trial will be designed on the basis of the findings of this study, which will focus on function-related outcomes and self-efficacy.

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