Pilot study to test the feasibility and pre-test the efficacy of the German language adapted PRO-SELF© Plus Pain Control Program, an educational intervention directed at patients and their family caregivers to reduce cancer pain and related symptoms (PEINCA)

Antje Koller, MNS.[1]; Sabina De Geest, PhD, RN, FAAN, FRCN[1]; Christine Miaskowski, PhD, RN, FAAN[2]; Professor Dr. med. Oliver Opitz[3]; Elisabeth Spichiger, PhD, RN[1]

[1]Institute of Nursing Science, Basel, Switzerland
[2]Department of Physiological Nursing, School of Nursing, University of California San Francisco, USA
[3]Tumorzentrum Ludwig Heilmeyer - Comprehensive Cancer Center Freiburg, Germany

Background

- Despite effective treatment options, pain control is not adequate in over 40% of cancer patients.
- For optimal pain management, patients and their family caregivers (FCs) need to use self care strategies on a daily basis.
- For this study the PRO-SELF© Plus Pain Control Program (PCP), developed at the University of California San Francisco was translated, culturally adapted and advanced on the basis of two prior studies[1,2], with the goal to increase its effectiveness.

Aims

- With this mixed-methods pilot study feasibility and effectiveness of the advanced PRO-SELF© Plus PCP will be tested, in order to prepare an adequately powered larger randomized controlled trial (RCT).
- In a qualitative sub study experiences of patients and their FCs with the PRO-SELF© Plus PCP will be analyzed.

Methods

- Design: Pilot-RCT (PRO-SELF© Plus PCP versus standard care with no standardized cancer pain patient education)

Patients und setting

Quantitative part:

- Sample: A convenience sample of 60 adult oncology outpatients (and their FCs if applicable) with cancer related pain ≥ 3 (0 = no pain; 10 = worst imaginable pain) will be recruited at the outpatient and radiotherapy departments of the Tumorzentrum Ludwig Heilmeyer – Comprehensive Cancer Center Freiburg
- Data collection: July 2009 – December 2010

Qualitative part:

- Sample: 10-15 patients of the intervention group

Intervention

- 3 key strategies: Information, skill building, and coaching
- 10-week educational program
- Structured components: Pain diary, weekly pillbox and instructions how to communicate about pain
- Individually tailored components: Academic Detailing, based on experiences and knowledge of patients and their FCs; individual coaching; setting of personal goals

Timetable

	2008	2009	2010	2011
Phase 1: Preparation of Pilot study (finished)				
Phase 2: Pilot study				

Variables and measurement

- Primary outcome: Patient reported pain intensity (numeric rating scale 0 = no pain to 10 = worst imaginable pain) measured daily during the 10-week program at weeks 14 and 22 after baseline.
- ***Secondary outcomes*:** Pain related knowledge[3], pain related interference of daily life activities[4], analgesic intake[1], pain treatment related symptoms[1] (with focus on constipation), quality of life[5]
- ***Covariables*:** Depression[6], anxiety[6], fatigue[7], functional status[8], cognition[9], other cancer related symptoms[10], self efficacy[1]
- ***Data collection qualitative study:*** After the 10-week program qualitative interviews are conducted

Data analysis

- Effect sizes for main effects, group- and group-by-time-interaction will be calculated for a longitudinal linear mixed model
- Qualitative interviews will be analyzed using content analysis[11]

Preliminary experiences in conducting trial

Response rate 30%:

- Most frequent reasons for refusal:
  - too many appointments already
  - do not need help
  - do not want study

→ Recruitment period extended

Attrition rate 36%:

- Reasons for drop out:
  - too ill / disease progression
  - too much effort
  - death

Recruitment and retention of oncology pain patients is challenging due to organizational and patient related factors

Patient related factors	Organizational factors
• disease status • prevailing other symptoms (nausea/emesis, fatigue, …) • too busy during treatment of disease • patient related barriers to pain management	• patients are allocated to clinics by disease not by symptoms • focus of health care professionals on treatment of disease → lack of comprehensive symptom assessment in routine care → lack of standardized documentation of symptoms

Qualitative results: Intervention patients who stayed in the study were very satisfied with the program.

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