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)

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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 and 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

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 knowledge1,2, pain related interference of daily life activities2,3,4, analgesic intake1,5, pain treatment related symptoms1 (with focus on constipation), quality of life5,6,7,8,9,10, self efficacy1
• Covariables: Depression1, anxiety6, fatigue2, functional status3,4, other cancer related symptoms11,12,13, self efficacy1
• 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 analysis11

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

References:

Variables and measurement

<table>
<thead>
<tr>
<th>Patient related factors</th>
<th>Organizational factors</th>
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<tbody>
<tr>
<td>• disease status</td>
<td>• patients are allocated to clinics by disease not by symptoms</td>
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<tr>
<td>• prevailing other symptoms (nausea/emesis, fatigue, ...)</td>
<td>• focus of health care professionals on treatment of disease</td>
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<td>• too busy during treatment of disease</td>
<td>• lack of comprehensive symptom assessment in routine care</td>
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<td>• patient related barriers to pain management</td>
<td>• lack of standardized documentation of symptoms</td>
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Timetable

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<tr>
<th>Phase 1: Preparation of Pilot study (finished)</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
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<td>Phase 2: Pilot study</td>
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