











PROAKTIV: A cluster randomized trial of systematic palliative needs assessment and care in general practice

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Goal

The goal of this study is to determine the effectiveness of a systematic palliative care approach in general practitioner (GP) practices.

Research questions

- 1. Does a systematic palliative care approach improve satisfaction with the quality of care as perceived by patients, family caregivers and community care providers?
- 2. Does a systematic palliative care approach in GP practices decrease use of hospital services and costs during the last six months of life in patients with advanced disease?

Methods

Study design: This study is a cluster-randomized trial of GP practices. Practices will be randomized to a systematic palliative care approach or to usual care.

Study setting: The study setting will be the Canton of Bern, in urban and rural regions with specialist palliative care mobile teams.

Intervention: The systematic palliative care approach versus usual care.

<u>Population:</u> Patients will be eligible to participate in this study if they have an advanced illness. Patients should live at home or in a nursing home, be 18 years of age or older, and be able to communicate adequately in German. The family caregiver of the patient will be eligible when he or she is 18 years old or older, and is able to communicate adequately in German.

<u>Patient selection:</u> Patients will be identified by the GP and the SPITEX using the "surprise question" combined with an indication for SPITEX assistance.

<u>Data collection</u>: Study data will be extracted from hospital administration databases (including hospital costs and ICU visits) and from study questionnaires (see table 1).

Qualitative study: Additionally a nested qualitative study will be performed to provide an in-depth understanding of patients' and families' preferences, needs and experiences.

Table 1: Overview of questionnaires and collection times

Measure	Questionnaire filled out by:	At baseline	At follow-up (every 2 months until end study or patient is deceased)	One week after patient is deceased	Four months after patient is deceased
Baseline questions	Patient and family caregiver	Yes	No	No	No
FACT-G	Patient	Yes	Yes	No	No
POS	Patient and/or family caregiver	Yes	Yes	No	No
FAMCARE	family caregiver	Yes	Yes	No	Yes
Distress thermometer	Family caregiver	Yes	Yes	No	Yes
Stanford HCU	Patient or family caregiver	Yes	yes	No	yes
Hospital administration data	Hospital administration personnel	No	No	Yes	No
Characteristics GP including Palliative care experience at start study	GP	Yes (1 time at inclusion GP)	No	No	No
Satisfaction with care- questionnaire	GP	No	No	Yes	No
Place of death and advance directives	GP	No	No	Yes	No
Qualitative interview	Sample of ±10 patients and ±10 family caregivers	No	One time (after 1st follow up questionnaire)	No	No

Fact-G=Functional assessment of cancer therapy: General, POS= palliative care outcome scale, FAMCARE=questionnaire to measure satisfaction with (palliative) care from the perspective of the patient and family, Stanford HCU= Stanford Healthcare Utilisation, GP = General practitioner

Expected results

- Increased satisfaction of patients and family in terms of coordination, anticipation and continuity of care, communication and feeling safe.
- GPs' increased satisfaction specifically in terms of interprofessional teamwork, advance care planning, and prevention of out-of-hours emergency situations.
- Decreased per day hospital costs and decreased number of ICU visits.

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