

Please note that this is a previous version of the lay summary.  
Since the study is not finalized yet, this version does not yet include the final results, as well as the significance of the results for science and practice. Thank you.

## Lay Summary

### A structured early palliative care intervention for patients with advanced cancer – a randomized controlled trial with a nested qualitative study

## Project team

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## **1. Background**

The diagnosis of recurrent or progressive cancer is a very stressful moment for patients and families. From literature it is known that health professionals usually avoid addressing and discussing “bad news” in terms of prognosis and potential outcomes including dying. Patients and family caregivers, however, are usually willing to discuss problems and challenges in advance, in order to be prepared in case of deterioration. It has been demonstrated that advance care planning or end of life discussions improve the quality of life and may even prolong the life expectancy of patients with advanced cancer possibly due to less aggressive treatment in the last months or weeks of life. Therefore, we initiated a new study to determine whether providing information early to patients with advanced diseases could improve their distress levels, their survival, and their quality of life. Early palliative care was provided through a structured discussion and planning of the patient’s problems and challenges in order for them and their families to be better prepared in case of deterioration.

## **2. Goals of the project**

The main goal of this study was to determine whether an early palliative care intervention structured by SENS (a systematic, problem-based assessment structure with the themes: Symptoms, End-of-life decisions, Network and Support of the family) in addition to standard oncology care would be more effective in relieving distress in patients with advanced cancer than standard oncology care alone. Secondary goals were to determine whether the SENS intervention could improve the patients’ quality of life, the patients’ overall survival, the distress of caregivers, as well as reduce health care costs and the intensity of care.

The study also focused on describing recruitment barriers specific to early palliative care, since they can provide valuable information not only for research purposes, but also in terms of how these early palliative care conversations can be implemented into formal clinical practice.

Lastly, through interviews with some of the patients who had participated in the conversations, the goal was to identify any shortcomings and/or advantages of the SENS intervention.

## **3. Methods**

The study was designed as a randomized controlled trial with a nested qualitative part. This means that after people accepted to participate, they would be randomly allocated to one of two groups: one with the SENS structured conversation plus standard care (called the intervention group), or to a group where only standard care was provided (known as control arm). We invited patients to participate if they were 18 years of age or older and diagnosed with advanced cancer (6 different types) within the previous 16 weeks. Patients could be recruited from three Swiss hospitals (Inselspital Bern, Kantonsspital Luzern, Kantonsspital St. Gallen).

We also systematically documented barriers to including patients into the study, as well as reasons why eligible patients eventually did not participate in the study.

### **Intervention group**

Patients in the intervention group received palliative care with the structured approach according to the SENS structure which is based on a model of care that goes beyond physical symptoms and focuses on other dimensions of importance, such as psychological and social aspects. This model is called the bio-psycho-social-spiritual model of care. The structure also incorporates the WHO definition of



palliative care, as well as the National Comprehensive Cancer Networks (NCCN) Practice Guidelines for Palliative Care. The SENS structure enables the assessment of areas and complexity of concerns from the patient perspective, determines the priority and structures the support needed. The intervention is performed by palliative care physicians and nurses collaboratively. It is generally utilized as a baseline assessment, but it can also be used between routine visits. Patients in this group were also given the same treatments that they would have received if they had not participated in the study. This means that they received standard oncology care throughout the study period.

#### Control group

Patients in the control group received only routine oncology care throughout the study period. This incorporates a routine assessment according to the standard protocols of the Swiss Group for Clinical Cancer Research which assesses overall symptoms. According to established practice, participants in this group could meet with the palliative care service on request of their treating team, or if they so wished.

All patients completed questionnaires about distress, quality of life, health care utilization, physical symptoms, psychological, emotional and spiritual problems, and information and support needs at the beginning of the study. This process was repeated every other month over the first six months using postal questionnaires. If patients forgot to send back the questionnaires, they would receive a phone call, and the questionnaires were completed over the phone. After the first six months in the study, patients were not asked to complete the questionnaires anymore, and only their survival status was assessed every six months for the following 18 months. If the patient died during the study, place of death, health care utilization, and costs of treatments provided to them were assessed.

#### 4. Results

Until July 31<sup>st</sup> 2017, 150 patients had participated in the study. Based on protocol the follow-up-data will continue to be collected until the end of April 2018. Statistical analyses will be performed after all study periods have finalized, and data about the study will be published and socialized in academic and public presentations. First results show improved stress-levels (primary outcome) 2 months after intervention.

As for the qualitative part of the study, all 20 interviews with patients in the intervention group have taken place. An analysis of the content of the interviews is ongoing but so far it has been identified that patients welcome the intervention and have found it useful in many different ways.

#### 5. Significance of the results for science and practice

Since we have not collected all data yet, we are unable to know whether the SENS structured conversations do change patients' levels of stress, their survival, or their quality of life. However, given the acceptance of SENS by health professionals, political bodies, and the patients themselves, we continue to implement the SENS in different settings, such as in Primary Care.

