

PRoF Award abstract – Call 2018

Deadline for submission: Thursday March 1st 2018 (12 o'clock noon)

Please send to: PRoF-Award@uzgent.be.

<IPaC: Integrated Palliative Care>

1. Research Outline

Acronym	IPaC
Project name in English	Integrated Palliative Care
Pitch (1 sentence)	“A new model of palliative care (early palliative care integrated in oncology care) improves the quality of life of patients with advanced cancer as well as that of their informal caregivers”
Executive summary (max. 10 lines)	
<p>Please provide an executive summary of the project, maximum 10 lines</p> <p>Patients with advanced cancer suffer from severe symptoms and have complex needs but this is often underestimated. These patients are often treated in the outpatient setting which also leads to increasing caregiving requirements for the caregivers and has a negative impact on their quality of life. Palliative care is an approach that can mitigate these problems. However, in usual practice, palliative care is only provided late in the course of the disease of the patient when death is imminent. We conducted a randomized controlled trial of early integration of palliative care in oncology care and assessed the effect on the self-reported quality of life of patients with advanced cancer and their caregivers. We found significant increases in the quality of life of patients and that of their caregivers. We want to develop an implementation guideline for integration of early palliative care in oncology care in Flemish Hospitals with the funding of the PRoF Award.</p>	

2. Cause and context of the research

Cause

Patients with advanced and incurable cancer typically suffer from a multitude of severe symptoms, which often appear to be underestimated and underdiagnosed¹. This underestimation can be explained by a lack of expert knowledge in symptom management, limited time to tend to patients and a strong orientation among health care providers towards cure or life-prolongation rather than quality of life, leading to lack of therapeutic pertinacity². Additionally, patients with advanced cancer are more and more often treated in the outpatient setting which leads to increasing caregiving requirements for informal caregivers. Family caregivers and friends often are poorly prepared and have little knowledge on how to fulfil these complex needs.³ Research shows that providing care for cancer patients negatively influences emotional well-being, physical health and overall quality of life (QOL) of caregivers⁴⁻⁷. Palliative care, defined as ‘an approach that improves the quality of life of patients and their families facing life-threatening illness through prevention and relief of symptoms’⁸ is an approach that can mitigate these problems. Palliative care emphasizes the well-being of patients and families coping with a serious medical illness at any point along their disease trajectory, whether the goal is living with cancer as a chronic disease, or responding to progression of illness. However, although early access is inherent in the definition of palliative care by the World Health Organisation⁸, in usual practice it is typically only provided late in the course of the disease of the patient, when disease-modifying treatments have been unsuccessful, no treatments can be offered, or when death is imminent⁹.

New model: Early Palliative Care

Recent studies question the traditional model and advocate for early integration of palliative care¹⁰⁻¹² that begins at the time of the diagnosis of advanced cancer or shortly after. In these studies, early palliative care is combined with anticancer treatment such as chemotherapy or radiotherapy and it involves empathetic communication with patients about their prognosis, advance care planning, and symptom management¹³. Up until today, five^{10,11,14-16} trials have indicated that early palliative care interventions have beneficial effects on quality of life of patients with advanced cancer. Some trials also found additional benefits for the caregivers of the patients: improved satisfaction with care¹⁷ and improved mood^{18,19}. However, these trials (six out of seven) have been conducted in the United States and Canada. Before early integration of palliative care in standard oncology care can become part of general clinical practice, this approach has to be tested in different centres and most importantly in different countries where standard oncology care and/or palliative care may be different.

Early Palliative Care in Belgium

Some of the previously mentioned studies of early palliative care suggested that the beneficial effect on quality of life is due to the increased focus on psychosocial support and coping of early palliative care compared with usual care⁹. In Belgium, psychosocial care is standardly offered to cancer patients since the implementation of the "National Cancer Plan". This specific multidisciplinary context²⁰ in usual oncology care in combination with the fact that the proportion of patients with cancer referred to palliative care in Belgium is approximately 56%, with a median time to first referral before death of 16 days²¹, led us to initiate a study on early and systematic integration of palliative care into oncological care. We designed a phase III randomized controlled trial to assess whether patients and their caregivers randomly assigned to early and systematic integration of palliative care in this specific context of usual care would show more benefit compared to the patients and caregivers assigned to usual oncology care. Patients with advanced cancer and a life-expectancy of one year were eligible for this study. Patients assigned to the intervention group met with nurses of the palliative care team of the University Hospital Ghent within three weeks of enrolment. Consultations were organized monthly until death to coincide with a planned hospital oncology consultation. The palliative care physician visited patients mostly on a referral from the palliative care nurse. The content of the palliative care consultations is based on the holistic approach of palliative care.

The intervention consisted out of four components:

- (1) training sessions by oncologists aimed at informing the palliative care nurses and the palliative care physician on specific cancer treatments typically administered early in the disease trajectory, and on the possible side effects of these treatments.
- (2) semi-structured monthly palliative care consultations by palliative care nurses, focusing on illness understanding and illness perception, symptom burden, psychological coping, spiritual coping and medical decision-making that allowed for an individual approach with patients.
- (3) additional monthly symptom assessment by the palliative care nurses through the use of the Edmonton Symptom Assessment Scale (ESAS²²).
- (4) integration into oncological care through participation of the palliative care nurses in multidisciplinary oncology meetings and reporting in the electronic patient file.

To assess the effect of early integration of palliative care on oncology care, 186 patients with advanced cancer and 115 caregivers treated at the University Hospital Ghent were included in this trial. All participants filled out questionnaires related to quality of life, mood and illness understanding at baseline, 12 weeks and six-weekly thereafter until death. Oncologists and general practitioners were

asked to complete a validated questionnaire to collect information about advance-care planning and end-of-life decision making. Information on the type of treatment, time of death, intensity of chemotherapy and number and duration of hospital admissions were collected from the medical file^{23,24}.

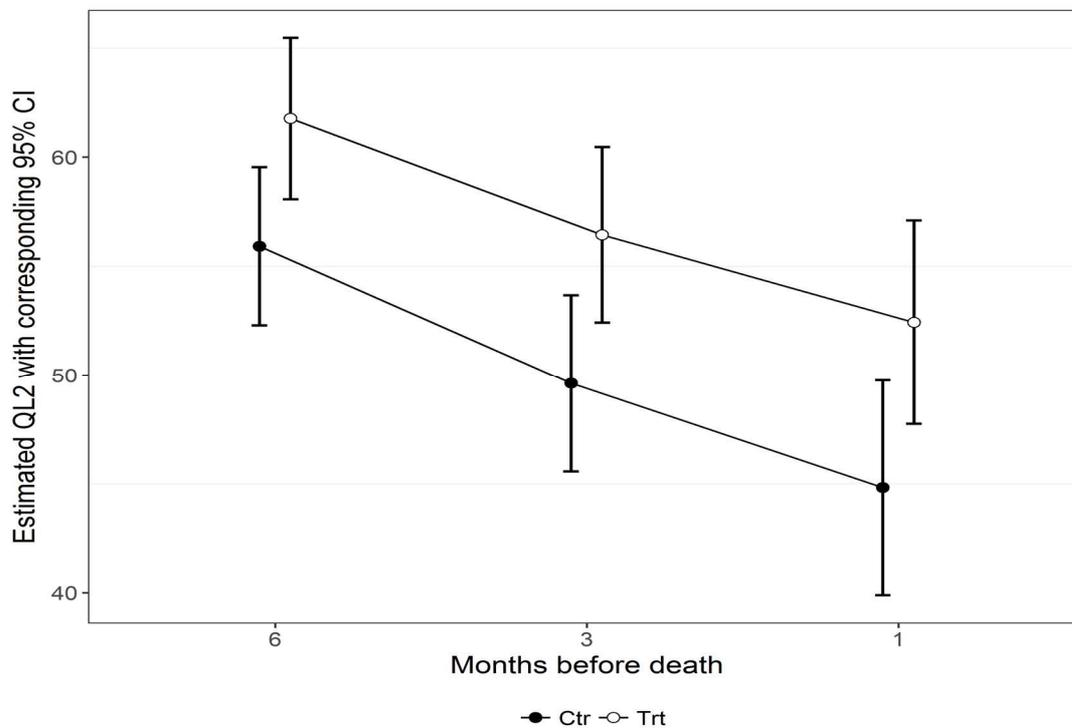
3. Innovation results achieved

Quality of life of patients

Patients with advanced cancer receiving early palliative care report a significantly higher overall quality of life at 12 weeks and 18 weeks after baseline. These are robust findings since these results are confirmed with two internationally validated questionnaires (EORTC QLQ C30 and McGill Quality of Life). The results have recently been published in February 2018 in the Lancet Oncology²⁴

We also found that patients receiving early palliative care report sustained significantly improved overall quality of life at 6 months, 3 months and one month prior to death. See Figure 1.

Figure 1. Quality of life (EORTC QLQ C30) of patients at six, three and one month before death

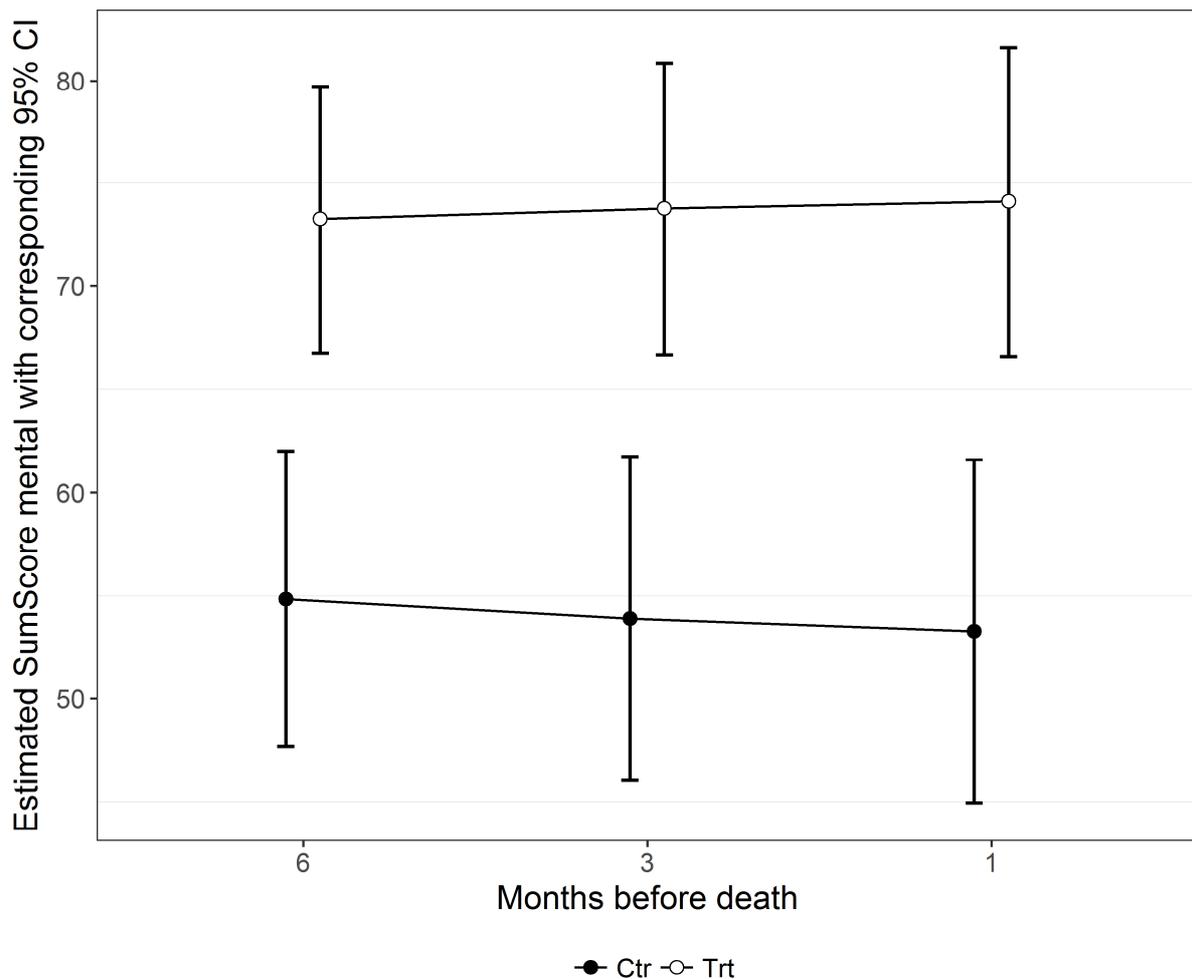




Caregivers

Caregivers of patients receiving early palliative care do not report a statistically significant benefit of the physical component or the mental component of quality of life (measured by the Short Form 36) at 12 weeks after baseline compared to caregivers in the control group. These caregivers, however, show a significant benefit in the mental component of quality of life at 18 weeks after baseline. This beneficial effect in the mental component of quality of life of caregivers receiving early palliative care is sustained at 6 months, 3 months and 1 month prior to the death of the patient (See Figure 2.)

Figure 2. Mental Component of quality of life (SF-36) of caregivers at 6 months, 3 months and 1 month prior to death of the patient



End-of-life care

The first study on early palliative care, which is considered as a landmark-study in this field and which formed the basis of this trial, also found a significant impact on end-of-life care. We have collected data regarding end-of-life care, advanced care planning and end-of-life decision making but these data still have to be analyzed.

Project of the PROF Award: valorization of the results of the study

Our IPaC project has shown that early palliative care integrated in oncology care has a significant beneficial effect on the quality of life of patients with advanced cancer and on that of their informal caregivers. We want to develop a tool (implementation guideline) for integration of early palliative care in oncology care in Flemish Hospitals. This tool will be developed with the funding of the PROF Award.

This tool will incorporate three major aspects:

- ❖ A manual for oncology teams on how and when to introduce early palliative care to patients with advanced cancer
- ❖ An action plan for palliative care teams on how to implement the four major components of our intervention of early integrated palliative care:
 - Training: how to organize a training by a treating oncologist on specific cancer treatments typically administered early in the disease trajectory, and on the possible side effects of these treatments.
 - Semi-structured consultation: how to conduct these consultations
 - Symptom assessment: how to use and interpret the ESAS during consultations
 - Integration of palliative care in oncology care: how to integrate the care in usual oncology care through for example referral checklists, etc.
- ❖ A website where specific documents of the tool can be accessed and where support is provided through up-to-date frequently asked questions (FAQ) and a contact form that allows for individual consultancy by the IPaC team.

This tool will be developed by organizing a project group that involves the experts of the IPaC project and members of the oncology team and palliative care team of three additional regional hospitals to allow for input from hospitals with different organizational structures from the University Hospital Ghent.

4. Link to the PRoF values

The IPaC project integrated a patient-centered approach of early palliative care into a tumour directed treatment approach in order to provide **minimal comfort** for advanced cancer patients and to enhance their overall quality of life. This improvement was achieved by providing semi-structured consultations with the palliative care nurse of the palliative support team which included aspects such symptom management, illness understanding, psychological, social and spiritual wellbeing and medical decision-making.

This semi-structured format of the consultations was chosen to allow **flexibility** in the topics discussed in order to address all needs and wishes of each individual patient. The goal of the first consultations was often to establish rapport with the patient and family, allowing to build up a **secure** relationship with the patients which is needed in order to bring up more difficult topics, such as prognosis and end-of-life decision making. The palliative care team also has a lot of attention to the **privacy** of patients and their families. The palliative care nurses know the hopes and desires of patients and their families and maintain confidentiality of patient information whilst appropriately disclosing information with consent of the patient about expressed needs and desires to other key players such as the oncology team.

Our project also shows that early integrated palliative care has a positive impact on the mental aspect of quality of life of the informal caregivers of patients. In this project, an informal caregivers was defined as a person that either lived with the patient or had in-person contact with the patient at least twice a week and who would likely accompany them to the hospital. In practice, this varied from spouses, friends to children of patients who benefited from this new model of care. This is congruent with the **inter-generational** value. Last, in contrast to the concern of many physicians that palliative care referral may be overwhelming for patients or diminish hope, our study shows that palliative care consultations are acceptable to patients who are early in their disease trajectory. This project has an important role in the **anti-stigmatisation** of palliative care, it shows that palliative care can offer more than terminal care for cancer patients.

5. Applicable IPR rules

Not applicable

6. Information on the partners

The IPaC project was carried out by the End-Of-Life Care Research group from the Vrije Universiteit Brussel and the University Ghent in combination with the department Medical Oncology, the Digestive Oncology Unit of the Department Gastroenterology, the unit Thoracic Oncology of the Department of Respiratory Medicine and the Palliative Care Team of the University Hospital Ghent. This project is an inter university and interdisciplinary collaboration since researchers, oncologists, an anesthesiologist, palliative care nurses and psychologists took part in the design and implementation of this project.

End-of-Life Care Research Group (University Ghent and Vrije Universiteit Brussel)

The End-of-Life Care Research Group is a joint research group of the Ghent University and the Vrije Universiteit Brussel (www.endoflifecare.be) that has acquired internationally recognized expertise in the domain of palliative and end-of-life care research, namely in measuring incidences of medical end-of-life decisions, involvement of patients in end-of-life decisions, describing characteristics of end-of-life care nationwide, examining accessibility of palliative care, studying (determinants of) place of death and place of care at the end of life, development of palliative care quality indicators, end-of-life care in dementia, etc. The research group is a multidisciplinary group with about 40-50 members with scientific backgrounds in sociology, psychology, health sciences, ethics, medicine and nursing. The research group has expertise on quantitative survey research as well as qualitative research methods. The group is being led by Prof. Luc Deliens, an experienced researcher, Co-Chair Research Network of the European Association for Palliative Care (EAPC RN) and Member of the Royal Academy of Medicine of Belgium and by Prof. Simon Van Belle, former Faculty Coordinator of the European Society of Medical Oncology (ESMO) in palliative care. Yearly 40-50 scientific papers are published in scientific journals (mostly D1/Q1; recently 5th Lancet paper has been accepted, next to 2 x NEJM, 3 x JAMA). The research group has also resulted in 37 PhD's and has about 25 ongoing PhD's.

The department of Medical Oncology and Palliative Care of the University Hospital of Ghent

This department of Medical Oncology and Palliative care of the University Hospital of Ghent, led by Prof. V. Cocquyt, is an ESMO Designated Centre of Integrated Oncology and Palliative Care. The department was created in 1992, when Prof. Simon Van Belle moved to the University Hospital. The Palliative Care unit has been part of this department since 2006. The department of Medical Oncology is integrated in the Oncology Centre which is composed of different diagnostic, medical, radiotherapy and surgical departments. The department has performed national and international research on different aspects of cancer therapy including supportive care, chemotherapy of cancer, basic research in breast cancer, etc. It has a ISO 9001:2008 certification since 2006. The department has played a key role in the development of the multidisciplinary approach of oncology in Belgium through the Oncology Centre involved in all types of cancer. It has an important role in teaching Palliative Care and Oncology to graduate and postgraduate students. Basic research is focused on breast cancer, translational and clinical research on all types of solid cancers.

The Digestive Oncology Unit of the Department Gastroenterology

The Digestive Oncology Unit, part of the Service of Gastroenterology in the University Hospital Ghent, is led by Prof. K Geboes and Prof. S Laurent. Prof K. Geboes was closely involved in the IPaC project and is an active member of the European Organisation for Research and Treatment of Cancer and the Belgian Group of Digestive Oncology. The Digestive Oncology Unit is also involved in major early phase I, phase II and III clinical trials with new therapeutic targets.

The Thoracic Oncology unit of the Department of Respiratory Medicine

The Thoracic Oncology Unit of the Department of Respiratory Medicine, led by Prof. V. Surmont who was closely involved in the IPaC project, collaborates with related oncological disciplines -thoracic surgery, radiotherapy and medical oncology. The Thoracic Oncology Unit has a broad portfolio of translational, diagnostic and interventional trials, either investigator-initiated or industry-initiated and promotes several pivotal multicentre phase 3 trials.

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Note:

If your project is selected as laureate for the Award Symposium, a powerpoint presentation that reflects the project as suggested will be required (in advance), including a future plan how the funding will be used.

If your project is selected as the winner of the Award, you will be invited to present the results achieved thanks to the award during the Award Symposium of the next year.



Addendum: Contact information

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