Jury

Chair:	Prof. dr. Ivo Lambrichts, *Hasselt University*
Promotor:	Prof. dr. Johan Hellings, *Hasselt University*
Co-promotor:	Prof. dr. Patrick Vankrunkelsven, *KULeuven*
Jury members:	Prof. dr. Frank Buntinx, *KULeuven and Maastricht University*
	Prof. dr. Jeroen Mebis, *Hasselt University*
	Dr. Paul Bulens, *Jessa Ziekenhuis*
	Prof. dr. Walter Sermeus, *KULeuven*
	Prof. dr. Marjan van den Akker, *KULeuven and Maastricht University*

Table of Content

1 Chapter

Source: CD cover Stromae; Globocan 2012 Map production IARC

General introduction

THE IMPACT OF CANCER

The epidemiological impact

Cancer is a disease with a huge impact. According the latest global statistics there were 14.1 million new cancer cases in 2012 [1]. This number is expected to increase to 24 million by 2035. Cancer is one of the leading causes of death worldwide, accounting for 8.2 million deaths in 2012. With 321.1 incident cases per 100.000, Belgium belongs to the group of countries with the highest cancer rates in the world (Figure 1) [1].

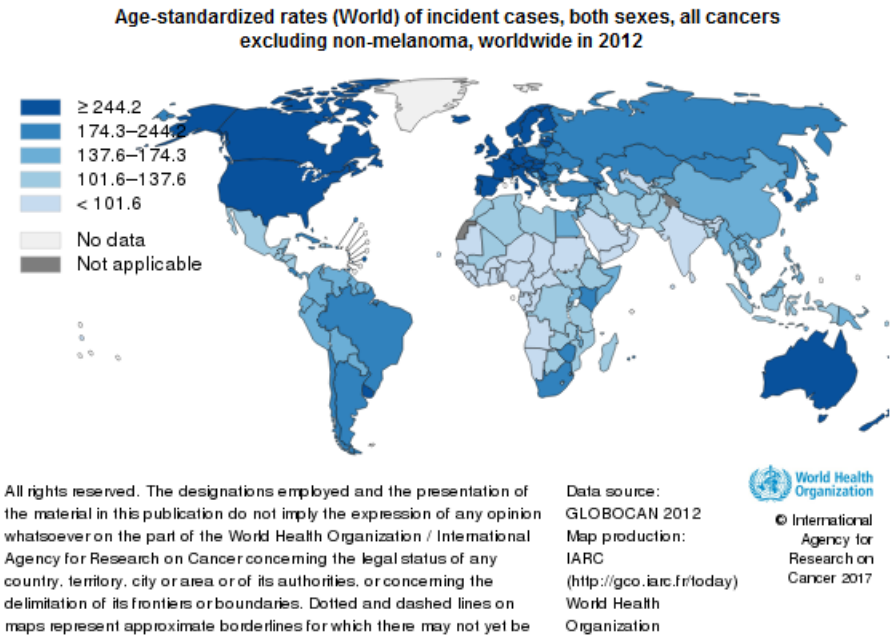
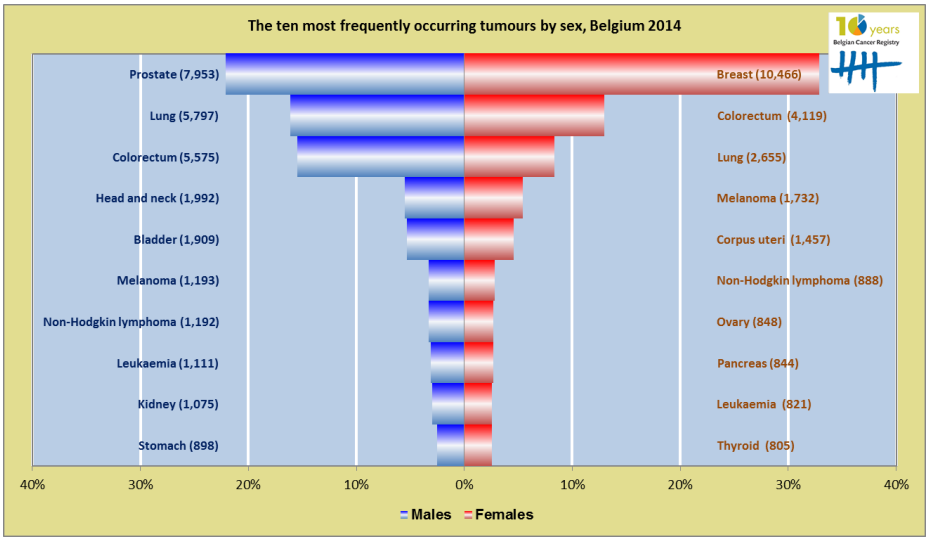


Figure 1 Worldwide cancer incidence 2012

In 2014 67.820 new cases of cancer were diagnosed in Belgium, of which 35.948 in men and 31.872 in women [2]. Prostate, lung, colorectal and breast cancer are the most frequent tumors (Figure 2).



Source: Belgian Cancer Registry

Figure 2 Ten most frequent tumors in Belgium 2014

Approximately one third of men and 25% of women will get diagnosed with the disease before their 75th birthday. Partly because the aging of the population, a significant increase is expected, with an estimated incidence of 95.001 cancer diagnoses in 2050 [2]. Currently, the 5-year relative survival proportions are 59% in males and 69% in females. Due to earlier detection and successful therapeutic approaches more and more patients survive or live longer with cancer. According the statistics of 2013 331,776 persons (3% of the total Belgian population) were alive after being diagnosed with cancer in the last 10 years [3].

The impact on patients' well-being

Biopsychosocial approach of well-being

For most cancer patients the impact goes way beyond the threat of one's physical health, also placing a burden on one's psychosocial health. The roots of the term 'psychosocial health' lie in the World Health Organization's (WHO)

definition of health as "a state of complete physical mental and social well-being, and not merely the absence of disease and infirmity" [4].

Before, the prevailing model in medical science was the biomedical model, in which disease was reduced to a problem in biological processes. However, behavior and environment affect the onset, progress and perception of disease. And disease, or illness also affect the psychological well-being and social relationships. George Engel has therefore extended the biomedical model with psychological and social aspects to the biopsychosocial model [5]. The biopsychosocial model displays a dynamic and interactional vision that explains the mutual influence of 'body' and 'mind' (Figure 3). Concrete examples can be found in the section 'Experienced consequences' (Table 1).

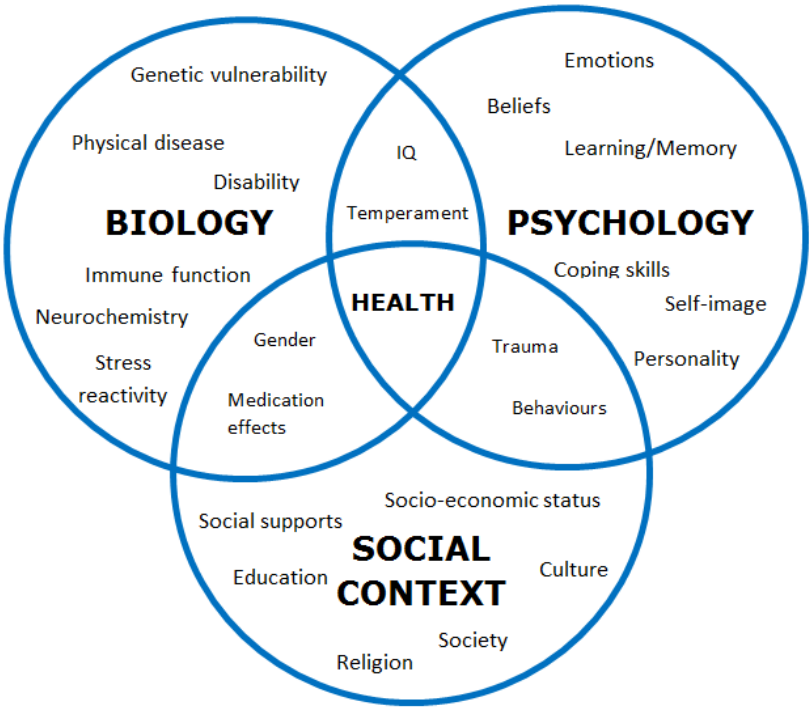


Figure 3 The biopsychosocial model of health
With this figure, I do not pretend to give an exact and exhaustive summary, but rather an illustration of the multitude and intertwining of biopsychosocial dimensions and elements that play a role in health.

In Belgium we only have one term for 'disease', though, in the English literature we see that the multidimensional characteristics of health and disease are reflected. Hofmann refers to the "triad disease-illness-sickness"[6]. This triad describes the approach of the same phenomenon from different perspectives:

- 'DISEASE' :
  One goes to the physician with symptoms, complaints or problems (Physical - Organic).
- 'ILLNESS':
  One is suffering from symptoms, feeling sick (Psychic - Phenomenologically).
- 'SICKNESS':
  Due to the illness the person gets the social role of the sick patient in the community, often linked to different expectations, rights and obligations (Social - Behavioral).

Engels' biopsychosocial model, that describes these multidimensional characteristics, brought a lasting contribution of widening the perspective on health [7]. The model was a call for reassessment of the way patients are understood and to broaden the domain of medical knowledge to meet the care needs of each patient [8].

Cancer patients' well-being

Experienced consequences

Due to the disease and corresponding treatments patients and survivors often struggle with multifactorial consequences of physical, psychological, and social nature. These are discussed below and illustrated with testimonies of patients and their relatives in Table 1.

Patients may experience physical consequences like pain, hair loss, nausea, weight gain/loss, fatigue, bowel-function issues and sleeping difficulties varying from short to long-term in nature [8, 9, 10, 11]. Physical problems can limit patients in their social participation, recreational activities and for example fertility issues can jeopardize their plans for the future [12]. Fatigue as a

consequence of disease and treatment appears to have a negative impact on all aspects of patients quality of life (QOL) [13, 14].

Cancer patients' psychosocial health is jeopardized by emotional distress, fear of recurrence, memory changes, worries about the well-being of relatives, sexual problems, social issues, employment and financial difficulties, often resulting in supportive care needs [11, 15, 16, 17, 18, 19]. Some patients feel stigmatized as 'the sick one' by their social context and experience little support. Others do experience support in their personal context, but also perceives a need for information and support in their relatives [17]. Patients that develop severe psychosocial problems, mostly experienced psychological problems already earlier in life [20].

Care needs

Each cancer patient follows an own path of physical and psychosocial adjustment [21]. Due to the large diversity and multidimensionality in care needs, there is a need for a flexible and individually tailored care offer [18, 22]. In contrast to physical rehabilitation needs, cancer patients' and survivors psychosocial care needs are less discussed with hospital staff and general practitioners [17, 23]. The recognition and detection of issues in patients psychosocial well-being seems to be insufficient, partly because patients themselves do not spontaneously express them [24]. Patients prefer that healthcare professionals take the initiative for a conversation on psychosocial issues [25]. Results from several studies show that not all patients express needs for support in this area [18, 26, 27]. According to a study of Ernstmann et al. 18.9% of their study sample expressed unmet care needs for psychosocial support, while only 9.5% were actually using psychosocial services [26]. Shyness and reluctance of patients to bring up such issues can play an important role in this [21]. There is a presumption that the degree in which the patient receives information on support options influences their expression of care needs [26]. Routine discussion of potential psychosocial concerns and psychosocial support options could encourage this [17, 28].

Table 1. Cancer patients' (and relatives') testimonies on the impact of cancer, with indication of the elements from the biopsychosocial model.

Patients'(and relatives') experiences	Elements from the biopsychosocial model that were influenced
"My brother and I were living in a student house, but decided to move back home, and took care of our dad together with mum. Our time together was valuable, but I am not going to lie about it…his illness was terrible." *Thomas, cancer affected the membrane of his fathers' lungs* [1]	Family relations Emotions Trauma Social context
"As a patient I had moments that I was barbaric: I said things that I didn't mean, I cursed and tortured, I smashed the doors…and particularly…I scold Karel, while he was just trying to take care of me. But I didn't want help. Everyone had to leave me alone, it was MY cancer." *Nicole, had breast cancer, her husband died from bladder cancer* [1]	Behavior Partner relation Coping Self-Image Temperament
"It takes some adjustments in terms of sexual habits, but fortunately, penetration does not determine sexual satisfaction, even for those of the partner" *Mark, was treated for prostate cancer* [1]	Disability Body-Image Partner relation Sexuality
"If your mobility is limited, you risk to be somewhat isolated…. People who do not know you ask if you had an accident, and then you have to tell the story all over again. In the end, you prefer to stay at home" *Bart, his leg was amputated because of bone cancer* [1]	Disability Social context and contacts Behaviors
"I suffer from memory and concentration problems, and because I have little energy, I have to plan a day a lot more consciously. Therefore, I am looking for depth in life nowadays. It's about quality, not about quantity. I read more spiritual books and have deeper conversations now." *Gerjan, he had a large tumor in his chest* [2]	Memory Spirituality Treatment effects Personality
"My first thoughts went out to my children: 'they are too young to live without a mother'. For a minute there was panic, sadness, fear to lose all." *Marie-Christine, was diagnosed with breast cancer* [3]	Emotions Parenthood
"In that sense cancer made my life more beautiful. I don't wait for my retirement to enjoy life, I am doing it right now." *Chantal, was diagnosed with breast cancer with metastases in the liver* [3]	Behavior
"People are just like animals, they like to belong to the herd. Suddenly I didn't belong to the herd anymore, with my weird cancer. I was ashamed of my "female illness" *André (♂), was diagnosed with breast cancer* [3]	Emotions Gender Self-Image
"Living without Lesley was not an option for me. If she had to die, I was going with her. I dropped my hobbies and my sports, I immediately started 'preparing' her for her treatments, and a healthier lifestyle. I saw it as my duty. From the start I was firmly convinced that my wife and child were going to make it." *Andy, his wife was diagnosed with breast cancer during her pregnancy* [3]	Emotions Behavior Social role Beliefs

"Mum never talked about it herself: she doesn't like worst case scenarios. She didn't want to think about it, nor talk about it." *Hanne, her mother was diagnosed with breast cancer* [3]	Coping
"I have forgiven my body now, that was a milestone for me. I had to start a hormones cure and finally I came into the pre-menopause at my 21st." *Nadège, was diagnosed with breast cancer* [3]	Body-Image Fertility
"As a CEO I had the chance to decide if and how long I was able to work. Employees should have that opportunity to, but for the law you are sick or not, there is nothing in between." *Tom, was diagnosed with colon cancer* [4]	Socio-Economic Society
"I don't see the disease as a punishment. Allah wants to warn me, point me to the fact that I did not live enough by the rules (praying, wearing my headscarf,…). He wants to give me the chance to wash away my sins for a better place in the afterlife. If it is good for me, I want to cure. If it is bad for me, I don't. If I'm going to commit worse sins if I live longer, I'd rather die now." *Selma, was diagnosed with breast cancer* [3]	Religion Spirituality Culture Self-Image

Sources: [1] *Leven*, Kom op tegen Kanker, July 2016, nr71; [2] *Kracht*, KWF Kankerbestrijding, March 2014, nr24; [3] *Pink Ribbon magazine*, Edition 2011; Leven, [4] Leven, Vlaamse Liga tegen Kanker, April 2014, nr 62.

Quantity of Life & Quality of Life

Through time, improved medical therapies resulted in increased life expectancy, and so life prolongation of life or 'quantity of life' alone was no longer a scale for successful treatment anymore. Consequently, the importance of the concept of 'Quality of Life' emerged. Although there was much debate on the conceptualization and definition of QOL, most agree that QOL is a multidimensional construct, with the minimum domains of physical, emotional, and social well-being [29, 30, 31]. This successfully captures a persons' abstract evaluation of life based on the values this person has regarding the meaning of life. Measuring patients' QOL can serve for monitoring purposes, as an exploratory process to better determine the symptom relief or rehabilitation needs of cancer patients. There is growing interest in QOL instruments to aid patient-clinician interaction and policy decision making, as well as increased application as outcome measures in clinical trials [32]. For example, in studies where small differences were expected in the traditional outcomes (e.g. survival or disease-free survival), yet a large discrepancy is anticipated regarding toxicity and/or tumor-related symptoms.

QUALITY CARE

With the shift from the biomedical to the biopsychosocial model in health care, the debate on quality of care increased. The most cited and adopted definition of quality care is that of the Institute of Medicine (IOM). The IOM defined care quality as the extent to which care for individuals and the entire population increases the chance of desired outcomes and this according to current science [33]. This way the concept of quality entails a relationship between the outcomes of care, and the normative frame of reference [34]. Outcomes of care can be: health, disabilities, handicaps, mortality, perceptions of care, or structural properties. The normative frame of reference is generated by norms and values, such as professional criteria or standards, guidelines, expectations of patients, ideals or desires of society, and cultural values.

In the report 'Crossing the quality chasm: a new health system for the 21st century', the IOM defined six 'aims' to improve the delivery of care: safety, effectivity, efficiency, timeliness, equitability and patient-centeredness [33]. Patient-centered healthcare was defined as: "Health care that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients' needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care" [33]. This caused a paradigm shift from supply-driven to demand-driven approaches in health care. Regularly, healthcare systems are determined by the expertise of healthcare professionals and their estimates of what a patient needs, based on the diagnosed disease. This results in fragmentation of care, and often also inefficient use of limited resources in health care [33]. However, the last couple of years, one intends to focus more on the patient's disease experience, or the personal meaning of illness for the patient. This way, care can be delivered in line with the patient's demands or needs, in the pursuit of personal health. This demand driven approach not only focusses on the patient's needs, but also invites the patient to actively participate as a stakeholder in his care management. By sharing their experiences and reflections on care, patients can contribute in the co-creation of care [35]. Epstein et al. stated that patient-centered care results from interactions between patients (and their families), clinicians, and health systems [36]. To obtain real patient-centeredness in care, it is important to ensure that

patients are well-informed, and get the opportunity and the appropriate tools to give input from their perspective in this interactional process [37].

Cancer care for 'The Whole Patient'

International recommendations and guidelines

To address the impact of cancer on patients and their relatives, cancer care should be comprehensive, integrating the medical and the psychosocial approach during active treatment, as well as in follow-up. In 2008 the National Institutes of Health (NIH) asked the IOM to study the delivery of psychosocial services to cancer patients and their families. The IOM concluded that many services that were available remained untapped, because patients were often unaware that they existed or did not know how to access them [38]. A 'Standard of Care' was provided by the IOM to function as a mechanism to incorporate attention to psychosocial needs into daily cancer care (Table 2).

Table 2. IOM's Standard of care for cancer patients' psychosocial concerns and needs

'The Standard of Care'

All cancer care should ensure the provision of appropriate psychosocial health services by:
▪ Facilitating effective communication between patients and care providers.
▪ Identifying each patient's psychosocial health needs.
▪ Designing and implementing a plan that:
  ○ Links the patient with needed psychosocial services.
  ○ Coordinates biomedical and psychosocial care.
  ○ Engages and supports patients in managing their illness and health.
  ○ Systematically following up on, re-evaluating, and adjusting plans.

Abbreviations: IOM (Institute Of Medicine).

In the resulting report 'Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs' the importance was underlined for authorities to incorporate attention to psychosocial needs into their policies, practices, and standards addressing clinical health care. These policies, practices, and standards should

be aimed at ensuring the provision of psychosocial health services to all patients who need them [38].

As well in 2008, the Council of the European Union (EU) presented their conclusions on reducing the burden of cancer [39]. They acknowledged the significance of psychosocial aspects of cancer care and stated that "to attain optimal results, a patient-centered comprehensive interdisciplinary approach and optimal psychosocial care should be implemented in routine cancer care, rehabilitation and post-treatment follow-up for all cancers" (par.5), with an open invitation to all EU member states "to take into account the psychosocial needs of patients and improve the quality of life for cancer patients through support, rehabilitation and palliative care" (par.19).

In the last decades, this EU Council statement and other international recommendations and guidelines on routine screening of cancer patients' psychosocial distress and care needs were written [38, 40, 41, 42, 43, 44, 45, 46]. Along with other vital signs (temperature, blood pressure, pulse, respiratory rate and pain), distress was considered the 'sixth vital sign' that deserves follow-up in cancer care [47, 48, 49]. Insights retained from the follow-up of this parameter can lead to better modification of treatment or referral for supportive care [50].

Meanwhile, the landscape of cancer care has positively evolved. There is a growing consensus that psychosocial care should be integrated into the routine care of patients with cancer [51, 52]. Psychosocial-oncology has grown to become a multi-disciplinary specialty in research and practice, covering the psychological, social and behavioral dimensions of cancer. Specialists in the field conclude that psychosocial-oncology is on the rise, though its implementation is often still situational, ad hoc and poorly structured [51, 53, 54]. Many countries do not have a national program to integrate the preventative, medical an psychosocial actions in the fight against cancer, and in the countries who do, often psychosocial oncology is not specifically offered except within the context of more, general psychological support [55]. In the future continued efforts should be made to achieve 'cancer care for the whole patient', for all patients.

The Belgian National Cancer Plan

National Cancer Control Programs (NCCP) are defined by the WHO as "public health programs designed to reduce cancer incidence and mortality and improve quality of life of cancer patients, through the systematic and equitable implementation of evidence-based strategies for the prevention, early detection, diagnosis, treatment and palliation, making the best use of available resources". In a survey of the European Partnership for Action Against Cancer (EPAAC), twenty-four out of 29 countries (83%) reported having some type of NCCP, among which Belgium [56]. Specific goals of NCCP vary by country, depending on what cancer services are already in place, how these are linked, how efficient they are, and how responsibilities are shared among stakeholders.

In Belgium, the National Cancer Plan 2008-2010 was launched in 2008 [57]. The plan integrated all the aspects of the fight against cancer, divided into three domains of actions:

- Domain 1 : Prevention and detection
- Domain 2 : Patient care, treatment and support
- Domain 3 : Research, innovation and evaluation.

All the actions were aiming at the support of involved healthcare professionals (HCP), patients as well as their relatives, thus in general aiming at the support of everyone who has to deal with this disease day-to-day. The second domain contained several actions and objectives to stimulate the psychosocial approach in cancer care (Table 3).

In 2011 the National Cancer Plan was critically evaluated by the Flemish League Against Cancer (a large patient advocacy organization) [58] and the Belgian Cancer Registry (BCR) [59]. It was agreed that the National Cancer Plan caused progression in the Belgian cancer policy, and cancer was placed higher on the social and political agenda. At the time of evaluation more than half of the actions of the National Cancer Plan were executed, partly executed or in preparation (Table 3).

Table 3. Actions of the National Cancer Plan in the domain of Patient care, treatment and support

Action 7.	Extended consultation for patients when the cancer diagnosis is communicated to them ✓
Action 8.	Promotion of multidisciplinary oncological consultation (MOC) ✓
Action 9.	Creation of transmural care plans for cancer patients with an important role for the GP [X]
Action 10.	Nursing and psychosocial support for patients within the framework of cancer care programs ✓
Action 11.	Funding of a data manager within the framework of the cancer care programs ✓
Action 12.	Definition and funding of a pediatric cancer care program »
Action 13.	Care for rare tumors »
Action 14.	Recognition of oncology nurse ✓
Action 15.	Improved cover for cancer treatments by compulsory health insurance ✓
Action 16.	Support for radiotherapy and oncological imaging »
Action 17.	Structural support for cell therapy banks and units for hematopoietic stem cells and cord blood ✓
Action 18.	Improved refund for certain costs associated with cancer treatments ✓
Action 19.	Developing functional rehabilitation of cancer patients in remission ✓
Action 20.	Setting the conditions for the recognition of post-treatment handicaps of cancer patients ✓
Action 21.	Support for parents of children with cancer ✓
Action 22.	Access to psychological support or participation in counselling groups or support activities ✓
Action 23.	Structural funding of pediatric care networks ("ongoing care for children") »
Action 24.	Support for pilot projects in the field of clinical geriatric oncology ✓
Action 25.	Improving the offer of palliative care for cancer patients »
Action 26.	Actions to be taken in consultation with the ministers competent at Federal level »
Add. Action	Reimbursement of transportation expenses for cancer patients ✓
Add. Action	Better treatment in the diet of cancer patients ✓

Abbreviations: GP (general practitioner), Add Action (Additional action added in the policy agreement of 1/12/2011 when the continuity of the cancer plan was warranted).
✓action executed at the time of evaluation of the National Cancer Plan in 2011.
» progress was made for this action at the time of evaluation of the National Cancer Plan in 2011.
[X] no progress for or execution of this action at the time of evaluation of the National Cancer Plan in 2011.

In the domain of 'Patient care, treatment and support' 13 actions were executed, six actions were in progress and one was not executed at all (Table 3). Although there is a positive influence of the actions taken, the effectivity and efficiency of some actions in practice is questioned. A long-term vision in combination with a number of measurable targets to evaluate the efficiency of the Cancer Plan actions is missing. Some actions undertaken reach the target population only to a limited extend. For example many physicians do not make use of the extended consultation yet. In 2015 the Belgian Health Care Knowledge Centre (KCE) evaluated the multidisciplinary oncology consultation

(MOC) and decided that these proved to have an added value for the quality of cancer care, by their effect on communication, coordination and care continuity [60]. Alertness was recommended in order to ensure that these MOCs are patient-centered and not disease-centered. In this perspective, the participation of the general practitioner (GP) in the MOC is of great importance, since this is the HCP best informed on the overall medical and psychosocial situation of the patient [61, 62]. GP play an important role in post- treatment cancer care [10, 63], and so the European Association for Quality in General Practice (EQuiP) has pointed to the interface between secondary care and GP as a critical point for quality of care [64]. However, the participation of GP to the MOCs is rather limited. Data from the BCR, and the Intermutualistic Agency (IMA/AIM) show low participation rates of GP for all cancers (e.g. 2% for breast cancer; 3% for lung cancer; 4% for colorectal cancer) [60]. A survey of the KCE revealed that in particular, the lack of an invitation to participate, practical and interpersonal aspects determine this [60].

Many new initiatives to improve the quality of cancer care were implemented, such as additional training and education, to contribute to the growth of knowledge and the professionals expertise. However, the places available in courses are limited. The cancer plan delivered more financial resources to hospitals to employ additional psychologists. For social workers, less resources were made available, while the latter belong to the secondary line of care and psychologists provide more specialized care that applies to a rather limited group of people. Currently, cancer patients can rely on a variety of (psychosocial) support options. However, this care offer is fragmented, situationally and regionally determined. There are pilot projects concerning supportive care initiatives which are financed from different sources (charities, government, hospitals,…), and for different lengths of time, without clarity on the criteria that initiatives must meet to be permanently implemented in the regular care offer. There is a need for structural embedding of psychosocial and supportive care on the financial and organizational level [59].

At the time of evaluation of the National Cancer Plan, no progress was made for Action 9 'Creation of transmural care plans for cancer patients with an important role for the GP'.

For the future, it was recommended to work with more integrated care pathways in cancer care [65]. This method for care organization was developed to reduce variation in care, decrease resource utilization, and improve quality of care [66]. Clinical pathways can provide a framework for the various healthcare disciplines involved, improve their multidisciplinary communication and have a positive influence on care process [67, 68]. The implementation of revalidation, systematic monitoring of patients psychosocial well-being, care needs and reintegration could also be included in care pathways. However, the development of such a complex intervention is not easy and the success in bringing change in patient management is largely depending on context and implementation [69]. Ownership of all HCP involved, sufficient resources, education and training, patient participation, and coordination with related health services are needed in a specific, comprehensive approach, in line with the patient's needs [70, 71].

OBJECTIVE AND OUTLINE OF THE PROJECT

Objective and research questions

While NCCP are designed to 'reduce cancer incidence and mortality, and improve QOL of cancer patients', the Belgian National Cancer Plan did not specify measures to monitor or evaluate patients' QOL and care needs. This is an important deficiency of the National Cancer Plan and unfortunately also of daily practice in the care of oncology patients. At the 3rd European Roundtable Meeting of the Union for International Cancer Control (UICC) it was emphasized once again how important it is to consider patients' perspective and patient reported information into developments in the field of cancer care and research [72]. After all, the quality of cancer care can only be realized when it is "state of the art care" and matches with the care needs of patients. Efforts should be made to integrate patients' QOL and care needs in routine care. Several studies have proven that psychosocial factors in the patient-healthcare professional relationship are important for patients' well-being, their satisfaction, and their perspective on quality of care [73, 74, 75].

The use of PROM could support this systematic integration of the psychosocial approach. The obtained data can be used to monitor the well-being and care needs of patients on an individual level, to evaluate the effectiveness of interventions, and if applied on a large scale may also provide valuable epidemiological data on the well-being of the population of cancer patients [65]. A good example of this is the PROFILES-registry that was designed in The Netherlands to collect data from patient-perspective with PROM, to study the physical and psychosocial impact of cancer and its treatments in short and long-term survivorship [76]. In the last six years the PROFILES-registry data was successfully used for over 40 studies that were conducted to identify patients at high risk, to analyze mediating mechanisms and to explore survivors' physical and psychosocial care needs.

The objective of this PhD-project is to provide insights that contribute to the research on psychosocial aspects in the well-being of cancer patients' and in current cancer care. There is a special focus on PROM, cancer patients' care needs, QOL and psychosocial well-being. To get a clear picture of psychosocial aspects in current cancer care, patients' as well as HCP's perspective was is explored.

Research question 1: *'How can we support the detection and monitoring of cancer patients' psychosocial care needs, in order to improve the comprehensive and patient-centered approach in cancer care?'*

Following the international recommendations on systematic screening or assessment of distress and care needs, we searched the literature for needs assessment tools since there was no validated tool available in Belgium. We found several systematic reviews that indicated the Cancer Rehabilitation Evaluation System (CARES) to be a tool that was rather complete in content and psychometrically robust. The question that subsequently arose was: *'Is the Flemish translation of the CARES eligible to measure QOL and care needs of cancer patients in our population?'.*

Corresponding sub-questions:

- *'Is the Flemish CARES psychometrically robust?'*
  (addressed in Chapter 2 and 3).

- *'Is the CARES an acceptable and feasible instrument, and is the content relevant and complete for patients in our population?'*
  (addressed in Chapter 4).

Research question 2: *'How do patients experience cancer care, and the match of the care offer with their care needs?'* (addressed in Chapter 5).

Research question 3: *'How does the multidisciplinary group of HCP involved in cancer care manage patients' psychosocial issues?*
Corresponding sub questions (all addressed in Chapter 6):

- *'What is the occurrence of psychosocial aspects being addressed in patient-HCP contacts?'*
- *'What is the extend of systematic approach in exploring the psychosocial well-being of patients?'*
- *'How do HCP experience the care or support they offer to patients in case of psychosocial problems?'*
- *'What is HCP referral policy for psychosocial problems or needs?'*
- *'Do these HCP experience barriers in the deliverance of psychosocial support or care to their patients? And if so, what barriers are experienced?'*

Research question 4: *'What is the effect of systematic screening and assessment of cancer patients psychosocial well-being and care needs, and which specific characteristics of these interventions potentially contribute to this effect?'* (addressed in Chapter 7).

Research question 5:
'How do patients and HCP experience the implementation of systematic QOL and needs assessment with the CARES in patients' care pathway?'
(addressed in Chapter 8).

Outline of this doctoral thesis

Chapter 1

In the first chapter of this doctoral thesis a general introduction is given. The impact of cancer is described in terms of epidemiology, as well as in the impact it can have on people's lives and well-being. International recommendations and guidelines for cancer care, plus the actions of the Belgian Cancer Plan are described to discuss the current and required psychosocial approach in cancer care.

Chapter 2

Chapter 2 describes the search for an eligible PRO tool for needs assessment in cancer patients. The instrument that met our criteria, the CARES, was found thru a review of the literature. In this chapter, the protocol for the validation study is discussed.

Chapter 3

The CARES, was translated to Flemish in a forward-backward translation process, and tested for its psychometric robustness in a quantitative study. Internal consistency, test-retest reliability, construct validity and concurrent validity were explored. The third chapter of this dissertation describes these psychometric qualities of the Flemish CARES version and its' short form.

Chapter 4

In chapter 4 the focus group study is described that was conducted to explore the content validity of the CARES. After all, the original CARES was developed in the United States in the early 90's. It was important to explore if the content of the instrument was also relevant and complete for the Flemish population, and if these patients experienced the CARES as a feasible and acceptable tool.

Chapter 5

In the focus groups organized to explore the content validity and feasibility of the CARES also a lot of data was obtained on patients' experiences with cancer

care and the detection and management of their needs. The insights we can derive from this are discussed in chapter 5.

Chapter 6

To complete the picture on psychosocial aspects in cancer care with input from different angles, HCP's perspective on this topic was explored as well. Chapter 5 describes a cross-sectional survey that was conducted in a multidisciplinary group of HCP involved in intramural and/or extramural cancer care. The survey focused on their perspective of the prevalence of psychosocial topics in communication with cancer patients, the care and referral they offer for issues in this area, and potential barriers that are experienced in the delivery of psychosocial care.

Chapter 7

Systematic reviews are valuable sources of information, because all available information on a certain issue is collected, and the resulting insights provide input for the development of guidelines and concrete interventions. Chapter 6 describes a Cochrane Systematic Review that was conducted with the objectives to: 1) to assess the effectiveness of screening and assessment of psychosocial well-being and care needs on the well-being of people with cancer; 2) to explore the intervention characteristics of these screening and assessment interventions (interventionists, instruments, procedures, implementation conditions,…).

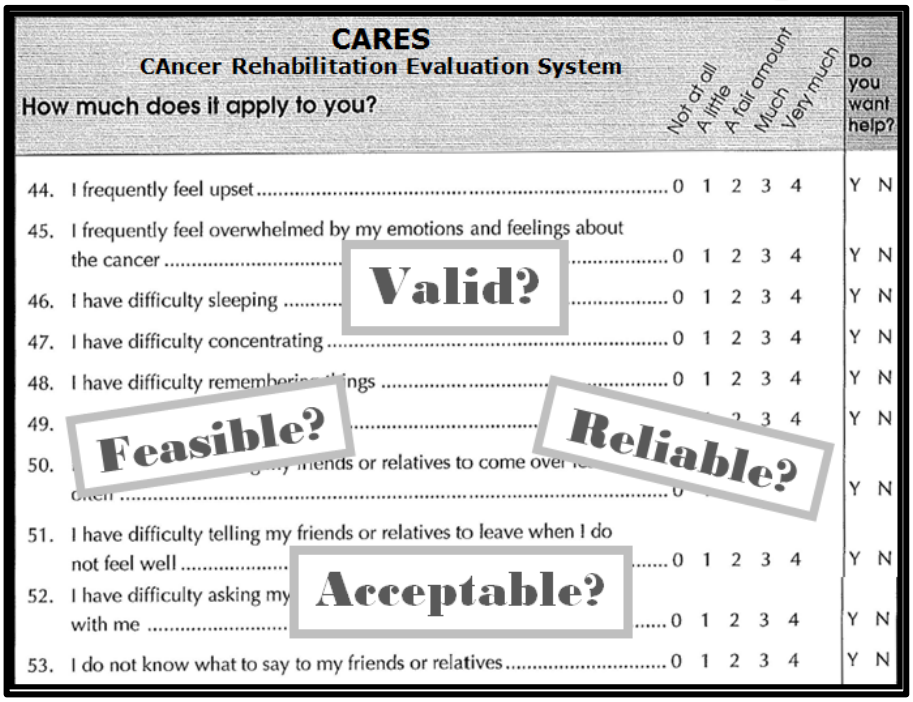
Chapter 8

Chapter 8 builds further on the evidence found in the studies described in previous chapters, and describes an explorative pilot study on systematic QOL and needs assessment in the follow-up of cancer patients in two gastroenterology departments. The Flemish CARES version was used to assess patients QOL and care needs at the start of treatment, three and six months after start of treatment, and short CARES-summary reports were provided for the reference nurse of the departments for use in follow-up. Patients and HCP were queried on the feasibility, acceptability and potential value of the intervention in clinical practice. As well, resulting insights on QOL and care needs were explored.

Chapter 9

This final chapter contains the general discussion and conclusions derived from the studies in this dissertation. Based on the findings of these studies, implications and recommendations for future research, clinical practice, and policy makers are described.

2 Chapter



Preparations for the CARES validation study: A protocol

This chapter is based on:

Schouten, Bojoura; Van Hoof, Elke; Vankrunkelsven, Patrick; Schrooten, Ward; Bulens, Paul; Buntinx, Frank; Mebis, Jeroen; Vandijck, Dominique; Cleemput, Irina & Hellings, Johan (2016) *Assessing cancer patients' quality of life and supportive care needs: Translation-revalidation of the CARES in Flemish and exhaustive evaluation of concurrent validity.* BMC Health Serv Res. 2016 Mar 11;16:86. doi: 10.1186/s12913-016-1335-4.

ABSTRACT

OBJECTIVE The prevalence of cancer increases every year, leading to a growing population of patients and survivors in need for care. To achieve good quality care, a patient-centered approach is essential. Correct and timely detection of needs throughout the different stages of the care trajectory is crucial and can be supported by the use of screening and assessment in a stepped-care approach. The Cancer Rehabilitation Evaluation System (CARES) is a valuable and comprehensive quality of life and needs assessment instrument. For use in Flemish research and clinical practice, the CARES tool was translated for the Dutch-speaking part of Belgium (Flanders) from its original English format. This protocol paper describes the translation and revalidation of this Flemish CARES version.

METHODS After forward-backward translation of the CARES into Flemish we aim to recruit 150 adult cancer patients with a primary cancer diagnosis (stage I, II or III) for validation. In this study with a combination of qualitative and a quantitative approach, qualitative data will be collected through focus groups and supplemented by two phases of quantitative data collection: i) an initial patient survey containing questions on socio-demographic and medical data, the CARES and seven concurrent instruments; and ii) a second survey administered after one week containing the CARES and supplementary questions to explore their impressions on the content and the feasibility of the CARES.

DISCUSSION With this extensive data collection process, psychometric validity of the Flemish CARES can be tested thoroughly using classical test theory. Internal consistency of summary scales, test-retest reliability, content validity, construct validity, concurrent validity and feasibility of the instrument will be examined. If the Flemish CARES version is found reliable, valid and feasible, it will be used in future research and clinical practice. Comprehensive assessment with the CARES in a stepped-care approach can facilitate timely identification of cancer patients' psychosocial concerns and care needs so it can contribute to efficient provision of patient-centered quality care.

KEYWORDS: cancer, psychosocial, quality of life, distress, needs assessment, validation, supportive care.

BACKGROUND

The diagnosis of cancer has an enormous impact on people's lives. In additional to the threat on one's physical health, cancer patients are confronted with psychosocial problems and care needs [1-13]. Timely and accurate detection of those psychosocial problems and care needs is of great importance to offer more patient-centered care, efficient referral and to prevent comorbid psychopathology [14-18].

Simple quality of life (QOL) measurement and distress-screening are popular methods to explore people's psychosocial well-being [9, 19-22]. In contrast, needs assessment is a strategy that focuses on identifying the unresolved concerns that patients are experiencing and determines if they desire further assistance throughout the continuum of care [23]. Indeed, not all patients experiencing distress or reduced QOL need professional support from the care system [24]. Needs assessment can provide important input from the patients' perspective and guide appropriate intervention in the multidisciplinary process of care. As a result of patient-report data, health care resources can be allocated in the most appropriate way. The use of needs assessment can therefore contribute to patient-centered quality cancer care [14, 25-27].

To our knowledge there are no validated Flemish needs assessment tools available. Therefore, this study will be dedicated to the validation of a needs assessment tool for use in Belgian research and clinical practice. To provide a good understanding of psychosocial healthcare needs, the content of a needs assessment tool should be comprehensive enough to benefit multidisciplinary stakeholders involved in cancer care i.e. medical specialists, nursing, psychologists, social welfare workers, general practitioners, health insurance agencies. In the search for an appropriate needs assessment tool, the following criteria were used: 1) the instrument should be generic across tumor type and staging, i.e. suitable in all cancer patients; 2) the assessment should encompass the biopsychosocial impact of the disease and treatment on patients' overall well-being i.e. physical, emotional, cognitive, social, relational, sexual and financial, their daily functioning and the potential resulting care needs; and, 3) the tool should have a proven psychometric robustness, demonstrating good reliability and validity, and be feasible for patients.

Several review studies describing needs assessment tools for adult cancer patients are available [28-30]. From the tools discussed 24 instruments are patient-reported outcomes (PRO) for adult patients with any type of cancer. These needs assessment tools and associated psychometric properties are presented in brief in Table 1 (and in full in Appendix 2.1).

Among other tools, the Cancer Rehabilitation Evaluation System (CARES) was positively evaluated [28-30]. The CARES is a QOL and needs assessment instrument, developed to provide an efficient way of gathering specific information about the day-to-day problems and rehabilitation needs of cancer patients. The instrument can be used for research or clinical objectives and has been applied across cancer type and stage [31-44]. The 139 items of the CARES are placed under 31 subscales and represented according to six summary scales, as shown in Table 2. A copy of the original CARES questionnaire and patient score profile can be found in Appendix 2.2 and Appendix 2.3.

The psychometric robustness of the CARES and its earlier development versions (the Cancer Inventory of Problem Situations) are well documented [33, 34, 36, 45]. The results demonstrate that the CARES and its summary scales have excellent internal consistency (α=0.87-0.94) and high test-retest correlations (r=0.84-0.95). The instrument has moderate to high correlations with the Symptom Checklist-90 (SCL-90) [46], Dyadic Adjustment Scale (DAS) [47], Karnofsky Performance status Scale (KPS) [48, 49] and a visual analogue scale [50] for QOL before and after cancer, that were used to investigate concurrent validity. The content validity was supported with the results from post-administration interviews [35, 45].

Considering the CARES is reported as a valid and feasible tool that can be used for all cancer patients to assess a comprehensive range of biopsychosocial aspects of well-being, this instrument was chosen to be translated and validated for further use in Flemish cancer care facilities and research.

The psychometric robustness of the Flemish CARES version will be tested thoroughly. We plan to evaluate the internal consistency of the CARES and its summary scales, the test-retest reliability will be considered, the construct validity will be explored, and the concurrent validity of the CARES and its summary scales will be checked with several comparative instruments. This paper describes the study protocol of this multi-stepped process.

Table 1. Summary of needs assessment tools and psychometric properties

	Validity		Reliability		Responsive-ness	Feasibility
Instrument	Content Validity	Other types of validity	Internal consistency	Reproducibility		Time , Reading Level, Acceptability
CaNDI	+	+	+	+	-	T:- RL:+ A:-
CARES	+	+	+	+	-	T:+ RL:- A:+
CARES-SF	+	+	+	+	+	T:+ RL:- A:-
CCM	+	+	+	+	-	T:+ RL:+ A:+
CHOICEs	+	-	+	-	-	T:+ RL:- A:+
Concerns checklist	+	+	-	-	-	T:- RL:- A:-
CNAT	+	+	+	-	-	T:- RL:- A:+
CNQ-SF	+	+	+	-	-	T:+ RL:+ A:+
CPILS	+	+	+	-	-	T:- RL:- A:-
CPNS	+	-	+	-	-	T: + RL:- A:+
CPNQ	+	+	+	+	-	T:+ RL:+ A:-
Distress management tool	+	-	-	-	-	T:- RL:- A:-
INM	+	-	+	-	-	T:- RL:- A:-
NEQ	+	+	+	+	-	T:- RL:- A:+
OCPC	+	-	-	-	-	T:- RL:- A:+
PINQ	+	+	+	-	+	T:- RL:- A:+
PNAS	+	-	+	-	-	T:- RL:- A:-
PNAT	+	+	+	+	-	T:+ RL:- A:-
PNI	+	+	+	-	-	T:- RL:+ A:-
Problem checklist	+	+	+	-	-	T:- RL:- A:+
SCNS	+	-	+	-	-	T:+ RL:+ A:+
SCNS-SF34	+	+	+	-	-	T:- RL:+ A:-
SNST	+	-	-	-	-	T:- RL:+ A:+
Symptoms and concerns checklist	+	+	+	+	-	T:+ RL:+ A:+

+ : evidence for psychometric property
- : no evidence for psychometric property or evidence not available
Abbreviations: CaNDI (Cancer Needs Distress Inventory), CARES (Cancer Rehabilitation Evaluation System), CARES-SF (Cancer Rehabilitation Evaluation System-Short Form), CCM (Cancer care monitor), CHOICEs assessment (Creating better health outcomes by improving communication about patients' experiences assessment), CNAT (Comprehensive needs assessment tool in cancer), CNQ-SF (Cancer Needs Questionnaire Short Form), CPILS (Cancer Problems in Living Scale), CPNS (Cancer Patient Need Survey) CPNQ (Cancer Patient Need Questionnaire), Distress management tool, INM (Information Needs Measure), NEQ (Need Evaluation Questionnaire), OCPC (Oncology Clinic Patient Checklist), PINQ (Patient Information Need Questionnaire), PNAS (Psychosocial needs assessment survey), PNAT (Patient Needs Assessment Tool), PNI (Psychosocial Needs Inventory), Problem checklist, SCNS (Supportive Care Needs Survey), SCNS-SF34 (Supportive Care Needs Survey Short Form), SNST (Supportive Care Needs screening Tool), Symptoms and concerns checklist.

Table 2. CARES Summary scales and subscales

Physical (26 items) Ambulation Activities of daily living Recreational activities Weight loss Difficulty working Pain Clothing	**Psychosocial** (44 items) Body image Psychological distress Cognitive problems Difficulty communicating with friends/relatives Friends/relatives difficulty interacting Anxiety in medical situations Worry Interaction with children* At work concerns*
Medical Interaction (11 items) Problems obtaining info from medical team Difficulty communicating with medical team Control of medical team	**Miscellaneous** (32 items) Compliance Economic barriers Dating* Chemotherapy-related problems* Radiation-related problems* Ostomy* Prosthesis* Miscellaneous items
Marital* (18 items) Communication with partner Affection with partner Interaction with partner Overprotection by partner Neglect of care by partner	
Sexual (8) items Sex interest Sexual dysfunction*	

* Items may not apply to all patients.

METHODS

Translation of the CARES

Belgium is a trilingual country with Dutch, French and German as official state languages. The Dutch language in Belgium, called Flemish, is slightly different from the Dutch language in The Netherlands in terms of vocabulary. Since current CARES translation is made for the Dutch-speaking part of Belgium, this paper refers to the Flemish CARES version only. We have no knowledge of a CARES translation appropriate for The Netherlands. However, there is a translation of the CARES-Short Form (CARES-SF) [77]. If one would like to use the full version of the CARES in The Netherlands, a revision of the translation should be considered.

The Flemish CARES version resulted from a forward-backward translation process with sworn translators and an expert group, following the guidelines for translating questionnaires described by Beaton et al. [78]. First, sworn

translators translated the original US English CARES into Flemish. Two independent researchers revised the resulting texts for content fidelity and an expert group, comprised of professionals from the field of care management, oncology, primary care and psychology, agreed on the final Flemish version. The questionnaire was again translated back into English by sworn translators and the original CARES and English back-translation were compared by a native speaker, concluding the content of the questionnaire was maintained.

Design of the study

A mix of qualitative and quantitative methods will be used for the validation study of the Flemish CARES.

Qualitative data collection, that will be used to evaluate *content validity* and *feasibility* of the instrument, will consist of conducting focus group discussions until data saturation is reached. We estimate that it will be necessary to arrange four or five focus group discussions with six to ten participants. The discussions will be facilitated with several key questions and transcribed afterwards for thematic content analysis. Further detailed description of this qualitative research activities will be part of another publication, since we prefer to focus on a detailed description of the quantitative research in this paper.

For the quantitative data collection, questionnaires containing the CARES and different complementary instruments (see further) will be used to evaluate *reliability*, *construct validity* and *concurrent validity.* This quantitative part of the validation study is described in further detail in this protocol.

Sample size

There are no general criteria for the sample size in a validation study, but a sample size of at least 50-100 is generally recommended [79]. Sample sizes in the validation research of the original CARES varied for each psychometric quality (Table 3) [80]. Two large sample sizes of 479 and 1047 were used for the investigation of construct validity. Other aspects of reliability and validity were tested with sample sizes of 22 to 120 participants. Given the available time and resources, setting the goal to include 150 participants for this validation study of the Flemish CARES version is feasible. Considering the response rates of 40-60% that are usually reached in the research domain of psycho-oncology,

inviting at least 250 eligible patients is a conservative approach to guarantee the minimal amount of 150 participants.

Table 3. Sample sizes validation research original CARES

Psychometric quality	Analysis	Sample size (N)
Test-retest reliability	Correlations between CARES summary scores	71 120
	Rating agreement	71 120
Construct validity	Factor analysis on all items	479
	Second-order factor analysis on 31 subscales	479 1047
Concurrent validity	Correlation between CARES and SCL-90	87
	Correlation between CARES and SCL-90, DAS, KPS and QOL visual analogue scale	120
Sensitivity	CARES compared to clinical interview	22
	CARES compared to a needs assessment interview	24 64
Content validity	Questions on relevance of CARES content,	22
Acceptability to patients	completion time, understandability and acceptability items.	64

Abbreviations: CARES (Cancer Rehabilitation Evaluation System), SCL-90 (Symptom Checklist-90), DAS (Dyadic Adjustment Scale), KPS (Karnofsky Performance status Scale).

Study population and recruitment

The CARES was constructed to detect rehabilitation needs and QOL, with a secondary intent to stimulate patients' competences and patient empowerment for increased involvement in their own rehabilitation. Therefore, only patients with a primary cancer diagnosis treated with a curative intent will be recruited for this validation study. Details on the in- and exclusion criteria are listed in Table 4.

Participants will be recruited from four Flemish hospitals (two public and two private, with a range from 340 to 1015 beds). In order to generate a representative research sample, several medical departments will conduct patient recruitment and include medical oncology, radiotherapy, gynecology, urology, and gastroenterology services.

Table 4. Inclusion and exclusion criteria for eligible patients

Inclusion criteria	Exclusion criteria
▪ Male and female cancer patients ▪ Primary stage I, II and III diagnosis * ▪ At different stages of the care process: recently diagnosed, currently undergoing treatment, and post-treatment in follow-up care. ▪ All types of cancer ▪ Aged between 25-60 years **	▪ Having had or having premorbid neurological problems or cognitive dysfunctions *** ▪ The lack of proficiency in Flemish-Dutch ***

* This criteria serves to exclude palliative patients, since we aim to include participants that have an perspective on rehabilitation.
** We believe the social context, role fulfillment, obligations and expectations differ between adolescents, adults and elderly resulting in other psychosocial concerns. To recruit adult cancer patients we chose the age range of 25-60 years.
*** This makes a person unsuitable for participation in questionnaire research.

Study procedure

Eligible patients will be selected by the medical team according to the inclusion and exclusion criteria. Given the complexity of the clinical field and variable structures of the participating departments, two alternative procedures to invite patients to participate in the study will be used. On the basis of team organization and availability of time, the physician of the medical unit will choose to recruit patients with either the 'face-to-face procedure' or the 'post procedure'. In the 'face-to-face procedure', a member of the medical team will explain the study briefly and invite the patient to participate. If the patient agrees to participate, he/she will immediately receive a study package with the informed consent form, a 'what to do'-scheme, the first questionnaire and a stamped and addressed envelope to return the questionnaire. In the 'post procedure', eligible patients will be sent an identical study package by post, containing a short letter explaining the study, the informed consent form, a 'what to do'-scheme, the first questionnaire and a stamped and addressed envelope to return the questionnaire. One week later participants have to fill in the second questionnaire, containing the CARES for test-retest reliability, and send it back in another stamped and addressed envelope provided. If the questionnaire is not sent back, the participants recruited via the 'face-to-face procedures will be contacted by a team member and asked if they still want to participate and asked to return a completed questionnaire. Participants invited

through post-procedure will be sent a reminder and second questionnaire package after one month. This study procedure is visualized in Figure 1.

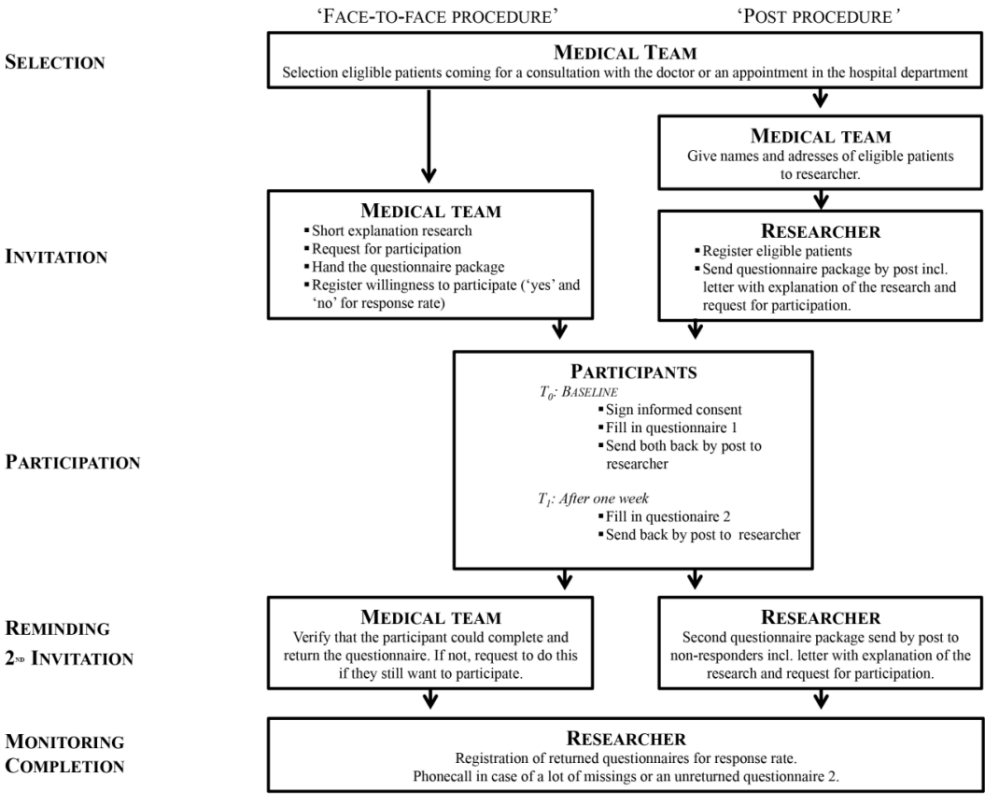


Figure 1 Study procedure

Participants will be contacted by phone or by e-mail when returned questionnaires have a large number of missing responses or if the second questionnaire is not received in the expected timespan. Ethical standards limit the number of participant contacts, there is a maximum of two attempts to contact a participant.

Questionnaires

Data collected with the *first questionnaire* includes socio-demographic characteristics, medical characteristics, the CARES and several concurrent instruments measuring the same concepts as the CARES or its subscales. These seven independent, but complementary, instruments are all considered to be international 'gold standards' or are frequently used instruments. These instruments were selected as they represent domains similar to the summary scales and global score of the CARES. All of them have been previously used in Belgian research. The concurrent validity of the original CARES was evaluated in comparison with the SCL-90, DAS and the KPS [81]. However, these instruments do not match the content of the CARES as completely as the set of concurrent measures in current study does. The concept equivalence and expected correlation with the CARES, to evaluate concurrent validity, is shown in Table 5.

Table 5. Expected correlations of concurrent measures with CARES summary scales and global score

CARES Summary scales and CARES global score	Concurrent instrument	Expected correlation[a]
Physical	KPS	-
Psychosocial	HADS-A	+
	HADS-D	
Psychosocial	SSL-I	-
	SSL-D	+
Marital	MMQ-M	-
Sexual	MMQ-S	-
CARES Global score	EORTC-QOL-C30	-
CARES Global score	DT	+
CARES Needs	Care Needs Questionnaire E. Pauwels	+

[a] '-'= negative correlation, '+'= positive correlation
Abbreviations: CARES (Cancer Rehabilitation Evaluation System), KPS (Karnofsky Performance status Scale), HADS (Hospital Anxiety and Depression Scale), SSL-I (Social Support List – Interactions), SSL-D (Social Support List – Discrepancies), MMQ-M (Maudsley Marital Questionnaire – Marital), MMQ-S (Maudsley Marital Questionnaire – Sexual), EORTC-QOL-C30 (European Organisation of Research and Treatment for Cancer Quality of Life Questionnaire Core 30), DT (Distress Thermometer).

CARES [80, 81, 82, 83, 84, 85, 86]: The original CARES contains 139 items; however, not all 139 items apply to all patients and therefore patients complete a minimum of 93 items or a maximum of 132 items. Patients can rate each

item, formulated as problem statement, on a 5-point Likert scale with zero representing "not at all" (no problem) and four representing "very much" (severe problem). The clinical form of the instrument that will be used in this study allows a patient to indicate which problems they believe require help, ticking 'yes' or 'no' on the question 'Do you want help?'. Scores for the five summary scales can be computed as well as a CARES global score and an average severity score.

Karnofsky Performance status Scale (KPS) [87, 88, 89]: The KPS is an 11-point scale to judge the physical and daily functioning of a patient and ranges from 0 (completely dependent, not able to care for oneself) to 100 (fully active, not dependent and capable of normal activity without limitations). This measure is currently used worldwide in research and practice and has been administered for many years. The KPS has got good psychometric properties (interrater reliability: r=.97; concurrent validity: p<.001; predictive validity: r= .30).

The Hospital Anxiety and Depression Scale (HADS)[90, 91, 92]: The HADS was developed to identify symptoms of anxiety and depression in medically ill patients, and is used extensively in cancer patients and had excellent psychometric qualities. The questionnaire contains 14 items with four possible answers with scores ranging from 0-3. Higher scores on the two subscales (each consisting of 7 items) indicate a higher level of anxiety or depression and the total score of the HADS (score-ranges from 0-42) can be used as a global measure of psychological distress. The HADS has got good psychometric properties (internal consistency: α=.67-.93; PCA: two factor solution; concurrent validity: r=.49-.83; subscale inter-correlations: r=.40-.74).

The Social Support List – Interactions and Discrepancies (SSL-I and –D) [93, 94, 95]: The SSL is a questionnaire with 75 items, 41 on experienced social interaction and 34 on experienced social discrepancies. In the first part of the questionnaire participants indicate how frequently certain social interactions occur on a 4-point Likert scale from 1 ('seldom or never') to 4 ('very often'), with higher scores representing higher levels of social support. A second part of the SLL indicates the social discrepancies participants experience ranging from 1 ('I would like it to happen more often') to 4 ('it happens too often'). Higher scores on the SSL-D indicate a greater lack of social support. The psychometric

properties of the SSL are positively evaluated (internal consistency: α=.53-.93, test-retest reliability: r=.62-.85).

The Maudsley Marital Questionnaire (MMQ) [96, 97, 98, 99]: The MMQ contains three scales exploring Marital (10 items), Sexual (five items) and General Life (five items) adjustment. The respondent is asked to indicate an answer from a series of possible answers, on a scale ranging from 0 to 8. The wording of response categories differ for each item depending on nature of the question. The MMQ has good psychometric properties (internal consistency: α=..66-.90; PCA: three factor solution; subscale inter-correlations: r=.33-.60).

The European Organisation of Research and Treatment for Cancer Quality of Life Questionnaire Core 30 (EORTC-QLQ-C30) [100]: The EORTC QLQ-C30 is an internationally validated and widely used cancer-targeted QOL instrument, incorporating five functional scales (physical, role, cognitive, emotional and social) and three symptom scales (fatigue, pain and nausea, and vomiting). Items are answered on a 4-point Likert scale from 1 ('not at all') to 4 ('very much'). The last two items on global health and QOL have 8-point answering scales ranging from 1 ('very poor') to 7 ('excellent'). The EORTC QLQ -C30 is subject of a many validation studies worldwide, generally concluding the questionnaire is a QOL instrument with good psychometric properties relevant to different cancer-patient populations (internal consistency: α=.52-.92; test-retest reliability: r=.72-.84; scale inter-correlations: r= -.69-.85; responsive to change of health status).

The Distress Thermometer (DT) together with a Problem List (PL) [101, 102, 103]: Patients are asked to rate their overall distress on a visual analogue scale (presented as a thermometer) from 0 ('no distress') to 10 ('extreme distress'). The DT is accompanied by the PL, which includes 35 items that address 5 life domains (practical, family/social, emotional, spiritual, and physical problems). Participants indicate if the topics of the items poses problems for them. At the end of the survey people are asked if they want to talk to a professional about their problems. The DT is frequently used in clinical practice and research all over the globe, in combination with the PL. This has proved to have good internal consistency (α=.80-.90).

Care Needs questionnaire [104]: The Care Needs questionnaire was developed to assess the care needs of cancer survivors regarding relevant themes during

reintegration: physical functioning, psychological functioning, self and body image, sexuality, relationship with partner, relationship with others and work and social security related aspects. For each theme, participants are asked whether they wish to receive information or support, in what way, when they prefer to receive information and support, and to what extent this need already has been met. Each of the questions are answered on 3- and 4-point Likert scales with different wording.

The *second questionnaire* contains a second CARES survey and specific supplementary questions to get data on participants' experiences with the CARES. This second study component will be completed to assess test-retest and a patient-acceptability of the measure. Table 6 gives a detailed summary on the composition of both questionnaires and the measured concepts.

Table 6. Composition of questionnaires for quantitative data collection

Questionnaires	Instrument	Data collected
Questionnaire 1 *T_0 Baseline*	Self-administered questions on socio-demographic and medical aspects	Age, sex, marital status, children, education, employment status, household income, social surrounding, involved care providers, diagnosis, date of diagnosis, treatment(s), start and end dates of treatments.
	CARES	Quality of life and rehabilitation needs
	KPS	Physical and daily functioning
	HADS	Symptoms of anxiety and depression
	SSL	Social support
	MMQ	Marital and sexual life adjustment
	EORTC-QOL-C30	Quality of life
	DT + PL	Distress and problems
	Care needs questionnaire administered by E. Pauwels	Care needs
Questionnaire 2 *T_1 After 1 week*	CARES	Quality of life and rehabilitation needs
	Self-administered questions	Relevance of CARES-topics, timespan filling in, mode preference,…

Abbreviations: CARES (Cancer Rehabilitation Evaluation System), KPS (Karnofsky Performance status Scale), HADS (Hospital Anxiety and Depression Scale), SSL (Social Support List), MMQ (Maudsley Marital Questionnaire), EORTC-QOL-C30 (European Organisation of Research and Treatment for Cancer Quality of Life Questionnaire Core 30), DT (Distress Thermometer), PL (Problem List).

Ethical considerations

All local ethical committees of the participating hospitals (Ethical Review Commission Jessa ziekenhuis; Committee Medical Ethics Ziekenhuis Oost-Limburg; Ethical Committee AZ Vesalius; Ethical Committee Mariaziekenhuis Noord-Limburg) and the university (Medical Ethical Committee Hasselt University) reviewed all study materials including: the recruitment materials and procedure, informed consent form, the questionnaires and the overall study protocol. The leading ethical committee (ERC Jessa ziekenhuis) coordinated the process, collected feedback and granted approval on 26th of February 2014 (BE24320149544). The leading ethical committee also reviewed and approved study protocol amendments.

Data analysis

The Statistical Package for Social Sciences (SPSS; Chicago, IL) version 22.0 will be used for statistical analyses of the quantitative data. A range of analyses are required to report the reliability and validity of the translated CARES version.

Reliability

The reliability of the CARES will be evaluated by computing the *internal consistency* of summary scales, with the aim to find a Cohen's Alpha of at least .70 [105, 106]. *Test-retest reliability* will be investigated by computing the intra-class correlations between the summary scale scores and total-CARES scores of the first and second CARES administration, requiring a correlation ≥ .70 [105, 107].

Construct validity

The five factor structure as found in previous CARES-research will be examined with principal component analysis to evaluate construct validity. Following previous validation techniques applied in the original CARES development process, items and subscales with a factor loading higher as .30 are seen as loading on a factor [80, 81]. Confirmatory factor analysis will not be applied since sample size will be limited. As well inter-correlations of summary scales and the CARES Total will be explored. Moderate correlations between the

subscales (r =|.30|-|.70|) and moderate to high correlations with the CARES Total (r ≥ .30) would support construct validity, since this would indicate that the subscales indeed measure distinct, but related concepts that contribute to the larger concept of QOL.

Concurrent validity

Spearmans rank correlations will be computed to evaluate concurrent validity of the CARES global score and the summary scales with the seven concurrent instruments (Table 5). Correlations will be judged low, moderate and high, when their absolute values are respectively < .30, from .30- .50 and ≥ .50 [108].
If the psychometric qualities do not show as expected, these will be studied in more detail with qualitative research data on CARES content and feasibility to search for explanations.

DISCUSSION

To achieve good quality care it is important to provide it as efficiently as possible, and adapted to the individual needs of every patient. A stepped care approach according to patients' level of need could serve to tailor care efficiently and appropriately , however this necessitates reliable and valid screening and assessment tools to support clinicians in the identification of psychosocial concerns and care needs of their patients. The current English CARES is such an instrument. This paper describes a comprehensive protocol for translating and validating a Flemish CARES version. This addresses a critical gap in current clinical screening, and adds a tool to assess and improve the delivery of patient-centered care.
Unique in this study is the use of a wide range of comparative instruments to examine the concurrent validity of the CARES. Many other validation studies use only a few dimensions, not reflecting the whole concept of the specific instrument [28, 29, 75]. In contrast, this study will include an instrument to examine concurrent validity almost for each summary scale and the CARES global score. While our study is set up to examine the psychometric quality of the Flemish CARES, an additional advantage is that the use of several concurrent instruments will provide us with a wealth of data. The use of the KPS,

HADS, SSL, MMQ, EORTC QLQ-C30, DT, PL and the Care needs questionnaire of Pauwels et. al. provides data on psychological, social, marital and sexual wellbeing, QOL, distress and care needs of patients treated for cancer. These can be used to explore potential relationships between mutual care-domains and with socio-demographic and medical characteristics. The recruitment for this study has begun (March 2014) and will continue until the end of 2014 or until the desired sample size is reached.

As in all studies, this study has some limitations. Firstly, the completeness of the CARES content to assess QOL and supportive care needs should be considered. In comparison to other psychometric positively evaluated needs assessment tools for cancer patients, like the Supportive Care Needs Survey (SCNS) [76], the CARES does not include items on spiritual and existential well-being [29]. However, on other domains of well-being, we can judge in favor of the CARES content. The content of the CARES matches with our thoughts about the biopsychosocial impact of cancer on patients' lives and possibly resulting care needs. Furthermore, the content validity, completeness and feasibility of the CARES for Flemish cancer patients will be explored in the qualitative part of the larger study combining qualitative and quantitative methods. If the results of the study described in this research protocol result in a negative evaluation of the CARES' psychometric properties, or it appears from the focus group discussions that there are deficits in the CARES content, formulation of items, or feasibility, adjustments for an improved Flemish version will be made. We plan to use this 'final' Flemish version in a pilot study where it will support the routine assessment and management of patients' psychosocial concerns and needs in a clinical pathway with medical and psychosocial components. In the future, the instrument will also be made available for use in clinical practice.

Secondly, the use of two procedures to invite patients to participate in the study can introduce bias. An invitation to participate in research from a member of the medical team or by post could result in different response rates in both subgroups. This is a demanding study for patients and therefore also for professionals to convince patients to participate. Hence, some flexibility in the process of patient recruitment is needed. Some departments prefer a personal approach and want to invite their patients for the research personally, while others do not find the time in the clinical appointment to do this. Both

procedures have been previously used in other validation research [66, 75, 77-80]. To assess any recruitment or consent bias, we will compare the data from the group of patients invited to participate in the hospital to the group invited by post.

Thirdly, the questionnaire package composed with the CARES and several concurrent instruments asks for a time-investment of approximately an hour. This could present a burden to participants, resulting in discontinuation of participation. However, preliminary study results report approximately 58% of the questionnaires distributed were returned completed. Eighty-four percent of the 153 participants who returned the first questionnaire also returned the second questionnaire completed.

Fourthly, the time between completing of the first and the second CARES survey could pose some problems. To examine test-retest reliability of an instrument the time period between two completions should be short enough to ensure that clinical change has not occurred, though long enough to prevent recall. While 1 or 2 weeks are recommended in literature [53], we ask participants to fill out the second questionnaire one week after the first. Preliminary results have shown some participants forget to fill in the second questionnaire or do not do so in a timely manner. They are reminded with a phone call by the researcher when de second questionnaire is not received in the recommended period of time. When data collection is completed, the time span between the two CARES-completions will be evaluated.

Fifthly, in earlier research the CARES was validated and used as a research tool for participants with various types of cancers, various cancer stages, at different phases of the care process, and often without age restrictions [31-44]. Because of the strict inclusion criteria we applied in our study, we have to state that the validation evidence from this study will not apply to patients above 60 years of age, and those with metastatic disease or in palliative care."

CONCLUSIONS

In summary, this study protocol describes a unique and thorough examination of the psychometric robustness of a QOL and needs assessment tool. Internal consistency of summary scales, test-retest reliability, content validity, feasibility,

construct validity and concurrent validity of the Flemish CARES are explored. Likewise, the use of several concurrent instruments will provide insight in the QOL, physical, emotional, social, relational and sexual functioning and well-being, distress and care needs of the research population. We expect to find positive results on the reliability and validity of the Flemish CARES version. Comprehensive assessment with the CARES throughout the care trajectory can contribute to timely identification of cancer patients psychosocial concerns and care needs to refer them to tailored care and improve the quality of psychosocial cancer care.

COMPETING INTERESTS

The authors declare they have no competing interests.

AUTHORS' CONTRIBUTIONS

BS is responsible for study conceptualization and design, data collection, study coordination, data analysis and drafting the protocol. JH participated in study conceptualization and design and in drafting the protocol. EVH and PV contributed to the design of the study and revised the protocol. WS was involved in refining plans for data analysis and revising the protocol. PB, FB, JM, DV and IC provided critical revisions to the protocol. All authors read and approved the final manuscript.

ACKNOWLEDGEMENTS AND FUNDING

This study is not commercially funded and the study protocol has not undergone peer-review by a funding body. We want to thank the hospitals and caregivers who want to work with us for the recruitment of participants. Many thanks go out to the native speaker Elizabeth Fradgley, for editing the manuscript for language.

Appendix 2.1

Table A2.1 Summary of needs assessment tools and their psychometric properties

		Validity		Reliability			
Instrument	**Items and domains**	**Content Validity**	**Other types of validity**	**Internal consistency**	**Reproducibility**	**Responsiveness**	**Feasibility**
CaNDI Cancer Needs Distress Inventory	39 items; 7 domains: depression, anxiety, emotional, social, health care, practical, physical	Derived from pool of items of concerns of cancer patients. Literature review. Revised in 2005, focus groups with patients and psycho-oncology professionals.	Good Spearman's r of total score with HADS, FACT-G, BSI and PDS. Good Spearman's r of CaNDI anxiety and depression with BSI anxiety and BSI depression. Lack sufficient power to adequately test the factor structure of the CaNDI Not all subscales validated.	All α >0.70 Time 1: 0.91 for full and retest Time 2: 0.92 for retest sample	Completed 2nd CaNDI 3 to 7 days ICCs ≥ 0.99	-	Time: N/A; Reading level: 5.5 reading grade level; Acceptability: N/A.
CARES Cancer Rehabilitation Evaluation System	93-132 items; 31 subscales taken together in 6 domains: physical, psychological, medical interaction, marital, sexual, miscellaneous	Literature. Interviews with patients & family. Expert review.	Factor-analysis resulted in 5-factor solution. Concurrent validity with SCL-90, KPS, DAS and visual analogue scale QOL. Good agreement with interviewers.	Domains α ranged from .87 to .94	Subscales and CARES-Total: r= .84 - .95 87% agreement n=71, time=1 week	-	Time: 20 min (range10-45); Reading level: N/A; Acceptability: most found it easy to use.

Instrument	Items and domains	Validity		Reliability		Responsiveness	Feasibility
		Content Validity	**Other types of validity**	**Internal consistency**	**Reproducibility**		
			Discriminant validity: able to distinguish patients with different disease stages.				
CARES-SF Cancer Rehabilitation Evaluation System-Short Form	38-57 items; 5 domains: physical, psychological, medical interaction, marital, sexual	Selected from the CARES by experts.	Factor-analysis resulted in 5 factor solution. Concurrent validity with CARES, FLIC, KPS, DAS. Large sample sizes.	Domains α ranged from .60 to .84	Dimensions: r=.69 - .92 81%-86% agreement n=120, time=10 days	Find physical, psychosocial change with time. Correlated with FLIC @ 1, 7, 14 months post-diagnosis	Time: on average 10min; Reading level: N/A; Acceptability: N/A.
CCM Cancer care monitor	38 items; 6 domains: general physical symptoms, treatment side effects, acute distress, despair, impaired ambulation, impaired performance (plus one global QOL-index)	Literature. Physician Judgements. Review by professionals and patients.	Convergent and divergent validity through comparison with BSI, SF-36, MSAS, LSI, SWLS.	Domains ranged from α= 0.80 to α= 0.89.	Time: between 1 and 7 days apart (correlations ranged from r=0.90 to 0.74) Time: between 8 and 14 days apart (correlations ranged from r=0.87 to 0.74).	-	Time: 20 min to complete paper version, 12 min to complete electronic version; Reading level: 85%, completed high school or greater education; Acceptability: patients expressed a strong preference for the electronic form (versus the paper form).
CHOICEs assessment Creating better health outcomes	112 items; 6 domains: Cancer specific symptoms, functional problems,	Literature. Review by an expert focus group	-	"Ease of Use": α= 0.98 "Satisfaction": α= 0.86	-	-	Time: median 9 min (range=0.5 to 49 min); 25% percent of the

Instrument	Items and domains	Validity		Reliability		Responsiveness	Feasibility
		Content Validity	Other types of validity	Internal consistency	Reproducibility		
by improving communication about patients' experiences assessment	physical, psychosocial, emotional, spiritual (plus 2 global ratings: health and QOL)	specialists in cancer care. Review by patients.					sample used ≤5 min; Reading level: N/A; Acceptability: (a) ease of use: 80% without assistance, 20% some assistance (weak, disability, convenience). Positive overall 'Ease of Use' score=5.06 (range −16 to +16) (b) Satisfaction: scores positively skewed in both groups.
Concerns checklist	Refined version:12items, original source:53 items; 3 domains: illness, practical, psychological	Literature. Retrospective study data. Pilot work. Review by patients.	Factor analysis resulted in 3-factor solution.	-	-	-	Time: N/A; Reading level: N/A; Acceptability: N/A.
CNAT Comprehensive needs assessment tool in cancer	59 items; 8 domains: information, psychological, health care staff, physical symptoms, hospital services, family/interpersonal, spiritual/religious, social.	Review of existing tools. Patient interviews. Patients and health professionals identified relevant items Pilot testing with 15 patients.	Exploratory factor analysis: 7 factor structure (64.2% variance). Convergent validity: low to moderate Spearman r with EQ5D.	All α >0.70 total scale α =0.97; subscales: α =0.80 to 0.97	-	-	Time: N/A; Reading level: N/A; Acceptability: N/A.

Instrument	Items and domains	Validity		Reliability		Responsiveness	Feasibility
		Content Validity	Other types of validity	Internal consistency	Reproducibility		
CNQ-SF Cancer Needs Questionnaire Short Form	32 items; 5 domains: psychological, health information, physical and daily living, patient care and support, interpersonal communication.	From original CNQ	Factor analysis resulted in 5 factors (68% of variance). Good correlation with EORTC QLQC-30 and BDI.	Domains ranged from α =0.77 to α =0.99.	-	-	Time: 20 min; Reading level: 4th or 5th grade; 25% non-completion rate; Acceptability: N/A.
CPILS Cancer Problems in Living Scale	31 items; 4 domains: physical distress, emotional distress, employment/financial problems, fear of recurrence.	Patient interviews. Patient surveys. Clinical opinion.	Exploratory Factor analysis resulted in 4 factors. Convergent validity: Physical correlated with RSCL-M (r=.50) and SF-36 (r= -.31 to -.45) Emotional correlated with POMS-SF (r=.27 to .38) and SF-36 (r= -.18 to -.31)	All α >0.70 Physical α =0.84 Emotional α =0.87 Financial α =0.78 Fear of recurrence α =0.84.	-	-	Time: N/A; Reading level: N/A; Acceptability: N/A.
CPNS Cancer Patient Need Survey	51 items; 5 domains: coping, help, information, work, and cancer shock	Interviews with nurses, patients, & caregivers using. Objective Content Test & Q-sort method.	-	Overall α= 0.91 Importance α: .83-.93 How well met α: .79-.95 Domains ranged from α= .88 to α= .92	-	-	Time: 2-45 min; Reading level N/A; Acceptability: reported no problems when used.

Instrument	Items and domains	Validity		Reliability		Responsiveness	Feasibility
		Content Validity	Other types of validity	Internal consistency	Reproducibility		
CPNQ Cancer Patient Need Questionnaire	71 items; 5 domains: psychological needs, health info, ADLs, patient care/support, interpersonal communication.	Literature. Interviews. Expert review. Pilot test.	Discriminant validity: able to distinguish patients with different disease stages.	Domains α ranged from .78 to .90	Intercorrelation all significant kappa > .4 n=124, time=10-14 days	-	Time: 20 min; Reading level: 4th or 5th grade; Acceptability: 25% non-completion rate.
Distress management tool	36 items; 5 domains: practical, family, emotional, spiritual/ religious, physical (plus 1 general distress item).	Literature. Expert review-NCCN panel.	-	-	-	-	Time: N/A; Reading level: N/A; Acceptability: N/A.
INM Information Needs Measure	9 information categories	Literature. Based on works by Derdiarian. Expert review.	-	Kendall zeta: .95-.99. Kendall coefficient of agreement: .20-.35.	-	-	Time: N/A; Reading level: N/A; Acceptability: N/A.
NEQ Need Evaluation Questionnaire	23 items; 4 domains: information regarding diagnosis/prognosis, examination/treatment, communication, relational, (plus 12 additional items)	Interviews. Pilot tests.	Factor analysis on the scale only partially confirms the hypothesized structure. Later study demonstrated good fit.	Domains: α ranged from .69-.81	Cohen's kappa ranged from .54-.94 Time=1week	-	Time: 5 min; Reading level: N/A; Acceptability: 63% of patients OK; 24% in-complete; 3% missing data.
OCPC Oncology Clinic Patient Checklist	86 Items; 15 domains: information, fatigue, pain, nutrition, speech and Language, respiration, bowel and bladder, transportation,	Data from previous research. Based on items from other tool.	-	-	-	-	Time: N/A; Reading level: N/A Acceptability: Checklist was accepted for practical use—

Instrument	Items and domains	Validity		Reliability		Responsiveness	Feasibility
		Content Validity	Other types of validity	Internal consistency	Reproducibility		
	mobility, self and home care, vocational and educational, interests and activities, family, interpersonal relationships, Emotional, (plus 3 open-ended questions)						process evaluation by staff (100% response rate) and patients 78%) (after 4 months); positive response from nursing staff. Usefulness, 82% (pilot work, n=11 patients)
PINQ Patient Information Need Questionnaire	17 items; 2 domains: disease-oriented and information about access to help & solution	Literature. Interviews.	Correlated with RSC, State-Anxiety Inventory & MMPI D-scale.	Domains ranged from α= .88 to α= .92; Inter-item correlation >0.2	-	Detected the changing needs of patients at three time points before and after first treatment	Time: N/A; Reading level:N/A Acceptability: reasons to refuse: not wanting to be reminded of their illness, feeling too old, etc.
PNAS Psychosocial needs assessment survey	34 items; 4 domains: informational, practical, supportive, spiritual.	Literature review. Clinical opinion.	-	No data on construct validity. Kuder-Richardson 20 statistic: Information: 0.90, Practical: 0.86, Supportive: 0.83, Spiritual: 0.90. Subscale correlations: r=.57 to .82	-	-	Time: N/A; Reading level: N/A; Acceptability: N/A.

Instrument	Items and domains	Validity		Reliability		Responsiveness	Feasibility
		Content Validity	Other types of validity	Internal consistency	Reproducibility		
PNAT Patient Needs Assessment Tool	16 items; 3 domains: physical, psychological, and social	Literature. Clinical experience.	Physical domain correlates with KPS; Psychological with GAIS, BSI MPAS, BDI Social with ISEL.	Domains ranged from α= .85 to α= .94	Interrater reliability: Friedman: .87, .76, .73; Spearman rank order: .59- .98	-	Time: 20-30 min.; Reading level: N/A; Acceptability: N/A.
PNI Psychosocial Needs Inventory	48 items; 7 domains: related to health professionals, information needs, related to support networks, identify needs, emotional and spiritual, practical and childcare need.	Literature. Interviews. Focus group.	Discriminant validity: detected the differences among needs at four critical movements of cancer trajectory.	$\alpha > .70$ for each of the first six domains.	-	-	Time: N/A; Reading level: N/A; Acceptability: 59% non-response rate and the characteristic of the non-respondents was examined.
Problem checklist	16 items; 4 domains: daily living, relationships, economics, emotions, (plus 2 other)	Literature. Audit data. Research study (n=505).	Factor analysis endorsed the 4-factor structure (accounting for 64% of variance) with the components on Economics and Emotions being particularly credible	Domains ranged from α= 0.70 to 0.82.	-	-	Time: N/A; Reading level: N/A; Acceptability: patients found it quick and easy to complete.
SCNS Supportive Care Needs Survey	61 items; 5 domains: psychological needs, health information, physical/daily living needs, patient care & support, and sexuality	Based on CPNQ. . Expert review. Pilot test.	-	Domains ranged from α= .87 to α= .97.	-	-	Time: 20 min; Reading level: 5th grade; Acceptability: patients found it understandable, 35% non-

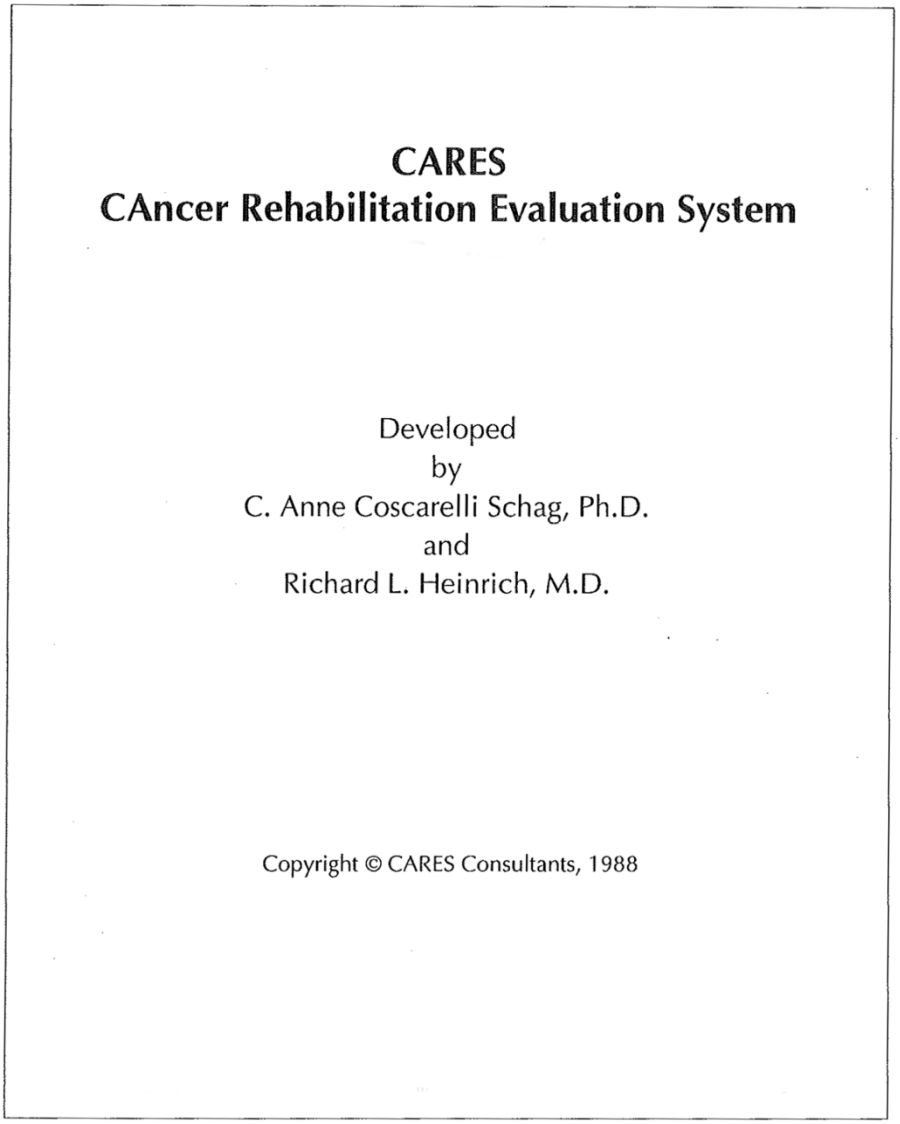
Instrument	Items and domains	Validity		Reliability		Responsiveness	Feasibility
		Content Validity	Other types of validity	Internal consistency	Reproducibility		
							completion.
SCNS-SF34 Supportive Care Needs Survey Short Form	34 items; 5 domains: psychological needs, health information, physical/daily living needs, patient care & support, and sexuality	Selected from original SCNS. 20 items factor loading >0.70 6 items: item-to-total correlation > domain cut-point & factor loading 0.51–0.69. 4 items factor loading 0.64–0.74 and clinically important 4 items clinically important	Confirmatory factor analysis (CFA) of five factors (73% of the total variance) Known-groups validity: remission vs no remission patient using summated domain mean score. Patients not in remission had higher scores. Convergent validity: Correlated good with DT, HADS anxiety, HADS depression and QLQ-C30 global.	All α>0.70 (α=0.86 to 0.96) Item-to-total score correlation coefficients r>0.55	-	-	Time: N/A; Reading level: Flesch–Kincaid Grade Level 7.2; Acceptability: N/A.
SNST Supportive Care Needs screening Tool	40 items; 5 domains: physical, social, psychological, information, spiritual.	Original pool 340 items taken from 20 existing tools. Expert opinion to reduce items. Pilot test	-	-	-	-	Time: N/A; Reading level: N/A; Acceptable to patients and staff Usability high for staff.

Instrument	Items and domains	Validity		Reliability		Responsiveness	Feasibility
		Content Validity	Other types of validity	Internal consistency	Reproducibility		
Symptoms and concerns checklist	29-32 items; 4 domains: physical symptoms, cognitive/ psychological, other concerns, patient defined	Patient interviews. Literature. Expert panel. Pilot work. Patient. Interviews.	Generally demonstrated convergent validity when compared with SDS, POS. Able to discriminate between different groups of patients (e.g. Outpatients vs. hospital inpatients).	Overall: α = .85	Time: over 2 consecutive days—weighted Kappa 0.35–0.77		Time: 5 min; Reading level: N/A; Acceptability: 97% felt comprehensive, 82% felt easy to complete, 79% good idea, 98% participated, 7% completed all items.

Abbreviations: HADS (Hospital Anxiety and Depression Scale), FACT-G (Functional Assessment of Cancer Therapy – General), *PDS* (Paulhus Deception Scales),SCL-90 (Symptom Checklist-90), DAS (Dyadic Adjustment Scale), KPS (Karnofsky Performance Status), FLIC (Functional Living Index-Cancer),BSI (The brief symptom inventory), SF-36 (The Short Form (36) Health Survey), MSAS (The memorial symptom assessment scale), LSI (The lifesatisfaction index–short form), SWLS (The satisfaction with life scale), EQ5D (EuroQOL five dimensions questionnaire), EORTC QLQC-30 (European Organisation of Research and Treatment for Cancer Quality of Life Questionnaire Core 30), RSCL-M (Rotterdam Symptom checklist-Modified), POMS-SF (Profile Of Mood States-Short Form), NCCN (National Comprehensive Cancer Network), RSC (Rotterdam Symptom Checklist), MMPI-D (Minnesota Multiphasic Personality Inventory-Depression), GAIS (Global Adjustment to Illness Scale), MPAS (Memorial Pain Assessment Scale), BDI (Beck Depression Inventory), ISEL (Interpersonal Support EvaluationList), PNI (Psychosocial Needs Inventory), SDS (Symptom Distress Scale), POS (Palliative care Outcome Scale).

Appendix 2.2

CARES Questionnaire



CARES
CAncer Rehabilitation Evaluation System

Developed
by
C. Anne Coscarelli Schag, Ph.D.
and
Richard L. Heinrich, M.D.

CARES
CAncer Rehabilitation Evaluation System

Patient Information

Name: _____ ID #: _____

Date: _____

Age: _____

Sex: M F

Type of Cancer: _____

Date of Diagnosis: _____ Name of Physician: _____

Instructions

Below is a list of Problem Statements that describe situations and experiences of individuals who have or have had cancer. Read each statement and circle the number that best describes **HOW MUCH EACH STATEMENT APPLIES TO YOU** during the **PAST MONTH, INCLUDING TODAY**. Some sections will not apply to you. Please skip these sections and proceed to the next one as directed. For any problem statement that you rate between 1 and 4, indicate whether this is a problem with which you would like help by circling *Y* for *yes* or *N* for *no*.

Example

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much	**Do you want help?**
1. I have difficulty walking	0	(1)	2	3	4	Y (N)
2. I find that food tastes bad	0	1	2	3	(4)	(Y) N

2 CARES

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much	Do you want help?
1. I have difficulty bending or lifting	0	1	2	3	4	Y N
2. I have difficulty walking and/or moving around	0	1	2	3	4	Y N
3. I have difficulty doing physical activities such as running and playing sports	0	1	2	3	4	Y N
4. I do not have the energy I used to	0	1	2	3	4	Y N
5. I have difficulty driving	0	1	2	3	4	Y N
6. I have difficulty doing household chores	0	1	2	3	4	Y N
7. I have difficulty bathing, brushing my teeth, or grooming myself	0	1	2	3	4	Y N
8. I have difficulty preparing meals	0	1	2	3	4	Y N
9. I am not interested in recreational activities like I used to be	0	1	2	3	4	Y N
10. I do not engage in the recreational activities that I used to	0	1	2	3	4	Y N
11. I do not have enough enjoyable activities to fill the day	0	1	2	3	4	Y N
12. I have difficulty planning activities because of the cancer or its treatments	0	1	2	3	4	Y N
13. I cannot gain weight	0	1	2	3	4	Y N
14. I am continuing to lose weight	0	1	2	3	4	Y N
15. I find food unappealing	0	1	2	3	4	Y N
16. I find that food tastes bad	0	1	2	3	4	Y N
17. I find it difficult to swallow	0	1	2	3	4	Y N
18. I find that the cancer or its treatments keep me from working	0	1	2	3	4	Y N
19. I find that cancer or its treatments interfere with my ability to work	0	1	2	3	4	Y N
20. I frequently have pain	0	1	2	3	4	Y N
21. I have chronic pain from scars and surgery	0	1	2	3	4	Y N
22. I have pain that is not controlled by pain medication	0	1	2	3	4	Y N

CARES 3

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much	Do you want help?
23. I have pain that is controlled by pain medication	0	1	2	3	4	Y N
24. I find that my clothes do not look good on me	0	1	2	3	4	Y N
25. I find that my clothes do not fit	0	1	2	3	4	Y N
26. I have difficulty finding clothes to fit	0	1	2	3	4	Y N
27. I find that the medical team withholds information from me about the cancer	0	1	2	3	4	Y N
28. I find that doctors don't explain what they are doing to me	0	1	2	3	4	Y N
29. I find that nurses don't explain what they are doing to me	0	1	2	3	4	Y N
30. I have difficulty asking doctors questions	0	1	2	3	4	Y N
31. I have difficulty asking nurses questions	0	1	2	3	4	Y N
32. I have difficulty expressing my feelings to the doctors and nurses	0	1	2	3	4	Y N
33. I have difficulty telling my doctor about new symptoms	0	1	2	3	4	Y N
34. I have difficulty understanding what the doctors tell me about the cancer or its treatments	0	1	2	3	4	Y N
35. I have difficulty understanding what the nurses tell me about the cancer or its treatments	0	1	2	3	4	Y N
36. I would like to have more control over what the doctors do to me	0	1	2	3	4	Y N
37. I would like to have more control over what the nurses do to me	0	1	2	3	4	Y N
38. I am embarrassed to show my body to others because of my illness	0	1	2	3	4	Y N
39. I am uncomfortable showing my scars to others	0	1	2	3	4	Y N
40. I am uncomfortable with the changes in my body	0	1	2	3	4	Y N
41. I frequently feel anxious	0	1	2	3	4	Y N
42. I frequently feel depressed	0	1	2	3	4	Y N
43. I frequently feel angry	0	1	2	3	4	Y N

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much	Do you want help?
44. I frequently feel upset	0	1	2	3	4	Y N
45. I frequently feel overwhelmed by my emotions and feelings about the cancer	0	1	2	3	4	Y N
46. I have difficulty sleeping	0	1	2	3	4	Y N
47. I have difficulty concentrating	0	1	2	3	4	Y N
48. I have difficulty remembering things	0	1	2	3	4	Y N
49. I have difficulty thinking clearly	0	1	2	3	4	Y N
50. I have difficulty telling my friends or relatives to come over less often	0	1	2	3	4	Y N
51. I have difficulty telling my friends or relatives to leave when I do not feel well	0	1	2	3	4	Y N
52. I have difficulty asking my friends or relatives to do something fun with me	0	1	2	3	4	Y N
53. I do not know what to say to my friends or relatives	0	1	2	3	4	Y N
54. I have difficulty asking friends or relatives to do things for me	0	1	2	3	4	Y N
55. I have difficulty telling my friends or relatives about the cancer	0	1	2	3	4	Y N
56. I have difficulty asking my friends or relatives to come over more often	0	1	2	3	4	Y N
57. I find that my friends or relatives tell me I'm looking well when I'm not	0	1	2	3	4	Y N
58. I find that my friends or relatives withhold information from me	0	1	2	3	4	Y N
59. I find that my friends or relatives avoid talking with me about the cancer	0	1	2	3	4	Y N
60. I find that my friends or relatives do not visit often enough	0	1	2	3	4	Y N
61. I find that my friends or relatives do not call often enough	0	1	2	3	4	Y N

CARES 5

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much	Do you want help?
62. I find that my friends or relatives are uncomfortable when they visit me	0	1	2	3	4	Y N
63. I find that friends or relatives have difficulty talking with me about my illness	0	1	2	3	4	Y N
64. I feel uncomfortable when I see other patients getting treatments	0	1	2	3	4	Y N
65. I become nervous when I have to go to the hospital	0	1	2	3	4	Y N
66. I become nervous when I am waiting to see the doctor	0	1	2	3	4	Y N
67. I become nervous when I am waiting to find out the results of tests	0	1	2	3	4	Y N
68. I become nervous when I am having diagnostic tests	0	1	2	3	4	Y N
69. I become nervous when I get my blood drawn	0	1	2	3	4	Y N
70. I worry about whether my treatments are working	0	1	2	3	4	Y N
71. I worry about whether the cancer is progressing	0	1	2	3	4	Y N
72. I worry about not being able to care for myself	0	1	2	3	4	Y N
73. I worry about how my family will manage if I die	0	1	2	3	4	Y N
74. I do not feel sexually attractive	0	1	2	3	4	Y N
75. I do not think my partner(s) finds me sexually attractive	0	1	2	3	4	Y N
76. I am not interested in having sex	0	1	2	3	4	Y N
77. I do not think that my partner(s) is interested in having sex with me	0	1	2	3	4	Y N
78. I sometimes don't show up for my doctor's appointment	0	1	2	3	4	Y N
79. I sometimes don't show up for my treatments	0	1	2	3	4	Y N
80. I sometimes don't take my medication as prescribed	0	1	2	3	4	Y N
81. I sometimes don't follow my doctor's instructions	0	1	2	3	4	Y N
82. I have financial problems	0	1	2	3	4	Y N

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much	Do you want help?
83. I have insurance problems	0	1	2	3	4	Y N
84. I have difficulty with transportation to and from my medical appointments and/or other places	0	1	2	3	4	Y N
85. I am gaining too much weight	0	1	2	3	4	Y N
86. I find some diagnostic procedures extremely painful	0	1	2	3	4	Y N
87. I have frequent episodes of diarrhea	0	1	2	3	4	Y N
88. I have times when I do not have control of my bladder	0	1	2	3	4	Y N
Do you have children? **Yes No** *If No, skip to next section.*						
89. I have difficulty taking care of the children and/or the grandchildren	0	1	2	3	4	Y N
90. I have difficulty helping my children cope with my illness	0	1	2	3	4	Y N
91. I have difficulty helping my children talk about my illness	0	1	2	3	4	Y N
Are you working or have you been been employed during the last month? **Yes No** *If No, skip to next section.*						
92. I have difficulty talking to my boss about the cancer	0	1	2	3	4	Y N
93. I have difficulty talking to the people who work with me about the cancer	0	1	2	3	4	Y N
94. I have difficulty telling my employer that I cannot do something because of my illness	0	1	2	3	4	Y N
95. I have difficulty asking for time off from work for medical treatments	0	1	2	3	4	Y N
96. I am worried about being fired	0	1	2	3	4	Y N

CARES 7

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much	Do you want help?
Did you look for work during the past month? **Yes** **No** ***If No, skip to next section.***						
97. I have difficulty finding a new job since I have had cancer	0	1	2	3	4	Y N
98. I find that employers are reluctant to hire people with a cancer history	0	1	2	3	4	Y N
Have you been sexually active since your cancer diagnosis? **Yes** **No** ***If No, skip to next section.***						
99. I find that the frequency of sexual activity has decreased	0	1	2	3	4	Y N
100. I have difficulty becoming sexually aroused	0	1	2	3	4	Y N
101a. I have difficulty getting or maintaining an erection (**Males**)	0	1	2	3	4	Y N
b. I have difficulty getting lubricated (**Females**)						
102. I have difficulty reaching orgasm	0	1	2	3	4	Y N
Are you married or in a significant relationship? **Yes** **No** ***If No, skip to next section.***						
103. My partner and I have difficulty talking about our feelings	0	1	2	3	4	Y N
104. My partner and I have difficulty talking about our fears	0	1	2	3	4	Y N
105. My partner and I have difficulty talking about what will happen after my death	0	1	2	3	4	Y N
106. My partner and I have difficulty talking about our future	0	1	2	3	4	Y N
107. My partner and I have difficulty talking about the cancer and what might happen	0	1	2	3	4	Y N

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much	Do you want help?
108. My partner and I have difficulty talking about wills and financial arrangements	0	1	2	3	4	Y N
109. I do not feel like embracing, kissing, or caressing my partner	0	1	2	3	4	Y N
110. My partner does not feel like embracing, kissing or caressing me	0	1	2	3	4	Y N
111. I am not interested in touching my partner	0	1	2	3	4	Y N
112. My partner is not interested in touching me	0	1	2	3	4	Y N
113. My partner and I are not getting along as well as we usually do	0	1	2	3	4	Y N
114. My partner and I are upset with each other more often than usual	0	1	2	3	4	Y N
115. My partner and I have so much time together that we get on each other's nerves	0	1	2	3	4	Y N
116. My partner and I are more distant than usual	0	1	2	3	4	Y N
117. My partner won't let me do activities that I am capable of doing	0	1	2	3	4	Y N
118. My partner spends too much time taking care of me	0	1	2	3	4	Y N
119. My partner does not take care of me enough	0	1	2	3	4	Y N
120. I have difficulty asking my partner to take care of me	0	1	2	3	4	Y N
Are you single and not in a significant relationship? **Yes** **No** ***If No, skip to next section.***						
121. I have difficulty initiating contact with potential dates	0	1	2	3	4	Y N
122. I have difficulty meeting potential dates	0	1	2	3	4	Y N
123. I am afraid to go to places that I used to visit to meet dates	0	1	2	3	4	Y N
124. I have difficulty telling a date about the cancer or its treatments	0	1	2	3	4	Y N
125. I am afraid to initiate a sexual relationship with someone	0	1	2	3	4	Y N

CARES 9

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much	Do you want help?
Have you had chemotherapy treatments in the last month? **Yes** **No**						
If No, skip to next section.						
126. I become nervous when I get chemotherapy	0	1	2	3	4	Y N
127. I become nauseated during and/or before chemotherapy	0	1	2	3	4	Y N
128. I vomit during and/or before chemotherapy	0	1	2	3	4	Y N
129. I feel sick when I think about my chemotherapy	0	1	2	3	4	Y N
130. I feel nauseated after I receive chemotherapy	0	1	2	3	4	Y N
131. I vomit after chemotherapy	0	1	2	3	4	Y N
132. I feel tired after my chemotherapy	0	1	2	3	4	Y N
133. I have other side effects after chemotherapy	0	1	2	3	4	Y N
134. I have lost my hair and/or it is growing back slowly because of chemotherapy	0	1	2	3	4	Y N
Have you had radiation therapy treatments in the last month? **Yes** **No**						
If No, skip to next section.						
135. I feel fatigued after my radiation treatments	0	1	2	3	4	Y N
136. I get nervous when I get radiation treatments	0	1	2	3	4	Y N
137. I feel nauseous or vomit after my radiation treatments	0	1	2	3	4	Y N
Do you have an ostomy? **Yes** **No**						
If No, skip to next section.						
138. I have problems with ostomy care and maintenance	0	1	2	3	4	Y N

10 CARES

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much	Do you want help?
Do you have a prosthesis? *If No, skip to next section.*	**Yes**	**No**				
139. I have difficulty with my prosthetic device (artificial limb, breast prosthesis, etc.)	0	1	2	3	4	Y N

Please list any additional cancer or treatment–related problems that may not have been addressed:

A. _____

B. _____

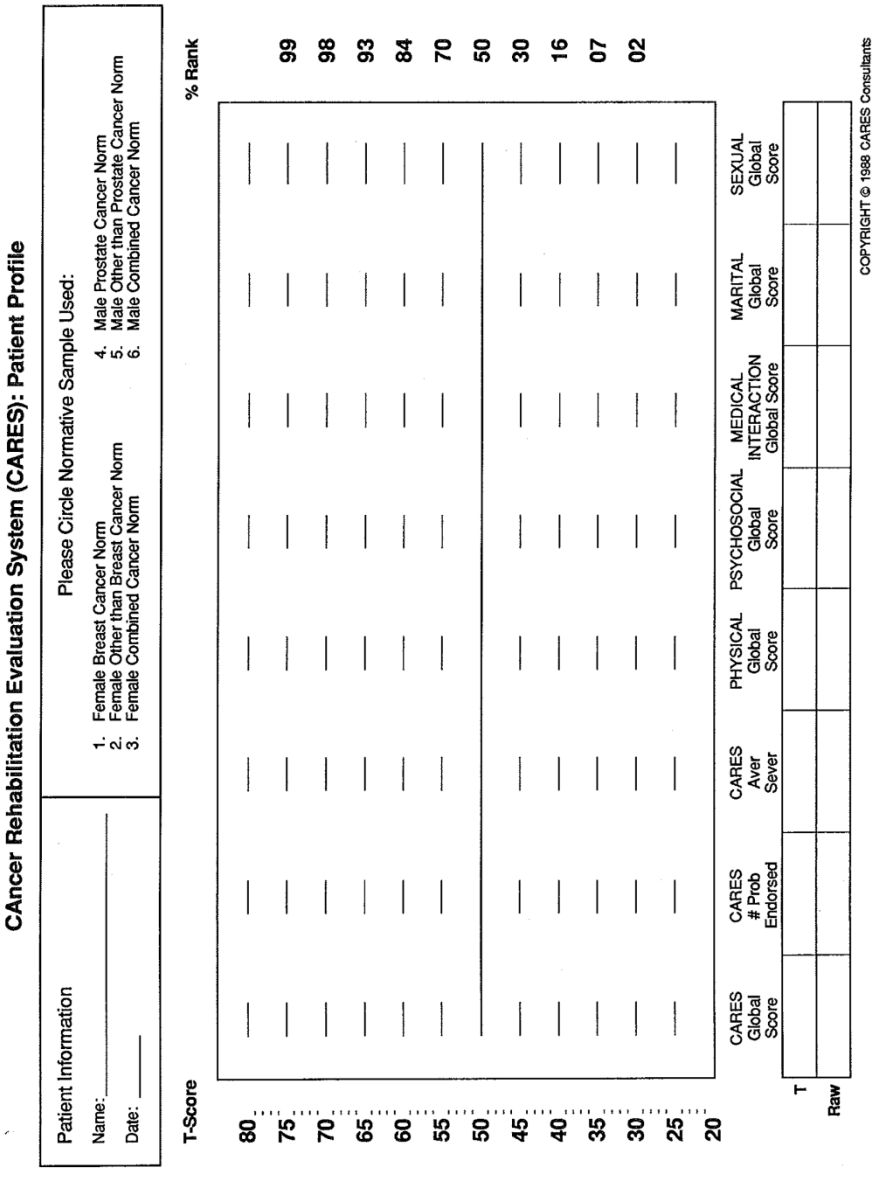
C. _____

D. _____

E. _____

Appendix 2.3

CARES Patient Profile



CARES score sheet

PHYSICAL

Ambulation
___ 1. diff bend or lift
___ 2. diff walk/move around
___ 3. diff do physical activ.
___ 4. reduction in energy

Activities of Daily Living
___ 5. diff driving
___ 6. diff household chores
___ 7. diff bathe, brush groom
___ 8. diff prepare meals

Recreational Activities
___ 9. no interest recreat activ
___ 10. not engage recreat activ
___ 11. not enough enjoyable activ
___ 12. diff planning activ

Weight Loss
___ 13. cannot gain weight
___ 14. continue to lose weight
___ 15. food unappealing
___ 16. food tastes bad
___ 17. diff swallowing

Difficulty Working
___ 18. cancer prevents work
___ 19. cancer interferes work

Pain
___ 20. frequently has pain
___ 21. chronic pain scars/surgery
___ 22. pain not controlled medication
___ 23. pain controlled medication

Clothing
___ 24. clothes not look good
___ 25. clothes not fit
___ 26. diff find clothes
___ *SUM ___ #(1-4) 26 # Potential*

MEDICAL INTERACTION

Problems Obtaining Info from Medical Team
___ 27. medical team withholds info
___ 28. doctors don't explain what do
___ 29. nurses don't explain what do

Difficulty Communicating with Medical Team
___ 30. diff ask doctors questions
___ 31. diff ask nurses questions
___ 32. diff express feelings MD/RN
___ 33. diff tell doctor new symptoms
___ 34. diff understand MD about cancer
___ 35. diff understand RN about cancer

Control of Medical Team
___ 36. wants more control over MD
___ 37. wants more control over RN
___ *SUM ___ #(1-4) 11 # Potential*

***MARITAL**

Communication with Partner
___ 103. diff talk feelings
___ 104. diff talk fears
___ 105. diff talk happen after death
___ 106. diff talk future
___ 107. diff talk cancer
___ 108. diff talk wills/financial matters

Affection with Partner
___ 109. doesn't feel like embrace,etc
___ 110. partner no feel like embrace, etc.
___ 111. no interest in touch partner
___ 112. partner no interest in touch

Interaction with Partner
___ 113. not get along as well usual
___ 114. upset with other more often
___ 115. so much time together, on nerves
___ 116. more distant than usual

Overprotection by Partner
___ 117. partner not let do activ capable of
___ 118. partner provides too much care

Neglect of Care by Partner
___ 119. partner takes too little care
___ 120. diff ask partner to take care
___ *SUM ___ #(1-4) 18,0*
Potential Circle

PSYCHOSOCIAL

Body Image
___ 38. embarrassed to show body
___ 39. uncomfor show scars
___ 40. uncomfor with body changes

Psychological Distress
___ 41. frequently anxious
___ 42. frequently depressed
___ 43. frequently angry
___ 44. frequently upset
___ 45. frequently overwhelmed by cancer
___ 46. diff sleep

Cognitive Problems
___ 47. diff concentrating
___ 48. diff remembering
___ 49. diff thinking clearly

Difficulty Communicat with Friends/Relatives
___ 50. diff tell frnd/rel to come less often
___ 51. diff tell frnd/rel to leave when not well
___ 52. diff ask frnd/rel to do fun things
___ 53. don't know what to say to frnd/rel
___ 54. diff ask frnd/rel help
___ 55. diff tell frnd/rel about cancer
___ 56. diff ask frnd/rel to come more

Friends/Relatives Difficulty Interacting
___ 57. frnd/rel say look well when not
___ 58. frnd/rel withhold information
___ 59. frnd/rel avoid talk cancer
___ 60. frnd/rel do not visit enough
___ 61. frnd/rel do not call enough
___ 62. frnd/rel uncomfor visiting
___ 63. frnd/rel diff talk about cancer

Anxiety in Medical Situations
___ 64. uncomfor see patients get treat
___ 65. nervous going to hospital
___ 66. nervous wait to see doctor
___ 67. nervous wait for test results
___ 68. nervous have diagnostic tests
___ 69. nervous get blood drawn

Worry
___ 70. worry whether treatments work
___ 71. worry whether cancer progress
___ 72. worry not able to care for self
___ 73. worry how family will manage

*Interaction with Children
___ 89. diff care for child/grandchild
___ 90. diff help children cope
___ 91. diff help children talk about illness

*At Work Concerns
___ 92. diff talk boss about cancer
___ 93. diff talk people at work
___ 94. diff tell employer cannot do work
___ 95. diff ask time off for treatments
___ 96. worried about being fired
___ *SUM ___ #(1-4) 44, 41, 39, 36*
Potential Circle

SEXUAL

Sex Interest
___ 74. doesn't feel sex. attract
___ 75. thinks not sexually attractive to partner(s)
___ 76. not interested in having sex
___ 77. doesn't think partner(s) interested in sex

*Sexual Dysfunction
___ 99. frequency of sex decreased
___ 100. diff become sexually aroused
___ 101. diff with erection (males)
___ 101. diff lubrication (females)
___ 102. diff reach orgasm
___ *SUM ___ #(1-4) 8, 4*
Potential Circle

* Items may not apply to all patients

MISCELLANEOUS

Compliance
___ 78. doesn't show for MD appoint
___ 79. doesn't show for treatments
___ 80. doesn't take medication
___ 81. doesn't follow MD's instruct
___ *SUM ___ #(1-4) 4 # Potential*

Economic Barriers
___ 82. financial problems
___ 83. insurance problems
___ 97. diff find new job**
___ 98. employers no hire CA hist**
___ *SUM ___ #(1-4) 4, 2*
Potential Circle

*Dating
___ 121. diff initiating dates
___ 122. diff meet dates
___ 123. afraid go places meet dates
___ 124. diff tell date about cancer
___ 125. afraid to initiate sex relation
___ *SUM ___ #(1-4) 5, 0*
Potential Circle

*Chemotherapy-Related Problems
___ 126. nervous get chemo
___ 127. nauseated during/before chemo
___ 128. vomit during/before chemo
___ 129. sick when think about chemo
___ 130. nauseated after chemo
___ 131. vomit after chemo
___ 132. tired after chemo
___ 133. other side effects chemo
___ 134. lost hair/grow slow from chemo
___ *SUM ___ #(1-4) 9, 0*
Potential Circle

*Radiation-Related Problems
___ 135. fatigued after rad
___ 136. nervous get rad
___ 137. nauseous/vomit after rad
___ *SUM ___ #(1-4) 3, 0*
Potential Circle

*Ostomy
___ 138. problems ostomy care/maint.
___ *SUM ___ #(1-4) 1, 0*
Potential Circle

*Prosthesis
___ 139. diff with prosthesis
___ *SUM ___ #(1-4) 1, 0*
Potential Circle

Miscellaneous Items
___ 84. diff with transport
___ 85. gain too much weight
___ 86. diagnostic proced painful
___ 87. frequent diarrhea
___ 88. poor bladder control
___ *SUM ___ #(1-4) 5 # Potential*

SUM ALL 8 MISCELLANEOUS SUMS ABOVE
___ *SUM ___ #(1-4) ____ # Potential*

Global and Average Severity for CARES and 5 Subscales

Scale	SUM	# Endor	# Poten	AVE Sever	GLOBAL
Physical	____	____	____	____	____
Psychoso	____	____	____	____	____
Med Int	____	____	____	____	____
Marital	____	____	____	____	____
Sexual	____	____	____	____	____
Miscell	____	____	____	____	____
CARES	____	____	____	____	____

CARES-SF score sheet

PHYSICAL SUBSCALE

— 1. diff bend or lift
— 2. reduction in energy
— 3. diff household chores
— 4. diff bathe, brush groom
— 5. diff planning activities
— 6. cannot gain weight
— 7. food unappealing
— 8. cancer interferes work
— 9. frequently has pain
— 10. clothes not fit
___ *SUM ___ #(1-4) 10 # Potential*

MEDICAL INTERACTION SUBSCALE

— 11. doctors don't explain what do
— 12. diff ask doctors questions
— 13. diff understand MD about cancer
— 14. wants more control over MD
___ *SUM ___ #(1-4) 4 # Potential*

PSYCHOSOCIAL SUBSCALE

— 15. uncomfor with body changes
— 16. frequently anxious
— 17. diff sleep
— 18. diff concentrating
— 19. diff ask frnd/rel help
— 20. diff tell frnd/rel about cancer
— 21. frnd/rel say look well when not
— 22. frnd/rel do not visit enough
— 23. frnd/rel diff talk about cancer
— 24. nervous wait to see doctor
— 25. nervous get blood drawn
— 26. worry whether cancer progress
— 27. worry not able to care for self

* Children
— 37. diff help children cope

* At Work Concerns
— 38. diff talk people at work about cancer
— 39. diff ask time off for medical treatments
— 40. worried about being fired
___ *SUM ___ #(1-4) 17,16,14,13*
 # Potential Circle

SEXUAL SUBSCALE

— 28. doesn't feel sex attract
— 29. not interested in having sex

* Sex Dysfunction
— 42. frequency of sex decreased
___ *SUM ___ #(1-4) 3,2*
 # Potential Circle

*MARITAL SUBSCALE

— 43. diff talk feelings
— 44. diff talk wills/financial matters
— 45. doesn't feel like embrace, kiss, caress
— 46. not get along as well usual
— 47. partner spends too much time providing care
— 48. diff ask partner to take care
___ *SUM ___ #(1-4) 6,0*
 # Potential Circle

MISCELLANEOUS SUBGROUPS

*Looking for Work
— 41. diff find new job

*Dating
— 49. diff initiating contact with dates
— 50. diff tell date about cancer

*Chemotherapy-Related Problems
— 51. nervous get chemo
— 52. nauseated during/before chemo
— 53. nauseated after chemo
— 54. vomit after chemo
— 55. other side effects chemo

*Radiation-Related Problems
— 56. nervous get rad
— 57. nauseous/vomit after rad

*Ostomy
— 58. problems ostomy care and maintenance

*Prosthesis
— 59. diff with prosthesis

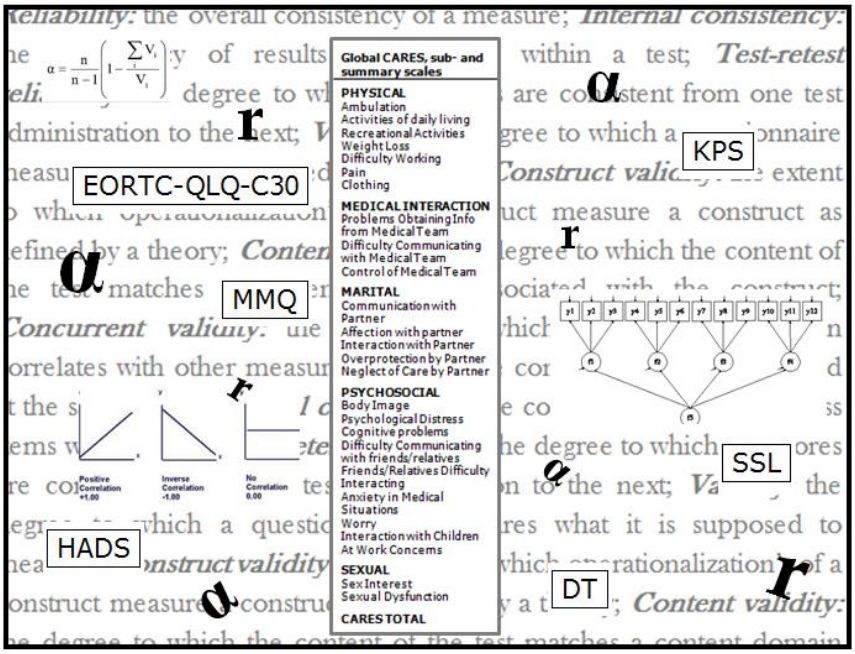
Miscellaneous Items
— 30. doesn't follow MD's instruct
— 31. financial problems
— 32. insurance problems
— 33. diff with transport
— 34. gain too much weight
— 35. frequent diarrhea
— 36. poor bladder control
___ *SUM ___ #(1-4) ____ # Potential*

Global and Average Severity for CARES-SF and 5 Subscales

SCALE	SUM	# Endor	# Poten	Ave. Sever.	Global
Physical	____	____	____	____	____
Psychoso	____	____	____	____	____
Med Int	____	____	____	____	____
Marital	____	____	____	____	____
Sexual	____	____	____	____	____
Miscell	____	____	____	____	____
CARES	____	____	____	____	____

* Items may not apply to all patients

3
Chapter



Psychometric validation of the CARES

This chapter is based on:

Schouten, Bojoura; Hellings, Johan; Van Hoof, Elke; Vankrunkelsven, Patrick; Bulens, Paul; Buntinx, Frank; Mebis, Jeroen; Vandijck, Dominique & Schrooten, Ward (2016) *Validation of the flemish CARES, a quality of life and needs assessment tool for cancer care.*BMC Cancer. 2016 Aug 30;16:696. doi: 10.1186/s12885-016-2728-9.

Bojoura Schouten; Johan Hellings; Patrick Vankrunkelsven; and Elke Van Hoof. *Translation And Validation Of A Quality Of Life And Needs Assessment Tool: The Cancer Rehabilitation Evaluation System And Its' Short Form.* 17th World Congress of Psycho-Oncology. 30 July-1 August 2015, Washington, United States [poster presentation].

Schouten, Bojoura; Van Hoof, Elke; Schrooten, Ward; Mebis, Jeroen; Vankrunkelsven, Patrick; Hellings, Johan. *Een instrument om kwaliteit van leven en zorgnoden bij kankerpatiënten in beeld te brengen.*Tijdschrift voor Geneeskunde -Accepted for publication.

ABSTRACT

OBJECTIVE The Cancer Rehabilitation Evaluation System (CARES) is a quality of life (QOL) and needs assessment instrument of US origin that was developed in the 90's. Since November 2012 the copyright and user fee were abolished and the instrument became publicly available the present study aims to reinvestigate the psychometric properties of the CARES for the Flemish population in Belgium.

METHODS The CARES was translated into Flemish following a translation-back translation process. A sample of 192 cancer patients completed the CARES, concurrent measures, and questions on socio-demographic and medical data. Participants were asked to complete the CARES a second time one week later, followed by some questions on their experiences with the instrument. Internal consistency, test-retest reliability, content validity, construct validity, concurrent validity and feasibility of the CARES were subsequently assessed.

RESULTS The Flemish CARES version demonstrated excellent reliability with high internal consistency (range .87-.96) and test-retest ratings (range .70-.91) for all summary scales. Factor analysis replicated the original factor solution of five higher order factors with factor loadings of .325-.851. Correlations with other instruments ranging from |.43| - |.75| confirmed concurrent validity. Feasibility was indicated by the low number of missing items (mean 2.3; SD 5.0) and positive feedback of participants on the instrument.

CONCLUSIONS The Flemish CARES has strong psychometric properties and can as such be a valid tool to assess cancer patients' QOL and needs in research, for example in international comparisons. The positive feedback of participants on the CARES support the usefulness of this tool for systematic assessment of cancer patients' well-being and care needs in clinical practice.

KEYWORDS: cancer, psycho-oncology, psychosocial, quality of life, needs assessment, validation, CARES

BACKGROUND

Cancer is a disease with a huge impact on patients and their relatives, going far beyond the physical aspects. Together with the rise of more successful therapeutic approaches and the increased life expectancy, the psychological and social aspects of care receive more attention as part of a holistic view of health care. Health care, and certainly cancer care, therefore requires a more integrated approach as a response to the fragmented delivery of health and social services[109]. Together with more integration, health is moving towards a more patient-centered approach. This is a process evolution as patient-centered care is an important dimension of quality of care [33]. Individualized, more integrated care plans and clinical care pathways are developed to improve outcomes for cancer patients, with an increasing emphasis on quality of life (QOL) [65]**.**

To integrate the psychosocial approach into cancer care, the implementation of routine psychosocial screening and needs assessment is recommended by international cancer systems and in guidelines [42, 43, 44, 110, 111, 112]. However, not all patients with a positive screen for distress or decreased QOL are interested in professional support [28]. In some cases programs involving systematic or routine screening for distress lead to a considerable number of unaccepted referrals [113, 114]. In contrast to QOL or distress screening, needs assessment not only focuses on identifying patients' unresolved concerns and problems, but furthermore explores whether or not there is a desire extra help [115]. This not only gives guidance from the patients' perspective for more integrated and holistic care plans, but also allows for the more effective and efficient use of resources. [28].

The Cancer Rehabilitation Evaluation System (CARES) is a self-administered QOL and needs assessment instrument that can be used for research or clinical purposes [80, 81, 82, 83, 84, 85, 86]. The instrument covers a broad range of topics relevant to the QOL disruption many cancer patients experience. The CARES consists of 139 items meant to reflect the multidimensional burden of cancer and its treatment can cause to patients and their relatives. The items can be scored broadly using the six summary scales medical interaction, physical, psychosocial, marital and sexual wellbeing and miscellaneous items; or in a more detailed manner grouped under 31 subscales. However, not all items

apply to all patients and therefore patients can complete a minimum of 93 items or a maximum of 132 items. Patients can rate each item, formulated as problem statement, on a five-point scale, zero representing "not at all" (no problem) and four representing "very much" (severe problem). For every applicable problem statement patients are asked to answer the question "Do you want help?" by ticking the box 'yes' or 'no'.

The psychometric robustness of the CARES and its' earlier development versions called the Cancer Inventory of Problem Situations (CIPS) are well documented and positively evaluated [80, 81]. With high Crohnbachs alpha's (α=0.87-0.94) and high test-retest correlations (r= 0.84-0.95) for the summary scales and CARES total the instrument demonstrates excellent reliability. The validity of the CARES was also rigorously tested. Results from post-administration interviews supported the content validity of the instrument [80, 116]. An extensive evaluation of concurrent validity was conducted with the Symptom Checklist-90 (SCL-90) [117], Dyadic Adjustment Scale (DAS) [118], Karnofsky Performance status Scale (KPS) [87, 119] and a visual analogue scale [120] for QOL before and after cancer, resulting in moderate to high correlations. In two studies investigating the feasibility of the CARES for patients, the participants on average needed 18 to 20 minutes to complete the CARES. The majority of them thought the questionnaire reflected relevant day-to-day problems of cancer patients; they understood the instructions well and found questions easy to understand and not offensive [80]. Despite this good quality the widespread use of the CARES and it's short form was limited by copyright and a user fee that the developers chose to impose. Since November 2012 this is no longer the case [121].

Due to the combination of feasibility for patients, psychometrical robustness and the wide representation of life domains that can be disrupted by a cancer diagnosis and the side effects associated with treatment, the CARES was chosen for further research on QOL and care needs in Belgium. However, time perspective, culture and language are important for the ecological dimension and validity of an instrument [122]. Careful translation and validation of an instrument are extremely important for the data to be valid [123, 124]. Consequently, a validation study on the CARES was conducted in the Flemish-

speaking part of Belgium. The thorough validation-exercise is described in this article.

METHODS

The protocol of this study, including a priori hypotheses and criteria, is described in detail in a previous publication [125]. The procedures used the general principles of scale development according to classical test theory.

Participants

There are no general criteria for the sample size in a validation study, but a sample size of at least 50-100 is generally recommended [79]. Sample sizes in the validation research of the original CARES varied for each psychometric quality from 22 to 1047 [80]. In this validation study of the CARES, the objective was set to include at least 150 participants.

A heterogeneous sample of cancer patients was recruited in several departments of four Flemish hospitals from March 2014 to February 2015. Non-palliative cancer patients aged between 25 and 60 years with a primary diagnosis of Stage I, II or III cancer [126], were included. The age restriction was chosen in the belief that these adult cancer patients have a psychosocial context which is clearly different from that of younger and older patients by means of significant relationships with children, partners, parents and the work context. There were no exclusion criteria with regards to sex, performance status or topology of the cancer. Patients were excluded from the sample if they lacked basic proficiency in Dutch, had cognitive problems or a history of major neurological disease.. Patients signed an informed consent form before participation.

Questionnaires

Participants had to complete two questionnaire bundles, within an interval of one week.

Data collected with the *first questionnaire bundle* included socio-demographic characteristics, medical characteristics, the CARES and seven concurrent instruments to assess concurrent validity.

Flemish CARES version:

The Flemish CARES version was produced through a forward-backward translation process with two sworn translators and an expert group.

In the ongoing study missing response categories for items 18 and 80 in the CARES were noticed, causing structural (non-random) missing answers (55.7% of the analyzed questionnaires). A second and corrected version was printed and replaced the first (44.3% of the analyzed questionnaires). To avoid possible bias, items 18 and 80 were excluded from analysis.

Karnofsky Performance status Scale (KPS) [87, 88, 119]: The KPS is an 11-point scale to evaluate the physical and daily functioning of a patient, ranging from 0 (completely dependent, not able to care for oneself) to 100 (fully active, not dependent and capable of normal activity without limitations).

Hospital Anxiety and Depression Scale (HADS) [90, 91]: The HADS was developed to identify symptoms of anxiety and depression in medically ill patients. The questionnaire contains 14 items with four response categories, ranging from 0-3. Higher scores on the two subscales (each consisting of 7 items) indicate a higher level of anxiety or depression and the total score of the HADS (score-ranges from 0-42) can be used as a global measure of psychological distress [127].

Social Support List – Interactions and Discrepancies (SSL-I and –D)[93, 94, 95]: The SSL is a questionnaire with 75 items, 41 on experienced social interaction and 34 on experienced social discrepancies. In the first part of the questionnaire participants indicate how frequently certain social interactions occur on a 4-point Likert scale from 1 ('seldom or never') to 4 ('very often'), with higher scores representing higher levels of social support. A second part of the SLL indicates the social discrepancies participants experience ranging from 1 ('I would like it to happen more often') to 4 ('it happens too often'). Higher scores on the SSL-D indicate a greater lack of social support.

Maudsley Marital Questionnaire (MMQ)[96, 97, 98]: The MMQ contains three scales exploring Marital (10 items), Sexual (five items) and General Life (five items) adjustment. The items of the MMQ are scored on a 9-point Likert scale (ranging from 0 to 8). The wording of response categories differs for each item depending on the nature of the question.

European Organisation of Research and Treatment for Cancer Quality of Life Questionnaire Core 30 (EORTC-QLQ-C30)[100]: The EORTC QLQ-C30 is a cancer-targeted quality of life instrument, incorporating five functional scales (physical, role, cognitive, emotional and social) and three symptom scales (fatigue, pain and nausea, and vomiting). Items are scored on a 4-point Likert scale from 1 ('not at all') to 4 ('very much'). The last two items on global health and quality-of-life have an 8-point Likert scale, ranging from 1 ('very poor') to 7 ('excellent').

Distress Thermometer (DT) together with a Problem List (PL) [101, 102, 103]: Patients are asked to rate their overall distress on a visual analogue scale (presented as a thermometer) from 0 ('no distress') to 10 ('extreme distress'). The DT is accompanied by a Problem List, which includes 35 items that address 5 life domains (practical, family/social, emotional, spiritual, and physical problems). Participants indicate if the stated problems apply to them. At the end of the survey participants are asked if they want to talk to a professional about their problems.

Care Needs Questionnaire [104]: The Care Needs Questionnaire was developed by Pauwels and Van Hoof to assess the care needs of cancer patients regarding specific themes during reintegration: physical functioning, psychological functioning, self and body image, sexuality, relationship with partner, relationship with others and work and social security related aspects. For each theme, participants are asked whether they wish to receive information or support, how they prefer to receive information and support, and to what extent this need already has been met. Each of the questions are answered on a 3- and 4-point Likert scale with different wording.

The *second questionnaire bundle*, filled in a week after the first one, contained the CARES and supplementary questions on patients' experiences with the CARES in relation to the importance and breadth of issues assessed, length of time to complete, and format of survey administration.

Study procedure

Eligible patients were selected by the medical team according to the inclusion and exclusion criteria [128]. On the basis of team organization and time

availability, two alternative procedures to invite patients to participate in the study were used.

In the 'face-to-face procedure', a member of the medical team explained the study briefly and invited the patient to participate. If the patient agreed, he/she immediately received a study package with the informed consent form, a 'what to do'-scheme, the first questionnaire bundle and a stamped and addressed envelope to return the questionnaire.

In the 'post procedure', eligible patients got sent an identical study package by post, plus a letter explaining the study. One week later participants had to complete the second questionnaire bundle and send it back in another stamped and addressed envelope provided.

If the questionnaire was not sent back, the participants recruited via the face-to-face procedures were contacted by a team member. Participants invited through the post procedure were sent a reminder and second questionnaire package after one month. The researcher contacted participants by phone or by e-mail when returned questionnaires had a large number of missing responses or if the second questionnaire was not received in the expected timeframe. Since ethical standards limit the number of participant contacts, there was a maximum of two attempts to contact a participant.

Data analysis

The Statistical Package for Social Sciences (SPSS; Chicago, IL) version 22.0 was used for statistical analyses of the data.

Descriptive statistics were used to analyze socio-demographic and medical data, as well as the data gathered with the supplementary questions from the second questionnaire bundle.

The reliability of the CARES was explored by the internal consistency of summary scales, with the aim to find a Cohen's Alpha of at least .70 [105, 106]. Test-retest reliability was investigated by computing Spearman's rho correlations between the summary scale scores and total-CARES scores of the first and second CARES administration, requiring a correlation ≥ .70 [105, 107]. Principal component analysis (PCA) and inter correlations of summary scales were computed to evaluate construct validity. Due to the complexity of the CARES, number of items and items only applicable for a subgroup of the sample,

one general factor analysis on all the individual items was not possible in this small sample. PCA with varimax rotation was used in two subsequent analyses to assess the underlying factor pattern of the Flemish CARES. A first PCA was carried out on the individual items of the five summary scales to explore the CARES subscales. A higher order (second-order) factor analysis on the 26 subscales was conducted to explore the five summary scales. As in previous CARES-research items and subscales with a factor loading higher than .30 were seen as loading on a factor [80, 81].

Spearman's rho correlations were computed to evaluate concurrent validity of the CARES global score and the summary scales with the seven concurrent instruments. Correlations were judged low, moderate and high, when their absolute values were respectively < .30, from .30- .50 and ≥ .50 [108].

RESULTS

Sample characteristics

With 197 of the 325 invited patients returning completed questionnaires the response rate was 61%. Of these, 85% (168/197) of the respondents returned both the first and second questionnaire. After exclusion of participants due to incorrect recruitment according to the age (n=4) and language-criterion (n=1), a large number of uncompleted questions (n=2), a missing first questionnaire (n=2), anonymous returned questionnaire (n=1) or return outside the time interval of data inclusion (n=11); data of 176 eligible patients (54% of the invited patients) was available for analysis.

The mean age of participants was 50.5 years (range 30-60); 30.7% were men and the vast majority were in a significant relationship (86.9%) and had children (median: 2, range: 1-4). These and further socio-demographic characteristics are displayed in Table 1.

Table 1. Socio-demographic and medical characteristics participants and non-responders

	Participants (N=176)				**Non-resp.** (N=122)[a]			
	M	**SD**	**n**	**%**	**M**	**SD**	**n**	**%**
Socio-demographic Characteristics								
Age	50.5	7.2			51.6	8.2		
Sex								
Men			54	30.7			38	31.1
Woman			122	69.3			83	68.0
Relational status								
Single			20	11.4				
Partner, married or living together			141	80.1				
Partner, not married or living together			12	6.8				
Widowed			3	1.7				
Having children			148	84.1				
Family members	11.9	10.8						
Supportive family members	6.6	4.2						
Supportive friends	13.5	12.6						
Graduation level								
Elementary school			13	7.4				
High school			101	57.7				
Graduate school			53	30.3				
University			8	4.6				
Job occupation								
Employed			41	23.3				
Work interruption/on sick leave			91	51.7				
Unemployed			12	6.8				
Disabled			20	11.4				
Housewife/houseman			6	3.4				
Retired			6	3.4				
Monthly house hold income								
< € 1500			51	30.7				
€ 1500 - € 3000			79	47.6				
> € 3000			36	21.7				
Medical Characteristics								
Type of treatment								
Surgery			138	81.7			94	84.7
Radiotherapy			104	61.2			52	46.8
Chemotherapy			109	64.5			57	51.8
Hormone therapy			58	34.3			27	24.3
Immune therapy			1	0.6			1	0.9
Concomitant radio-chemotherapy			18	10.7			16	14.4
Bone marrow transplantation			0	0.0			0	0.0
Isotopes			1	0.6			0	0.0
Other treatment			5	3.0			6	5.5
Time since diagnosis (weeks)[b,c]	62.8	104.5			-	-		
Phase of care trajectory								
Active treatment phase			115	65.3				
Completion of treatment			13	7.4				
Follow-up phase			47	26.9				

Abbreviations: Non-resp. (non-responders), M (mean), SD (standard deviation), n (number of participants).
[a] Data of only 117 out of 128 non-responders received;
[b] Date of questionnaire completion or diagnosis missing for some participants, mean time since diagnosis based on n=158;
[c] Time since diagnosis unknown for non-responders, since date of invitation to participate in the research was not registered.

Feasibility

CARES item characteristics

The mean number of missing answers on the QOL-items in participants' CARES completion was 2.3 (SD 5.0). Telephone follow-up with participants revealed that missing answers were mainly due to the accidental skipping of items or participants' not deeming an item(s) to be applicable to them. Examples of reasons given are as follows: "I am a widow and I don't have sex anymore, so I didn't answer on the statement 'I do not feel sexually attractive'"; "I don't own a car so I couldn't answer the question on having difficulty with driving"; "I couldn't answer the question 'I have difficulty preparing meals', because my wife is the one that cooks at home, I never do". Outliers of 66 and 58 missing answers are found on item 18 and 80. This was due to missing response categories in the first printed version of the questionnaire.

The mean number of missing answers on the Help-items of the CARES was 12.4 (SD 21.5) - considerably higher than the number of missing values on corresponding QOL-items. Participants answered the Help-questions by marking the response categories in three different ways: by marking each 'yes' or 'no' for each Help-question individually; by circling the words 'yes' or 'no' on the top of the column; or by circling the whole column of yes- or no-responses on the page. Only 49 participants (27.8%) had no missing answers on the help-items (93-132 items). Both concurrent needs assessment measures had a lower number of missing values. For the one single help-question joining the DT and PL only four participants (2.3%) did not complete the help-question. For the Care Needs Questionnaire only four to 10 participants (2.3-5.7%) did not complete the life domain specific help-question.

Patients' experiences in completing the CARES

On average participants needed 31 minutes (SD=24.209) to complete the CARES. Ninety percent felt this to be acceptable, 10% thought this was too long and too time consuming. Participants in this study had to complete the CARES on paper. Seventy-three percent preferred this option while 21% would have preferred an electronic version. The reasons mentioned for preferring paper were as follows: easier for concentration; limited burden on the eyes; the ability to fill in anywhere; the lack of familiarity with the computer. On the other hand,

reasons for preferring an electronic version for the computer or tablet included environmental concerns, the completion time of a screening and easier processing of results.

Reliability

Internal consistency and Test-Retest Reliability

To explore the reliability of the CARES total, sub- and summary scales, alpha coefficients were calculated (Table 2). The mean for all subscales was .79 (range .21-.94). For the five summary scales of the CARES the mean of alpha coefficients was .92 (range.87 - .96).

The average timespan between the first and second CARES completion of participants was 12.62 days (SD 9.3). Spearman's rho correlations between the two completions were computed to explore test-retest reliability. For all subscales high correlations were found ranging from .53 to .89 with an average of .76. Test-retest correlations for the five summary scales were all high, with an average of .85 (Table 2). The CARES total scores had a high correlation of .92. These reliability ratings demonstrate an excellent test-retest reliability of the Flemish CARES.

Validity

Content Validity

The majority of participants rated all life domains addressed in the CARES to be important to very important in a QOL and needs assessment tool (Table 3). Most of them (90%) evaluated the content of the CARES to be complete. The three main areas where deficiencies were cited were the feeling of loneliness in the disease experience, financial concerns due to the disease and treatment and the lack of questions addressing the coping of patients' loved ones.

Table 2. Reliability Ratings and Factor Pattern for the Flemish CARES (N=176)

	Internal Consistency	Test-Retest Correlation		Factor loadings[b]				
Global CARES, sub- and summary scales	α	n	r [a]	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
PHYSICAL	**.93**	**156**	**.90**					
Ambulation	.83	158	.84	**.749**			.371	
Activities of daily living	.85	158	.83	**.795**				
Recreational Activities	.81	157	.73	**.729**				
Weight Loss	.74	157	.68	**.733**				
Difficulty Working	.93	152	.81	**.728**				
Pain	.71	156	.77	**.430**			.448	.369
Clothing	.94	156	.76	**.344**			.347	.322
MEDICAL INTERACTION	**.87**	**156**	**.70**					
Problems Obtaining Info from Medical Team	.85	156	.61					**.836**
Difficulty Communicating with Medical Team	.86	157	.69		.540			**.397**
Control of Medical Team	.77	157	.69					**.776**
MARITAL	**.90**	**133**	**.84**					
Communication with Partner	.93	155	.82		.469	**.636**		
Affection with partner	.85	155	.74			**.851**		
Interaction with Partner	.88	155	.80			**.705**		
Overprotection by Partner	.56	155	.53	.313		**.461**		
Neglect of Care by Partner	.21	155	.63			**.574**		.326
PSYCHOSOCIAL	**.96**	**156**	**.91**					
Body Image	.84	157	.80		**.385**		.549	
Psychological Distress	.86	157	.89	.302	**.589**		.466	
Cognitive problems	.89	157	.81	.429	**.325**		.413	
Difficulty Communicating with friends/relatives	.83	158	.77		**.610**			
Friends/Relatives Difficulty Interacting	.73	156	.65		**.538**		.324	
Anxiety in Medical Situations	.89	156	.86		**.772**			
Worry	.83	157	.84	.359	**.664**			
Interaction with Children	.78	155	.73	.330	**.525**			
At Work Concerns	.81	155	.67		**.566**			
SEXUAL	**.92**	**142**	**.89**					
Sex Interest	.82	156	.85			.460	**.648**	
Sexual Dysfunction	.92	154	.84				**.533**	
CARES TOTAL	**.88**	**158**	**.92**					

[a] all r significant at 0.01 level (2-tailed), [b] Only factor loadings ≥ .30 are presented, factor loadings of facets belonging to each of the five CARES summary scales are in bold.

Table 3. Participants' evaluation of the content of the CARES (N=159)

How important do you think several areas of well-being are to be addressed in the CARES, when the purpose is to comprehensively assess quality of life and care needs with the instrument?	**Response distribution**[a] (n (%))			
	Very important	Important	Not so important	Totally not important
Physical well-being	90 (56.6%)	62 (39.0%)	2 (1.3%)	0 (0.0%)
Medical interaction	93 (58.5%)	59 (37.1%)	3 (1.9%)	0 (0.00%)
Relational well-being	82 (51.6%)	59 (37.1%)	7 (4.4%)	1 (0.6%)
Psychosocial well-being				
Body image	31 (38.4%)	82 (51.6%)	12 (7.5%)	0 (0.00%)
Problems with memory and/or concentration	68 (42.8%)	79 (49.7%)	7 (4.4%)	0 (0.00%)
Stress, fear, concerns on disease and treatment	84 (52.8%)	66 (41.5%)	4 (2.5%)	0 (0.00%)
Dealing with family and friends	63 (39.6%)	79 (49.7%)	12 (7.5%)	0 (0.00%)
Dealing with the children	78 (49.1%)	66 (41.5%)	7 (4.4%)	0 (0.00%)
Concerns about work	53 (33.3%)	77 (48.4%)	19 (11.9%)	3 (1.9%)
Sexual interest and functioning	43 (27.0%)	79 (49.7%)	27 (17.0%)	2 (1.3%)
Miscellaneous				
Financial difficulties	51 (32.1%)	80(50.3%)	18 (11.3%)	5 (3.1%)
Finding a partner	22 (13.8%)	52 (32.7%)	37 (23.3%)	27 (17%)
Difficulties with regard to treatment	67 (42.1%)	66 (41.5%)	12 (7.5%)	4 (2.5%)

Was there a topic missing in the CARES that you find important in an assessment on psychosocial concerns and care needs?	No	Yes
	132 (89.80%)	15 (10.20%)

[a] Percentages do not count up to 100% due to missing values.

Concurrent Validity

Spearman rho correlations for CARES total, summary scores and convergent measures were in the expected directions (Table 4). The KPS and CARES physical scale have a large negative correlation (r = -.67). HADS scores and the CARES psychosocial scale are strongly positive related (r = .75 and r = .64). From the SSL only the D-subscale had a significant moderate correlation with the Psychosocial CARES summary scale (r = .43). The Marital and Sexual CARES summary scales are moderate to strongly positive related to the MMQ-M (r = .48) respectively MMQ-S (r = .55). Also the large correlations of the CARES

Total score with the EORTC-QLQ-C30 (r = -.56 and r = -.53) and DT (r = .63) confirm the concurrent validity of the CARES.

Table 4. Correlations of CARES Total and Summary scores with Concurrent Validity Measures

Concurrent Validity Measures	CARES Total	Physical	Medical Interaction	Psychosocial	Marital	Sexual
KPS	**-.50****	**-.67****	-.15*	-.38	-.23**	-.39**
HADS-A	**.68****	.48**	.36**	**.75***	.48*	.38**
HADS-D	**.67****	.60**	.32**	**.64***	.45*	.45**
SSL-I	**.09**	.17*	-.19*	**.07**	-.02	-.001
SSL-D	**.38****	.18*	.33**	**.43***	.37**	.25**
MMQ-M	**.25****	.11	.18*	.18*	**.48****	.26**
MMQ-S	**.54****	.36**	.27**	.39**	.54**	**.55***
EORTC-QOL-C30 GH	**-.56****	-.71**	-.19*	-.36**	-.26**	-.38**
EORTC-QLQ-C30 QOL	**-.53****	-.67**	-.15*	-.37**	-.21**	-.28**
DT	**.63****	.64**	.21**	.54**	.37**	.43**

Abbreviations: CARES (Cancer Rehabilitation Evaluation System); KPS (Karnofsky Performance status Scale); HADS-A and -D (Hospital Anxiety and Depression Scale, Anxiety and Depression); SSL-I and -D (Social Support List, Interactions and Discrepancies); MMQ-M and -S (Maudsley Marital Questionnaire,Marital and Sexual); EORTC-QOL-C30 (European Organisation of Research and Treatment for Cancer Quality of Life Questionnaire Core 30); DT (Distress Thermometer). Correlations of interest are in bold.
** r significant at 0.01 level (2-tailed).
* r significant at 0.05 level (2-tailed).

Construct validity

There are *intercorrelations* of .32 - .60 between CARES summary scales, indicating that these measure related but different dimensions of concerns and care needs. The summary scales all have a high correlation with the CARES Total, indicating an important role in the quality of life disruption measured by the CARES (Table 5).

Table 5. Intercorrelations of CARES Total and Summary Scales

	CARES Total	Physical	Medical	Marital	Psychosocial
Physical	.80				
Medical	.49	.32			
Marital	.71	.42	.42		
Psychosocial	.88	.56	.49	.60	
Sexual	.71	.48	.29	.51	.58

* all r significant at 0.01 level (2-tailed).

To ensure that the data were suitable for *factor analysis* standard diagnostic tests were run each time. Both the Kaiser-Meyer-Olkin (KMO) test of sampling adequacy criterion (KMO ≥ .6) and Bartlett's test of sphericity criterion (p <.05) were fulfilled and indicated factorability of the data.

Firstly, the CARES subscales were explored. For the items of the marital summary scale four factors were found. Physical-items loaded on six factors, medical interaction-items on three, psychosocial-items on nine, and the items of the sexual summary scale on two factors (Table 6a – Table 6e).

Secondly, the summary scales were explored. Based on Kaiser's criterion (eigenvalue ≥1) seven factors were distinguished with the PCA, explaining a total of 65.5 % of the variance. However, based on Catell's scree test, only the first five factors should be retained to get a good fitted model of factors explaining the variance in our data set. Subsequently a PCA with varimax rotation and fixed number of five factors was conducted resulting in the factor solution visualized in Table 2. The resulting factor solution approximately corresponds to the subdivision of the CARES in the five summary scales: physical, interaction with the medical team, marital, psychosocial and sexual.

Table 6a. Varimax Rotation Factor Pattern of the Marital summary scale items (N=153)

	Factor loadings[a]			
CARES items[b]	1	2	3	4
103.Diff. talk feelings	**.786**		.372	
104.Diff. talk fears	**.825**			
105.Diff. talk happen after death	**.804**			.344
106.Diff. talk future	**.834**			
107.Diff. talk cancer	**.888**			
108.Diff. talk wills/financial matters	**.823**			
109.Doesn't feel like embrace. etc.			**.739**	
110.Partner no feel like embrace. etc.			**.830**	
111.No interest in touch partner			**.714**	
112.Partner no interest in touch			**.774**	
113.Not get along as well usual		**.825**		
114.Upset with other more often		**.869**		
115.So much time together. on nerves		**.632**		
116.More distant then usual		**.778**	.302	
117.Partner not let do activ. capable of				**.771**
118.Partner provides too much care				**.751**
119.Partner takes too little care		.575		
120.Diff. ask partner to take care	.350			.493

[a] Only factor loadings ≥ .30 are presented. factor loadings of facets belonging to each of the CARES subscales are in bold.
[b] Order of items is determined by the original order of the subscales in the CARES.

Table 6b. Varimax Rotation Factor Pattern of the Physical summary scale items (N=176)

	Factor loadings[a]					
CARES items[b]	1	2	3	4	5	6
1.Diff. bend or lift	**.650**				.341	
2.Diff. walk/move around	**.641**	.355			.324	
3.Diff. do physical activ.	**.687**					
4.Reduction in energy	**.530**		.323			
5.Diff. driving	**.710**			.340		
6.Diff. household chores	**.715**	.331				
7.Diff. bathe. brush. groom	**.712**					.310
8.Diff. prepare meals	**.630**	.377		.353		
9.No interest recreat. active.		**.729**				
10.Not engage recreat. active.	.429	**.640**				
11.Not enough enjoyable activ.		**.664**				
12.Diff. planning active.		**.779**				
13.Cannot gain weight						**.713**
14.Continue to lose weight				**.412**		**.743**
15.Food unappealing				**.803**		
16.Food tastes bad				**.763**		
17.Diff. swallowing				**.686**		
19.Cancer interferes work	.377	**.480**				
20.Frequently has pain	.380				**.725**	
21.Chronic pain scars/surgery					**.676**	
22.Pain not controlled medication					**.780**	
23.Pain controlled medication					**.502**	
24.Clothes not look good			**.912**			
25.Clothes not fit			**.898**			
26.Diff. find clothes			**.882**			

[a] Only factor loadings ≥ .30 are presented. factor loadings of facets belonging to each of the CARES subscales are in bold.
[b] Order of items is determined by the original order of the subscales in the CARES.

Table 6c. Varimax Rotation Factor Pattern of the Medical Interaction summary scale items (N=176)

	Factor loadings[a]		
CARES items[b]	1	2	3
27.Medical team withholds info		**.877**	
28.Doctors don't explain what do		**.843**	
29.Nurses don't explain what do		**.860**	
30.Diff. ask doctors questions	**.864**		.303
31.Diff. ask nurses questions	**.799**		.304
32.Diff. express feelings doctor/nurses	**.834**		
33.Diff. tell doctor new symptoms	**.764**		
34.Diff. understand doctor about cancer			**.775**
35.Diff. understand nurses about cancer			**.852**
36.Wants more control over doctor		.618	**.543**
37.Wants more control over nurses			**.758**

[a] Only factor loadings ≥ .30 are presented. factor loadings of facets belonging to each of the CARES subscales are in bold.
[b] Order of items is determined by the original order of the subscales in the CARES.

Table 6d. Varimax Rotation Factor Pattern of the Psychosocial summary scale items (N=176)

	Factor loadings[a]								
CARES items[b]	1	2	3	4	5	6	7	8	9
38.Embarrassed to show body					**.847**				
39.Uncomfor. show scars					**.830**				
40.Uncomfor. with body changes					**.661**				
41.Frequently anxious	.414	**.559**							
42.Frequently depressed		**.710**							
43.Frequently angry		**.752**							
44.Frequently upset		**.738**							
45.Frequently overwhelmed by cancer	.399	**.524**				.321			
46.Diff. sleep				.455		.520			
47.Diff. concentrating				**.828**					
48.Diff. remembering				**.813**					
49.Diff. thinking clearly				**.816**					
50.Diff. tell frnd/rel. to come less often			**.747**						
51.Diff. tell frnd/rel. to leave when not well			**.742**						
52.Diff. ask frnd/rel. to do fun things			**.731**						
53.Don't know what to say to frnd/rel.								.750	
54.Diff. ask frnd/rel. help			**.659**						
55.Diff. tell frnd/rel. about cancer	.592				.372			.449	
56.Diff. ask frnd/rel. to come more			**.727**						
57.Frnd/rel. say look well when not	.356		.435						.313
58.Frnd/rel. withhold information								.721	
59.Frnd/rel. avoid talk cancer									.699
60.Frnd/rel. do not visit enough							**.889**		
61.Frnd/rel. do not call enough							**.836**		
62.Frn/rel. uncomfor. visiting							**.325**		.558
63.Frnd/rel. diff. talk about cancer							**.527**	**.**303	.566
64.Uncomfor. see patients get treat.	**.765**								
65.Nervous going to hospital	**.755**								
66.Nervous wait to see doctor	**.765**								
67.Nervous wait for test results	**.717**					.314			
68.Nervous have diagnostic tests	**.462**	.493							
69.Nervous get blood drawn	**.680**								
70.Worry whether treatments work	.453	.359				**.594**			
71.Worry whether cancer progress	.355	.386				**.610**			
72.Worry not able to care for self						**.696**			
73.Worry how family will manage						**.660**			

[a] Only factor loadings ≥ .30 are presented. factor loadings of facets belonging to each of the CARES subscales are in bold.
[b] Order of items is determined by the original order of the subscales in the CARES.

Table 6e. Varimax Rotation Factor Pattern of the Sexual summary scale items (N=175)

CARES items[b]	Factor loadings[a] 1	2
74.Doesn't feel sex. attractive	.510	**.670**
75.Thinks not sexually attractive to partner(s)		**.927**
76.Not interested in having sex	.798	**.331**
77.Doesn't think partner(s) interested in sex		**.828**
99.Frequency of sex decreased	**.811**	.342
100.Diff. become sexually aroused	**.913**	
101.Diff. with erection (males) / Diff. lubrication (females)	**.847**	
102.Diff. reach orgasm	**.883**	

[a] Only factor loadings ≥ .30 are presented. factor loadings of facets belonging to each of the CARES subscales are in bold.
[b] Order of items is determined by the original order of the subscales in the CARES.

Psychometric properties CARES-SF

Since the original short form of the CARES (CARES-SF) was derived by taking 59 items of the full version (min. 32- max. 57), we could as well use our data to examine the psychometric quality of the Flemish CARES-SF. In the CARES-SF, no summary scales can be computed, since sometimes only one or two items from a subscale in the full version of the tool were selected for the short form.

The item scores are directly added up to the six domain scores that are combined to compute the CARES-SF total score.

For the CARES-SF the internal consistency ratings of the domains ranged from .72-.92, test-retest correlations ranged between .70-.90. The examination of concurrent validity resulted in the expected significant correlations of the CARES-SF Total and summary scales with the concurrent instruments, with the only exception of the SSL-I that showed no significant correlation with the psychosocial summary scale. Intercorrelations of the CARES-SF Total and Summary scales were medium to high (.32-.78). Details are displayed in Appendix 3.2.

Clinical insights on participants' QOL and care needs

Quality Of Life

If we look at the clinical insights obtained with the CARES, we see that each problem stated in the instrument is experienced by 1-88% of the participants (Appendix 3.3). The 10 problems most frequently experienced are: 'I worry that

the cancer is progressing' (88.1%); 'I do not have the energy I used to' (86.9%); 'I get nervous when I am waiting for test results' (76.1%); 'I find that the cancer or its treatments keep me from working' (73.3%); 'I have difficulties doing physical activities such as running and playing sports' (70.4%); 'I frequently feel overwhelmed by my emotions and feelings about the cancer' (70.4%); 'I worry whether my treatments are working' (69.9%); 'I worry about how my family will manage if I die' (67.1%), 'I frequently have pain' (67.0%), 'I have difficulty concentrating' (65.3%).

The responses of the participants on the individual CARES items were combined to calculate the average number of experienced problems per life domain, and the average severity with which these concerns or problems affect their QOL (Table 7).

Table 7. Means, standard deviations, and range for CARES total and summary scales

	Number of problems experienced				Mean severity of problems		
CARES scales	**M**	**SD**	**Range**	**Max. CARES[b]**	**M**	**SD**	**Range**
Physical	11.32	6.28	0-24	26	1.74	0.54	1-3.31
Psychosocial[a]	17.76	9.04	0-42	36-44	1.62	0.58	1-4.00
Medical interaction	1.88	2.56	0-10	11	1.33	0.64	1-4.00
Marital[a]	4.27	4.56	0-15	0-18	1.52	0.67	1-4.00
Sexual[a]	3.7	2.60	0-8	4-8	1.99	0.93	1-4.00
Miscellaneous[a]	4.78	4.11	0-21	11-32	1.77	0.71	1-3.92
CARES Total	43.72	21.14	1-88	93-132	1.70	0.50	1-3.60

Note: QOL-score range of each item from 0 - 4: 0= "Not at all", 1= "A little", 2= "A fair amount", 3= "Much", 4= "Very Much", on the question "How much does this apply to you?".
Abbreviations: M (mean); SD (standard deviation).
[a] Not all items are applicable for every patient.
[b] Maximum number of items in the CARES, not all items are applicable for each participants, therefore sometimes a range of maximum number of items is given.

Care needs

The percentage of participants that indicates to desire help for the problems they experience is limited (Appendix 3.1). For 123 of the 139 problems stated in the CARES one or more participants indicate a care need. Only for three of these problems, namely 'I have difficulties doing household chores', 'I have difficulty

sleeping', and 'I worry about whether the cancer is progressing', more than 10% of the study sample desires specific help.

DISCUSSION

This study explored the validity of the Flemish CARES version, resulting in a positive evaluation of the instrument.

The small number of missing answers on CARES' QOL-items indicates that the items were clear to the vast majority of participants, which supports the feasibility of the instrument for wider application or use among Flemish cancer patients. Participants also reported positive experiences with the content and completion time of the CARES. The number of missing answers on the Help-items of the CARES is relatively higher. The question is raised whether if it is relevant to have a help-question for each QOL-item. Possibly circling requires a great effort of participants, resulting in a larger number of missing answers, while domain specific help-questions could be sufficient to reveal patients supportive care needs. The smaller number of missing answers on the concurrent needs assessment instruments, may indicate that a simplified help-questioning could be more feasible. For example the 93-132 help-items could be reduced to several life domain specific help-questions presented each time after a group of QOL-items. Although this aspect could use some improvement, the majority of the participants are in favor of the use of a QOL and needs assessment tool like the CARES in clinical practice.

The CARES provides a total score and five domain specific scores, which all demonstrated high reliability. The two subscales with low alpha coefficients 'Overprotection by Partner' (α = .56) and 'Neglect of care by partner' (α = .21) are scales with only two items. Having fewer items in a scale is known to have a lowering effect on the alpha coefficient. These reliability ratings correspond to those of the original CARES.

The results of the PCA confirm the existence of five distinguishable components of QOL measured with the Flemish CARES, similar to the physical, medical interaction, relational, psychosocial and sexual summary scale of the original instrument. However, some subscales have double loadings. PCA should be reproduced as soon as a larger research sample is available.

Concurrent validity of the CARES and its' summary scales with several instruments was confirmed with moderate to high correlations. This implies that the CARES could be used to obtain a comprehensive summary of patients' overall QOL and care needs from their own perspective instead of having to combine several other patient reported outcome tools.

The completion of the CARES by participants resulted in insights on a wide range of dimensions of their functioning and well-being, and all problem statements of the instrument proved to be relevant. If a shorter tool is desirable for implementation in practice, our results show that the CARES-SF is a good alternative.

Limitations of this study should be noted. Rules-of-thumb for the number of subjects included in factor analysis vary from four to 10 subjects per item of the questionnaire [79]. With 176 participants our research sample is rather limited. However, the factor pattern of the original instrument was already known and even with our relatively small number of participants the original factor solution could be replicated. The CARES was developed for cancer patients in general, though the representativeness of our sample could be questioned. To pursue representativeness, recruitment was performed in several departments of the participating hospitals. This resulted in a heterogeneous sample of 25-60 years aged cancer patients, with breast, colorectal, prostate and head-neck cancer as most common cancer types. This matches the national statistics [129], and characteristics of our group of non-responders. Non-responders seem to have undergone less invasive treatment (Table 1). However, there is a lack of further information, for example on 'time since diagnosis', to make a detailed comparison. The selection of patients aged between 25-60 years to capture the adult population of cancer patients, was an inherent limitation as it limited the generalizability of results since approximately three-quarters of cancers are diagnosed in people aged over 60 years. The utility and validity of the Flemish CARES should further be explored in patients aged older than 60 years, before the instrument is implemented in clinical practice.

While this study demonstrates rigor of the Flemish CARES version across key psychometric properties, we must acknowledge that other indices were not explored, e.g. known groups comparison, predictive validity, responsiveness.

Consequently, future studies that focus on these aspects could strengthen the evidence of the validity of the Flemish CARES version.

CONCLUSIONS

This study confirms the Flemish CARES version to be a comprehensive and feasible QOL and needs assessment instrument with good psychometric properties. Consequently, the Flemish CARES can be used in further research to assess QOL and care needs. Further translational research studies are needed to explore how the use of such a tool can be implemented efficiently in clinical practice to contribute to quality patient-centered care.

DECLARATIONS

Ethics approval and consent to participate

All ethical committees of the participating hospitals (Ethical Review Commission Jessaziekenhuis; Committee Medical Ethics Ziekenhuis Oost-Limburg; Ethical Committee AZ Vesalius; Ethical Committee Mariaziekenhuis Noord-Limburg) and the university (Medical Ethical Committee Hasselt University) reviewed the research protocol and study materials. The leading ethical committee (ERC Jessaziekenhuis) collected the feedback and granted approval on 26th of February 2014 (BE24320149544).

Consent to publish

All participants consent to aggregated data to be presented in publications; no individual data was presented.

Availability of data and materials

The datasets during and/or analyzed during the current study available from the corresponding author on reasonable request.

Competing interests

The authors declare not to have any competing interests.

Funding

This study is part of a PhD-project that is supported by Limburg Sterk Merk (LSM). This funding body played no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Authors' Contributions

BS is responsible for study conceptualization and design, data collection, study coordination, data analysis and drafting the protocol. JH participated in study conceptualization and design and in drafting the protocol. EVH and PV contributed to the design of the study and revised the protocol. WS was involved in refining plans for data analysis and revising the protocol. PB, FB, JM, and DV provided critical revisions to the protocol. All authors read and approved the final manuscript.

Acknowledgements

We thank the medical departments and patients for their collaboration and participation in this study. We want to acknowledge Aisha Andrewin, for editing the manuscript for language.

Appendix 3.1

Table A.3.1. Involvement of professional and non-professional care givers in participants' care context

Health professionals involved in cancer care	**N=159**	
	n	**(%)**
Intramural		
Oncologist	142	89.3
Other attending physician (gynecologist, gastroenterologist, urologist, …)	128	80.5
	135	84.9
Nursing	92	57.9
Specialized nursing (onco-coach, breast nurse,…)	47	29.6
Psychologist	42	26.4
Social worker	3	1.9
Religious worker	41	25.8
Dietician	53	33.3
Physiotherapist	14	8.8
Lymphedema therapist	4	2.5
Other		
Extramural		
General practitioner	138	86.8
Home nursing	73	45.9
Physiotherapist	42	26.4
Lymphedema therapist	4	2.5
Dietician	2	1.3
Pharmacist	102	64.2
Primary care psychologist	4	2.5
Center for general wellbeing and mental health support	1	0.6
Health insurance	82	51.6
Social services	10	6.3
Self-support groups or peer groups	1	0.6
Non-professional support services for cancer patients free of payment	6	3.8
Other	6	3.0

Appendix 3.2

Table A3.2.1. Reliability Ratings CARES-SF

	Internal Consistency	**Test-Retest Correlation**
	α	r *
Global CARES and Scales		
PHYSICAL	.83	.89
MEDICAL INTERACTION	.72	.70
MARITAL	.74	.80
PSYCHOSOCIAL	.92	.90
SEXUAL	.85	.85

* all r significant at 0.01 level (2-tailed), [a] research sample N=176, [b] test-retest sample n=158;

Table A3.2.2. Correlations of CARES-SF Total and Summary scores with Concurrent Validity Instruments

Convergent Validity Measures	CARES-SF Total	Physical	Psychosocial	Marital	Sexual
KPS	-.54*	-.69*			
HADS-A	.66*		.73*		
HADS-D	.67*		.63*		
SSL-I	.09		.06		
SSL-D	.36*		.42*		
MMQ-M	.24*			.54*	
MMQ-S	.53*				.61*
EORTC-QOL-C30 GH	-.58*				
EORTC-QPM-C30 QOL	-.54*				
DT	.63				

* all r significant at 0.01 level (2-tailed)

Table A3.2.3 Intercorrelations of CARE-SF Total and Summary Scales

	CARES-SF Total	Physical	Medical	Marital	Psychosocial
Physical	.78*				
Medical Interaction	.47*	.32*			
Marital	.60*	.33*	.35*		
Psychosocial	.67*	.55*	.46*	.51*	
Sexual	.74*	.49*	.28*	.51*	.63*

* all r significant at 0.01 level (2-tailed)

Appendix 3.3

Table A3.3. Percentage of participants with a certain problem rating and desire for help (N=176).

	Problem severity (%[a])					Desire for help (%[a])	
CARES items	**0**	**1**	**2**	**3**	**4**	**Yes**	**No**
1. Diff. bend or lift	43.8	34.7	11.4	5.7	4.0	9.1	81.8
2. Diff. walk/move around	49.4	33.0	9.1	6.3	1.1	5.1	85.2
3. Diff. do physical activ.	27.3	31.3	17.0	10.2	11.9	7.4	77.8
4. Reduction in energy	11.9	25.0	22.7	17.6	21.6	9.1	75.0
5. Diff. driving	67.0	21.0	4.5	1.1	3.4	6.3	84.7
6. Diff. household chores	40.3	30.7	13.6	8.0	5.1	18.2	69.9
7. Diff. bathe. brush. groom	73.3	19.3	3.4	2.3	0.6	6.3	87.5
8. Diff. prepare meals	64.8	25.0	5.7	2.3	0.6	9.1	84.7

9. No interest recreat. activ.	43.8	29.0	15.9	8.0	2.8	2.8	83.0
10. Not engage recreat. activ.	34.7	26.1	17.6	11.4	9.1	2.3	81.8
11. Not enough enjoyable activ.	54.0	28.4	10.2	4.5	1.1	4.0	82.4
12. Diff. planning active.	35.2	33.0	19.3	7.4	4.0	5.1	79.0
13. Cannot gain weight	61.4	21.6	9.1	2.8	2.8	4.5	85.8
14. Continue to lose weight	88.1	7.4	0.6	1.7	1.1	2.3	94.9
15. Food unappealing	68.8	14.8	10.2	2.3	3.4	2.8	88.1
16. Food tastes bad	68.2	14.2	9.1	2.3	5.7	2.8	89.2
17. Diff. swallowing	77.8	13.1	1.7	2.8	2.8	2.8	89.8
18. Cancer prevents working [c]	19.9	9.7	10.2	4.0	18.8	5.1	44.9
19. Cancer interferes work	24.4	15.9	19.3	14.2	23.9	8.0	73.9
20. Frequently has pain	32.4	39.2	16.5	8.5	2.8	6.3	77.8
21. Chronic pain scars/surgery	61.4	23.3	9.1	3.4	1.1	2.8	88.6
22. Pain not controlled medication	80.1	10.8	4.5	1.1	1.7	2.3	91.5
23. Pain controlled medication	55.7	20.5	15.9	4.0	2.8	2.3	85.8
24. Clothes not look good	70.5	15.9	6.3	2.3	4.5	1.7	90.3
25. Clothes not fit	65.9	19.3	6.3	3.4	4	2.8	88.6
26. Diff. find clothes	76.1	14.2	2.3	2.8	3.4	0.6	93.8
27. Medical team withholds info	92.0	4.0	1.7	0.6	0.6	1.1	96.6
28. Doctors don't explain what do	84.1	11.9	1.1	1.1	1.1	2.3	94.9
29. Nurses don't explain what do	90.9	5.7	1.1	1.1	0.6	0.6	96.0
30. Diff. ask doctors questions	79.5	13.1	4.0	1.1	1.7	2.8	93.8
31. Diff. ask nurses questions	83.0	11.9	2.3	1.1	1.1	2.3	93.2
32. Diff. express feelings doctor/nurses	65.3	23.9	6.3	2.8	1.1	3.4	89.2
33. Diff. tell doctor new symptoms	83.5	11.4	2.8	0.6	0.6	1.7	94.9
34. Diff. understand doctor about cancer	79.5	16.5	2.3	1.1	0	3.4	92.0
35. Diff. understand nurses about cancer	88.1	9.7	1.1	0.6	0	1.7	94.9
36. Wants more control over doctor	75.6	14.2	6.3	2.3	1.1	3.4	89.8
37. Wants more control over nurses	83.0	12.5	3.4	0	0.6	2.3	92.0
38. Embarrassed to show body	53.4	25.6	8.0	6.8	5.7	5.1	87.5
39. Uncomfor. show scars	53.4	21.6	10.2	7.4	5.1	4.0	86.4
40. Uncomfor. with body changes	34.7	22.7	22.2	10.8	8.0	7.4	79.5
41. Frequently anxious	40.9	34.7	11.4	6.8	5.1	8.5	81.3
42. Frequently depressed	36.9	43.2	10.8	5.7	2.8	9.1	77.8
43. Frequently angry	48.9	31.8	11.4	4.5	2.8	5.7	84.7
44. Frequently upset	47.7	36.4	8.0	5.7	1.7	5.1	84.1
45. Frequently overwhelmed by cancer	29.0	42.0	16.5	7.4	4.5	6.8	77.8
46. Diff. sleep	35.8	25.6	16.5	11.9	9.1	10.8	72.7
47. Diff. concentrating	33.5	27.8	21.0	8.5	8.0	8.0	76.1
48. Diff. remembering	35.2	33.0	19.3	6.3	5.7	4.5	83.0
49. Diff. thinking clearly	49.4	27.8	10.8	7.4	3.4	4.5	83.0
50. Diff. tell frnd/rel. to come less often	76.1	14.2	5.1	2.3	1.7	2.8	90.9
51. Diff. tell frnd/rel. to leave when not feeling well	62.5	23.3	8.0	3.4	2.3	2.8	88.1
52. Diff. ask frnd/rel. to do fun things	71.6	15.9	9.1	2.3	0.6	2.8	90.9
53. Don't know what to say to frnd/rel.	84.1	10.8	2.8	1.1	0.6	1.1	93.2
54. Diff. ask frnd/rel. help	46.0	27.3	16.5	8.0	1.7	5.1	80.7
55. Diff. tell frnd/rel. about cancer	80.7	12.5	4.0	1.1	1.1	1.1	92.0
56. Diff. ask frnd/rel. to come more	80.7	13.1	1.7	1.7	1.7	1.1	91.5
57. Frnd/rel. say look well when not	61.9	26.7	6.3	2.8	1.1	1.1	89.2
58. Frnd/rel. withhold information	94.9	3.4	1.1	0.0	0.0	0.6	96.6
59. Frnd/rel. avoid talk cancer	73.9	17.6	5.7	2.3	0.0	0.0	94.3
60. Frnd/rel. do not visit enough	78.4	14.8	4.0	2.3	0.0	0.0	92.6
61. Frnd/rel. do not call enough	77.3	15.9	4.0	2.3	0.0	0.0	92.0
62. Frn/rel. uncomfor. visiting	76.7	15.9	2.3	2.8	1.7	0.0	92.6
63. Frnd/rel. diff. talk about cancer	68.8	23.3	4.5	2.3	0.6	0.6	92.8
64. Uncomfor. see patients get treat.	54.5	29.5	9.1	3.4	2.8	2.8	83.5
65. Nervous going to hospital	40.9	32.4	14.8	6.8	4.5	4.5	77.8
66. Nervous wait to see doctor	40.3	33.0	14.2	5.1	6.3	6.3	76.7
67. Nervous wait for test results	23.3	40.9	12.5	11.9	10.8	5.7	74.4
68. Nervous have diagnostic tests	50.0	25.6	9.1	8.0	6.8	4.5	81.3
69. Nervous get blood drawn	39.2	34.1	14.2	4.5	7.4	3.4	81.3
70. Worry whether treatments work	29.5	36.4	11.9	11.4	10.2	5.7	76.1
71. Worry whether cancer progress	10.2	43.8	21.0	11.4	11.9	10.2	65.9
72. Worry not able to care for self	46.0	27.3	11.9	9.1	4.5	8.0	76.1
73. Worry how family will manage	30.7	27.3	11.4	11.9	16.5	8.0	75.6

74. Doesn't feel sex. attractive	35.2	27.3	14.8	12.5	8.5	4.5	79.0
75. Thinks not sexually attractive to partner(s)	55.7	20.5	9.1	6.3	2.8	4.0	84.7
76. Not interested in having sex	34.7	23.3	11.9	14.2	12.5	5.7	75.0
77. Doesn't think partner(s) interested in sex	61.4	17.0	6.8	4.5	3.4	1.1	87.5
78. Doesn't show for MD appointments	98.3	0.6	0.6	0.0	0.0	0.0	99.4
79. Doesn't show for treatments	98.3	0.6	0.0	0.0	0.0	0.0	99.4
80. Doesn't take medication [c]	63.6	2.8	0.0	0.6	0.0	0.0	65.3
81. Doesn't follow MD's instructions	90.9	8.5	0.0	0.0	0.0	0.0	97.2
82. Financial problems	75.6	12.5	3.4	4.5	3.4	6.3	86.4
83. Insurance problems	89.9	6.3	1.1	1.1	0.6	2.8	92.6
84. Diff. with transport	88.1	8.5	2.3	0.0	0.6	2.8	93.8
85. Gain too much weight	56.3	25.0	8.0	4.5	5.7	8.5	81.8
86. Diagnostic procedures are painfull	57.4	26.7	8.5	2.8	2.8	4.0	80.7
87. Fequent diarrhea	69.3	18.2	6.8	2.8	2.3	2.3	88.1
88. Poor bladder control	73.3	21.6	2.3	1.1	1.1	3.4	89.2
89. Diff. care for child/grandchild [b]	58.0	14.8	5.7	2.3	0.6	2.8	90.9
90. Diff help children cope [b]	61.4	15.9	2.3	1.7	0.0	1.7	90.3
91. Diff. help children talk about illness [b]	62.5	13.1	4.0	1.1	0.6	2.3	90.3
92. Diff. talk boss about cancer [b]	23.9	4.0	2.8	0.6	0.6	0.0	96.6
93. Diff. talk people at work [b]	23.9	4.5	2.8	0.0	0.6	0.0	96.6
94. Diff. tell employer cannot do work [b]	20.5	7.4	2.8	0.6	0.6	0.0	95.5
95. Diff. ask time off for treatments [b]	24.4	2.8	3.4	0.6	0.6	0.0	96.6
96. Worried about being fired [b]	25.0	2.3	1.7	2.3	0.6	0.0	96.0
97. Diff. finding new job [b]	0.6	0.0	0.0	0.6	0.0	0.0	98.3
98. Employers less inclined to hire Employees with cancer history. [b]	0.6	0.0	0.6	0.0	0.0	0.0	98.3
99. Frequency of sex decreased [b]	18.2	20.5	8.0	9.7	11.4	3.4	83.5
100. Diff. become sexually aroused [b]	24.4	17.0	8.0	10.8	7.4	4.0	81.8
101. Diff. with erection (♂) / Diff. lubrication (♀)[b]	22.2	13.6	10.2	8.0	12.5	4.5	83.0
102. Diff. reach orgasm [b]	27.8	14.2	8.5	8.5	6.8	2.3	85.2
103. Diff. talk feelings [b]	51.1	22.7	8.0	3.4	1.1	5.1	86.4
104. Diff. talk fears [b]	48.3	22.7	9.7	3.4	1.1	5.1	85.8
105. Diff. talk happen after death [b]	40.9	22.2	8.5	8.5	4.0	4.0	84.1
106. Diff. talk future [b]	51.7	19.9	4.5	6.3	2.8	3.4	87.5
107. Diff. talk cancer [b]	51.1	18.8	9.1	3.4	2.3	4.0	84.7
108. Diff. talk wills/financial matters [b]	56.8	13.1	8.0	3.4	2.3	4.5	85.8
109. Doesn't feel like embrace. etc. [b]	66.5	6.3	5.1	3.4	4.0	1.7	92.0
110. Partner no feel like embrace. etc. [b]	73.9	6.8	1.1	2.8	1.1	0.0	95.5
111. No interest in touch partner [b]	65.3	11.9	5.1	2.8	1.1	2.3	90.9
112. Partner no interest in touch [b]	73.3	7.4	1.7	2.3	1.7	1.7	93.8
113. Not get along as well usual [b]	65.3	13.6	3.4	2.3	0.6	1.1	93.8
114. Upset with other more often [b]	64.2	14.8	4.0	2.8	0.6	0.6	95.5
115. So much time together. on nerves [b]	71.6	7.4	5.7	1.1	0.6	1.7	95.5
116. More distant then usual [b]	68.8	11.9	4.0	1.1	0.6	1.1	94.3
117. Partner not let do activ. capable of [b]	66.5	11.4	4.0	1.7	2.3	0.6	94.3
118. Partner provides too much care [b]	59.7	15.3	6.8	2.8	1.7	2.3	89.2
119. Partner takes too little care [b]	80.1	3.4	1.1	0.6	1.1	1.1	97.2
120. Diff. ask partner to take care [b]	58.5	18.8	5.1	1.1	1.7	1.7	92.0
121. Diff. initiating dates [b]	5.7	2.8	2.8	1.1	0.0	1.1	97.2
122. Diff. to meet dates [b]	5.7	2.8	2.8	1.1	0.0	1.1	97.2
123. Afraid going to places where I met dates [b]	7.4	3.4	1.1	0.6	0.0	0.6	97.7
124. Diff. tell date about cancer [b]	4.5	4.0	1.7	1.7	0.6	1.1	97.2
125. Afraid to initiate sexual relation [b]	5.1	2.3	0.6	2.3	2.3	1.1	97.2
126. Nervous get chemo [b]	12.5	14.2	5.7	1.7	2.8	2.3	90.9
127. Nauseated during/before chemo [b]	15.9	13.1	2.8	2.8	2.8	4.5	88.6
128. Vomit during/before chemo [b]	27.8	6.8	0.0	1.7	0.6	1.7	93.8
129. Sick when think about chemo [b]	19.3	9.7	1.7	4.5	1.7	1.7	93.2
130. Nauseated after chemo [b]	11.4	14.2	5.1	2.3	4.5	4.0	89.2
131. Vomit after chemo [b]	25.6	6.3	0.6	2.3	1.7	2.3	93.2
132. Tired after chemo [b]	6.3	4.5	7.4	9.1	9.1	6.3	85.8
133. Other side effect chemo [b]	13.6	6.8	4.0	6.3	6.3	5.1	88.1
134. Lost hair/grow slow from chemo [b]	15.3	1.1	2.8	1.1	15.9	4.0	90.9

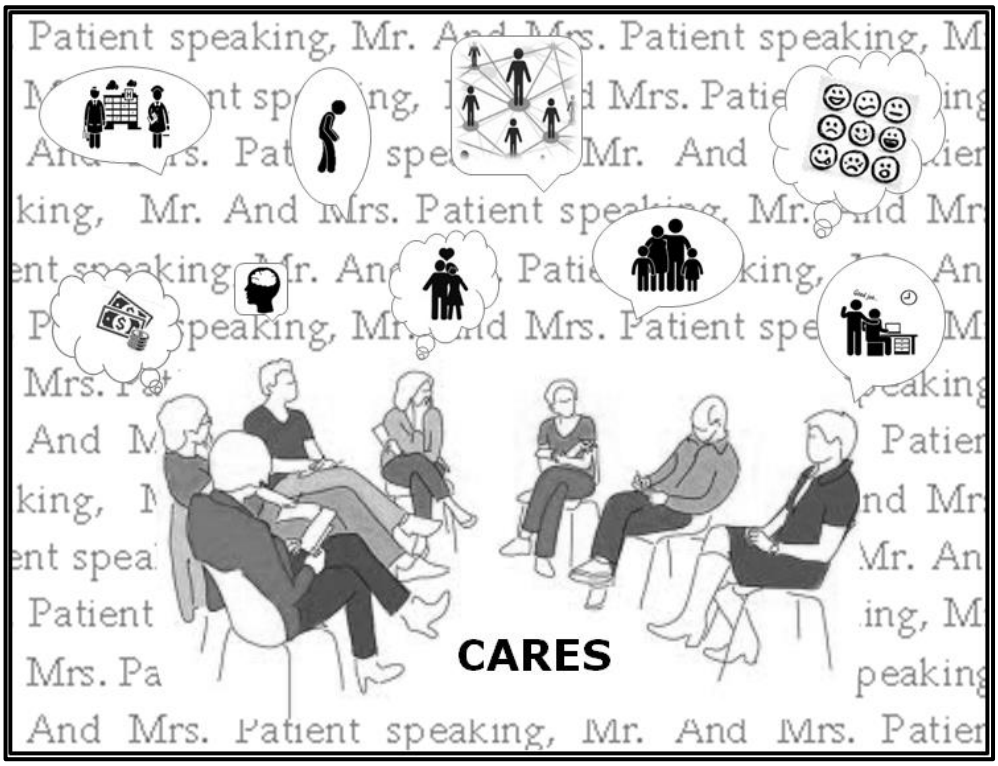
135. Fatigued after radiotherapy [b]	13.1	13.1	11.9	8.0	2.3	3.4	86.4
136. Nervous to get radiotherapy [b]	35.2	9.7	2.3	1.7	0.6	1.1	93.2
137. Nauseous/vomit after radiotherapy [b]	44.3	3.4	0.6	0.6	0.0	0.6	97.2
138. Problems ostomy care/maintenance [b]	1.1	1.1	0.0	0.0	0.0	0.6	99.4
139. Diff. with prosthesis [b]	8.5	1.7	2.3	0.6	1.1	1.1	97.2

Note: QOL-score range of each item from 0 - 4: 0= Not at all. 1= A little. 2= A fair amount. 3= Much. 4= Very Much. on the question 'Does this apply to you?'. Need for help-score is retrieved by the indication 'Yes' or 'No' on the question 'Do you want help?'.

[a] Percentages do not count up to 100% due to missing values for some participants.

[b] Item not applicable to each patient. [c] Percentages for items 18 and 80 are not clinically relevant. as there were a significant number of missing values for those items due to an error in the first questionnaire response (55.7%).

4
Chapter



Focus groups on the content validity and feasibility of the CARES

This chapter is based on:

Schouten, Bojoura; Hellings, Johan; Vankrunkelsven, Patrick; Mebis, Jeroen; Bulens, Paul; Buntinx, Frank; Vandijck, Dominique & Van Hoof, Elke (2017) *Qualitative research on the Belgian Cancer Rehabilitation Evaluation System (CARES): An evaluation of the content validity and feasibility.* J Eval Clin Pract. 2017 Jun;23(3):599-607. doi: 10.1111/jep.12681. Epub 2017 Jan 23.

ABSTRACT

RATIONALE, AIMS AND OBJECTIVES The systematic assessment of cancer patients well-being and care needs is internationally recommended to optimize comprehensive cancer care. The Cancer Rehabilitation Evaluation System (CARES) is a psychometrically robust quality of life and needs assessment tool of US origin, developed in the early '90s. This article describes Belgian patients' view on the content validity and feasibility of the CARES for use in current cancer care.

METHOD Participants were cancer patients recruited through media. Data were gathered in four focus groups (n=26). The focus group discussions were facilitated with key questions. A moderator and an observer conducted and followed the discussion. The audio file was transcribed verbatim and afterwards analyzed thematically.

RESULTS Participants experience concerns and needs in a wide range of life domains: physical, emotional, cognitive, social, relational, sexual, financial, work-related and in the interaction with care professionals. According to participants, the items of the CARES are all relevant to capture the possible life disruption that cancer patients and survivors experience. One important theme is missing in the CARES, namely the well-being of loved ones. The completion time of the CARES was judged to be feasible, and according to participants only a few items need a reformulation .

CONCLUSION In general, the results of this study support the content validity and feasibility of the CARES. However, little adjustments in formulation and a few extra items are needed. The instrument can be used to obtain a comprehensive assessment of cancer patients' overall well-being and care needs to take dedicated action in care.

KEYWORDS: cancer, quality of life, care needs, assessment, patient-centeredness.

INTRODUCTION

Cancer is a disease with a huge impact, going far beyond the threat of physical health. Patients and survivors often struggle with multifactorial consequences of physical, psychological (cognitive, emotional), and social nature [23, 115, 130]. Since scientific evolutions increased survival in the cancer patient population, attention for quality of life (QOL) in cancer care became more and more important. Along with other vital signs (temperature, blood pressure, pulse, respiratory rate and pain), distress or psychosocial well-being is considered the 'sixth vital sign' that deserves follow-up in cancer care [47, 48, 49].

Most patients do not disclose their psychological problems spontaneously, they rather frequently wait on the initiative of their doctor to discuss psychosocial topics [25]. The majority of specialists working in medical oncology acknowledge the need to detect psychosocial distress. Though, clinicians are not always accurate in identifying patients who are significantly distressed and often underestimate emotional matters in patients [24]. A mutual expectation of doctors and patients that the other will introduce the topic often leaves psychosocial concerns undiscussed [25]. Care providers should ensure to minimize barriers for patients to disclose emotional issues [24]. The use of a screening or assessment instrument prevents doctors from having to ask questions that they may feel are intrusive to the patient. Therefore, for example in Europe, Australia and the United States, guidelines were developed to systematically screen for levels of psychosocial distress and care needs of cancer patients [38, 40, 42, 43, 44, 131, 132]. In Belgium there are no such guidelines, and psychosocial screening is not standardly applied in cancer care. A limitation in Belgian research and practice is the absence of a validated comprehensive assessment instrument to identify psychosocial concerns and care needs of cancer patients. However, multi-domain screening can facilitate the dialogue between patients and clinicians and help detect distress [46, 133]. A subsequent in-depth assessment of distressed individuals could determine which unmet needs have contributed to distress and give insights for triage and referral to different levels of intervention appropriate to each patient. In this way, a stepped care approach supported by the use of screening or assessment results would contribute to the organization of a more patient-centered and cost-efficient care.

In several systematic reviews [46, 134, 135], the psychometric qualities of needs assessment tools were compared, mainly resulting in a positive evaluation of the Cancer Rehabilitation Evaluation System (CARES), and the Supportive Care Needs Survey (SCNS). Since the researchers believe that the CARES assesses 'health' care needs with the greatest depth in terms of biopsychosocial content, this instrument was chosen for further use. The CARES is a QOL and needs assessment instrument, developed in the nineties to provide an efficient way of gathering specific information about the day-to-day problems and rehabilitation needs of cancer patients. In the past this instrument was successfully used for research and clinical purposes [85, 136, 137, 138, 139]. Unfortunately, the widespread use of the CARES was limited by a copyright and user fee imposed by the developers. Since the user fee was abolished in November 2012 the instrument gained further visibility in research [140, 141, 142, 143].

The time perspective, culture and language are important for the ecological dimension and validity of an instrument. A correct adaptation for a different language and culture requires a broader design that takes into account linguistic as well as technical and conceptual aspects in measuring health status [122]. Since the CARES was not frequently used in recent years, the validity in current patient populations is still uncertain. To resolve this issue, new validation research had to be undertaken. Two studies were conducted to examine the validity of the CARES for the Belgian population: a quantitative study on the translation and validation of the Belgian CARES was conducted to examine the psychometric robustness of the instrument in terms of reliability, construct validity and concurrent validity [125, 144], and the qualitative study that is described in this article.

The aim of this qualitative study is to involve the target population, namely Belgian cancer patients, in answering the following questions: 'Is the content of the CARES relevant and complete enough to have the potential to capture the QOL and supportive care needs of Belgian patients?' and 'Is the CARES an acceptable and feasible instrument for these patients?'

METHODS AND MATERIALS

The method of focus group (FG) discussions was used to deepen our understanding of participants' experiences and the meaning they attribute to such experiences. The diversity of participants in the group ensured that the insights on the discussion topic were obtained from different angles and perspectives, and not merely based on individual opinions. This is important for this study since it needed to explore the degree to which the content of the CARES allowed to capture the QOL and supportive care needs of Belgian patients in general. Each participant was encouraged to actively participate in the discussion.

Participants and setting

Participants were adult cancer patients recruited through a call in the local newspaper and on the radio in May 2014. There were no restrictions on type and time of cancer diagnosis, gender and age ('adult' was defined as 18 years and older). Patients were excluded when they lacked proficiency in Dutch as this would hamper their participation in the FG discussions. The FG took place in the course of the summer of 2014 in 'Huis Erika Thijs', an open and well accessible house in Hasselt, Belgium, which offers various non-professional support to cancer patients, survivors and their relatives.

The QOL and needs assessment tool

The original CARES contains 139 items (min. 93 and max. 132 applicable per person). Patients can rate each item, formulated as problem statement, on a 5-point ordinal scale with zero representing "not at all" (no problem) and four representing "very much" (severe problem). Additionally, patients are asked to indicate for which problems they would want help, ticking 'yes' or 'no' to the question 'Do you want help?'. The items of the CARES can be placed under 31 subscales, and subsequently taken together in six summary scales as shown in Table 1.

Table 1. Life domains covered by CARES summary scales and subscales

CARES Summary scales (n items)	**CARES Subscales**
Physical (26)	Ambulation Activities of daily living Recreational activities Weight loss Difficulty working Pain Clothing
Medical Interaction (11)	Problems obtaining info from medical team Difficulty communicating with medical team Control of medical team
Marital[a] (18)	Communication with partner Affection with partner Interaction with partner Overprotection by partner Neglect of care by partner
Psychosocial (44)	Body image Psychological distress Cognitive problems Difficulty communicating with friends/relatives Friends/relatives difficulty interacting Anxiety in medical situations Worry Interaction with children[a] At work concerns[a]
Sexual (8)	Sex interest Sexual dysfunction[a]
Miscellaneous (32)	Compliance Economic barriers Dating[a] Chemotherapy-related problems[a] Radiation-related problems[a] Ostomy[a] Prosthesis[a] Miscellaneous items[a]

[a] Items do not apply to all patients.

Procedure

Interested patients were contacted and the date of their participation was registered. One week before FG took place, participants were sent an envelope containing an information letter, an informed consent form, and a short questionnaire on socio-demographics, type of cancer and treatment. They were asked to fill in these documents and bring them to the FG. All participants provided informed consent before taking part in this validation study, which was

approved by the local medical ethics committee. A copy of the CARES was also included in the preparatory documentation for the participants, so that they could get acquainted with the assessment tool and bring it to the FG.—The moderator (BS) and an observer (WE or EVH) conducted and followed the FG discussion while it was audiotaped with prior consent. The group discussion was facilitated with several key questions (Table 2). Each FG lasted about 120 minutes.

Table 2. Interview guide for the focus group

Opening question	**1.** Can you please introduce yourself shortly and share with the group what your motivation was to participate in this study?
Introductory questions	**2.** Were you ever asked in care to fill in a questionnaire regarding your well-being? Which professional asked you this and with what purpose?
Transition and key questions	*The CARES is an assessment tool developed to explore the well-being and care needs of people confronted with cancer. There are several aspects of well-being discussed, that we have listed for you.* **3.** If one wants to explore the well-being of cancer patients, which topics are according to you the most relevant/important? Are they included in the CARES? Which topics are less important? **4.** Are there topics not mentioned in the CARES that are important when one wants to explore cancer patients' well-being? Which? **5.** How did you experience the wording of the CARES-items? **6.** If such an assessment tool or questionnaire would be integrated as a standard part in care, what would be the value of this?* **7.** If you look back at the cancer care you have experienced until now, did a caregiver notice the concerns and care needs you experienced? * **8.** How did they detect these? / How could they have detected these? * **9.** What is the best way to introduce support in response to detected needs? *
Ending question	*Our goal was to get a clear perspective on the topics cancer patients consider important to be followed up in care and the properties an instrument should meet in order to serve this goal. Specifically, we have asked you to evaluate the content and acceptability of the CARES as an assessment tool. (+ summary of what is been said during the focus group discussion)* **10.** Is there something I have overlooked or something that still has to be discussed?

* These questions go beyond the scope of the present paper and most data resulting from these are not discussed in depth in the present paper.

Data analysis

The digital audio files of the focus groups were transcribed verbatim (BS) and analyzed using thematic content analysis [145, 146, 147]. FG were organized until data saturation was reached. Through repeated reading of transcriptions, initial codes were noted by two independent readers (BS and EVH). Subsequently the codes were organized into meaningful groups and combined in overarching themes. After reviewing the subdivision of themes, categories and codes were given to two naïve readers (JH and PV) to revise for semantic correctness. The resulting 'thematic map' was used to code all FG data.

RESULTS

Participants

Twenty-six cancer patients participated in four FG discussions (with seven, six, six and seven participants, respectively). The mean age was 56.2 years (range 28-78). Counts and percentages of further socio-demographic and medical characteristics are displayed in Table 3.

Table 3. Participants' socio-demographic and medical characteristics (N=26)

Socio-demographic characteristics	**n**	**%**	**Medical characteristics**	**n**	**%**
Gender			Cancer diagnosis [b]		
Men	4	15.4	Breast	11	42.3
Woman	22	84.6	Colorectal	4	15.4
Relational status [a]			Lung	1	3.8
Single	2	7.7	Ovarian	1	3.8
In a relationship: living with partner/married	22	80.8	Non-Hodgkin Lymphoma	2	7.7
			Hodgkin Lymphoma	2	7.7
In a relationship: not living with partner/married	-	-	Brain	1	3.8
			Prostate	1	3.8
Widowed	1	3.8	Thyroid	1	3.8
Children [a]			Maligne melanoma	1	3.8
No	3	11.5	Pancreas	1	3.08
Yes	22	80.8	Liver	1	3.8
Level of education [a]			Uterine body	1	3.8
Elementary school	1	3.8	Other	1	3.8
High school	9	24.6	Treatment [c]		
Graduate school	13	50.0	Surgery	17	65.4
University	1	3.8	Chemotherapy	15	57.7
Employment [a]			Radiotherapy	12	46.2
Employed	7	26.9	Hormonal therapy	7	26.9
Work interruption/on sick leave	2	7.7	Immune therapy	1	3.8
Unemployed	1	3.8	Bone marrow transplantation	1	3.8
Disabled	6	23.1			
Housewife/houseman	-	-	Phase of care trajectory		
Retired	8	30.8	Active treatment phase	6	23.1
Monthly household income [a]			Phase when active treatment is completed	1	3.8
< € 1500	4	15.4			
€ 1500- € 3000	15	57.7	Follow-up phase	18	69.2
> € 3000	4	15.4			

[a] Not all characteristics count up to 100% due to missing answers of some participants, [b] Cancer diagnosis in total counts up to more than 100%, because several participants got diagnosed with more than one type of cancer in the course of time, [c] Treatment types in total counts up to more than 100%, because most participants got treated with a combination of treatment types.

Qualitative analysis results

The FG resulted in a large data corpus. All themes are shown in Appendix 4.1. However, only the data set relevant to content validity and feasibility of the CARES will be described in this article.

Three themes divided in subthemes are discussed below. The first, 'Cancer and treatment related consequences', contains the subthemes 'complaints and symptoms', 'financial impact', 'work-related impact' and 'well-being loved ones'. The second theme is 'Interaction with care professionals'. The third theme, 'Assessment of psychosocial well-being and care needs', is divided in the subthemes 'experiences with patient-reported outcome measures in care',

'content CARES' and 'feasibility CARES'. For each theme a few example quotes are presented in Table 4. More quotes can be found in Appendix 4.2.

THEME Cancer and treatment related consequences

Complaints and symptoms

Cancer patients mentioned experiencing different kinds of *physical consequences* of cancer treatment. A common complaint is the lack of energy making it difficult for people to regain their former level of activity. Some patients experience limitations due to pain in the muscles or joints, loss of taste, or deterioration of the skeleton. Temporary or permanent loss of fertility is a frequent concern for female patients since it can change their future family perspectives.

Participants experience *psychological consequences* in terms of changes in cognitive functioning, emotions and personality. Memory problems are often named, as well as feelings of fear, sorrow, loneliness, anger, shame, guilt, insecurity, etc. Before they recognized these emotions patients were often overwhelmed and not aware of their perception of the situation. For some, the experience was so heavy and hopeless that thoughts about the desire to be dead came to their mind.

Social life changes occurred, either because the patient was pushing others away or because their context became avoidant. Likewise, the opposite was experienced if the context of the patient responded supportively and involved itself: relationships became closer and new friendships arose.

Patients *marital and sexual life is put to the test*. The patient and their partner sometimes cope with the situation differently leading to relational tension. Damaged as well as strengthened relationships are experienced. Likewise, physical and emotional aspects can induce a discrepancy in sexual needs. Amputations, scarves, baldness and weight gain affect people's body image and sometimes influences their sense of masculinity or femininity.

Table 4. Themes from thematic data analysis and example quotes

THEME: CANCER AND TREATMENT RELATED CONSEQUENCES

COMPLAINTS AND SYMPTOMS

Physical

I have noticed that the problems are quite the same for everyone, in general I mean. Like being tired, the lack of energy…regardless whether you have breast cancer or any another type (FG-07).

Psychological

Sometimes I am so forgetful…at those moments, I think 'am I developing Alzheimer's or what?!' (FG-09)

I'm not easily scared, but in the waiting room, in the hospital department… there I get scared (FG-20)

I experience everything more intensely and view it positively. If I experience something with my children I always think, 'yesss that I have had already', not 'maybe I will not live to see that again' (FG-12).

Social

When I was sick, I could not breathe ... so many people came to visit me! This went on for weeks and weeks... and after that no one came any more (FG-05).

Marital/Sexual

… my husband was really struggling with the situation and yes ... his way of coping was actually quite annoying (FG-11)

I had a good sexual relationship with my wife, and from one day to the other it was done. I started with the treatment with Zoadex…. It suppresses the production of testosterone. And of course that effect on testosterone ... for a man ... that was chemical castration! (FG-15).

FINANCIAL IMPACT

We had bought our house on the basis of two full-time incomes, of which one failed because of my illness. But my loan will not decrease. It remains the same, the banks want their money (FG-06).

WORK RELATED IMPACT

I've heard …as soon as my sick leave ends, I'm getting fired (FG-09).
I am independent, I cannot stop working, so I've just been working…but in in a limited way (FG-02).

WELLBEING LOVED ONES

My mom stayed at home to care for me. Their whole life changes and you already feel guilty and bad and then you also see them suffering from the situation (FG-10).

We get a lot of attention like 'how are you?', but the fear of the partner …who possibly ends up alone… there is almost no one thinking about how they are doing (FG-14).

THEME: INTERACTION WITH CARE PROFESSIONALS

If they would have had attention for my deepest fear at the time I was sick to death of my chemo…the fear that said 'What if something goes wrong with me, what with my two sons?'…I think I would have been a lot more resilient to cope with the chemo (FG-26).

… the nursing staff were guardian angels for me. I had a lot of questions. They answered me and if there was something they didn't know, then the doctor came up with an answer. So I felt 'there is something happening here' (FG-13).

I have the experience that few doctors or specialists can identify with the psyche ... I think they are good technical people for surgery, but there are few who can empathize with the psyche of the patient (FG-17).

THEME: ASSESSMENT OF PSYCHOSOCIAL WELL-BEING AND CARE NEEDS

EXPERIENCES WITH PATIENT-REPORTED OUTCOME MEASURES IN CARE

Not from the hospital, but from the health insurance…a questionnaire on self-reliance…really ridiculous questions they ask you, like 'do you have a handrail on the toilet? They use these to score…to decide if you are

disabled or not (FG-13).

The hospital sent me a questionnaire like that (like the CARES)… I experienced it as something positive that they are interested in your well-being. That there is follow-up of your situation even if you're not in the hospital anymore… I did me well (FG-25).

POTENTIAL ROLE OF PSYCHOSOCIAL SCREENING

Then you know 'what I feel is completely normal'…sometimes you feel abnormal, but if you know that there are other people that are feeling that way…and it is a topic in follow-up…you would feel a lot better already (FG-11).

Aaaaah yes, I admit I answered some questions I would never talk about with my oncologist... or even with my general practitioner. And yet I'd like to get help for those things, but I don't dare to bring it up myself (FG-06).

APPLICABILITY OF PSYCHOSOCIAL SCREENING

When I started with chemo I wasn't sick and I thought "well I'm doing good, everything is going perfect"… but after that first week I felt completely different (FG-06).

CARES

Content CARES

Everything is important, it depends on your own situation what is most. I can imagine that other aspects for some people are less important. I wouldn't let any topic out of the questionnaire (FG-21).

I think it certainly is important that there is attention for all those who are around you, how are they doing at that stage ... My partner, my children and so ... they also suffered a lot (FG-01).

Feasibility CARES

I think…if it would be possible to shorten it…everything must be addressed, but not too extensive (FG-12).

Financial impact

The confrontation with cancer was also said to increase the health expenditure and induce huge financial burden on those not properly insured. Even with good insurance, the loss of income requires adequate spending and sometimes a change of life style. Even years after being cured from cancer, one can experience problems with financial benefits like the application for a mortgage, insurances, scholarships, reimbursements, etc.

Work-related impact

Patients working as independent entrepreneurs mentioned that they often have difficulties to stop working during treatment because of the risk to lose clients and income, and they therefore cannot stay at home to focus on treatment and recovery. For patients on sick leave, a part of their social context is missing because there is no more daily contact with colleagues. Once returned to work there is sometimes little understanding for the altered ability to work and the risk to be fired arises.

Well-being loved ones

Most participants talked about the impact their disease experience had on their loved ones. Partners, children and parents had to change their lives to take care of the patient, manage the household on their own, deal with the fact that their loved one was sick and possibly incurable. Some participants notice feelings of fear, anger or sorrow in their partners or children, others don't know how their loved ones are coping with the situation because the topic is avoided. According to participants, there is a lack of attention for the well-being of patients' loved ones in cancer care.

THEME Interaction with care professionals

Patients expect a comprehensive approach including medical care and psychosocial support. They report positive and negative experiences with care mostly determined by aspects such as trust, personal approach, multidisciplinary cooperation and referral, follow-up, holistic approach, availability/time, communication style, clarity of information and familiarity with patients' medical or personal situation.

THEME Assessment of psychosocial well-being and care needs

Experiences with patient-reported outcome measures in care

Some participants had to complete questionnaires on their physical functioning for the insurance company or other institutions. Their experiences with these questionnaires were negative. According to participants the questions were too limited to properly assess aspects that matter for insurance companies. Only three participants were familiar with the use of a patient-reported outcome tool in clinical care to assess and follow-up their psychosocial well-being and care needs. They received the Distress Thermometer and Problem List in follow-up. Their experiences on the use of this tool were positive.

Potential role of psychosocial screening

According to our participants, the use of a psychosocial screening tool could be of great value in practice. An instrument with questions on the overall well-being could give help recognize patients' experiences and normalize the taboo of psychosocial problems. Using psychosocial screening tools could also lower the

threshold to mention concerns and needs and stimulate the communication between patients and caregivers. In this way, problems and care needs could be detected more easily by caregivers and allow them to provide input for designated action in care.

Applicability of psychosocial screening

The potential value and applicability of psychosocial screening depends on personal situation, personality, preferences, and approachability.

According to cancer patients a screening instrument should be readily accessible and concise. When certain concerns or problems are denoted, a more profound assessment can follow.

Repeated application of screening and assessment is seen as desirable by participants since well-being and supportive care needs can change. The desired timing for psychosocial screening differs according to personal experiences with the disease, treatment and recovery.

If screening and assessment were applied in practice, the majority of our FG participants would prefer to complete this in a paper version. Some reasons often mentioned include better concentration, limited burden on the eyes, ability to fill in anywhere, and lack of familiarity with the computer. Environmental concerns, the speed of filling in a screening and processing of results nonetheless made other participants prefer screening in a digital format.

Participants emphasize that the use of psychosocial screening can only be valuable if the obtained insights yield to action and if revealed needs are monitored in follow-up and matched to the appropriate care.

CARES

Content CARES

The whole content of the CARES is seen as relevant and important for the wellbeing of someone confronted with cancer, though this can vary according to the phase of the disease-trajectory one is going thorough or according to one's personal situation. Topics mentioned as most important are mostly physical and daily functioning, emotional well-being and relations with loved ones. Generally, the content of the CARES is judged to be complete. According to several participants, one very important element is missing in the CARES as well as in

cancer care, namely the well-being of their relatives. Likewise, feelings of uncertainty and loneliness associated with cancer are experienced by several participants and insufficiently discussed in the CARES.
Items that were added to the final Flemish CARES in response to these findings are presented in Appendix 4.3.

Feasibility CARES
The CARES is experienced as a long questionnaire, yet participants find this acceptable considering the importance of capturing people's overall wellbeing rigorously for utility in cancer care. The formulation of the CARES in general is positively evaluated, and everything was clear for the participants. The only comment that was raised is that the questionnaire might be difficult for non-native Dutch speakers because of the vocabulary used. Some suggestions were raised to reformulate a few items to clarify or to make the formulation less confronting. The 'yes'/'no' response categories linked to the question 'Do you want help?' were also seen as an issue as sometimes neither 'yes' nor 'no' would fully allow patients to express themselves (e.g. "My partner has problems with talking about his emotions, but I don't. So what should I answer then? Yes or no?"). One participant suggested that some people might get anxious when they are confronted with some of the items, such as 'my clothes do not fit anymore', 'relapse', and 'the emotional experience'.
Items that were rephrased in the final Flemish CARES in response to these findings are presented in Appendix 4.3.

After the qualitative analysis process, all data was reviewed again and CARES items were ticked if the topic was discussed. Most items of the CARES (103/139) were covered spontaneously by participants in the FG discussion (Appendix 4.4.). A great percentage of the non-discussed items are the items that do not apply to all patients (e.g. 'Difficulties to help the children cope').

DISCUSSION

The findings of this study, along with the quantitative research on the psychometric robustness of the instrument [144], show a positive evaluation of the validity of the CARES.

As in other research populations participants in this study experience concerns and needs in a wide range of life domains [23, 82, 115, 130]. Physical problems, limitations in daily functioning as well as memory problems are often named. The confrontation with cancer, related treatment and consequences may cause feelings of fear, sorrow, loneliness, anger, shame, guilt and insecurity. Social life changes took place for some, and both marital and sexual life are challenged. Work related and financial consequences are experienced not only in the active phase of disease and treatment, but also later on.

The interaction with professional care givers plays an important role in the extent to which concerns are addressed and care needs are met. Similar to other studies our data suggest that patients frequently want their doctor to initiate discussion of psychosocial topics [25], or at least to minimize barriers to disclose emotional issues [24]. For participants, an important concern – and sometimes even a real burden – was the well-being of loved ones. Patients partners and children sometimes struggled with the situation, but this was not noticed nor discussed in the care system. The use of screening and assessment tools could initiate and facilitate the dialogue between patients and clinicians regarding psychosocial topics and promote early identification of patients' distress and related needs [46, 133].

The findings of our qualitative data collection are congruent with past study results on the content of the original CARES [84, 116], namely that the content of the instrument is very relevant. In the literature on the original CARES, no substantive shortcomings were mentioned. In our sample however, the absence of items on the experience of loneliness and well-being of loved ones were explicitly stated as lacking. Participants noticed a considerable impact of their disease and treatment regime on the lives and the well-being of their spouses, parents and children. Patients often perceived the concern for their loved ones as burdensome, but this difficulty was not recognized nor detected by health care professionals and might also be undetected by the CARES since the questionnaire contained no item on this topic. In future studies, items on these

missing topics were added in the Belgian CARES screening tool (Appendix 9.1). The relevance of these items' content will emerge from the CARES data in our future studies.

Our participants judged the CARES to be a feasible instrument. Completion of the instrument is experienced to be time consuming, but acceptable. In our quantitative study which was conducted to test the psychometric qualities of the CARES [144], data showed that all CARES item were indicated as being a problem for 0.6-88.1% of the participants, and therefore relevant for a population of cancer patients. Nonetheless, the suggestion was made to previously conduct a shorter screening version and to subsequently assess patients' QOL and needs more profoundly with the CARES if distress is detected. These preferences are in favor of a stepped-screening approach. The CARES-Short Form, which includes 59 items of the full version, could potentially be used for such initial screening purpose [77, 148]. The original CARES items were constructed with involvement of patients [81, 116]. However, according to participants of this study, some items of the CARES could be adjusted with simpler or less confronting vocabulary to optimize feasibility. Most participants favor completing a paper version. Nevertheless, according to them both a paper and digital version should be available for the application of the instrument in clinical practice. This would tailor psychosocial screening to individual convenience.

Several methodological considerations about this study should be mentioned. First, the representativeness of the research population can be discussed. With a mean age of 56.2 years (range 28-78), our research population was slightly younger than the average Belgian population of cancer patients, where respectively 66 percent of the women and 77 percent of the men are 60 years or older at the time of diagnosis. The recruitment of participants via media potentially gave opportunity for the emergence of a self-selection bias. Nevertheless, results on the socio-demographic and medical characteristics show that the study sample is comparable to the general populations of cancer patients in Belgium [129]. Compared to the proportion found in the general Belgian population of cancer patients, more women than men participated in our study. However, this is often seen in psycho-oncology research, presumably because men are less prone to talk about psychosocial concerns [149, 150].

Participants were recruited without specification of cancer type, which led to a strong representation of breast cancer patients in the research population. However, this is in accordance with the prevalence of this type of cancer in our female population. In all likelihood, findings can be applicable for the broader population of cancer patients in Belgium. Secondly, no participants with a low proficiency in Dutch and few people with a low level of education participated in the FG, yet these people represent a significant proportion of the Belgian society. Thirdly, the neutrality of the study setting can be questioned. 'Huis Erika Thijs' was chosen for the FG to take place given that it is outside the hospital context, centrally located, and that the care offer of the initiative could be discovered by participants visiting the center. Some FG participants had never heard of 'Huis Erika Thijs', some had heard of it before, but the majority of the group did not visit the center before. If the location was of influence for some participants, the effect probably was not uniform. Fourthly, in this study only the full version of the CARES was discussed with participants, although, the CARES-Short Form was also validated in Flemish. Letting patients compare both versions in content, completeness and feasibility would have been interesting.
We suggest that future research efforts should aim to enhance understanding of the feasibility of the CARES for immigrants and patients with a low level of education. More future research could aim to compare between the content and feasibility of the short and long CARES version, as well as on the key points for implementation of effective QOL screening and needs assessment in clinical practice.

In conclusion, the results of this study suggest the CARES is a feasible QOL and needs assessment instrument with acceptable content validity for use in a population of Belgian patients in current cancer care. The CARES can be used to detect a wide range of problems and care needs and according to patients, its use can be of value for the integration of psychosocial follow-up in supportive cancer care. In response to participants' input in this qualitative study, minor adjustments to the CARES will be made before it is further used in research and clinical practice: a few items regarding the well-being of loved ones will be added and the wording of some items will be adjusted. This will increase the

ecological fit and validity of the instrument with the Belgian patient population in which we wish to use the CARES for further research and clinical application.

ACKNOWLEDGEMENTS

Our gratitude goes out to the team of Huis Erika Thijs for their hospitality and for the provision of facilities during the focus groups. We would like to thank Willem van de Esschert for his practical support in conducting the focus groups, Noémie Aubert Bonn for editing the manuscript for the English language, and Limburg Sterk Merk (LSM) for funding the PhD-research project of Bojoura Schouten .

Appendix 4.1

Table A4.1. Themes resulting from thematic data analysis.

CANCER AND TREATMENT RELATED CONSEQUENCES
- PHYSICAL
  - *Limited energy*
  - *Pain*
  - *Fertility*
  - *Body changes (scars, weight,…)*
  - *Changed physical or sensorial ability*
- PSYCHOLOGICAL
  - *Emotional experience*
    - Overwhelmed
    - Not aware/no sense of…
    - Bewildered
    - Lonely, not understood
    - Insecure
    - Burdened (to be strong for loved ones)
    - Sad, depressed
    - Anxious
    - Angry
    - Ashamed
    - Ashamed
    - Guilty
  - *Cognitive functioning*
  - *Personality changes*
- SOCIAL
  - *Social participation*
  - *Social context*
- MARITAL
- SEXUAL
  - *Practical consequences due to energy and mindset*
  - *Femininity*
  - *Masculinity*
  - *Body image*
- FINANCIAL
  - *Loss of income*
  - *Health expenditures*
  - *Ability to get a loan*
  - *Need to change in spending*
  - *Administrative complications related to finances*
- WORK RELATED
  - *Stigma on cancer: related difficulties, little understanding*
  - *Changed ability to function*
- WELLBEING LOVED ONES

COPING WITH DIAGNOSIS AND TREATMENT
- PERSONAL COPING AND REACTION
  - *Putting in perspective*
  - *Accepting*
  - *Operating on autopilot*
  - *Avoiding/in denial*

CARE NEEDS AND EXPECTATIONS
- RECOGNITION AS AN (EX)CANCER PATIENT
- INVOLVEMENT IN CARE CHOICES AND DECISIONS
- CLARITY ON PERSONAL(MEDICAL) SITUATION & ON TREATMENT AND SUPPORTIVE CARE OPTIONS
- DEPENDENT ON DISEASE AND TREATMENT PHASE DEPENDENT ON INDIVIDUAL
- DETECTION OF AND INITIATION ABOUT PSYCHOSOCIAL TOPIC BY CARE PROFESSIONALS
- SUPPORT IN REHABILITATION
- CENTRAL CONTACT FOR QUESTIONS AND NEEDS
- NEED FOR OPTIMIZATION OF CARE

EXPERIENCES WITH CANCER CARE
- INTEGRATION OF MEDICAL AND PSYCHOSOCIAL CARE
- MEDICAL CARE
- PSYCHOSOCIAL CARE
  - *Barriers*
  - *Restrictions, gaps*
  - *Care offer often is unclear*
  - *Lack of continuity*
  - *Cost outside the hospital*
  - *Timing issues*
  - *To general to address individual needs*
  - *Positive Experiences*
  - *Necessary part of regular care*
- BROCHURES
- INTERACTION WITH CARE PROFESSIONALS
  - *Trust*
  - *Affinity with psychosocial concerns*
  - *Take some time*
  - *Familiarity of patient with care professional*
  - *Familiarity with the patient and the total health file, work with multidisciplinary collaboration and referral*
  - *Inform the patient*
  - *Communication style*

SCREENING AND ASSESSMENT OF PSYCHOSOCIAL WELL-BEING AND CARE NEEDS
- EXPERIENCES WITH PATIENT-REPORTED OUTCOME MEASURES IN CARE
- POTENTIAL ROLE OF PSYCHOSOCIAL SCREENING
  - *Normalization psychosocial topic*
  - *Stimulates the communication*
  - *Potentially improves recognition, and detection*
  - *Need to use resulting insights*
  - *Adverse effects*
- CARES
  - *Content CARES*

Suicidal ideation
Openness about it/hide for others
COPING AND REACTION OF PEOPLE IN THE CONTEXT
Putting in perspective
Avoiding/in denial, anxious, uncomfortable
Little understanding
Shame
Positive, encouraging
DISCREPANCY OWN AND OTHERS REACTION

SOURCES OF PSYCHOSOCIAL SUPPORT
PEER SUPPORT
PERSONAL CONTEXT
CARE PROFESSIONALS

Relevance- importance of topics and items
Missing topics
Feasibility CARES
General impression
Wording
Potential adverse effects

MOTIVATION PARTICIPATION IN THIS FOCUS GROUP DISCUSSION
CONTRIBUTION TO OPTIMIZATION FUTURE CANCER CARE
CHARE EXPERIENCES/LISTEN TO OTHERS' EXPERIENCES
OBTAIN INFORMATION ON CARE OFFER FROM RESEARCHERS AND BUDDIES.

Note: These are all the themes resulting from the thematic analysis, however, only the ones belonging to the scope of the paper are discussed in detail.

Appendix 4.2

Table A4.2. Quotes from focus group participants.

THEME: CANCER AND TREATMENT RELATED CONSEQUENCES

COMPLAINTS AND SYMPTOMS

Physical

I have noticed that the problems are quite the same for everyone, in general I mean. Like being tired, the lack of energy…regardless whether you have breast cancer or any another type (FG-07).

…my type cancer affects my skeleton, I am full of holes…sitting down or standing up for a long time is no longer possible for me … (FG-13).

I was 31 years old, and I was in my menopause, and could not have children anymore. And although I actually had three healthy children already,... the day I heard that I couldn't get any more children, I had a very hard time with this…and still… (FG-06).

Now with the immune therapy... every eight weeks ... I get it and sequential I have pain in my joints and my bones and everything for 2,5 weeks ... (FG-20).

Psychological

Sometimes I am so forgetful…at those moments I think 'am I developing Alzheimer's or what?!' (FG-09).

…people ask 'are you cured?'… I really never feel the same as before I had surgery and so on. There's always a fear, an uncertainty that lingers (FG-19).

I'm not easily scared, but in the waiting room, in the hospital department… there I get scared (FG-20).

(sexual problems) … I just feel guilty towards my husband. And that while he doesn't blame me, I feel very guilty because he doesn't deserve this (FG-06).

You can have so many people around you, but in fact you are all alone with your illness. You can get much help … my husband does everything, my children do a lot for me, but in the experience of my illness I am all alone (FG-07).

I experience everything more intensely and view it positively. If I experience something with my children I always

think, 'yesss that I have had already', not 'maybe I will not live to see that again' (FG-12).

Sometimes I think, 'It would have been better to die during the operation', then everyone would be rid of all concerns and burden' …you get depressed thoughts like that sometimes… (FG-07).

My mom stayed at home to care for me. Their whole life changes and you already feel guilty and bad and then you also see them suffering from the situation (FG-10).

It's very difficult sometimes thinking 'am I crazy in my head or what? ...do I really need a psychologist to be able to handle this? ' and so you don't get that kind of help…the threshold is so high (FG-11).

But now with this immune therapy I should heal completely, so I'm like, 'I'll believe it '. But somehow you continue to have doubts, for cancer is coming at you so hard ... I had no pain, I was not sick ... I only occasionally had a leg that felt a bit numb (FG-20).

Sometimes that also applies planning….they say 'next year…this or that'. And then you think 'How will I be doing next year? If, for example, someone says: "next year I'll get married" or with a rebuilding or…then I think: 'well yes…next year'…it's hard for me (FG-11).

...I think I got a difficult time afterwards and I think that's strange. Why was I doing so well back then and am I struggling right now? (FG-05).

At first you are occupied with the cancer and the chemo…survival…it's later on that you realize ….oeh….that had a serious impact on me (FG-13).

Social

When I was sick, I could not breathe ... so many people came to visit me! This went on for weeks and weeks... and after that no one came any more (FG-05).

We still have a chemo-club…we regularly go out to have dinner together, go on a trip to the coast, go to each other's birthday,… (FG-23).

…actually at this moment… I am pushing everyone away from me (FG-08).

Marital/Sexual

… my husband was really struggling with the situation and yes ... his way of coping was actually quite annoying (FG-11).

I had a good sexual relationship with my wife, and from one day to the other it was done. I started with the treatment with Zoadex…. It suppresses the production of testosterone. And of course that effect on testosterone ... for a man ... that was chemical castration! (FG-15).

Emotionally you change if you experience that fear….you yell a little more as usual…it's important that your partner knows that, that he is informed if that that can happen. … (FG-18).

FINANCIAL IMPACT

We had bought our house on the basis of two full-time incomes, of which one failed because of my illness. But my loan will not decrease. It remains the same, the banks want their money (FG-06).

I have a good insurance for health and hospitalization … I am glad, because otherwise you can't afford everything (FG-03).

Also further on in life you will still have to face the fact that you had cancer in the past, for example if you want to get a mortgage…you have to take a credit insurance… (FG-10).

If you need to go to a psychiatrist or a psychologist, you have to pay 50 euro's yourself. If you knew that it was only for one time and it could help you, you could deal with it .But if you need to go there for a year and you have to pay that amount of money each time….than there is a financial problem that occurs (FG-17).

My husband has taken leave to take care of me at home ... and he had to take so many leave in that year…unpaid leave. So while I myself already had a very large financial loss, he also lost on his salary (FG-20).

WORK RELATED IMPACT
I've heard …as soon as my sick leave ends, I'm getting fired (FG-09).

I run my own business, I cannot stop working, so I've just been working…but in in a limited way (FG-02).

Even with the computer program I was very familiar with…I was like 'how does it work, what do I have to do?' Really simple things…I felt bad that I had to ask so much…not only asking, but also the fact that that knowledge and skills of mine were gone (FG-11).

And soon I went back to work fulltime. I have a managerial position and then you can't say 'oh yes, well I'll try', no if you go back to work, you have to function properly (FG-12).

WELLBEING LOVED ONES
My mom stayed at home to care for me. Their whole life changes and you already feel guilty and bad and then you also see them suffering from the situation (FG-10).

We get a lot of attention like 'how are you?', but the fear of the partner …who possibly ends up alone… there is almost no one thinking about how they are doing (FG-14).

I have a husband that doesn't talk about his emotions and…I know that I was in my 7th or 8th chemo and my husband was emotionally crashing…but no one knew (FG-06).

THEME: Interaction with care professionals
TRUST
You have to trust them fully, but sometimes like with those medications…they damage your confidence. You are scared, worried and you feel disappointed…and yet the next time you go back you have to trust them again (FG-26).

AFFINITY WITH PSYCHOSOCIAL CONCERNS
It's the same with sexual problems. That is something difficult to discuss with doctors in the hospital (FG-02).

I have the experience that few doctors or specialists can identify with the psyche ... .I think they are good technical people for surgery, but there are few who can empathize with the psyche of the patient (FG-17).

Last year I went to the gynecologist for a normal gynecological examination…and he asked me "How are you?" and I said "Fine, I come for my examination". Then he said "No no… I'm asking how you are doing? You have been through a lot so…?". He took his time and started asking me how I coped with the cancer psychologically and how I dealt with it (FG-11).

If they would have had attention for my deepest fear at the time I was sick to death of my chemo…the fear that said 'What if something goes wrong with me, what with my two sons?'…I think I would have been a lot more resilient to cope with the chemo (FG-26).

The second time I went to my doctor… when she came to get me out of the waiting room, she said "you are scared". I said "How do you know that?". "I see it in your eyes…scared for all that is to come". And then she also asked me "Do you want to talk to a psychologist?" and I immediately said yes (FG-20).

TAKE SOME TIME
Once in Leuven I had a very emotional morning. I don't know…I can't tell exactly why. One of the nurses noticed and took some time for me. That was fantastic! (FG-21).

And the oncologist was not really open to it. I told about my symptoms, but ... he was like "pffff …well yes". There was no time for questions….you stood there with the handle in your hand and uh ... you had to get dressed quickly and yes ... the next patient was already there (FG-24).

…for example, I still have to go to the physiotherapist for my arms and for lymphatic drainage. For me that is a more suitable person to talk to about my worries, because he is treating me for half an hour (FG-16).

the doctor who did my surgery…I saw him once before the surgery and…never again. I was in the hospital for a

week, went home and had to go back to the hospital for another week because of an inflammation … my doctor didn't come…that was difficult for me because I had so many questions (FG-08).

FAMILIARITY WITH THE PATIENT AND THE TOTAL HEALTH FILE, WORK WITH MULTIDISCIPLINARY COLLABORATION AND REFERRAL

I suffered a lot from nausea and that was dismissed as…'well it was not possible'. But I was in follow-up with an assistant in the department of radiology and at the same time I got chemotherapy. The nausea was a consequence of the chemo…but the radiology assistant didn't thought about that. I went to another hospital for my further follow-up and thank god it is totally different there. The intestinal specialist is my attending physician and he knows my whole file (FG-21).

I had an onco-coach. She discussed some information with me, gave a brochure with the information and she also gave me her phone number. She had a center position in the hospital team and she instantly knew "ah yes you have that problem so I refer you to that person and this is available, that is available,…" (FG-22).

…in the breast center… at the beginning when I had a consultation ... I always had another oncologist who was not familiar with my file (FG-26).

INFORM THE PATIENT

I had a lot of questions, but the oncologist herself didn't know the answer. And so…she said "well you can use the computer, you can look on the internet". (FG-08).

The thing she told me on the credit insurance for example, that was something practical but…when I consulted her for follow-up she said 'In the next time there will be a lot of things coming your way confronting you with the fact that you had cancer.' …with that she in a way prepared me for 'what is next'. I experienced it as something really positive (FG-10).

The nurse who accompanied me said "you are only getting an echography". But, that turned out to be incorrect, yet it was a different kind of examination. Well and I was driving home for 14 kilometers and…suddenly it started leaking at my bottom. It was terrible. ..when I came home I was wet to the skin…and they didn't tell me that that could happen (FG-17).

… the nursing staff were guardian angels for me. I had a lot of questions. They answered me and if there was something they didn't knew, then the doctor came up with an answer. So I felt 'there is something happening here' (FG-13).

COMMUNICATION STYLE

…the second option was to bring me into the menopause , which would shut down everything for a while. They were not sure what effect it would have on me and well…the oncologist said "It's that option or the other…you don't have to start whining how you will feel about it. We have to start with the chemo so …decide." (FG-10).

They removed a part of the small intestine, what was in fact a tumor and he didn't say 'cancer'…that's what I asked him and then he said 'Yes in fact, that is what it is' (FG-17).

Yes well….I had two consultations with a psychologist, but for me this was not a positive experience. She was saying like "I can't help you"…it didn't feel good and I didn't schedule any further appointments. "You have to figure it out for yourself" she said….bud you contact them just because you cannot cope with it yourself…isn't it? (FG-24).

THEME: Assessment of psychosocial well-being and care needs

EXPERIENCES WITH PATIENT-REPORTED OUTCOME MEASURES IN CARE

Not from the hospital, but from the health insurance…a questionnaire on self-reliance…really ridiculous questions they ask you, like 'do you have a handrail on the toilet? They use these to score…to decide if you are disabled or not (FG-13)

The hospital sent me a questionnaire like that…I experienced it as something positive that they are interested in your well-being. That there is follow-up of your situation even if you're not in the hospital anymore…I did me well (FG-25).

Yes, I think three months after my treatment and six months after they sent me a questionnaire ... to ask what the impact was for me, what it did to my partner and I was asked "may the results also be sent to your general practitioner?"... I thought it that was a good thing to use the questionnaire for follow-up. (FG-12).

POTENTIAL ROLE OF PSYCHOSOCIAL SCREENING

Recognition, normalize

Then you know 'what I feel is completely normal'….sometimes you feel abnormal, but if you know that there are other people that are feeling that way…and it is a topic in follow-up…you would feel a lot better already (FG-11).

Stimulate the communication

Aaaaah yes, I admit I answered some questions I would never talk about with my oncologist...or even with my general practitioner. And yet I'd like to get help for those things, but I don't dare to bring it up myself (FG-06).

Plus also the possibility that ... all of it is sent to the general practitioner, your counselor still to a large extent. And if the screening results in concerning things, he will perhaps take this opportunity to make those things negotiable (FG-12).

Problems and supportive care needs easier detected

(questionnaires, doctors and the topic sexuality) If they get the signal that there is a need to discuss it, than they can refer for help (FG-01).

APPLICABILITY OF PSYCHOSOCIAL SCREENING

I think most patients would complete it differently, while most of them have some kind of need (FG-01).

First you don't take it into consideration, you think 'no I have enough, the support of my context suffices', but then…after a while you suddenly do experience a need. And so it seems easier to me if a questionnaire like that would be available for people (FG-10).

Accessible and concise

Yes but it has to be understandable for everyone. People who don't understand the language so good…it has to be easy approachable and understandable and an initial questionnaire shouldn't be too long (FG-12).

…tailored…so that you have the chance to mention things, and that there is something done with it further on (FG-21).

Repeated application

I completed it three times: once before the radiation started and the week after that for the questionnaire study and now for the focus group…I think my responses differed each time (FG-02).

When I started with chemo I wasn't sick and I thought "well I'm doing good, everything is going perfect"….but after that first week I felt completely different (FG-06).

I think it depends of the phase you are in…on certain moments you have other needs or desires (FG-26).

Need to do something with the obtained insights

If there is something done with the results. Otherwise I think it is useless, because completing it requires some energy (FG-07).

CARES

Content CARES

Everything is important, it depends on your own situation what is most. I can imagine that other aspects for some people are less important. I wouldn't let any topic out of the questionnaire (FG-21).

I think it certainly is important that there is attention for all those who are around you, how are they doing at that stage ... My partner, my children and so ... they also suffered a lot (FG-01).

Feasibility CARES

I think…if it would be possible to shorten it…everything must be addressed, but not to extensive (FG-12).

The language needs to be simple…for example for immigrants who lack deficiency in Dutch it should be

understandable too. Indeed, hey are part of our population (FG-01).

There is always the statement 'my partner and I have difficulty' or 'my partner and I ...' but every time I thought ...'yes my partner does, but I don't ' and the other way around. I can't judge us together. I think that should be asked separately (FG-12).

For me was very strange to read the statement about ... 'my partner and I struggle to talk about what will happen after my death'. I was like, 'What?!?, the only thing I don't want to be doing is thinking about 'what if… I die', I have to focus on healing. If you also want to use that item for people in the beginning of their disease, you have to formulate the item more carefully (FG-20).

Appendix 4.3

Items added in response to findings

- Ik voel me vaak eenzaam
- Ik maak me zorgen over de manier waarop mijn dierbaren (partner, kinderen, ouders,…) omgaan met het feit dat ik een kankerdiagnose kreeg.

Items rephrased in response to findings

- Ik heb problemen met **huishoudelijke taken**
  (previously: 'Ik heb problemen met het huishouden')
- Ik maak me zorgen of mijn gezin het zal redden **in het geval ik zou overlijden**
  (previously: Ik maak me zorgen of mijn gezin het zal redden als ik overlijd)
- Ik denk dat **anderen** me niet seksueel aantrekkelijk vindt(vinden)
  (previously: Ik denk dat mijn partner(s) me niet seksueel aantrekkelijk vindt(vinden))
- Ik denk dat mijn **(eventuele)** partner geen zin heeft in seks met mij
  (previously: Ik denk dat mijn partner(s) geen zin heeft (hebben) in seks met mij)
- Mijn partner en ik hebben moeite om **samen** over onze gevoelens te praten
  (previously the sentence was phrased without 'samen'= together)
- Mijn partner en ik hebben moeite om **samen** over onze angsten te praten
  (previously the sentence was phrased without 'samen'= together)
- Mijn partner en ik hebben moeite om **samen** te praten over wat er **zal gebeuren indien ik zou overlijden**
  (previously: Mijn partner en ik hebben moeite om te praten over wat er na mijn dood te gebeuren staat)
- Mijn partner en ik hebben moeite om **samen** over onze toekomst te praten
  (previously the sentence was phrased without 'samen'= together)

- Mijn partner en ik hebben moeite om **samen** te praten over de kanker en over wat er kan gebeuren
  (previously the sentence was phrased without 'samen'= together)
- Mijn partner en ik hebben moeite om **samen** te praten over een testament en financiële regelingen
  (previously the sentence was phrased without 'samen'= together)
- Ik voel me moe na mijn radiotherapie-behandelingen **(bestralingen)**
  ('bestralingen' was added as extra information between brackets as some patients are less familiar with the term 'radiotherapie')
- Ik word nerveus als ik radiotherapie-behandelingen **(bestralingen)** krijg
  ('bestralingen' was added as extra information between brackets as some patients are less familiar with the term 'radiotherapie')
- Ik voel me misselijk of ik moet braken na mijn radiotherapie-behandelingen **(bestralingen)**
  ('bestralingen' was added as extra information between brackets as some patients are less familiar with the term 'radiotherapie')

Appendix 4.4

Table A.4.4. Topics from CARES items discussed in the focus group interviews.

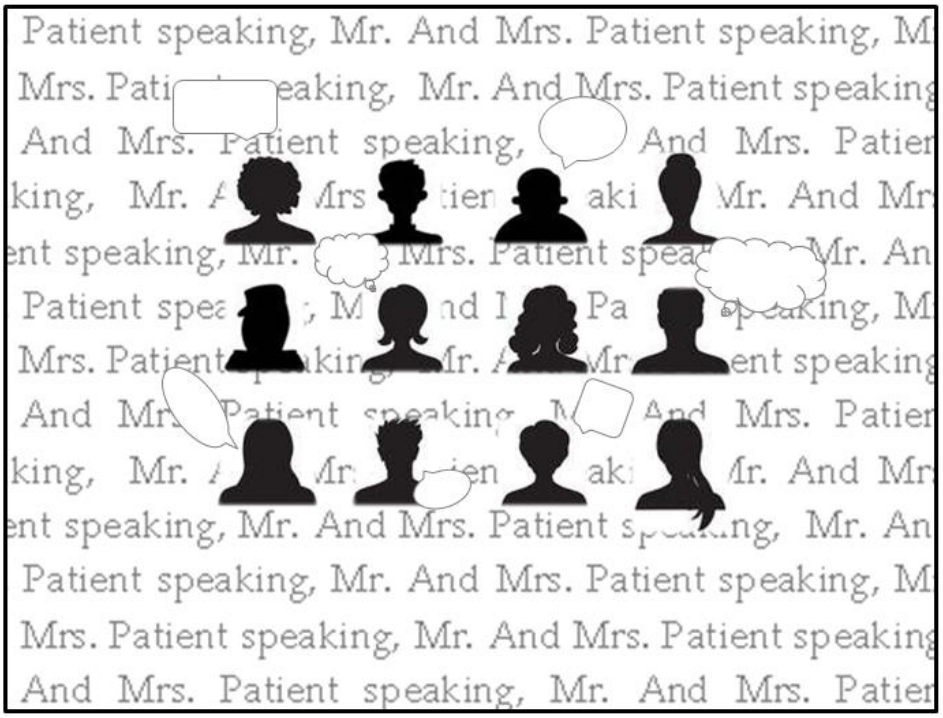
CARES items	Discussed in FG
1. Diff. bend or lift	Y
2. Diff. walk/move around	Y
3. Diff. do physical activ.	Y
4. Reduction in energy	Y
5. Diff. driving	N
6. Diff. household chores	Y
7. Diff. bathe. brush. groom	N
8. Diff. prepare meals	N
9. No interest recreat. activ.	Y
10. Not engage recreat. activ.	Y
11. Not enough enjoyable activ.	Y
12. Diff. planning active.	Y
13. Cannot gain weight	N
14. Continue to lose weight	N
15. Food unappealing	Y
16. Food tastes bad	Y
17. Diff. swallowing	N
18. Cancer prevents working	Y
19. Cancer interferes work	Y
20. Frequently has pain	Y
21. Chronic pain scars/surgery	Y
22. Pain not controlled medication	N
23. Pain controlled medication	N
24. Clothes not look good	Y
25. Clothes not fit	Y
26. Diff. find clothes	Y

27. Medical team withholds info	Y
28. Doctors don't explain what do	Y
29. Nurses don't explain what do	Y
30. Diff. ask doctors questions	Y
31. Diff. ask nurses questions	Y
32. Diff. express feelings doctor/nurses	Y
33. Diff. tell doctor new symptoms	Y
34. Diff. understand doctor about cancer	Y
35. Diff. understand nurses about cancer	Y
36. Wants more control over doctor	Y
37. Wants more control over nurses	N
38. Embarrassed to show body	Y
39. Uncomfor. show scars	Y
40. Uncomfor. with body changes	Y
41. Frequently anxious	Y
42. Frequently depressed	Y
43. Frequently angry	Y
44. Frequently upset	Y
45. Frequently overwhelmed by cancer	Y
46. Diff. sleep	Y
47. Diff. concentrating	Y
48. Diff. remembering	Y
49. Diff. thinking clearly	Y
50. Diff. tell frnd/rel. to come less often	Y
51. Diff. tell frnd/rel. to leave when not well	Y
52. Diff. ask frnd/rel. to do fun things	Y
53. Don't know what to say to frnd/rel.	Y
54. Diff. ask frnd/rel. help	Y
55. Diff. tell frnd/rel. about cancer	Y
56. Diff. ask frnd/rel. to come more	Y
57. Frnd/rel. say look well when not	Y
58. Frnd/rel. withhold information	N
59. Frnd/rel. avoid talk cancer	Y
60. Frnd/rel. do not visit enough	Y
61. Frnd/rel. do not call enough	Y
62. Frn/rel. uncomfor. visiting	Y
63. Frnd/rel. diff. talk about cancer	Y
64. Uncomfor. see patients get treat.	N
65. Nervous going to hospital	N
66. Nervous wait to see doctor	Y
67. Nervous wait for test results	Y
68. Nervous have diagnostic tests	Y
69. Nervous get blood drawn	N
70. Worry whether treatments work	Y
71. Worry whether cancer progress	Y
72. Worry not able to care for self	Y
73. Worry how family will manage	Y
74. Doesn't feel sex. attractive	Y
75. Thinks not sexually attractive to partner(s)	Y
76. Not interested in having sex	Y
77. Doesn't think partner(s) interested in sex	Y
78. Doesn't show for MD appointments	N
79. Doesn't show for treatments	N
80. Doesn't take medication	N
81. Doesn't follow MD's instructions	N
82. Financial problems	Y
83. Insurance problems	Y
84. Diff. with transport	Y
85. Gain too much weight	Y
86. Diagnostic procedures are painful	N
87. Frequent diarrhea	N
88. Poor bladder control	N
89. Diff. care for child/grandchild [a]	Y
90. Diff help children cope [a]	Y
91. Diff. help children talk about illness [a]	Y
92. Diff. talk boss about cancer [a]	Y

93. Diff. talk people at work [a]	Y
94. Diff. tell employer cannot do work [a]	Y
95. Diff. ask time off for treatments [a]	N
96. Worried about being fired [a]	Y
97. Diff. finding new job [a]	Y
98. Employers less incl. to hire with cancer hist. [a]	Y
99. Frequency of sex decreased [a]	Y
100. Diff. become sexually aroused [a]	Y
101. Diff. with erection (♂) / lubrication (♀)[a]	Y
102. Diff. reach orgasm [a]	N
103. Diff. talk feelings [a]	Y
104. Diff. talk fears [a]	Y
105. Diff. talk happen after death [a]	Y
106. Diff. talk future [a]	Y
107. Diff. talk cancer [a]	Y
108. Diff. talk wills/financial matters [a]	Y
109. Doesn't feel like embrace. etc. [a]	Y
110. Partner no feel like embrace. etc. [a]	Y
111. No interest in touch partner [a]	Y
112. Partner no interest in touch [a]	Y
113. Not get along as well usual [a]	Y
114. Upset with other more often [a]	Y
115. So much time together. on nerves [a]	Y
116. More distant then usual [a]	Y
117. Partner not let do activ. capable of [a]	N
118. Partner provides too much care [a]	N
119. Partner takes too little care [a]	Y
120. Diff. ask partner to take care [a]	Y
121. Diff. initiating dates [a]	N
122. Diff. to meet dates [a]	N
123. Afraid going to places where I met dates [a]	N
124. Diff. tell date about cancer [a]	Y
125. Afraid to initiate sexual relation [a]	N
126. Nervous get chemo [a]	Y
127. Nauseated during/before chemo [a]	Y
128. Vomit during/before chemo [a]	N
129. Sick when think about chemo [a]	N
130. Nauseated after chemo [a]	N
131. Vomit after chemo [a]	N
132. Tired after chemo [a]	Y
133. Other side effect chemo [a]	Y
134. Lost hair/grow slow from chemo [a]	Y
135. Fatigued after radiotherapy [a]	Y
136. Nervous to get radiotherapy [a]	N
137. Nauseous/vomit after radiotherapy [a]	N
138. Problems ostomy care/maintenance [a]	N
139. Diff. with prosthesis [a]	N

Abbreviations: FG focus group discussions; Y yes; N no.
[a] Items do not apply to all patients.

5
Chapter



A look at cancer care and patients' care needs from patient-perspective:

A (Mis)Match?

This chapter is based on:

Schouten, Bojoura, Hellings, Johan; Vankrunkelsven, Patrick; Van Hoof, Elke. *'(Mis)Match between cancer care and cancer patients concerns.'* 4th ARPH Conference, 5-6 February 2015, Ghent, Belgium [poster presentation].

ABSTRACT

BACKGROUND Quality cancer care in the first place should be organized in match with patients' needs. This article describes patients' experiences with Belgian cancer care, and the way this relates to their care needs.

METHODS Data were gathered in four focus groups. The 26 participants were adult cancer patients recruited in a larger quantitative study and via a call in local media. The FG discussions were facilitated with an interview guide, conducted and followed by a moderator and an observer. The discussions were audiotaped with prior consent, transcribed verbatim and afterwards thematically analyzed.

RESULTS Patients had positive and negative experiences with cancer care, influenced by several aspects: accessibility, comprehensiveness, continuity and timing of care; trust; holistic and personal approach; availability/time; multidisciplinary cooperation and referral; professionals' communication style; clarity of information; shared decision-making, and health care professionals' familiarity with patients' medical or personal situation.

Patients indicated that care needs and expectations differ depending on the person, the diagnosis, and the timing in the care process. Several needs which were repeatedly mentioned and important to take into account in the organization of cancer care were: the need for clear information on their medical condition, treatment and supportive care options; a desire for involvement in care choices and decisions; initiation about psychosocial topic by care professionals; support in rehabilitation; the availability of a central contact person in care to discuss questions and needs.

CONCLUSION Interpersonal and organizational aspects seem to play an important role in the establishment of the (mis)match between cancer care and cancer patients' care needs. This focus group study provides input on points of attention for the pursuit of comprehensive, patient-centered cancer care.

KEYWORDS: cancer care; patient-perspective; focus group, qualitative research.

INTRODUCTION

Cancer patients can experience difficulties of physical, cognitive, emotional, relational and social nature even longer time after diagnosis and treatment completion, often resulting in supportive care needs [8, 15, 151, 152, 153, 154, 155, 156, 157]. This reveals the importance of comprehensive and quality cancer care, monitoring and supporting patients in their physical, mental as well as in their social well-being. The importance of psychosocial care has been internationally recognized. In national cancer plans recommendations are formulated to integrate psychosocial support into cancer care [55].

The Institute Of Medicine (IOM) states that cancer care should be respectful of and responsive to patients' experiences, needs, preferences and values and that patients' input on these should guide all clinical decisions [33]. In America, Europe and Australia clinical practice guidelines and recommendations have been written on routine assessment of patients levels of psychosocial well-being and care needs, aiming at an improvement of holistic patient-approach [33, 41, 131, 132]. However, in Belgium no such guidelines and recommendations on routine psychosocial screening or needs assessment are available.

We conducted a quantitative study to explore the reliability and validity of needs assessment tool, the Cancer Rehabilitation Evaluation System (CARES), for the Belgian population [125, 144]. Additionally, focus groups (FG) were organized to explore the content validity of the instrument and patients' experiences with systematic screening of psychosocial well-being and care needs. Insights on the content validity of the CARES, and patients' experiences with screening are described in another article [158]. This article describes cancer patients experiences with current cancer care, the detection of their psychosocial concerns and care needs by health care professionals, and their care needs and expectations.

METHODS

Participants, recruitment and setting

Participants were adult cancer patients recruited in the sample of a larger quantitative study, through a call in the local newspaper and on the radio in May

2014. We defined 'adult' as 18 years and older. There were no restrictions on gender, type and time of cancer diagnosis. Participants were recruited in several phases of the care trajectory: recently diagnosed, in active treatment, at the end of active treatment and in follow-up. Since they all have the experience of being diagnosed with cancer, we will refer to all of them as 'cancer patients' in this paper, even if they are already in follow-up for a long time without a relapse. Indeed, there are many people who still get adjuvant therapy after the period of active treatment for a long time. Patients were excluded when they lacked proficiency in Dutch to participate in the FG discussions.

The FG took place in the course of the summer of 2014 in 'Huis Erika Thijs', an open and well accessible house in Hasselt where cancer patients, survivors and their relatives can explore a varied offer of non-professional support.

Material

A *questionnaire on sociodemographic and medical data* was constructed to collect data on: age, gender, relational status, family composition, level of education, employment status, household income, type of diagnosis, type of treatment(s) and the composition of the multidisciplinary group of professional and non-professional care givers surrounding the patient, what we will further refer to as 'care context'.

The *CARES* is a quality of life (QOL) and needs assessment tool that was used in this study as a primer to the discussion. The tool presents problem statements for which the patients need to indicate in what extent they apply to him/her [125].The originally US English CARES [80, 81, 82, 83, 84, 85, 86] was translated and psychometrically validated for the Flemish population in Belgium by Schouten et al. [125, 144]. The content validity of the tool was explored in these FG discussions with cancer patients [158].

Procedure

Patients who responded to the call for participation in the study were contacted and their name, address and date of participation was registered. One week before FG took place participants were send a postal item containing an information letter, an informed consent form, the CARES form and a questionnaire on socio-demographics and medical data. They were asked to fill

in these documents, and bring them to the FG. This way socio-demographic and medical data could be collected and patients could get acquainted with completing a tool for screening of psychosocial well-being and care needs. All participants provided informed consent before taking part in this study.
Each FG discussion was guided by a moderator (BS), who used an interview guide [158]. An observer (EVH or WE) took notes, timed and co-supported the discussion, while it was audiotaped with prior consent. Each FG lasted about 120 minutes.

Data analysis

FG were organized until data saturation was reached. The digital audio files of the FG were transcribed verbatim (BS) and analyzed using thematic content analysis [145, 146, 147]. During repeated reading of transcriptions initial codes were noted by two independent readers (BS and EVH). Subsequently the codes were organized into meaningful groups and combined in overarching themes. The subdivision of themes, categories and codes from the two independent readers demonstrated great similarity and was incorporated in one final version. This thematic content structure was given to two naïve readers that were not involved with the data (JH and PV) to revise for semantic logic. The resulting 'thematic map' was used to code all FG data.

Ethical approval

The protocol and study materials of the qualitative study described in this article were submitted to the Medical Ethical Committee of Hasselt University and the leading Ethical Committee of the Jessa Hospital Hasselt, together with the application for approval of a related large quantitative study. The studies were approved and registered (BE24320149544).

RESULTS

Study population

Twenty-six cancer patients participated in four FG discussions. The mean age was 56.21 years (SD: 12.39; range 28-78). For the 18 participants in follow-up

phase mean time since active treatment was 36.53 months (SD: 48.39; range 2-168). Further socio-demographic and medical characteristics are displayed in Table 1.

Table 1. Participants' socio-demographic and medical characteristics (N=26)

Socio-demographic characteristics	**n**	**%**	**Medical characteristics**	**n**	**%**
Gender			Cancer diagnosis [b]		
Men	4	15.4	Breast	11	42.3
Woman	22	84.6	Colorectal	4	15.4
Relational status [a]			Lung	1	3.8
Single	2	7.7	Ovarian	1	3.8
In a relationship: living with partner/married	22	80.8	Non-Hodgkin Lymphoma	2	7.7
			Hodgkin Lymphoma	2	7.7
In a relationship: not living with partner/married	-	-	Brain	1	3.8
			Prostate	1	3.8
Widowed	1	3.8	Thyroid	1	3.8
Children [a]			Maligne melanoma	1	3.8
No	3	11.5	Pancreas	1	3.08
Yes	22	80.8	Liver	1	3.8
Level of education [a]			Uterine body	1	3.8
Elementary school	1	3.8	Other	1	3.8
High school	9	24.6	Treatment [c]		
Graduate school	13	50.0	Surgery	17	65.4
University	1	3.8	Chemotherapy	15	57.7
Employment [a]			Radiotherapy	12	46.2
Employed	7	26.9	Hormonal therapy	7	26.9
Work interruption/on sick leave	2	7.7	Immune therapy	1	3.8
Unemployed	1	3.8	Bone marrow transplantation	1	3.8
Disabled	6	23.1			
Housewife/houseman	-	-	Phase of care trajectory		
Retired	8	30.8	Active treatment phase	6	23.1
Monthly household income [a]			Phase when active treatment is completed	1	3.8
< € 1500	4	15.4			
€ 1500- € 3000	15	57.7	Follow-up phase	18	69.2
> € 3000	4	15.4			

[a] Not all characteristics count up to 100% due to missing answers of some participants, [b] Cancer diagnosis in total counts up to more than 100%, because several participants got diagnosed with more than one type of cancer in the course of time, [c] Treatment types in total counts up to more than 100%, because most participants got treated with a combination of treatment types.

Depending on diagnosis participants received treatment and follow-up from the medical oncologist, another attending physician (gynecologist, gastroenterologist, urologist, …) or both. In the hospital patients experienced the nursing discipline to be closely involved in their care and approximately half of the participants received nursing care at home after their hospitalization. In

this sample most participants rely on a broad network of intramural and extramural healthcare support (Table 2).

Table 2. Involvement of professional and non-professional care givers in participants' care context

Health professionals involved in cancer care	**N=26**	
	n	**(%)**
Intramural		
Oncologist	22	84.0
Other attending physician (gynecologist, gastroenterologist, urologist, …)	21	80.0
Nursing	22	84.0
Specialized nursing (onco-coach, breast nurse,…)	12	46.0
Psychologist	13	50.0
Social worker	8	30.0
Religious worker	2	7.0
Dietician	6	23.0
Physiotherapist	9	34.0
Lymphedema therapist	1	3.0
Other	-	-
Extramural		
General practitioner	24	92.0
Home nursing	13	50.0
Physiotherapist	12	46.0
Lymphedema therapist	1	3.0
Dietician	-	-
Pharmacist	18	69.0
Primary care psychologist	3	11.0
Center for general wellbeing and mental health support	3	11.0
Health insurance	16	61.0
Social services	2	7.0
Self-support groups or peer groups	12	46.0
Non-professional support services for cancer patients free of payment	11	42.0
Other	4	15.0

Data analysis results

Data on experiences with cancer care, and care needs are discussed in this article, and illustrated with example quotes. In Table 3 an overview of main themes and subthemes is displayed.

Table 3. Themes resulting from thematic data analysis

THEME Experiences with cancer care

- Integration of medical and psychosocial care
- Psychosocial care
  - Barriers
  - Restrictions, gaps
  - Care offer often is unclear
  - Lack of continuity
  - Cost outside the hospital
  - Timing issues
  - To general to address individual needs
  - Positive Experiences
  - Necessary part of regular care
- Brochures
- Interaction with care professionals
  - Trust
  - Affinity with psychosocial concerns
  - Take some time
  - Familiarity of patient with care professional
  - Familiarity with the patient and the total health file, work with multidisciplinary collaboration and referral
  - Inform the patient
  - Communication style

THEME Care needs and expectations

- Involvement in care choices and decisions
- Clarity on personal(medical) situation & on treatment and supportive care options
- Dependent on disease and treatment phase
- Dependent on individual
- Recognition as an (ex)cancer patient
- Detection of and initiation about psychosocial topic by care professionals
- Support in rehabilitation
- Central contact for questions and needs
- Need for optimization of care

THEME Experiences with cancer care

Medical care and psychosocial care

According to past and current experiences of participants, cancer care has evolved positively. Progress in knowledge and skills has improved medical treatment and care. Despite several positive experiences with psychosocial care, attention for the psychosocial topic still is lagging behind and the ideal of comprehensive care seems to be an aspirational target rather than a fact.

> *"If you take into account the psychosocial aspect in hospital care and then the medical ... that's ... the two worlds do not intertwine "(FG-13)*

> *"The experience I have as a patient… I must admit that there is an enormous progress technically ... but from the patients I have spoken, no one is satisfied with the support…the human aspect, how they are treated as patient" (FG-25)*

There are several barriers experienced with psychosocial care. The *psychosocial care offer often is unclear* and in case of needs patients have to ask for information and referral explicitly or search for existing initiatives themselves.

"You don't know what kind of supportive care exists. Meanwhile I now it all, but I have encountered that you have to search for it yourself. If you sit on the fence, there will be no one helping you" (FG-07)

"….. more like… support for social concerns and so on, that is not offered spontaneously. You have to ask for it yourself" (FG-13)

"It's bad that you must be assertive like that to get appropriate care, why aren't psychosocial concerns addressed standardly?" (FG-21)

When psychosocial support is offered, a *bad timing and lack of continuity* is experienced, making it hard for cancer patients to make use of it when they are in need.

"Actually in the beginning they overwhelm you with everything…when you're only just coping with your treatment and the fact that you have cancer. But when that phase has passed you expect them to return to you again with their care offer, but then… they don't come" (FG-11)

"They give you information and ask during your chemo-treatment if you want support ….but that is too soon, at that point you are not in need of it. If you have a consult for follow-up there should be someone saying 'Look you can go there, find support here,…' At this point, at the stage I'm in right now,…I sometimes think 'Actually, now I really want to do something about it'" (FG-02)

During treatment, psychosocial care in the hospitals is mostly integrated in the hospital costs. However, when problems and needs arise for a longer time after active treatment, the *cost* of psychological support outside the hospital can represent a barrier.

"Since I'm still in treatment in the hospital the support from the psychologist for me is for free. That is luxury for me compared to others that have to pay 50 euro's for one time. I thing that is a large difference, I can imagine that it is not possible for everyone to be able to make use of that kind of support" (FG-16)

Brochures are seen as valuable sources of information on medical and psychosocial support options, but not appropriate for everyone and insufficient as a tool for cross-disciplinary referral.

"The hallway here is full of leaflets and there is a list of support groups hanging on the wall ... so there is an offer. Yet, everywhere you hear that people have the feeling that their needs are not met" (FG-01)

"It is surely a sign that leaflets do not always reach people, isn't it…" (FG-06)

"In the beginning I thought 'I'm not going to read them, I don't need that'. But after session three or four of the chemo I thought: 'Oh yeah, maybe I should read those leaflets, because now they could apply to me'." (FG-10)

"In my opinion it is difficult…you have a leaflet with support information and contacts on it, but to take it and call someone …at that point when you are struggling… I can understand that there are people who don't use it, there is still a threshold "(FG-21)

Interaction with professional care givers

The existence, continuity, clarity, cost and communication of concrete care initiatives or specialized disciplines is important. On the other hand, the interaction with professional care givers is critical. There are several aspects that contribute to good and bad experiences in that regard.

The feeling that one can *trust* a care giver is important to have good experiences with care.

"You have trust them fully, but sometimes like with those medications…they damage your confidence. You are scared, worried and you feel disappointed…and yet next time you go back you have to trust them again" (FG-26)

The sense of comprehensiveness of care can be influenced by the extent to which care givers have *affinity with psychosocial concerns* and discuss them spontaneously.

"The second time I went to my doctor… when she came to get me out of the waiting room, she said "you are scared". I said "How do you know that?". "I see it in your eyes…scared for all that is to come". And then she also asked me "Do you want to talk to a psychologist?" and I immediately said yes" (FG-20)

"Last year I went to the gynecologist for a normal gynecological examination…and he asked me "How are you?" and I said 'Fine, I come for my examination". Then he said "No no… I'm asking how you are doing? You have been through a lot so…?'. He took his time and started asking me how I coped with the cancer psychologically and how I dealt with it" (FG-11)

"If they would have had attention for my deepest fear at the time I was sick to death of my chemo…the fear that said 'What if something goes wrong with me, what with my two sons?'…I think I would have been a lot more resilient to cope with the chemo" (FG-26)

Participants are more comfortable with a care giver who not only discusses the specific affected organ, the course of treatment and prognosis, but who can *take some time* for the patient as a person as well.

"Once in Leuven I had a very emotional morning. I don't know…I can't tell exactly why. One of the nurses noticed and took some time for me. That was fantastic!" (FG-21)

"There was no time for questions. I stood there with the door handle in my hand and uh ... had to dress quickly and the next patient was already there." (FG-24)

"…for example, I still have to go to the physiotherapist for my arms and for lymphatic drainage. For me that is a more suitable person to talk to about my worries, because he is treating me for half an hour." (FG-16)

"The doctor who did my surgery…I saw him once before the surgery and…never again. I was in the hospital for a week, went home and had to go back to the hospital for another week because of an inflammation … my doctor didn't come…that was difficult for me because I had so many questions." (FG-08)

The degree to which care givers are *familiar with the patient and the total health file*, the degree to which they *work with multidisciplinary collaboration and referral* is determining patients' well-being and satisfaction with care.

"I had an onco-coach (navigator). She discussed some information with me, gave a brochure with the information and she also gave me her phone number. She had a center position in the hospital team and she instantly knew "ah yes you have that problem so I refer you to that person' and 'this is available, that is available,…" (FG-22)

"Even physical complaints were not taken seriously. I suffered a lot from nausea and that was dismissed as…'well it was not possible'. But I was in follow-up with an assistant in the department of radiology and at the same time I got chemotherapy. The nausea was a consequence of the chemo…but the radiology assistant didn't thought about that. I went to another hospital for my further follow-up and thank god it is totally different there. The intestinal specialist is my attending physician and he knows my whole file." (FG-21)

Participants feel less comfortable without clear explanations; they want *to be informed* about their personal situation and what they can expect later on.

"The thing she told me on the credit insurance for example, that was something practical but…when I consulted her for follow-up she said 'In the next time there will be a lot of things coming your way confronting you with the fact that you had cancer.' …with that she in a way prepared me for 'what is next'. I experienced it as something really positive." (FG-10)

"The nurse who accompanied me said "you are only getting an echography". But, that turned out to be incorrect, yet it was a different kind of examination. Well and I was driving home for 14 kilometers and…suddenly it started leaking at my bottom. It was terrible. ..when I came home I was wet to the skin…and they didn't tell me that that could happen." (FG-17)

Care givers *communication style* is of great importance for the experience patients have with care as well.

"…the second option was to bring me into the menopause , which would shut down everything for a while. They were not sure what effect it would have on me and well…the oncologist said "It's that option or the other…you don't have to start whining how you will feel about it. We have to start with the chemo so …decide." (FG-10)

"They removed a part of the small intestine, what was in fact a tumor and he didn't say 'cancer'…that's what I asked him and then he said 'Yes in fact, that is what it is'" (FG-17)

"Yes well….I had two consultations with a psychologist, but for me this was not a positive experience. She was saying like "I can't help you"…it didn't feel good and I didn't schedule any further appointments. "You have to figure it out for yourself" she said….bud you contact them just because you cannot cope with it yourself…isn't it?" (FG-24)

THEME Care needs and expectations

Participants agree that concerns and needs differ according to one's personal situation, personality and the phase of disease and treatment one is going through.

Getting *clear information on medical, psychological and social aspects* could help patients in coping with their situation.

"…so that you know 'oh what I experience is normal'…I….sometimes you almost feel abnormal, but if you know that there are a lot of people experiencing those thoughts and feelings, you already feel much better. So in that respect there also should be given more information, it's always the medical things they talk about "(FG-11)

"We don't know much about the medication we have to take for so long (hormones) and about side-effects…if you used it for six years and you can stop…what then? To who do you have to turn to with questions?" (FG-14)

Next to being informed some patients want *to be involved* in *their care management and decision making* as well. Not only technical and medical data are guiding elements; likewise emotional and personal preferences are important in making care choices.

"The things they suggested to do…there was no consultation of our opinion. We had our doubts, but they wouldn't listen to that, they were God almighty and could do everything…until it went wrong…our doubts and fear turned out to be relevant." (FG-21)

"At the moment you get sick, the doctors expect you to follow them slavishly, that you…euhm…agree with what they propose. You have to remain mute; setting your limits and standing on principle seems to be difficult for them to handle" (FG-26)

Patients have better experiences when care is characterized by *comprehensiveness and continuity*. The *initiative of care givers to introduce the psychosocial topic and support* next to the physical is desirable to disclose and detect psychosocial concerns and problems. Participants emphasize the importance of *support in rehabilitation* after the active treatment phase, and believe that *a central contact to turn to* in case of questions or needs could facilitate reintegration in society and workplace.

"The psychological support at that moment is not what it should be…you have to ask for it yourself….there should be someone…a bodyguard who frequently passes by to check how you are doing." (FG-13)

"Health care professionals should be educated to be alert for patients psychosocial well-being, and then it is the choice of the patient if he wants to reveal things or not." (FG-01)

"You give the wrong signal…you want help, but it's a difficult thing. If someone introduces himself you think "what do you do? I don't need that, you can leave again.". I didn't want to get all kinds of explanations and brochures and so you give the wrong signal." (FG-12).

"In my case….there was a point in time when I didn't realize myself how much I was struggling …but maybe if others would have had more attention for that, they would have detected this concluding I was in need for help." (FG-24)

"Next time I want more to be done about….or more attention for support in the period afterwards. Even so going back to work…it's all very difficult." (FG-11)

"….taking that step if you need that kind of support…you don't …you are so down and then it's even harder….It's very difficult…you're sometimes thinking 'am I crazy in my head or what ...do I really need a psychologist to be able to handle this? ' and so you don't apply for that kind of help…the threshold is so high. They should contact the patient spontaneously." (FG-11)

Both participants who are still struggling in coping with their situation, and the ones that have the feeling they went on with their lives again seem to have *the need to be acknowledged as an (ex-) cancer patient*. They are sensitive to statements and judgments about cancer patients made by others.

"I have difficulties with my own brother in law…who even lives very close to me…not knowing anymore I had breast cancer a few years ago" (FG-05)

"You almost would be jealous not having breast cancer. I had the feeling…I've had three types of cancer and no one speaks about that." (FG-07)

(when colleagues at work are talking about breast cancer as a disease that is easy to handle and to treat) "…when they are talking like that I'm really annoyed, because…than… I feel like they are talking about me…" (FG-12)

DISCUSSION

The results of this study support the importance of attention for psychosocial aspects in cancer care. This is why psychosocial care guidelines are included in the national cancer plans [55]. However, according to our participants and their peers in other research, the integration of psychosocial support in cancer care is still incomplete and care does not always match the experienced needs of patients [159].

Our participants often experience the psychosocial care offer as being unclear, badly timed or only available in a certain part of the care trajectory. Similar to other studies, cost, inaudibility, a lack of communication and multidisciplinary collaboration can be a threshold for cancer patients to get support for their psychosocial concerns [160, 161]. The positive and negative experiences with care were often determined by characteristics in the interaction with their professional care givers. Trust, affinity with the psychosocial topic, available time, familiarity with the patients' situation and health file, multidisciplinary collaboration, clarity of information and communication style play an important role. Patients long for comprehensiveness and continuity of care. These are important determinants in realizing quality cancer care [161, 162].

There are a few methodological considerations in this study that can be discussed . Firstly, the recruitment our FG participants in the sample of a larger quantitative study and via a call in the local media provides opportunity for the emergence of a self-selection bias. This could have comprised the representativeness of the sample. However, the results on the socio-demographic and medical characteristics show that the study population is comparable to the Belgian population of cancer patients and to other research populations in this field [129]. Proportionally, more women than men participated in our FG study. Besides, the group of breast cancer patients was strongly represented. Both this seemingly over-representation of females and breast cancer is also observed in other studies [16, 153, 163]. In all likelihood findings can be applicable for the broader population. Secondly, patients with a low proficiency in Dutch were excluded for participating in the FG for practical reasons in the application of this qualitative study method, yet these people represent a significant proportion of our Belgian society.

CONCLUSION

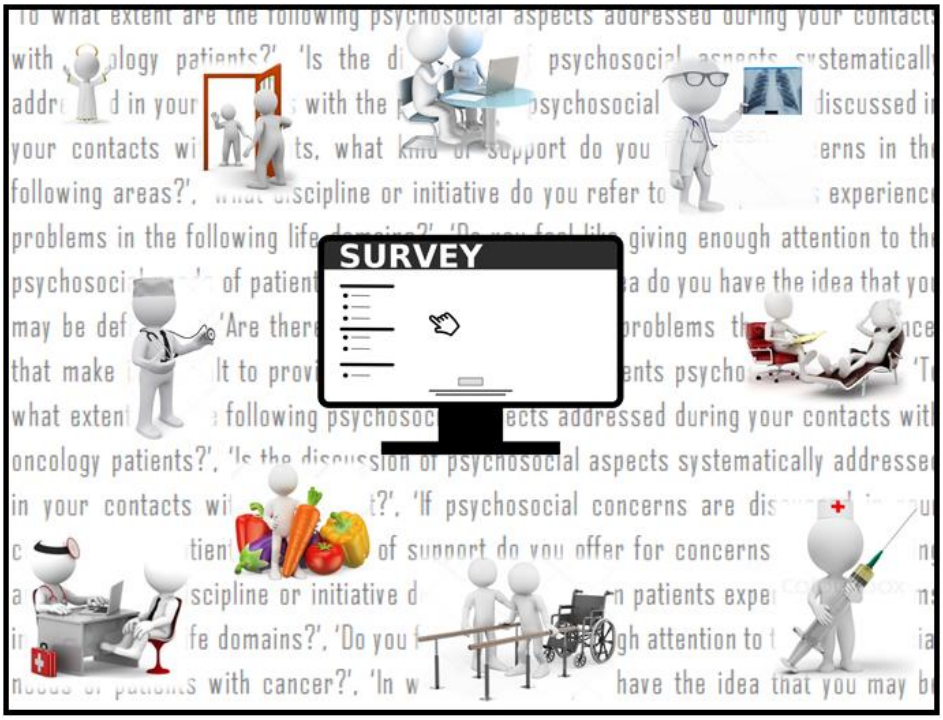
The interactions of patients with health care professionals play a major role in the experienced quality of cancer care, and consequently in patients' well-being. Despite positive experiences participants had the impression that psychosocial concerns and care needs frequently go unnoticed, since the psychosocial topic is not systematically addressed in daily cancer care. According to participants the

opportunities for psychosocial support are often unclear, fragmented, lacking continuity, and depending on the affinity of the health care professional with the psychosocial topic. This way patients psychosocial concerns and needs are not always adequately addressed. Insight from this study, obtained from patient-perspective, could serve as points of attention in the further pursuit of organizing patient-centered, comprehensive of cancer care.

ACKNOWLEDGEMENTS

This study is part of a PhD-research project that is funded by Limburg Sterk Merk (LSM). Our gratitude goes out to the team of Huis Erika Thijs for their hospitality and for the provision of facilities during the focus groups. We would like to thank Willem van de Esschert for his practical support in conducting the focus groups, and prof. Erik Caers for editing the manuscript for the English language.

6
Chapter



Professionals' perspective on psychosocial issues in cancer care

This chapter is based on:

Schouten Bojoura; Bergs, Jochen; Vankrunkelsven, Patrick; Hellings, Johan. *An exploratory survey of professionals' perspective with regard to the prevalence, barriers, and management of psychosocial issues in cancer care.*– Under review.

ABSTRACT

OBJECTIVE This cross-sectional survey of healthcare professionals involved in intra- and outpatient care for cancer patients explores the professionals' perspective on the prevalence of psychosocial topics in their contacts with cancer patients and the way these are approached in practice.

METHODS Participants were recruited through coordinators in hospitals, outpatient professional associations and discipline-specific networks. All participants were invited through an e-mail containing the weblink to the online survey with multiple choice and open-ended questions.

RESULTS The survey was completed by 368 healthcare professionals. The majority do not use a systematic approach to discuss psychosocial concerns with patients, 37.5% use the general question 'How are you?', and 65.0% percent spontaneously address various psychosocial aspects. A range of psychosocial topics are regularly discussed. Sexuality and return to work are rarely mentioned. About 50% of the participants are convinced that enough attention is paid to the psychosocial well-being of cancer patients: by merely listening, engaging in a deeper conversation, providing advice, and through referral. Patients are usually referred to a psychologist, a general practitioner, a social worker, a specialized nurse, or a center for well-being and mental health. The barriers that healthcare professionals experience in providing psychosocial support can be attributed to the patients, to themselves or other healthcare professionals, and the healthcare system itself.

CONCLUSIONS This study provides data on professionals' perspective on psychosocial aspects in current cancer care, and on the barriers that professionals need to overcome to make a better match with patients' needs.

KEYWORDS: Oncology, cancer care, psychosocial, multidisciplinary, health care professionals.

BACKGROUND

Although the survival rate of cancer has been increasing year after year, the cancer diagnosis is still confrontational for patients and their relatives. Cancer patients can experience physical, cognitive, emotional, relational, and social problems and needs. These emerge — with a large individual variation — at each stage of the treatment process, and even after treatment completion [15, 18, 164]. A wide variety of healthcare professionals (HCP) are involved. Oncologists, hematologists, and nurses are customarily involved throughout the inpatient cancer care trajectory. In many countries, the general practitioner (GP) plays a key role in the outpatient field [165]. Services from other paramedical and psychosocial disciplines are integrated to reduce patients' suffering, help patients adhere to prescribed treatments, and/or to support recovery and rehabilitation [166, 167, 168, 169, 170, 171, 172]. Since cancer and related treatments have a bio-psycho-social impact, patients' experiences and needs can only be adequately addressed through 'Cancer Care for the Whole Patient' [38]. Hence, multidisciplinary cooperation between all these disciplines is essential to achieve an effective cancer care policy that matches with patients' experiences and care needs [173].

Over the past decade, national cancer plans have been launched to optimize cancer care, including the integration of the psychosocial approach [55, 174]. It is not the sole responsibility of psychosocial care professionals to reinforce this approach. All HCP involved in the cancer care trajectory must be alert to psychosocial and other concerns to achieve comprehensive, patient-centered care. Though providing psychosocial care is not part of each HCP's role, providing a certain degree of spontaneous psychosocial support has proven to be valuable for patients [74].

To optimize and further improve the integration of psychosocial aspects in cancer care, it is also important to hear the voice of the HCP involved. Therefore, a cross-sectional survey was conducted to explore the prevalence and management of psychosocial issues and barriers experienced in the multidisciplinary transmural care context of cancer patients.

METHODS

Design, setting and participants

A cross-sectional survey study design was used to collect both quantitative and qualitative data. A multidisciplinary sample of HCP was recruited in the inpatient and outpatient healthcare context. Medical doctors, nurses, healthcare assistants, psychologists, social and spiritual workers, dieticians, pharmacists, physical, occupational, and lymphedema therapists were invited to participate (recruitment details in Appendix 6.1.).

HCP working with cancer patients in the *inpatient* context were recruited from five medium to small acute care hospitals. Medical directors and heads of departments were contacted to obtain the permission to recruit participants from their hospital, and to plan the distribution of the survey.

HCP working in the *outpatient field* were recruited trough professional associations and discipline-specific networks. We obtained the cooperation of GP- and physical therapist circuits, home care and home nursing services, health insurance services and discipline- specific professional associations. Regional coordinators and chairpersons assisted in distributing the survey.

There were no restrictions on age, gender, professional discipline, duration of career or job time spent working with the cancer patient population, as these were all included as variables in the study.

Material

Participants were queried on a wide range of psychosocial topics, with a subdivision based on the Cancer Rehabilitation Evaluation System (CARES) [85, 144] (for survey questionnaire see Appendix 6.2.). Multiple choice (MPC), matrix table, and open-ended questions were used to collect data on the following five topics:

1. Socio-demographic and professional characteristics;
2. Prevalence of psychosocial topics being addressed in contacts with cancer patients;
3. Care offered to cancer patients in case of psychosocial problems;
4. Referral policy for psychosocial problems;

5. Potential barriers experienced in the delivery of psychosocial care or support for cancer patients.

The questionnaire was pilot-tested in a group of 10 HCP from eight disciplines. Based on their feedback, adjustments and linguistic refinements were made.

Procedure

All HCP received the same e-mail explaining the study objective, information on the informed consent procedure, and a Qualtrics-weblink to complete the survey. A time frame of 14 days was provided to complete the survey. Participants were actively recruited in October and November 2016. In early December, a reminder was sent with a request for non-responders to indicate why they chose not to participate. The online survey was closed at the end of December 2017.

Data-analysis

Descriptive statistics were used to summarize participant characteristics and responses to MPC and ordinal items. Data from open-answer options was subjected to thematic analysis in NVivo.

Ethical considerations

The research protocol and study materials were approved by the Medical Ethics Committee of Hasselt University and the ethical committees of all participating hospitals (Jessa ziekenhuis, Ziekenhuis Oost-Limburg, Sint-Fransiscus ziekenhuis, Regionaal ziekenhuis Sint-Trudo, Mariaziekenhuis Noord-Limburg).

RESULTS

Participants

An invitation to participate in the study was sent to 4965 HCP (608 inpatient, and 4357 outpatient), of which 583 responded (12% response rate), and 368 surveys were fully completed.

Some of the invited HCP provided a reason for not participating in the study: 'no interest in participating' (8.6%); 'lack of time' (22.9%); 'not applicable to me, since I never or rarely work with cancer patients' (54.3%); another not specified reason (14.3%).

The mean age in the sample was 43 years (sd 11.51, 21-81), the mean years of professional experience was 18 years (sd 11.39, <1-47), and 23.9 percent of the participants was male. Further information on socio-demographic and professional characteristics is displayed in Table 1.

Table 1. Socio-demographic and professional characteristics sample

	Participants (N=368)	
Characteristics	n	%
Professional context		
Inpatient	124	33.7
Outpatient	219	59.5
Both inpatient and outpatient	25	6.8
Timing of HCP involvement in the care trajectory		
In the diagnostic phase	196	53.3
Between diagnosis and start of treatment	227	61.7
During intensive treatment (S, CT, RT,…)	277	75.3
During follow-up or maintenance	273	74.2
Inpatient professional discipline		
Medical doctor specialized in cancer treatment	7	1.9
Medical doctor with other specialty	13	3.5
Nurse	66	17.9
Nurse specialist	15	4.1
Healthcare assistant	1	0.3
Psychologist	16	4.3
Social worker	8	2.2
Pastoral worker	3	0.8
Dietician	7	1.9
Physical therapist	4	1.1
Lymphedema therapist	3	0.8
Occupational therapist	4	1.1
Other	4	1.1
Outpatient professional discipline		
General practitioner	41	11.1
Medical doctor with other specialty	1	0.3
Home nurse	76	20.7
Healthcare assistant	40	10.9
Psychologist	7	1.9
Dietician	3	0.8
Physical therapist	27	7.3
Occupational therapist	3	0.8
Lymphedema therapist	7	1.9
Pharmacist	2	0.5
Health insurance service (social work,…)	23	6.3
Centre for social welfare (social work,…)	8	2.2
Other	6	1.6

Abbreviations: number of participants (N), surgery (S), chemotherapy (CT), radiotherapy (RT).

Prevalence and addressing of psychosocial topics in patient-professional contact

The majority of HCP indicated that most of the psychosocial topics were '*sometimes*' or '*often*' addressed in contact with cancer patients (Figure 1). There were three topics that deviated from this tendency. Thoughts about the disease, treatment, and recovery were more frequently discussed with patients. In contrast, sexuality, and resumption of work were clearly less often discussed. Similar response tendencies were found when comparing the answers from HCP providing inpatient and outpatient care.

A minority of the participants (1.9%) use a systematic approach to address psychosocial concerns: checklists to assess patients' well-being (n=5) and patient-reported outcome tools (n=2) are used. The vast majority of HCP do not use a systematic approach. A minority (2.7%) believe that addressing psychosocial issues is not part of their job; 37.5% percent use the general question *'How are you?',* so patients can bring up any psychosocial problems themselves if desired; 56.0% percent spontaneously address various psychosocial aspects when exploring cancer patients' well-being.

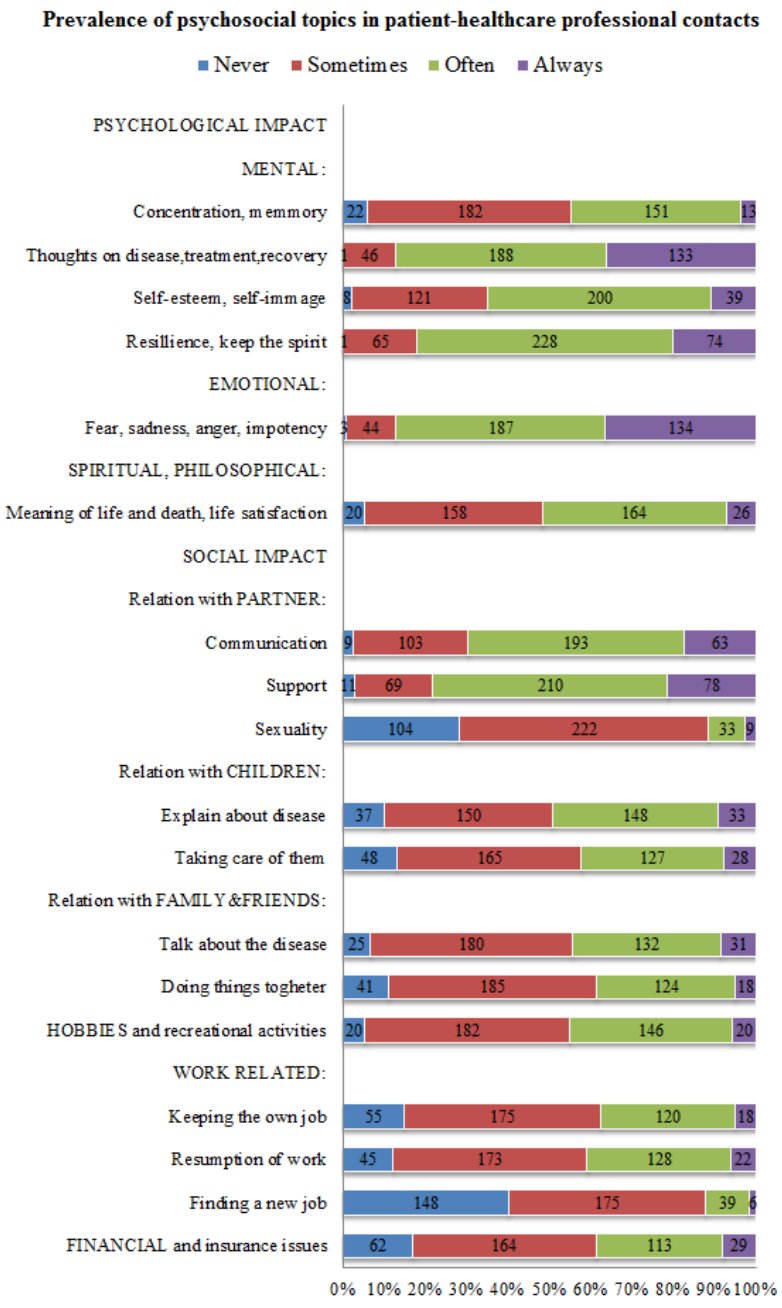


Figure 1 Prevalence of psychosocial topics in patient-healthcare professional contacts

Psychosocial support or care provided

Half of the HCP (51.9%) believe he or she *'usually'* provides enough attention to the psychosocial needs of cancer patients. Nine percent indicated they '*always*' do so, 29.6 percent '*sometimes*'. A small portion of the HCP (9%) reported '*never*' giving sufficient attention to the psychosocial needs of patients.

The three most prevalent types of care and support offered are: listening (38.5%), a more in-depth conversation or advice (29.4%), and referral (19.3%). The use of brochures (written information) in response to psychosocial concerns or problems is limited (4.0%). Other care or support actions — as questioned — are used even less. A similar response tendency was found when comparing the answers from HCP in inpatient and outpatient care. Further details are displayed in Appendix 6.3.

Referral policy

All tables with quantitative referral details are listed in Appendix 6.4., the main findings are discussed below and displayed in Table 2.

Referral towards inpatient HCP or services

In the inpatient field, patients are most frequently referred to a hospital-based psychologist (20.7%), social worker (17.4%), or specialized nurse (10.8%). The options '*Inpatient referral is not applicable to me'* (18.0%) and '*I do not refer, I provide care or support for this aspect myself*' (9.0%) complete the top five.

Referral to outpatient HCP or services

In the outpatient field, patients expressing psychosocial concerns or problems are mostly referred to the GP (18.3%), psychologist (14.5%), or centers for well-being and mental health (12.6%). The options to '*I do not refer, I provide care or support for this aspect myself*' (11.2%) and 'O*utpatient referral is not applicable to me*' (11.0%) complete the top five.

Table 2. Referral of intra- and outpatient healthcare professionals for several psychosocial issues

Referrals to inpatient HCP or service[a]			**Referrals to outpatient HCP or service**[a]		
	By Int. HCP[b] n (rank)	**By Ext. HCP**[c] n (rank)		**By Int. HCP**[b] n (rank)	**By Ext. HCP**[c] n (rank)
MD cancer treatment	142 (7th)	136 (6th)	General practitioner	361 (1st)	599 (1st)
MD other specialty	48 (8th)	24 (12th)	MD with other specialty	22 (12th)	45 (11th)
Nurse	180 (6th)	101 (8th)	Home nurse	144 (7th)	198 (8th)
Specialist nurse	350 (3rd)	200 (5th)	Physical therapist	16 (13th)	45 (11th)
Psychologist	648 (1st)	418 (2nd)	Lymphedema therapist	-	5 (13th)
Social worker	494 (2nd)	394 (3rd)	Dietician	-	6 (14th)
Pastoral worker	234 (4th)	118 (7th)	Psychologist	280 (3rd)	473 (4th)
Dietician	21 (11th)	21 (13th)	Pharmacist	29 (11th)	11 (12th)
Physical therapist	16 (12th)	32 (11th)	Centre for well-being and MH	190 (4th)	498 (2nd)
Lymphedema therapist	3 (14th)	3 (14th)	Medical insurance service	171 (5th)	271 (6th)
			Centre for social welfare	147 (6th)	258 (7th)
Other discipline	26 (10th)	62 (10th)	Other discipline	57 (9th)	180 (9th)
No referral, own care offer	195 (5th)	271 (4th)	No referral, own care offer	124 (8th)	487 (3rd)
Not applicable for me to refer	40 (9th)	914 (1st)	Not applicable for me to refer	289 (2nd)	297 (5th)
No referral, issue not a point of attention for my discipline	10 (13th)	90 (9th)	No referral, issue not a point of attention for my discipline	51 (10th)	103 (10th)

Abbreviations: HCP healthcare professional; Int. inpatient, Ext. outpatient; MD medical doctor; MH mental health.
[a] The order of the HCP in this table corresponds to the sequence of the multiple choice options in the survey.
[b] For inpatient HCP: N = 124.
[c] For outpatient HCP: N = 219.

Shortcomings or barriers in the provision of psychosocial support or care

The open-ended questions show that 51.4% of the sample experience shortcomings and barriers in the provision of psychosocial care or support to cancer patients. Some are specific to the HCP, others can be attributed to the healthcare system. Sometimes patients have no need for extra help — or are in denial — and do not accept psychosocial or supportive care.

Healthcare professionals' shortcomings

HCP often experience a *lack of opportunity to discuss psychosocial aspects* with their patients. Limited contact, lack of privacy, and lack of time and workload play a major role in this.

> *"Not enough time, too much workload, not enough experience… it's not pleasant to start a conversation with a patient and then after 2 minutes you have to interrupt the conversation to react on the call of another patient."*

Participants expressed feeling *having insufficient knowledge or education* to effectively meet the psychosocial needs of cancer patients. Medical, oncological, and psychological knowledge is mentioned, as well as knowledge of emotional, financial, palliative aspects, and return to work.

> *"Help for emotional pain, coping with the diagnosis...often I don't know how to help patients with this."*

Consequently, participants think that *more HCP with the appropriate education and training* are needed to optimally support cancer patients in the care process.

Problems with communication are frequently mentioned as a barrier for good supportive care provision. Sometimes patients are not consulted and informed enough by HCP about the diagnosis, implications of treatment or prognosis. HCP themselves also experience poor information transfer, limited multidisciplinary and transmural consultation and cooperation.

> *"Patients are insufficiently informed about their disease and prognosis. For poor prognosis, sometimes the 'truth-communication' is inadequate."*

> *"Sometimes I don't get enough information on the patient's situation: mostly only the referral for the physical aspect without information on the psychosocial well-being"*

HCP experience several *barriers in the referral for psychosocial or supportive care*. Referral is complicated by a limited awareness of referral options. Hence, patients often receive insufficient information regarding the available care or support options. When a referral to psychosocial services is made, there are long waiting times before patients receive actual care. Some HCP felt that their own psychosocial or paramedical care offer is not recognized and valued by other HCP, resulting in limited referral of patients.

"Ignorance about offered services that would be useful for a patient to be referred to"

"Sometimes referral does not go smoothly, or there is a waiting time, which can be very stressful for people"

Some participants experience their *own emotional vulnerability* as a difficulty. As cancer patients are often supported by HCP over several years, there can be a strong inter-human relationship. The feeling of impotency is also mentioned, as well as the fear that one can never fulfil the expectations related to psychosocial concerns.

"The feeling sometimes to be powerless in situations…that you cannot do enough for clients. "

A *lack of empathy* for the patients' situation is experienced by some HCP, who believe they could provide better psychosocial support had they had a personal experience with cancer.

"It is difficult to understand patients' needs. Only when you are confronted with it yourself you can better indulge yourself in the thoughts and experience of the patient"

Barriers in the healthcare system

Participants indicate that the healthcare *financing system* is mainly based on a 'fee for service system', and the time available for patients is sometimes limited. *There is no funding for certain psychosocial care aspects*, so *patients need to pay for it themselves*. It is conceivable that this has an impact on the accessibility of the care needed.

"There is no opportunity for me as a doctor to take sufficient time .... in fact I do most of the work (in time ...) for free, in between…and this with the following consideration: although without financial compensation, there is a lot of gratitude from patients for the time that I spend on it."

"Often I want to refer to a psychologist, but patients have to pay the full costs themselves"

In several areas, *the psychosocial or supportive care offer is experienced as limited or unclear*. To HCP, there seems to be no general systematic approach in cancer care for topics like emotional and sexual functioning, pain relief, social, financial, spiritual issues, rehabilitation, and return to work. Participants experience a limited access, availability or continuity in psychosocial or supportive care across the different phases in the care process. Sometimes the opposite is experienced: an oversupply and competition in supportive care options offered by several disciplines or patient advocacy organizations.

"There is a lack of understanding by the National Health Service concerning the resumption of work, the psychological burden of the disease is often underestimated."

"There is sufficient psychological support during admission for surgery in the hospital (nursing, psychologist, social worker, breast nurse) but too little follow-up post-surgery, usually this is done at the request of the patient and not systematically."

HCP mention several *shortcomings in follow-up of patients*. There is too little attention for home support, information on financial consequences and reimbursements, contact with buddies, and support for patients' relatives and minor children. Some participants speak of the need for a permanent care coordinator, who patients, but also the different HCP involved, can address in case of questions, discussion and organization of care.

" Concerning the financial aspect…often people don't know where they stand and what they can do. Also concerning care and support people usually don't know what the possibilities are and where they can request it."

"Care for minor children of cancer patients seems insufficiently structurally embedded to me. And aftercare, after the death of the parent. I think there is too little attention for this ..."

The *paperwork* that needs to be done when supportive care is applied for is often perceived as burdensome and time-consuming, both for patients and for HCP.

"All the hassle of paperwork that long or serious illness entails."

DISCUSSION

In this study, a multidisciplinary group of HCP was surveyed regarding their perspective on the prevalence of psychosocial issues in patient - HCP interactions, the types of care they provide themselves, their referral policy, and potential barriers in the delivery of psychosocial care.

According to respondents, a variety of psychosocial topics are addressed in HCP-patient contacts. This is done rather spontaneously and not according to a systematic approach. However, without a systematic approach, attention for, and detection of patients' psychosocial problems will vary [175]. Previous studies have demonstrated that HCP do not always make a good estimate of patients' psychosocial distress or needs [24]. Patients on their part, often wait for the HCP's initiative to discuss certain topics [176]. We found that sexuality and return to work issues are rarely covered. Other studies suggest that sexuality issues are discussed less because of taboo or feelings of shame related to the topic [177]. Return to work issues are less prominent during the active treatment phase, yet become an important issue later in the phase of cancer survivorship [178].

The majority of respondents (67.9%) provide spontaneous psychosocial support to cancer patients by listening, engaging in a more in-depth conversation, or giving advice. Further they refer mainly to psychologists, social workers, specialized nurses, centers for well-being and mental health, and the GP. In this study, as well as in other studies, the GP is perceived as a central figure in primary care — with an important role in the follow-up of cancer care [165]. A considerable proportion of the HCP working in the inpatient field have indicated that referral to outpatient care options was not applicable for them. The same idea exists amongst in the outpatient field working HCP regarding inpatient referral. In other words, participating HCP do not seem to be inclined to do transmural referrals.

Our findings regarding experienced barriers are in line with other studies. Lack of time and resources, inadequate interdisciplinary communication and cooperation, limited knowledge of and familiarity with psychosocial well-being and care options were found to be barriers for HCP to integrate the psychosocial approach in routine care [160, 179, 180]. As found in the study of Travado et al. [181], HCP feel that the existing financing system of cancer care, and the (lack

of) coordination in the psychosocial approach induce thresholds. Nurses could, for example, have a more explicit role in detecting, working with, and referring for psychosocial needs of cancer patients, integrated in a multidisciplinary team approach [182]. However, for this the task allocation and inter-disciplinary attunement need to be discussed. The challenges integrating the psychosocial approach are not specific to cancer care, these could partly be explained by the fragmentation in primary care and limited transdisciplinary communication and collaboration [183].

This study had some limitations. Firstly, the response rate (12%) was low. To obtain a representative sample, we tried to recruit all HCP serving the population of cancer patients to a greater or lesser extent. After all, each HCP is a care provider and potential referrer for these patients. Recruitment was especially difficult in the outpatient field because of the fragmentation that characterizes primary care, and the lack of visibility regarding specializations. Our exhaustive approach in recruitment probably led to the invitation of HCP for whom our study topic was not relevant, since they rarely or never work with cancer patients. This presumption is confirmed as 54.3% of the non-responders, of whom we have information, indicated not participating for this reason. Secondly, as most surveys, our survey has the potential for selection bias. We used an exhaustive approach to prevent bias in recruitment, however self-selection bias cannot be prevented. HCP who have more affinity with the psychosocial topic could have been more inclined to participate in this survey [184].

CONCLUSION

Listening to the voice of HCP is needed to further improve care for cancer patients. A variety of psychosocial topics are discusses during patient - HCP interactions, and often care is given in line with the patient's needs. However, half the HCP believe that not enough attention is paid to the psychosocial needs of cancer patients — for some leading to feelings of impotency. The main barriers in providing psychosocial support to cancer patients are: limited knowledge in order to optimally support the patient in coping with their experiences, inadequate (interdisciplinary) communication and collaboration, and a lack of time and resources to integrate the psychosocial approach in

routine inpatient and outpatient care. The psychosocial approach in cancer care seems to depend more on the individual approach of HCP than on the healthcare system. As a result of the financing system, the accessibility of specific psychosocial care aspects could be under pressure. Explicit detection of psychosocial needs is missing and the response to those needs, from a team perspective and an integrated approach, is not yet common practice. A more explicit approach of psychosocial needs for cancer patients can also provide important insights for training, continuing education and support of the involved HCP.

CONFLICTS OF INTEREST

Authors declare to have no conflicts of interest.

ACKNOWLEDGEMENTS

We want to acknowledge: Jessa ziekenhuis, Ziekenhuis Oost-Limburg, Sint-Fransiscus ziekenhuis, Regionaal ziekenhuis Sint-Trudo, Mariaziekenhuis Noord-Limburg, LISTEL, the circuits for GP, physical therapists and psychologists, CM, Solidariteit voor het Gezin, De Voorzorg, Thuisverpleging Lemmens, Thuisverpleging A tot Z, Familiehulp, ONS, Liberale Mutualiteit, OCMW's, Orthos, CGG group LITP and group DAGG, Flemish federation of occupational therapy, KLAV and the LMN's. Many thanks go out to Eva Cordery who has reviewed the script, and has improved the English language. We also thank LSM for funding.

Appendix 6.1.

Table A6.1.1. Recruitment details In-hospital care context

Hospitals	DOC	NUR	SNU	HCA	PSY	SOC	PAS	DIE	PHY	LYM	OCC	Un-specified*
Jessa Ziekenhuis												273
Ziekenhuis Oost-Limburg												81
St.-Franciscusziekenhuis	14	102	3	8	1	1	2	1	5	0	0	
St-Trudo ziekenhuis	10	16	0	0	3	1	1	1	3	0	0	
Mariaziekenhuis Noord-Limburg	20	43	4	0	5	3	2	3	2	0	0	
	44	**161**	**7**	**8**	**9**	**5**	**5**	**5**	**10**	**0**	**0**	**354**
608:	**TOTAL NUMBER OF IN-HOSPITAL HCP INVITED**											

Abbreviations: DOC (doctors involved in treatment and follow-up of cancer patients), NUR (nurse), SNU (specialized nurse: e.g. onco-coach, breast nurse,…), HCA (healthcare assistant), PSY (psychologist), SOC (social worker), PAS (pastoral worker), DIE (dietician), PHY (physical therapist), LYM (lymphedema therapist), OCC (occupational therapist).
* Some hospitals did not respond to our request to mention the number of potential participants for each discipline separately, and only gave the total number of HCP that received our invitation to participate in the survey.

Table A6.1.2. Recruitment details Ambulatory care context

Recruitment source	GP	HNU	PHY	OCC	LYM	DIE	SOC	PSY	PHA	HCA
17 GP networks	658									
4 home nursing organizations		1220								
7 networks of physical therapists			368							
1 professional association for occupational therapists				850						
3 organizations for orthopedics and bandagistry					14					
8 local networks with dieticians						107				
4 mutuality/medical insurance organizations							156			
3 professional associations for psychologists								142		
3 organizations for healthcare assistance									122	
1 professional association for pharmacists										720
	658	**1220**	**368**	**850**	**14**	**107**	**156**	**142**	**122**	**720**
4357:	**TOTAL NUMBER OF AMBULATORY HCP INVITED**									

Abbreviations: GP (general practitioner), HNU (home nurse), PHY (physical therapist), OCC (occupational therapist), LYM (lymphedema therapist), DIE (dietician), SOC (social worker), PSY (psychologist), PHA (pharmacist), HCA (healthcare assistant).

Appendix 6.2

Survey Questionnaire healthcare professionals

SOCIO-DEMOGRAPHIC CHARACTERISTICS

Your sex: O man O woman **Your age:** ☐☐ years

Years of job experience : ☐☐ years

Your work with patients is situated in: O the inpatient field
O the outpatient field
O both, you work in the inpatient and outpatient field

Please specify your function/discipline:

→ If you are working in the inpatient field

- O Physician specialized in cancer treatment (oncologist, hematologist,…)
- O Physician with other specialization → ☐
- O Nurse
- O Specialized nurse → ☐
- O Healthcare assistant
- O Hospital based psychologist
- O Social worker
- O Pastoral worker
- O Dietician
- O Physiotherapist
- O Lymphedema therapist
- O Occupational therapist
- O Other → ☐

→ If you are working in the outpatient field

- O General practitioner
- O Physician with other specialization → ☐
- O Home nurse
- O Healthcare assistant
- O Physiotherapist
- O Occupational therapist
- O Lymphedema therapist
- O Dietician
- O Pharmacist
- O Ambulatory working psychologist
- O Centre for well-being and mental health
- O Health insurance service (social worker,…)
- O Centre for social welfare (social worker,…)
- O Other → ☐

In which phase of the patients' care pathway do your interventions take place?
(more options possible)

O around the time of clinical testing and diagnosis
O between diagnosis and start of treatment
O during the phase of active treatment (surgery, chemotherapy, radiation,…)
O during the phase of follow-up and/or after treatment (hormonal therapy or other)

PSYCHOSOCIAL ASPECTS IN THE CARE FOR CANCER PATIENTS

All the following questions relate to your personal contact with patients, please answer the questions from your personal perspective and not from the perspective or offer of the setting you work.

1. To what extent are the following psychosocial aspects addressed during your contacts with oncology patients?

	Never	Sometimes	Often	Always
PSYCHOLOGICAL IMPACT				
Mentally				
Difficulties with concentration and memory,…	O	O	O	O
Thoughts about disease, treatment and recovery.	O	O	O	O
Self-appreciation, self-image.	O	O	O	O
Resilience, being able to relativize, keep courage	O	O	O	O
Emotionally				
Anxiety, sadness, anger, impotence,…	O	O	O	O
Spiritually				
Concerns about the meaning of life, about death and 'life after death', satisfaction with life.	O	O	O	O
SOCIAL IMPACT				
Social roles				
Relationship with partner:				
- Communication	O	O	O	O
- Support	O	O	O	O
- Sexuality	O	O	O	O
Relationship with the children:				
- Explaining about the disease	O	O	O	O
- Taking care of them	O	O	O	O
Relations with family members, friends, acquaintances:				
- Telling about the disease	O	O	O	O
- Doing things together	O	O	O	O
Hobbies, leisure activities	O	O	O	O
Work				
- Keeping the own job	O	O	O	O
- Resuming work	O	O	O	O
- Searching for a new job	O	O	O	O
Financial and insurance issues	O	O	O	O

2. Is the discussion of psychosocial aspects systematically addressed in your contacts with the patient?

O No, this is not part of my car services or follow-up of the patient.
O Yes, I always ask patients the general question "How are you?" And then they can tell about any difficulties themselves if they want to.
O Yes, I always ask patients about their well-being regarding various psychosocial aspects: emotional, mental, social, relational. This is done spontaneously and not systematically.
O Yes, I use a checklist on psychosocial al overall well-being to discuss this systematically.
O Yes, I ask patients to complete a questionnaire on their psychosocial and overall well-being, I use the results for discussion with the patients in my consultations.

O Other ……

3. If psychosocial concerns are discussed in <u>your contacts with patients, what kind of support do you offer</u> for concerns in the following areas?

	Just listening	Deeper conversation, giving advice	Counseling, therapy	Revalidation program	Collective information session	Informative brochure	Referral	Other
<u>PSYCHOLOGICAL IMPACT</u>								
Mentally								
Difficulties with concentration and memory,…	O	O	O	O	O	O	O	O
Thoughts about disease, treatment and recovery.	O	O	O	O	O	O	O	O
Self-appreciation, self-image.	O	O	O	O	O	O	O	O
Resilience, being able to relativize, keep courage	O	O	O	O	O	O	O	O
Emotionally								
Anxiety, sadness, anger, impotence,…	O	O	O	O	O	O	O	O
Spiritually								
Concerns about the meaning of life, about death and 'life after death', satisfaction with life.	O	O	O	O	O	O	O	O
<u>SOCIAL IMPACT</u>								
Social roles								
Relationship with partner:								
- Communication	O	O	O	O	O	O	O	O
- Support	O	O	O	O	O	O	O	O
- Sexuality	O	O	O	O	O	O	O	O

Relationship with the children:								
- Explaining about the disease	O	O	O	O	O	O	O	O
- Taking care of them	O	O	O	O	O	O	O	O
Relations with family members, friends, acquaintances:								
- Telling about the disease	O	O	O	O	O	O	O	O
- Doing things together	O	O	O	O	O	O	O	O
Hobbies, leisure activities	O	O	O	O	O	O	O	O
Work								
- Keeping the own job	O	O	O	O	O	O	O	O
- Resuming work	O	O	O	O	O	O	O	O
- Searching for a new job	O	O	O	O	O	O	O	O
Financial and insurance issues	O	O	O	O	O	O	O	O

Specify if you have indicated 'other':

……

4. What discipline(s) or initiative(s) do you refer to in the inpatient field when patients experience problems in the following life domains?

	Physician specialized in cancer treatment	Physician with other specialization	Nurse	Specialized nurse (onco-coach, breast nurse, trajectory nurse,…)	Psychologist	Social worker	Pastoral worker	Dietician	Physical therapist	Lymphedema therapist	Other	I do not refer, I provide care or support for this aspect myself	I do not refer, this issue is no point of attention for my discipline	Inpatient referral is not applicable to me
PSY. IMPACT	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Mentally	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Emotionally	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Spiritually	O	O	O	O	O	O	O	O	O	O	O	O	O	O
SOC. IMPACT	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Social roles	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Relationship with partner	O	O	O	O	O	O	O	O	O	O	O	O	O	O

Relationship with the children	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Relations with family members, friends, acquaintances	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Hobbies, leisure activities	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Work	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Financial and insurance issues	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O

5. What discipline(s) or initiative(s) do you refer to in the outpatient field when patients experience problems in the following life domains?

	General practitioner	Ambulatory working physician with other specialization	Home nurse	Physiotherapist	Lymphedema therapist	Dietician	Ambulatory working psychologist	Pharmacist	Centre for well-being and mental health	Medical insurance service	Centre for social welfare	Other	I do not refer, I provide care or support for this aspect myself	I do not refer, this issue is no point of attention for my discipline	Inpatient referral is not applicable to me
PSY. IMPACT	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Mentally	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Emotionally	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Spiritually	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
SOC. IMPACT	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Social roles	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Relationship with partner	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Relationship with the children	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Relations with family members, friends, acquaintances	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Hobbies, leisure activities	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Work	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
Financial and insurance issues	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O

6. Do you feel like giving enough attention to the psychosocial needs of patients with cancer?

O never
O sometimes
O often
O always

7. In which area (s) do you have the idea that you may be deficient?

……
……
……

8. Are there any other shortcomings or problems (not related to yourself) that you experience, that make it difficult to provide appropriate care for patients psychosocial needs?

O yes
O no

If yes, which?

……
……
……

Appendix 6.3

Table A6.3.1. Support or care offered by all HCP for psychosocial concerns and problems (N=368)

	LIS		CON		THE		REV		INF		BRO		REF		OTH	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
PSYCHOLOGICAL IMPACT																
Mental																
- Concentration, memory	270	73.4	142	38.6	17	4.6	23	6.3	9	2.4	29	7.9	123	33.4	10	2.7
- Thoughts about the disease, treatment and recovery	221	60.1	214	58.2	39	10.6	30	8.2	15	4.1	48	13.0	129	35.1	5	1.4
- Self-esteem, self-image	237	64.4	210	57.1	46	12.5	16	4.3	6	1.6	16	4.3	105	28.5	3	0.8
- Resilience, placing into perspective, keep the spirit	220	59.8	233	63.3	41	11.1	19	5.2	19	5.2	18	4.9	100	27.2	3	0.8
Emotional																
Fear, sadness, anger, impotency	250	67.9	235	63.9	53	14.4	7	1.9	8	2.2	12	3.3	135	36.7	5	1.4
Spiritual/Philosophical																
Meaning of life, death, 'the afterlife', life satisfaction	266	72.3	187	50.8	28	7.6	2	0.5	6	1.6	21	5.7	132	35.9	6	1.6
SOCIAL IMPACT																
Social roles																
Relation with partner:																
- Communication	267	72.6	200	54.3	35	9.5	5	1.4	6	1.6	15	4.1	104	28.3	6	1.6
- Support	261	70.9	193	52.4	29	7.9	6	1.6	7	1.9	18	4.9	96	26.1	8	2.2
- Sexuality	265	72.0	110	29.9	28	7.6	8	2.2	8	2.2	29	7.9	137	37.2	14	3.8
Relation with children:																
- Explain about disease	238	64.7	207	56.3	23	6.3	3	0.8	6	1.6	59	16.0	134	36.4	13	3.5
- Taking care of them	255	69.3	175	47.6	19	5.2	3	0.8	4	1.1	22	6.0	125	34.0	18	4.9
Relation with other family and friends																
- Talk about the disease	276	75.0	169	45.9	19	5.2	2	0.5	5	1.4	29	7.9	90	24.5	9	2.4
- Doing things together	259	70.4	161	43.8	20	5.4	16	4.3	4	1.1	24	6.5	86	23.4	16	4.3
Hobbies and recreational activities	241	65.5	176	47.8	13	3.5	26	7.1	4	1.1	37	10.1	117	31.8	18	4.9
Work																
- Keeping the own job	248	67.4	149	40.5	18	4.9	20	5.4	8	2.2	18	4.9	132	35.9	19	5.2
- Resumption of work	237	64.4	460	43.5	20	5.4	20	5.4	6	1.6	19	5.2	147	39.9	19	5.2
- Finding a new job	249	67.7	112	30.4	15	4.1	9	2.4	8	2.2	22	6.0	160	43.5	23	6.3
Financial and insurance issues	249	67.7	109	29.6	10	2.7	5	1.4	3	0.8	28	7.6	211	57.3	23	6.3

Abbreviations: HCP healthcare professionals, n number of participants, LIS Listening, CON Conversation/advice, THE Therapy, REV Revalidation program, INF Collective info session, BRO Information Brochure, REF Referral, OTH Other form of care/support.

Table A6.3.2. Support or care offered by intramural HCP for psychosocial concerns and problems (N=124)

	LIS		CON		THE		REV		INF		BRO		REF		OTH	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
PSYCHOLOGICAL IMPACT																
Mental																
- Concentration, memory	92	74.2	49	39.5	4	3.2	12	9.7	6	4.8	10	8.1	54	43.5	2	1.6
- Thoughts about the disease. treatment and recovery	78	62.9	76	61.3	16	12.9	15	12.1	8	6.5	24	19.4	56	45.2	1	0.8
- Self-esteem. self-image	84	67.7	66	53.2	22	17.7	8	6.5	3	2.4	4	3.2	53	42.7	2	1.6
- Resilience. placing into perspective. keep the spirit	78	62.9	75	60.5	19	15.3	9	7.3	5	4.0	5	4.0	57	46.0	1	0.8
Emotional																
Fear. sadness. anger. impotency	82	66.1	79	63.7	26	21.0	5	4.0	5	4.0	2	1.6	65	52.4	1	0.8
Spiritual/Philosophical																
Meaning of life. death. 'the afterlife'. life satisfaction	89	71.8	60	48.4	15	12.1	1	0.8	3	2.4	70	56.5	3	2.4	0	0.0
SOCIAL IMPACT																
Social roles																
Relation with partner:																
- Communication	70	56.5	19	15.3	4	3.2	3	2.4	5	4.0	55	44.4	2	1.6		0.0
- Support	91	73.4	66	53.2	17	13.7	4	3.2	3	2.4	6	4.8	52	41.9	3	2.4
- Sexuality	89	71.8	47	37.9	12	9.7	5	4.0	5	4.0	11	8.9	64	51.6	2	1.6
Relation with children:																
- Explain about disease	83	66.9	72	58.1	10	8.1	1	0.8	3	2.4	25	20.2	57	46.0	3	2.4
- Taking care of them	84	67.7	64	51.6	9	7.3	2	1.6	1	0.8	52	41.9	52	41.9	5	4.0
Relation with other family and friends																
- Talk about the disease	88	71.0	63	50.8	10	8.1	1	0.8	2	1.6	9	7.3	33	26.6	4	3.2
- Doing things together	90	72.6	55	44.4	8	6.5	4	3.2	1	0.8	8	6.5	31	25.0	7	5.6
Hobbies and recreational activities	95	76.6	55	44.4	3	2.4	8	6.5	2	1.6	11	8.9	45	36.3	5	4.0
Work																
- Keeping the own job	92	74.2	47	37.9	4	3.2	7	5.6	5	4.0	5	4.0	57	46.0	5	4.0
- Resumption of work	87	70.2	54	43.5	6	4.8	7	5.6	4	3.2	6	4.8	59	47.6	4	3.2
- Finding a new job	87	70.2	39	31.5	3	2.4	5	4.0	3	2.4	1	0.8	56	45.2	7	5.6
Financial and insurance issues	93	75.0	34	27.4	3	2.4	2	1.6	1	0.8	5	4.0	88	71.0	8	6.5

Abbreviations: HCP healthcare professionals. n number of participants. LIS Listening. CON Conversation/advice. THE Therapy. REV Revalidation program. INF Collective info session. BRO Information Brochure. REF Referral. OTH Other form of care/support.

Table A6.3.3. Support or care offered by extramural HCP for psychosocial concerns and problems (N=219)

	LIS		CON		THE		REV		INF		BRO		REF		OTH	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
PSYCHOLOGICAL IMPACT																
Mental																
- Concentration. memory	159	72.6	84	38.4	12	5.5	8	3.7	2	0.9	17	7.8	60	27.4	6	2.7
- Thoughts about the disease. treatment and recovery	127	58.0	127	58.0	19	8.7	14	6.4	6	2.7	22	10.0	65	29.7	3	1.4
- Self-esteem. self-image	137	62.6	128	58.4	20	9.1	8	3.7	3	1.4	12	5.5	47	21.5	1	0.5
- Resilience. placing into perspective. keep the spirit	128	58.4	142	64.8	19	8.7	10	4.6	3	1.4	13	5.9	38	17.4	2	0.9
Emotional																
Fear. sadness. anger. impotency	149	68.0	140	63.9	23	10.5	2	0.9	3	1.4	10	4.6	63	28.8	3	1.4
Spiritual/Philosophical																
Meaning of life. death. 'the afterlife'. life satisfaction	159	72.6	116	53.0	12	5.5	1	0.5	6	2.7	18	8.2	55	25.1	2	0.9
SOCIAL IMPACT																
Social roles																
Relation with partner:																
- Communication	153	69.9	120	54.8	13	5.9	1	0.5	2	0.9	10	4.6	45	20.5	3	1.4
- Support	152	69.4	113	51.6	7	3.2	2	0.9	3	1.4	11	5.0	39	17.8	4	1.8
- Sexuality	156	71.2	57	26.0	13	5.9	3	1.4	3	1.4	17	7.8	62	28.3	10	4.6
Relation with children:																
- Explain about disease	137	62.6	121	55.3	11	5.0	1	0.5	3	1.4	30	13.7	69	31.5	9	4.1
- Taking care of them	152	69.4	100	45.7	9	4.1	1	0.5	3	1.4	62	28.3	62	28.3	12	5.5
Relation with other family and friends																
- Talk about the disease	166	75.8	98	44.7	8	3.7	3	1.4	18	8.2	54	24.7	5	2.3	0	0.0
- Doing things together	150	68.5	96	43.8	10	4.6	8	3.7	3	1.4	14	6.4	49	22.4	8	3.7
Hobbies and recreational activities	128	58.4	111	50.7	7	3.2	12	5.5	1	0.5	23	10.5	65	29.7	12	5.5
Work																
- Keeping the own job	136	62.1	96	43.8	13	5.9	10	4.6	3	1.4	13	5.9	65	29.7	13	5.9
- Resumption of work	130	59.4	98	44.7	13	5.9	10	4.6	2	0.9	13	5.9	75	34.2	15	6.8
- Finding a new job	142	64.8	68	31.1	10	4.6	4	1.8	5	2.3	19	8.7	90	41.1	15	6.8
Financial and insurance issues	138	63.0	70	32.0	6	2.7	2	0.9	2	0.9	21	9.6	105	47.9	14	6.4

Abbreviations: HCP healthcare professionals. n number of participants. LIS Listening. CON Conversation/advice. THE Therapy. REV Revalidation program. INF Collective info session. BRO Information Brochure. REF Referral. OTH Other form of care/support.

Appendix 6.4

INTRAMURAL REFERRAL

Table A6.4.1. Intramural referral by all HCPs for psychosocial concerns and problems (N=368)

	ONC		SPE		NUR		SNU		PSY		SOC		PAS		DIE		PHY		LYM		OTH		OWN		NO		NA	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Psy. Impact																												
Mental	77	20.9	23	6.3	39	10.6	107	29.8	206	56.0	99	26.9	61	16.6	18	4.9	18	4.9	4	1.1	7	1.9	38	10.3	8	2.2	106	28.8
Emotional	43	11.7	8	2.2	56	15.2	94	25.5	216	58.7	84	22.8	61	16.6	3	0.8	5	1.4	1	0.3	6	1.6	59	16.0	7	1.9	98	26.6
Spir.-Philo.	18	4.9	6	1.6	31	8.4	44	12.0	124	33.7	52	14.1	172	46.7	0	0	1	0.3	0	0	14	3.8	43	11.7	9	2.4	110	29.9
Soc. Impact																												
Social roles																												
To partner	31	8.4	10	2.7	34	9.2	80	21.7	183	49.7	101	27.4	21	5.7	0	0	2	0.5	0	0	4	1.1	56	15.2	10	2.7	108	29.3
To children	27	7.3	7	1.9	37	10.1	76	20.7	179	48.6	96	26.1	20	5.4	0	0	2	0.5	0	0	4	1.1	63	17.1	10	2.7	109	29.6
To FA&FR.	14	3.8	4	1.1	39	10.6	64	17.4	124	33.7	84	22.8	21	9.7	0	0	1	0.3	0	0	4	1.1	78	23.6	15	4.1	116	31.5
Hobbies	22	6.0	7	1.9	35	9.5	66	17.9	60	16.3	97	26.4	14	3.8	0	0	23	6.3	2	0.5	18	4.9	87	23.6	15	4.1	116	31.5
Work	65	17.7	15	4.1	19	5.2	54	14.7	54	14.7	161	43.8	7	1.9	0	0	11	3.0	1	0.3	23	6.3	46	12.5	13	3.5	118	32.1
Financial	11	3.0	4	1.1	7	1.9	21	5.7	9	2.4	199	54.1	1	0.3	0	0	0	0	0	0	16	4.3	31	8.4	20	5.4	115	31.3

Abbreviations: HCP healthcare professionals, n number of participants, ONC dr. cancer treatment, SPE dr. other specialty, NUR nurse, SNU specialist nurse, PSY psychologist, SOC social worker, PAS pastoral worker, DIE dietician, PHY physical therapist, LYM lymphedema therapist, OTH to other discipline, OWN no referral but own care offer, NO no referral because not a point of attention for my discipline, NA not applicable for me to refer.

In the answer-category *'other'* participants indicated to refer to: palliative support; sexologist; revalidation program; other type of cultural/spiritual worker; patients' family/personal context; brochures; groups for self-help, buddies, or patient advocacy.

Table A6.4.2. Intramural referral by intramural HCPs for psychosocial concerns and problems (N=124)

	ONC		SPE		NUR		SNU		PSY		SOC		PAS		DIE		PHY		LYM		OTH		OWN		NO		NA	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Psy. Impact																												
Mental	32	25.8	11	8.9	23	18.5	58	46.8	110	88.7	45	36.3	38	30.6	11	8.9	7	5.6	3	2.4	4	3.2	16	12.9	0	0.0	1	0.8
Emotional	24	19.4	6	4.8	31	25.0	53	42.7	108	87.1	35	28.2	39	31.5	1	0.8	1	0.8	0	0.0	2	1.6	25	20.2	0	0.0	0	0.0
Spir.-Philo.	8	6.5	4	3.2	18	14.5	22	17.7	66	53.2	20	16.1	98	79.0	0	0.0	1	0.8	0	0.0	6	4.8	15	12.1	1	0.8	3	2.4
Soc. Impact																												
Social roles																												
To partner	13	10.5	6	4.8	20	16.1	41	33.1	99	79.8	52	41.9	14	11.3	0	0.0	1	0.8	0	0.0	0	0.0	23	18.5	0	0.0	3	2.4
To children	14	11.3	4	3.2	23	18.5	42	33.9	99	79.8	46	37.1	13	10.5	0	0.0	1	0.8	0	0.0	0	0.0	24	19.4	0	0.0	6	4.8
To FA&FR.	7	5.6	3	2.4	24	19.4	42	33.9	81	65.3	46	37.1	16	12.9	0	0.0	1	0.8	0	0.0	0	0.0	31	25.0	3	2.4	5	4.0
Hobbies	9	7.3	4	3.2	26	21.0	41	33.1	44	35.5	50	40.3	10	8.1	9	7.3	0	0.0	0	0.0	4	3.2	40	32.3	4	3.2	7	5.6
Work	29	23.4	6	4.8	12	9.7	36	29.0	36	29.0	91	73.4	6	4.8	0	0.0	4	3.2	0	0.0	7	5.6	13	10.5	1	0.8	9	7.3
Financial	6	4.8	4	3.2	3	2.4	15	12.1	5	4.0	109	87.9	0	0.0	0	0.0	0	0.0	0	0.0	3	2.4	8	6.5	1	0.8	6	4.8

Abbreviations: HCP healthcare professionals, n number of participants, ONC dr. cancer treatment, SPE dr. other specialty, NUR nurse, SNU specialist nurse, PSY psychologist, SOC social worker, PAS pastoral worker, DIE dietician, PHY physical therapist, LYM lymphedema therapist, OTH to other discipline, OWN no referral but own care offer, NO no referral because not a point of attention for my discipline, NA not applicable for me to refer.

Table A6.4.3. Intramural referral by extramural HCP for psychosocial concerns and problems (N=219)

	ONC		SPE		NUR		SNU		PSY		SOC		PAS		DIE		PHY		LYM		OTH		OWN		NO		NA	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Psy. Impact																												
Mental	38	17.4	8	3.7	15	6.8	38	17.4	80	36.5	44	20.1	18	8.2	5	2.3	10	4.6	1	0.5	3	1.4	20	9.1	7	3.2	101	46.1
Emotional	16	7.3	1	0.5	22	10.0	33	15.1	92	42.0	44	20.1	16	7.3	2	0.9	4	1.8	1	0.5	4	1.8	29	13.2	7	3.2	94	42.9
Spir.-Philo.	9	4.1	1	0.5	12	5.5	18	8.2	49	22.4	23	10.5	61	27.9	0	0.0	0	0.0	0	0.0	7	3.2	26	11.9	7	3.2	101	46.1
Soc. Impact																												
Social roles																												
To partner	15	6.8	2	0.9	13	5.9	31	14.2	69	31.5	43	19.6	7	3.2	0	0.0	1	0.5	0	0.0	4	1.8	30	13.7	9	4.1	100	45.7
To children	9	4.1	2	0.9	12	5.5	27	12.3	65	29.7	40	18.3	6	2.7	0	0.0	1	0.5	0	0.0	3	1.4	37	16.9	9	4.1	98	44.7
To FA&FR.	5	2.3	1	0.5	11	5.0	16	7.3	34	15.5	33	15.1	3	1.4	0	0.0	0	0.0	0	0.0	3	1.4	43	19.6	15	6.8	104	47.5
Hobbies	10	4.6	2	0.9	7	3.2	18	8.2	11	5.0	37	16.9	2	0.9	0	0.0	11	5.0	1	0.5	14	6.4	43	19.6	10	4.6	105	47.9
Work	31	14.2	7	3.2	5	2.3	14	6.4	14	6.4	57	26.0	5	2.3	14	6.4	5	2.3	0	0.0	14	6.4	30	13.7	10	4.6	105	47.9
Financial	3	1.4	0	0.0	4	1.8	5	2.3	4	1.8	73	33.3	0	0.0	0	0.0	0	0.0	0	0.0	10	4.6	21	9.6	16	7.3	106	48.4

Abbreviations: HCP healthcare professionals, n number of participants, ONC dr. cancer treatment, SPE dr. other specialty, NUR nurse, SNU specialist nurse, PSY psychologist, SOC social worker, PAS pastoral worker, DIE dietician, PHY physical therapist, LYM lymphedema therapist, OTH to other discipline, OWN no referral but own care offer, NO no referral because not a point of attention for my discipline, NA not applicable for me to refer.

EXTRAMURAL REFERRAL

Table A6.4.4. Extramural referral by all HCPs for psychosocial concerns and problems (N=368)

	GP		HNU		PHY		LYM		DIE		PSY		PHA		CEN		MED		SOW		OTH		SPE		OWN		NO		NA	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Psy. Impact																														
Mental	203	55.2	67	18.2	14	3.8	3	0.8	3	0.8	160	43.5	5	1.4	116	31.5	40	10.9	32	8.7	22	6.0	13	3.5	70	19.0	8	2.2	51	13.5
Emotional	177	48.1	69	18.8	3	0.8	0	0	1	0.3	166	45.1	3	0.8	106	28.8	23	6.3	21	5.7	22	6.0	8	2.2	83	22.6	7	1.9	48	13.0
Spir.-Philo.	106	28.8	44	12	1	0.3	0	0	0	0	90	24.5	3	0.8	76	20.7	18	4.9	14	3.8	61	16.6	4	1.1	72	19.6	18	4.9	76	20.7
Soc. Impact																														
Social roles																														
To partner																														
To children	149	40.5	51	13.9	5	1.4	0	0	1	0.3	132	35.9	0	0	99	26.9	31	8.4	31	8.4	15	4.1	7	1.9	73	19.8	18	4.9	65	17.7
To FA&FR.	125	34.0	44	12.0	2	0.5	0	0	1	0.3	132	35.9	0	0	107	29.1	19	5.2	19	5.2	16	4.3	6	1.6	80	21.7	13	3.5	71	19.3
Hobbies	89	24.2	33	9.0	0	0	0	0	0	0	86	23.4	1	0.3	82	22.3	17	4.6	13	3.5	7	1.9	3	0.8	89	24.2	31	8.4	83	22.6
Work	62	16.8	32	8.7	27	7.3	2	0.5	0	0	30	8.2	0	0	43	11.7	33	9.0	27	7.3	36	9.8	6	1.6	106	28.8	31	8.4	82	22.3
Financial	106	28.8	23	6.3	15	4.1	2	0.5	0	0	30	8.2	0	0	53	14.4	127	34.5	92	25.0	36	9.8	15	4.1	41	11.1	24	6.5	79	21.5
Psy. Impact	34	9.2	11	3.0	0	0	0	0	0	0	5	1.4	0	0	39	10.6	156	42.4	183	49.7	25	6.8	7	1.9	27	7.3	28	7.6	76	20.7

Abbreviations: HCP healthcare professionals, GP general practitioner, HNU home nurse, PHY physical therapist, LYM lymphedema therapist, DIE dietician, PSY psychologist, PHA pharmacist, CEN centre for well-being and mental health, MED medical insurance, SOW centre for social welfare, OTH other, SPE dr with specialization, OWN no referral but own care offer, NO no referral because not a point of attention for my discipline, NA not applicable for me to refer.

In the answer-category 'other' participants indicated to refer to: out-patient mental healthcare; patients' family/personal context; palliative support; groups for self-help, buddies or patient advocacy; specific cultural/spiritual worker; relaxation therapist; sexologist; relation therapist; books; the school of patients' children or a student's counselling center; leisure organizations; occupational physician; employer; trade union; public employment service; bank or insurance agency; notary; health insurance service; home healthcare service.

Table A6.4.5. Extramural referral by intramural HCPs for psychosocial concerns and problems (N=124)

	GP		HNU		PHY		LYM		DIE		PSY		PHA		CEN		MED		SOS		OTH		SPE		OWN		NO		NA	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Psy. Impact																														
Mental	63	50.8	25	20.2	5	4.0	0	0.0	0	0.0	50	40.3	1	0.8	30	24.2	12	9.7	10	8.1	3	2.4	5	4.0	15	12.1	3	2.4	29	23.4
Emotional	57	46.0	25	20.2	1	0.8	0	0.0	0	0.0	58	46.8	28	22.6	28	22.6	7	5.6	5	4.0	3	2.4	5	4.0	17	13.7	2	1.6	27	21.8
Spir.-Philo.	38	30.6	15	12.1	0	0.0	0	0.0	0	0.0	30	24.2	0	0.0	16	12.9	6	4.8	4	3.2	18	14.5	2	1.6	17	13.7	2	1.6	35	28.2
Soc. Impact																														
Social roles																														
To partner	54	43.5	23	18.5	2	1.6	0	0.0	0	0.0	46	37.1	0	0.0	29	23.4	13	10.5	10	8.1	5	4.0	3	2.4	11	8.9	5	4.0	31	25.0
To children	46	37.1	17	13.7	1	0.8	0	0.0	0	0.0	51	41.1	0	0.0	26	21.0	7	5.6	5	4.0	5	4.0	2	1.6	14	11.3	3	2.4	31	25.0
To FA&FR.	35	28.2	14	11.3	0	0.0	0	0.0	0	0.0	32	25.8	0	0.0	23	18.5	6	4.8	6	4.8	1	0.8	1	0.8	21	16.9	9	7.3	33	26.6
Hobbies	21	16.9	13	10.5	5	4.0	0	0.0	0	0.0	12	9.7	0	0.0	15	12.1	13	10.5	10	8.1	9	7.3	1	0.8	22	17.7	11	8.9	37	29.8
Work	34	27.4	8	6.5	2	1.6	0	0.0	0	0.0	0	0.0	0	0.0	15	12.1	50	40.3	35	28.2	6	4.8	1	0.8	4	3.2	8	6.5	34	27.4
Financial	13	10.5	4	3.2	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	8	6.5	57	46.0	62	50.0	7	5.6	2	1.6	3	2.4	8	6.5	32	25.8

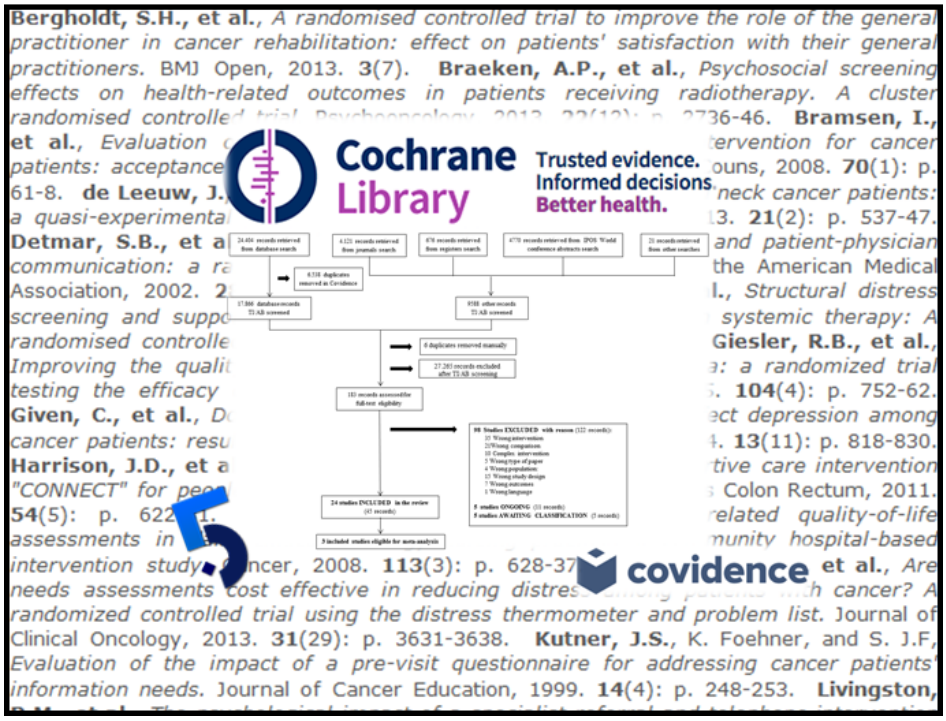
Abbreviations: HCP healthcare professionals, GP general practitioner, HNU home nurse, PHY physical therapist, LYM lymphedema therapist, DIE dietician, PSY psychologist, PHA pharmacist, CEN centre for well-being and mental health, MED medical insurance, SOW centre for social welfare, OTH other, SPE dr with specialization, OWN no referral but own care offer, NO no referral because not a point of attention for my discipline, NA not applicable for me to refer.

Table A6.4.6. Extramural referral by extramural HCP for psychosocial concerns and problems (N=219)

	GP		HNU		PHY		LYM		DIE		PSY		PHA		CEN		MED		SOS		OTH		SPE		OWN		NO		NA	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Psy. Impact																														
Mental	125	57.1	39	17.8	9	4.1	3	1.4	3	1.4	96	43.8	4	1.8	81	37.0	27	12.3	20	9.1	18	8.2	8	3.7	51	23.3	4	1.8	19	8.7
Emotional	108	49.3	39	17.8	2	0.9	0	0.0	1	0.5	96	43.8	3	1.4	71	32.4	16	7.3	16	7.3	19	8.7	2	0.9	62	28.3	4	1.8	18	8.2
Spir.-Philo.	58	26.5	25	11.4	1	0.5	0	0.0	0	0.0	55	25.1	3	1.4	57	26.0	12	5.5	9	4.1	41	18.7	2	0.9	52	23.7	13	5.9	36	16.4
Soc. Impact																														
Social roles																														
To partner	83	37.9	22	10.0	3	1.4	0	0.0	1	0.5	79	36.1	0	0.0	67	30.6	15	6.8	18	8.2	10	4.6	4	1.8	58	26.5	11	5.0	31	14.2
To children	66	30.1	24	11.0	1	0.5	0	0.0	1	0.5	71	32.4	0	0.0	78	35.6	12	5.5	14	6.4	11	5.0	4	1.8	62	28.3	7	3.2	34	15.5
To FA&FR.	44	20.1	15	6.8	0	0.0	0	0.0	0	0.0	47	21.5	1	0.5	57	26.0	11	5.0	6	2.7	6	2.7	2	0.9	65	29.7	17	7.8	43	19.6
Hobbies	35	16.0	16	7.3	18	8.2	1	0.5	0	0.0	13	5.9	0	0.0	24	11.0	19	8.7	15	6.8	27	12.3	5	2.3	79	36.1	17	7.8	39	17.8
Work	64	29.2	12	5.5	11	5.0	1	0.5	0	0.0	12	5.5	0	0.0	34	15.5	71	32.4	52	23.7	30	13.7	13	5.9	34	15.5	14	6.4	39	17.8
Financial	16	7.3	6	2.7	0	0.0	0	0.0	0	0.0	4	1.8	0	0.0	29	13.2	88	40.2	108	49.3	18	8.2	5	2.3	24	11.0	16	7.3	38	17.4

Abbreviations: HCP healthcare professionals, GP general practitioner, HNU home nurse, PHY physical therapist, LYM lymphedema therapist, DIE dietician, PSY psychologist, PHA pharmacist, CEN centre for well-being and mental health, MED medical insurance, SOW centre for social welfare, OTH other, SPE dr with specialization, OWN no referral but own care offer, NO no referral because not a point of attention for my discipline, NA not applicable for me to refer.

7
Chapter



The effect of systematic screening and assessment of psychosocial well-being and care needs in cancer patients: A Cochrane Review

This chapter is based on:

Schouten, Bojoura; Bekkering, Geertruida; Vankrunkelsven, Patrick; Mebis, Jeroen; Van Hoof, Elke; Hellings, Johan & Van Hecke, Ann (2016) *Systematic screening and assessment of psychosocial well-being and care needs of people with cancer [Protocol].* In: Cochrane Database of Systematic Reviews, 10 (Art N° CD012387).

Schouten, Bojoura; Avau, Bert; Bekkering, Geertruida; Vankrunkelsven, Patrick; Mebis, Jeroen; Hellings, Johan & Van Hecke, Ann (2016) *Systematic screening and assessment of psychosocial well-being and care needs of people with cancer [Review].* – Under review

ABSTRACT

BACKGROUND A diagnosis of cancer and related treatments can have a significant impact on patients' physical, and psychosocial well-being. To ensure that cancer care addresses all aspects of patients' well-being, systematic screening for distress and supportive care needs is recommended. This could support the integration of the psychosocial approach in daily routine, in order to achieve holistic cancer care. Moreover, a better match between specific care needs of patients with cancer and the organization of cancer care will improve patient centeredness of care.

OBJECTIVES To examine the effectiveness of screening and assessment of psychosocial well-being and care needs on the well-being of cancer patients, and to explore the intervention characteristics of these screening and assessment interventions.

SEARCH METHODS We searched five electronic data bases (CENTRAL, MEDLINE, PsycINFO, Embase, CINAHL), and five trial registers (Clinical Trials Gov., the National Research Register, the ISRCTN registry, the Dutch trial register, and the RePORT Expenditures and Results query tool) from inception to December 2016. Additionally, we searched the tables of contents from the journals Psycho-Oncology and Supportive Care in Cancer, and the abstract proceedings of the IPOS World Congresses from 2010 to 2016, as well as the reference lists of all included records, relevant reviews or clinical guidelines, to find published and unpublished trials.

SELECTION CRITERIA We included randomized controlled trials (RCT) and non-randomized controlled trials (NRCT) that studied the effect of screening interventions addressing the psychosocial well-being and care needs of cancer patients. These interventions could involve self-report of patients with a patient-reported outcome measure (PROM), or a semi-structured interview with a screening interventionist. Only studies measuring (health-related) quality of life ((HR)QOL), distress, care needs, patient satisfaction, other forms of psychosocial well-being (e.g. psychosocial adjustment, marital functioning, anxiety), and adverse events were included.

DATA COLLECTION AND ANALYSIS For each included study two review authors independently extracted the data and assessed methodological quality. Study authors were contacted if additional information or data was needed. Due to a high level of heterogeneity in included studies, only three were included in meta-synthesis. For the remaining 21 studies, the evidence on outcomes of interest was included in a narrative synthesis.

MAIN RESULTS We included 24 studies involving 6532 participants in the review, of which 16 RCT and eight NRCT. We judged five, six, and five RCT to have low, high, and unclear risk of bias, respectively. Six NRCT were judged to have a serious risk of bias, one to have critical risk of bias, and for one there was not enough information to make a judgement.

Due to large heterogeneity in intervention characteristics, outcome measures and time points pooling of all studies was not appropriate. The meta-analysis of three studies revealed no beneficial effect of the studied intervention on cancer patients' (HR)QOL, distress or care needs. In the narrative synthesis of the remaining 21 studies, limited evidence of a positive effect of the screening on (some subdomains of) cancer patients' (HR)QOL was found in seven studies, on their distress in two studies, on care needs in two studies, on patients' satisfaction in one study. However, negative effects were also observed. In one study patients' (HR)QOL was lower in the intervention condition, compared to the control condition. In one study intervention patients experienced more distress. Intervention patients' satisfaction (for some subdomains) was lower than in the control condition of one study, and in one study they expressed relatively more needs. In none of the studies an effect on other domains of patients' psychosocial well-being was found.

In the studies where some effects could be identified, no recurring relationships were found between intervention characteristics and effectiveness of screening interventions.

AUTHORS' CONCLUSIONS The evidence found with this systematic review does not support the effectiveness of screening and assessment of psychosocial well-being and care needs on cancer patients' well-being, neither on the intervention characteristics that could be determinative in the effectiveness of the intervention.

PLAIN LANGUAGE SUMMARY

Systematic screening and assessment of psychosocial well-being and care needs of people with cancer.

Although cancer is a medical condition, the disease and related treatments can affect the physical, psychological, emotional, sexual, social, practical and occupational functioning of patients' and their relatives. The experienced problems and care needs have a strong individual variation, and can occur in the short and/or long term. In order to address the biopsychosocial impact on patients' well-being, cancer care should be comprehensive, with an integration of psychosocial concerns in follow-up. In order to achieve this 'Cancer Care for the Whole Patient', as the leading Institute Of Medicine named it, focusing on patients' distress and supportive care needs was recommended. Simultaneously guidelines on systematic screening for distress were written, and efforts were made to implement this intervention in studies and clinical practice. As a result several adjustments in healthcare delivery were found (e.g. increased detection of, communication on, and referral for psychosocial concerns). It's assumed that this systematic screening or assessment will also benefit patients' well-being. To verify this assumption, this systematic review was conducted with the objective to examine the effectiveness of screening and assessment of psychosocial well-being and care needs on the well-being of cancer patients, and to explore characteristics of the intervention.

We found 16 RCT and eight NRCT to be eligible for inclusion in this review. These 24 studies involved 6532 adult cancer patients. With only five studies receiving a low risk of bias judgement the overall quality of evidence was limited. Individual study results showed some beneficial effects of the screening interventions on subdomains of health-related quality of life (HR)QOL, on distress, on care needs, and on patient satisfaction. However, negative effects on (HR)QOL, care needs, and patient satisfaction were as well observed in some studies. There was a large variation in screening content ((HR)QOL, distress, care needs, psychosocial and physical well-being), mode of screening (patient reported outcome measure or screening interventionist), timing and frequency of screening (1 to 12 times), outcome measures, and outcome time points. Only three studies could be included in the meta-analysis, which did not detect a beneficial effect of the intervention of interest.

In conclusion, the good-quality evidence in this area is limited. However, the evidence found with this review does not support the effectiveness of screening and assessment of cancer patients' psychosocial well-being and care needs. More research is needed. We recommend for future studies to work with core outcome sets (COS) to stimulate homogeneity in outcomes, to use intervention description guidelines (e.g. TIDieR, CReDECI 2) to increase the possibility of replication, and to combine subjective PRO outcomes with objective outcomes. Potentially, studies focusing on subpopulations with elevated risk of high levels of QOL disruption, distress, and care needs, may give clearer insights into the effectiveness of the interventions of interest in this review.

BACKGROUND

Description of the condition

Cancer is one of the leading causes of mortality and morbidity worldwide. According to the latest global statistics, there were 14.1 million new cancer cases in 2012 and this number is expected to increase to 24 million by 2035 [1]. Cancer accounted for 8.2 million deaths in 2012. With the increase of more successful therapeutic approaches, life expectancy of cancer patients is increasing, resulting in a growing population of cancer patients and survivors. In 2012, there were 32.6 million people living with cancer (within five years of diagnosis) worldwide [1].

Cancer and related treatments have a biopsychosocial impact on patients' health and well-being. Cancer patients may experience physical consequences such as pain, hair loss, nausea, weight gain/loss, fatigue, and sleeping difficulties varying from short to long term in nature [8, 9, 10]. Their psychosocial health is put to the test by emotional distress, fear of recurrence, memory changes, worries about the well-being of relatives, sexual problems, social issues, employment and financial difficulties, often resulting in supportive care needs [11, 15, 16, 17, 18].

The term 'Psychosocial well-being' is used in this review as an umbrella term comprising the experience of psychological, emotional, cognitive, spiritual, existential, relational, familial and social role functioning of a person. In clinical practice and research, the psychosocial well-being of patients, or the disruption of it, is measured on the basis of these components and with the degree to which supportive care needs are experienced. It is often also conceptualized and measured as a whole in terms of 'Quality of Life' (QOL) [30], 'Health-Related Quality of Life' (HRQOL) [100, 138], or 'distress' [41]. The resulting 'care needs' can be defined as "the requirement of some action or resource in care that is necessary, desirable, or useful to attain optimal well-being" for the person [115].

Depending on the studies and participating populations, the prevalence of distress within cancer patients varies from 35% to 55% [8]. The experienced distress can result in supportive care needs with a high individual variability for all life domains, ranging from 1% to 93% patients who desire extra support

[130]. Thus, cancer patients who experience high levels of distress or psychosocial burden do not necessarily desire extra supportive care. We believe, this is an important finding that indicates the need of a quality cancer care that is organized and driven by patient-centered initiatives in order to spend the limited healthcare budgets as efficiently as possible.

In order to address the biopsychosocial impact on patients' well-being, cancer care should be comprehensive, as well as integrating psychosocial concerns in follow-up [38, 185]. The Institute of Medicine (IOM) stated that care should be patient-centered, respectful of, and responsive to, patients' experiences, needs, preferences and values, and that patients' input on these should guide all clinical decisions [33]. National cancer plans were launched to integrate the psychosocial approach in cancer care [55], and routine screening of distress and needs is recommended as good practice across international cancer systems and in guidelines [38, 40, 42, 43, 44, 110, 111].

Description of the intervention

In this review, the intervention of interest is screening and assessment of psychosocial well-being and care needs in cancer patients. A literature search showed wide variation in screening terms and definitions, as well as in the scope of the used instruments, the timing of assessment and the participants [46, 186, 187]. We defined screening of psychosocial well-being as a concise measurement of psychosocial well-being using a patient-reported outcome measure (PROM), or a structured interview. An assessment was seen as a more extended or profound form of screening.

How the intervention might work

Screening for distress and supportive care needs in cancer care is primarily recommended to integrate the psychosocial topic in daily routine to achieve 'Cancer Care for the Whole Patient' [38]. This screening and assessment of psychosocial well-being and care needs can stimulate (1) detection of, (2) communication on, and (3) tailored referral for psychosocial concerns [114, 188, 189], increasing the chance that patients with psychosocial difficulties receive the appropriate treatment to support them. If the application of interventions for screening and assessment of patients' psychosocial well-being and care needs

contributes to a more efficient and effective healthcare delivery, it is expected that it consequently can improve cancer patients' well-being [190, 191]. Likewise, actively querying patients' experiences and needs could stimulate patients to fulfil a more active role in their own care trajectory [192]. This induces the patient-centeredness that is needed to create a good match between patients' care needs and the delivered care. Comprehensiveness, efficiency, and patient-centeredness are essential components in achieving high-quality cancer care [161, 193].

Why it is important to do this review

Several Cochrane systematic reviews focused on the effect of psychological and psychosocial interventions for cancer patients [194, 195, 196, 197]. However, results were inconclusive. A significant variation in participants, mode of intervention delivery, discipline of the involved care professionals and intervention content was observed [194, 197]. To respond to these findings, we chose to focus on a specific type of psychosocial intervention, namely the screening and assessment of patients' psychosocial well-being and care needs. It is expected that these interventions bring an added value to the organization of health care, and have a positive impact on the well-being of patients. This type of screening in cancer care is widely recommended. However, this is often based on consensus of professionals and policy makers. The existence of evidence-based data, collected in earlier reviews, seemed to be scarce and was quite often contradictory [46, 187, 198].

Thus, the question remained whether systematic screening and assessment of psychosocial well-being and care needs has a positive effect on cancer patients' well-being. We are aware that there are many factors that contribute to the psychosocial well-being and care needs of cancer patients. Both patients' socio-demographic, as well as medical characteristics such as age, gender, socioeconomic and other social factors, health status , tumor and treatment type are important [15, 153, 154, 199, 200]. We assume that the characteristics of care interventions as well can have an important role. Therefore, we also explored the characteristics of psychosocial screening and assessment interventions that were implemented in international practice and research. This with the assumption that it could provide insights in the extent to which

differences in these characteristics contributed to the effect that the screening interventions had on the psychosocial well-being and care needs of the target audience. Consequently, we addressed the following two research questions in this systematic review:

- What is the effect of screening and assessment of psychosocial well-being and care needs on the well-being of people with cancer?
- What are important intervention characteristics in screening and assessment of cancer patients' psychosocial well-being and care needs?

We expected this systematic review to add value compared to earlier reviews on this topic and related topics. Firstly, we relied on a more extensive collection of sources for the search of studies. Secondly, we included randomized clinical trials (RCT) as well as non-randomized controlled trials (NRCT). RCT designs are seen as the most reliable and bias-resistant research designs, and several of previous reviews have only focused on this type of study design. However, the nature of the clinical field and interventions make it hard to only evaluate evidence with RCT [201]. Thirdly, in our search strategy we focused on a wide range of outcomes that are used in research focusing on patients' psychosocial well-being, wider than some other reviews. Fourthly, we did not only focus on the final effect of the specific psychosocial screening and assessment interventions. Like Ranchor and colleagues [202], we intended to describe the specific characteristics and components of these interventions (e.g. the instruments used, the procedures undertaken, the conditions set, as well as the care professionals that are involved in the intervention). Fifthly, calls for screening intervention research [46] and study protocol papers [203] suggested that there would be more recent evidence-based data.

This systematic review provides a complete summary of international studies on this topic, relevant for research, policy and practice. Shortcomings in research were identified and provide information for future research into the composition of, or conditions for effective screening and assessment of psychosocial well-being and care needs. Policy makers can be provided with comprehensive evidence-based data. Likewise, the findings of studies in this review clarify the effects or value of psychosocial screening and assessment for clinical practice.

OBJECTIVES

- To assess the effectiveness of screening and assessment of psychosocial well-being and care needs on the well-being of cancer patients.
- To explore the intervention characteristics of these screening and assessment interventions (interventionists, instruments, procedures, implementation conditions).

METHODS

Criteria for considering studies for this review

We included studies described in English, French and Dutch. Publication status was not an exclusion criterion.

Types of studies

We included RCT on screening interventions. RCT are considered as the golden standard to evaluate intervention effects. However, RCT are often not available to address questions about the effects of health system interventions and implementation strategies, due to the nature of the field [201]. Consequently, we also included NRCT, such as controlled before-after studies (CBAs), interrupted-time-series studies (ITS), repeated measures studies (RMS) and historically-controlled studies (HCTs).

Types of participants

Adult cancer patients, at any time point of their care trajectory (at diagnosis, in active treatment, at completion of treatment, in follow-up or survivorship) were included. We excluded research literature specifically on children, teenagers and adolescents. The minimum age was 18 years. References were excluded when the study authors appointed their study population specifically with the term ‘children’, 'teenagers', 'adolescents', or related terms.

Types of interventions

In this review, the intervention of interest was the screening and assessment of psychosocial well-being and care needs in cancer patients. The term

'psychosocial' screening and assessment in this review should be interpreted in terms of screening and assessment of psychosocial, psychological, emotional or social well-being, quality of life, distress, anxiety or depression, or supportive care needs.

We expected to find studies that focused on the evaluation of rather solitary or simple screening interventions (e.g. PROM- or face-to-face-screening, followed by availability of screening-results for healthcare professionals with no further instructions), and to find studies with screening or assessment interventions that were part of a larger intervention combining the screening with co-interventions actively using the screening results (e.g. PROM- or face-to-face-screening, followed by use of screening results according to previously described guidelines on results discussion, interdisciplinary referral, computer generated care algorithms,…).

The studies of interest at least had to compare a psychosocial screening or assessment condition with a standard care condition. We considered standard care as the condition which is described by the study authors as 'standard care' or 'usual care', and did not contain any form of screening or assessment of psychosocial well-being and care needs

Interventions that reported only combined outcomes after screening plus more complex interventions (e.g. therapy, coaching, full care pathways or care programs) were excluded, as it would be impossible to disentangle the effects of screening from the full intervention.

Types of outcome measures

Outcomes had to be collected with self-report questionnaires, and potentially through interviews with use of PROM.

Primary outcomes

Cancer patients' psychosocial well-being and care needs had to be measured in terms of:

- *(HR)QOL:* e.g. measured with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC-QLQ-C30) [100], or the Short Form Health Survey (SF-36) [204];

- *Distress*: e.g. measured with the Hospital Anxiety and Depression Scale (HADS) [91]; the Beck Depression Inventory (BDI) [205], or the Distress Thermometer (DT) [101];
- *Supportive care needs*: e.g. measured with the Supportive Care Needs Survey (SCNS) [115], or the Cancer Survivors' Unmet Needs measure (CaSUN) [206].
- *Adverse events*: overburdening of patients by screening procedures, or induced fear or stress by discussing potential concerns and care needs with patients who normally might prefer to use an avoidance-coping strategy.

Secondary outcomes

- *Psychosocial well-being* measured by contributing components, defined by study authors as follows: cognitive, emotional, psychological, social or spiritual well-being; mental health; and symptoms of anxiety or depression'.
- *Patients' satisfaction*: e.g. measured with the EORTC cancer in-patient satisfaction with care measure (EORTC IN-PATSAT32) [207, 208], or the Patient Satisfaction and Quality in Oncological Care (PASQOC) [209, 210].

Search methods for identification of studies

To identify records for inclusion in this systematic review, we used several resources.

Electronic searches

The following databases were searched from their inception to 16th November 2016:

- The Cochrane Central Register of Controlled Trials (CENTRAL);
- MEDLINE (through Ovid);
- PsycINFO (through Ovid);
- Embase (through Ovid);
- CINAHL (through EBSCO);

The search strategies consisted of a combination of controlled vocabulary and free text terms for 'cancer', 'care model', 'psychosocial', 'screening' and 'assessment'. The initial search strategy was developed for MEDLINE, and was subsequently adjusted for the other databases (Appendix 7.1.).

Searching other resources

Reference lists

We screened reference lists of all included records, as well as reference lists of relevant reviews or clinical guidelines for relevant records.

Focused literature search

We searched the tables of contents of the last six years (2010 to 2016) in the journals *Psycho-Oncology* and *Supportive Care in Cancer*.

Trial registers

We also searched the following trial registers in an attempt to identify unpublished screening studies: Clinical Trials Gov. (https://clinicaltrials.gov), the National Research Register (http://webarchive.nationalarchives.gov.uk); the ISRCTN registry (http://www.isrctn.com/), the Dutch trial register (NRT) (http://www.trialregister.nl/trialreg/index), and the RePORT Expenditures and Results (RePORTER) query tool (http://report.nih.gov). These registers were consulted with a search combining 'cancer' with 'care model', 'psychosocial' and 'screening' or 'assessment' (Appendix 7.2.).

Conference abstracts

We searched relevant research initiatives presented on the World Congress of Psycho-Oncology by screening the abstract proceedings of the World Congresses organized from 2010 to 2016. This search, and the trial registers search were introduced to minimize the risk of publication bias.

Data collection and analysis

Data collection and analysis was carried out in accordance with the guidelines published in the *Cochrane Handbook for Systematic Reviews of Interventions* [211].

Selection of studies

All records retrieved from the electronic search in the databases, were imported in Covidence, systematic review software developed in collaboration with Cochrane (Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org), and duplicates were removed. Two review authors independently screened titles and abstracts for relevancy (BS paired by AVH, BA, TB, JM, PV). Two review authors inspected the full texts of the relevant records independently (BS paired by AVH or BA), to judge on the eligibility according to the inclusion and exclusion criteria. Reasons for exclusion were documented. Possible cases of disagreement between the two review authors were resolved by discussion or by involving a third independent review author (AVH or BA). We included a PRISMA flow-diagram in the results section to display the screening process [212].

Data extraction and management

Two review authors (BS, paired by AVH and BA) independently extracted data from the included studies. Hereto, a data extraction file was constructed in accordance with the checklist proposed by Cochrane [211] and the CReDECI 2-guideline [213] (Appendix 7.3.). Where possible, the following data was obtained from every study:

- *Study information:* authors, publication year, source of publication, funding of studies and any conflicts of interest reported by authors;
- *Methods:* study design, study duration;
- *Participants:* country of recruitment, description of patient population, setting of recruitment, inclusion criteria, exclusion criteria;
- *Intervention:* type of randomization, aim of the study, content of screening or assessment, interventionist or executor of the concrete screening intervention, description of the screening or assessment intervention procedure (defined as 'solitary screening intervention' or 'screening intervention with co-intervention to use screening results' added with a description of the intervention procedure), conditions for intervention implementation (e.g. necessary equipment for the screening, training for involved professionals, developed guidelines or handbooks, care or referral protocols, scheduled inter- or multidisciplinary meetings),

theoretical basis of the studied screening or assessment intervention, description of the procedure for the comparative condition(s), protocol adherence, length of follow-up;

- *Outcomes:* primary and secondary outcome(s) defined by study authors, outcome time points;
- *Study results:* sample size, number of participants on which the analysis is based, mean age of sample, ratio of gender in sample, results of primary outcomes relevant to the review focus, results of secondary outcomes relevant to the review focus;
- *Review authors' conclusion:* conclusion on the results of the primary and secondary outcomes belonging to the scope of this review;
- *Evaluation of potential bias:* sample size calculation, sequence generation, allocation concealment, blinding of personnel and patients, blinding of outcome assessors, completeness of outcome data, reporting on outcome data, other sources of bias.

In case of disagreement, discussion took place to reach consensus, or an additional review author was involved (AVH or BA). When any of the record information was missing or unclear, BS made multiple attempts to contact the study authors to obtain further details.

Assessment of risk of bias in included studies

RANDOMISED STUDIES (RCT)

Two review authors (BS, paired by AVH and BA) independently assessed the risk of bias of included RCT by using Cochrane's tool for assessing the risk of bias [211]. Each of the domains of potential bias were labelled as 'high risk', 'low risk' or 'unclear risk'. Possible disagreements between the two review authors were resolved by discussion or involvement of a third review author (AVH or BA).

We based the overall bias judgement of included RCT on the following three domains of Cochrane's tool for assessing the risk of bias [211]: 'adequate sequence generation', 'blinding of outcome assessors', and 'selective outcome reporting'. In case of low risk on all of these domains, the RCT was labelled as a 'low-risk study'. In case of high risk on one of these domains, the RCT was labelled as a 'high-risk study'. We indicated that the risk of bias in a study was

'unclear' if there was no clear information on the risk of bias for one or more key domains, but no high risk for any domain.

Selection bias

Sequence generation

We assessed the method used to allocate participants to the conditions to check whether it could produce comparable groups. We assessed the methods as 'low risk' if random components were used (coin-tossing; throwing dice; random computer assignment), 'high risk' if allocation was predictable (alternation; assignment based on date of birth; case record number and date of presentation), or 'risk unclear' if there was insufficient information to judge sequence generation.

Allocation concealment

We evaluated the methods used to conceal the allocation sequence to determine whether condition allocation could be foreseen. We labeled methods as 'low risk' if allocation could not have been foreseen (central or telephone randomization; consecutively numbered sealed envelopes), 'high risk' if it could have been foreseen (printed lists of computer randomized allocation; unsealed envelopes; date of birth), or 'unclear risk' if there was insufficient information to judge allocation concealment.

Performance bias

We assessed the methods used, if any, for blinding of study participants and personal from knowledge of the received intervention. These were assessed as 'low risk' (participants and personnel blinded, or if we judged that not blinding could not have affected the results), 'high risk' (no or incomplete blinding), or 'unclear risk' if there was insufficient information on potential blinding.

Detection bias

All outcomes in the scope of this review were subjective outcomes queried with self-report measures or in interviews, and thus -strictly seen- were sensitive to potential bias (influence of social desirability in answering). However, there were differences between studies in the efforts made to blind interviewers or other

outcome assessors, to prevent an extra person inducing potential bias by knowledge of condition allocation. And so we used this domain of detection bias to evaluate the blinding of outcome assessors from knowledge of condition allocation. Methods were labelled as 'high risk' (outcome assessor was familiar with the intervention the participant received), 'low risk' (outcome assessor not aware of the intervention the participant received, or outcomes were retrieved by self-report of patients), or 'unclear risk' if there was insufficient information to assess potential detection bias.

Attrition bias

We assessed the amount, nature, or handling of incomplete data to assess the attrition bias. We assessed methods as 'low risk' (e.g. no missing outcome data; missing outcome data balanced across groups), 'high risk' (e.g. missing data for one or more of the primary outcome measures, numbers or reasons for missing data unbalanced across groups), or 'risk unclear' if there was insufficient information to asses potential attrition bias. We felt the need to determine a cut-off for judging drop-out rates to be high or low. In reference to the literature we chose to judge rates above 15% as 'high dropout rate' [214, 215], resulting in high risk of attrition bias.

Reporting bias

We evaluated the data that support the assessment of selective outcome reporting. For this domain, we coded studies as 'low risk' (study protocol is available and all of the study's pre-specified outcomes are reported in a pre-specified way, or the study protocol is not available, but it is clear that all the published reports include all expected outcomes including those that were pre-specified), 'high risk' (not all the pre-specified primary outcomes have been reported), or 'unclear risk' (insufficient information to evaluate reporting bias).

NON-RANDOMISED CONTROLLED TRIALS (NRCT)

Two review authors (BS, paired by AVH and BA) independently assessed the risk of bias of the included NRCT by using the Cochrane tool for bias assessment in NRCT, the Risk Of Bias In Non-randomized Studies - of Interventions (ROBINS-

I) [216]. With the ROBINS-I, studies were assessed for their risk of bias on the following seven domains:

- Bias due to confounding;
- Bias in selection of participants into the study;
- Bias in classification of interventions;
- Bias due to deviations from intended intervention;
- Bias due to missing data;
- Bias in measurement of outcomes;
- Bias in selection of the reported result.

Table 1. Reaching risk of bias judgements in ROBINS-I: pre-intervention and at-intervention domains

Judgement	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions
Low risk of bias (the study is comparable to a well-performed RCT with regard to this domain).	No confounding expected.	All participants who would have been eligible for the target trial were included in the study *and* start of follow-up and start of intervention coincide for all participants.	Intervention status is well-defined and based solely on information collected at the time of intervention
Moderate risk of bias (the study is sound for a NRCT with regard to this domain but cannot be considered comparable to a well-performed RCT.)	Confounding expected, all known important confounding domains appropriately measured and controlled for; *and* reliability and validity of measurement of important domains were sufficient, such that we do not expect serious residual confounding.	Selection into the study may have been related to intervention and outcome, but the authors used appropriate methods to adjust for the selection bias; *or* start of follow-up and start of intervention do not coincide for all participants, but (a) the proportion of participants for which this was the case was too low to induce important bias; (b) the authors used appropriate methods to adjust for the selection bias; or (c) the review authors are confident that the rate (hazard) ratio for the effect of intervention remains constant over time.	Intervention status is well-defined but some aspects of the assignments of intervention status were determined retrospectively.
Serious risk of bias (the study has some important problems).	Switches in treatment, co-interventions, or problems with implementation fidelity are apparent and are not adjusted for in the analyses.	Proportions of missing participants differ substantially across interventions; *or* reasons for missingness differ substantially across interventions; *and* missing data were addressed inappropriately in the analysis; *or* the nature of the missing data	The methods of outcome assessment were not comparable across intervention groups; *or* the outcome measure was subjective (i.e. likely to be influenced by knowledge of the intervention received by study participants) and was assessed by outcome

		means that the risk of bias cannot be removed through appropriate analysis.	assessors aware of the intervention received by study participants; *or* error in measuring the outcome was related to intervention status.
Critical risk of bias (the study is too problematic to provide any useful evidence on the effects of intervention).	Substantial deviations from the intended intervention are present and are not adjusted for in the analysis.	(Unusual) There were critical differences between interventions in participants with missing data that were not, or could not, be addressed through appropriate analysis.	The methods of outcome assessment were so different that they cannot reasonably be compared across intervention groups.
No information on which to base a judgement about risk of bias for this domain.	No information is reported on whether there is deviation from the intended intervention.	No information is reported about missing data or the potential for data to be missing.	No information is reported about the methods of outcome assessment.

Source: Sterne 2016.

'Risk of bias' judgements led to labelling the studies on these domains as 'critical risk', 'serious risk', 'moderate risk', 'low risk' or 'no information'. Potential risk of bias for the pre-intervention and at-intervention domains this is displayed in Table 1. Table 2 shows the way to reach 'Risk of bias' judgements for post-intervention domains. Possible disagreements between the two review authors were resolved by discussion or involvement of a third review author (AVH or BA).

Table 2. Reaching risk of bias judgements in ROBINS-I: post-intervention domains

Judgement	Bias due to dev. from intended interv.	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
Low risk of bias (the study is comparable to a well-performed RCT with regard to this domain).	No bias due to deviation from the intended intervention is expected, for example, if both the intervention and	Data were reasonably complete; *or* proportions of and reasons for missing participants were similar across intervention groups;	The methods of outcome assessment were comparable across intervention groups; *and* the outcome measure was unlikely to be influenced by	There is clear evidence (usually through examination of a pre-registered protocol or statistical analysis plan) that all reported

	comparator are implemented over a short time period, and subsequent interventions are part of routine medical care, or if the specified comparison relates to initiation of intervention regardless of whether it is continued.	*or* analyses that addressed missing data are likely to have removed any risk of bias.	knowledge of the intervention received by study participants (i.e. is objective) *or* the outcome assessors were unaware of the intervention received by study participants; *and* any error in measuring the outcome is unrelated to intervention status.	results correspond to all intended outcomes, analyses and sub-cohorts.
Moderate risk of bias (the study is sound for a NRCT with regard to this domain but cannot be considered comparable to a well-performed RCT).	Bias due to deviation from the intended intervention is expected, and switches, co-interventions, and some problems with intervention fidelity are appropriately measured and adjusted for in the analyses. Alternatively, most (but not all) deviations from intended intervention reflect the natural course of events after initiation of intervention.	Proportions of missing participants differ across interventions; *or* reasons for missingness differ minimally across interventions; *and* missing data were not addressed in the analysis.	The methods of outcome assessment were comparable across intervention groups; *and* the outcome measure is only minimally influenced by knowledge of the intervention received by study participants; *and* any error in measuring the outcome is only minimally related to intervention status.	The outcome measurements and analyses are consistent with an *a priori* plan; or are clearly defined and both internally and externally consistent; *and* There is no indication of selection of the reported analysis from among multiple analyses; *and* there is no indication of selection of the cohort or subgroups for analysis and reporting on the basis of the results.
Serious risk of bias (the study has some important problems).	Switches in treatment, co-interventions, or problems with implementation fidelity are apparent and are not adjusted for in the analyses.	Proportions of missing participants differ substantially across interventions; *or* reasons for missingness differ substantially across interventions; *and* missing data were addressed inappropriately in the analysis; *or* the nature of the missing data means that the risk of bias cannot be removed	The methods of outcome assessment were not comparable across intervention groups; *or* the outcome measure was subjective (i.e. likely to be influenced by knowledge of the intervention received by study participants) and was assessed by outcome assessors aware of the intervention received by study participants; *or* error in measuring the outcome was related	Outcome measurements or analyses are internally or externally inconsistent; *or* there is a high risk of selective reporting from among multiple analyses; *or* the cohort or subgroup is selected from a larger study for analysis and appears to be reported on the

		through appropriate analysis.	to intervention status.	basis of the results.
Critical risk of bias (the study is too problematic to provide any useful evidence on the effects of intervention).	Substantial deviations from the intended intervention are present and are not adjusted for in the analysis.	(Unusual) There were critical differences between interventions in participants with missing data that were not, or could not, be addressed through appropriate analysis.	The methods of outcome assessment were so different that they cannot reasonably be compared across intervention groups.	There is evidence or strong suspicion of selective reporting of results, and the unreported results are likely to be substantially different from the reported results.
No information on which to base a judgement about risk of bias for this domain.	No information is reported on whether there is deviation from the intended intervention.	No information is reported about missing data or the potential for data to be missing.	No information is reported about the methods of outcome assessment.	There is too little information to make a judgement (for example, if only an abstract is available for the study).

Source: Sterne 2016.

As prescribed in the manual of the ROBINS-I, we labelled a NRCT as a 'low-risk study' if the study was judged to be at low risk of bias for all domains; as a 'moderate-risk study' if the study was judged to be at low or moderate risk of bias for all domains; as a 'serious-risk study' if the study was judged to be at serious risk of bias in at least one domain, but not at critical risk of bias in any domain; as a 'critical risk study' if the study was judged to be at critical risk of bias in at least one domain; and we indicated that there was 'no information on a NRCT' if there was no clear indication that the study was at serious or critical risk of bias, and there was a lack of information in one or more key domains.
For the NRCT, we checked if covariance analyses were performed. Doing this, there was a correction of the results in function of potential influences from other variables than the intervention of interest, and the risk of bias in results was reduced.

Measures of treatment effect

Continuous data of similar measures were analyzed with the mean difference (MD) and used standardized mean difference (SMD) when measures were different. For dichotomous data, we used risk ratio (RR) for presentation of results. The method for handling ordinary scales depended on the length of the scale. We used the RR for scales that could be dichotomized, and for five-point

Likert scales or longer, we calculated the MD. For all measures of treatment effect, we determined the 95% confidence intervals (CIs).

According to the recommendations in the Cochrane Handbook of Systematic Reviews of Interventions [211], we have corrected the direction of the scales in case similar outcomes were reported with different scales, but with a different direction of magnitude. This allowed correct meta-analyses, and facilitated interpretation of data presented in an evidence summary in case meta-analyses were not possible. The symptom subscales of the quality of life tools FLIC (Functional Living Index-Cancer), SF-36, FACT-C (Functional Assessment of Cancer Therapy-Colorectal) and PCQoL (Prostate Cancer-Related Quality of Life Scales) all represent less symptoms with higher scores, while the EORTC symptom subscales represent more symptoms with higher scores. Therefore, the reported symptom scales of the EORTC were adjusted by subtracting the reported score from the maximal score possible (100). We made similar adjustments to two scales used for measuring psychosocial well-being: the Locke-Wallace marital adjustment scale (LWMAS) (reported data subtracted from the maximal score of 158) and the Dyadic Adjustment Scale (DAS) (reported data multiplied by -1, as data were presented as a change from baseline).

Unit of analysis issues

If possible cluster-RCT was used to examine the effect of screening and assessment on the psychosocial well-being and care needs of cancer patients. In the meta-analysis that was conducted, the results were analyzed together with the results from the individually-randomized trial after adjustment of the sample sizes as described in the Cochrane Handbook of Systematic Reviews of Interventions [211]. For this purpose, an estimate of the intra-cluster correlation coefficient (ICC) was used, preferably from a similar trial. If no such estimate was available, a conservative ICC of 0.05 was used. We assessed the impact of cluster-RCT on the results in a sensitivity analysis if applicable.

Dealing with missing data

Dropout rates of all included studies were evaluated if possible. In case of ambiguity or incompleteness of data, one of the authors (BA) undertook multiple

attempts to contact the study authors for additional information. In the absence of response, the lack of data for the Evidence Summary (Appendix 7.8.) was indicated with N/A (not available) and N/E (not estimable).

Assessment of heterogeneity

In concordance with the Cochrane guidelines we decided to only perform a meta-analysis when a group of studies was sufficiently homogeneous to provide a meaningful summary; if not we decided to perform a narrative data synthesis. In our meta-analysis, we used the Chi2 test included in the forest plots to examine heterogeneity in intervention effects. We calculated the I2 statistic to quantify inconsistency of the observed effects. With this, the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance) was calculated. We adopted the guide for interpretation suggested by the Cochrane Handbook of Systematic Reviews of Interventions [211]:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

The significance of the observed value was interpreted in the context of the magnitude and direction of effects, and on the strength of evidence for heterogeneity (e.g. P value from the Chi2 test).

Assessment of reporting biases

In order to assess publication bias, we planned to produce funnel plots (estimated treatment effects against their standard error), if more than 10 studies would be included in the meta-analyses.

Data synthesis

If two or more eligible studies were identified and found to be sufficiently homogeneous, we performed a meta-analysis using Review Manager 5.3 [217]**.** A random-effects model was used as we expected at least some heterogeneity between the studies.

We performed a narrative data description of the study results of each individual study, in case studies were too heterogeneous. All available data from these studies are presented in the Evidence Summary Table (Appendix 7.8.).

Subgroup analysis and investigation of heterogeneity

Studies with a RCT design and studies with a NRCT design were seen as two subgroups in the analysis of results. If there was agreement in the conclusions resulting from RCT and NRCT, one final conclusion on the effect of screening and assessment of psychosocial well-being and care needs was formulated. If considerable heterogeneity in outcome was found (I2 > 75%) within these two subgroups of studies, we tried to explain the heterogeneity by assessing potential differences in clinical characteristics. We imagined that potential heterogeneity in outcomes could be induced by clinical and methodological characteristics: patient characteristics (e.g. age group, gender), medical characteristics (e.g. cancer type, disease prognosis or stage, type and degree of (pre-) treatment), or characteristics of the intervention of interest (e.g. simple or complex screening of psychosocial well-being and care needs, studies that address more than one relevant intervention condition). If we found that several studies were focused on these specific characteristics, we performed subgroup-analyses.

Sensitivity analysis

We conducted a sensitivity analysis to assess the robustness of our findings. After all, intervention effects could be larger in NRCT and RCT of less quality by overestimation. However, this could equally be the other way around and effects could be underestimated in RCT studies [201] We conducted a meta-analysis including the eligible RCT and NRCT. Subsequently, we repeated meta-analysis for both separately to explore the impact on the final results. With this we could explore the effect of including NRCT in this review.

RESULTS

Description of studies

Results of the search

Figure 1 illustrates the process of record screening and study selection for the review.

The electronic search of databases identified 5.781 records for MEDLINE, 9.087 records for CENTRAL, 1.152 records for PsychInfo, 2.457 records for CINAHL, and 6.967 records for Embase. After deduplication in Covidence, 17.866 database records were left for screening. The search in trial registers identified 33 records for ClinicalTrialsGov., 300 records for the ISRCTN Registry, 182 records for the NRT, 74 for RePORTER, 87 for the UK National Research Register.

Six duplicates, incorrectly retained after deduplication in Covidence, were deleted. The screening of the electronic records, and the records found through screening of the two selected journals, conference abstracts, and reference lists resulted in 183 records that were potentially relevant. We assessed these remaining records for full-text eligibility. Ninety eight studies were excluded due to the reasons specified in the excluded studies section (Appendix 7.5.). We classified five studies as 'ongoing' (Appendix 7.6.), and five as 'awaiting classification', since there was not enough information to judge on eligibility (Appendix 7.7.). We deemed 24 studies suitable for inclusion in the review (Appendix 7.4).

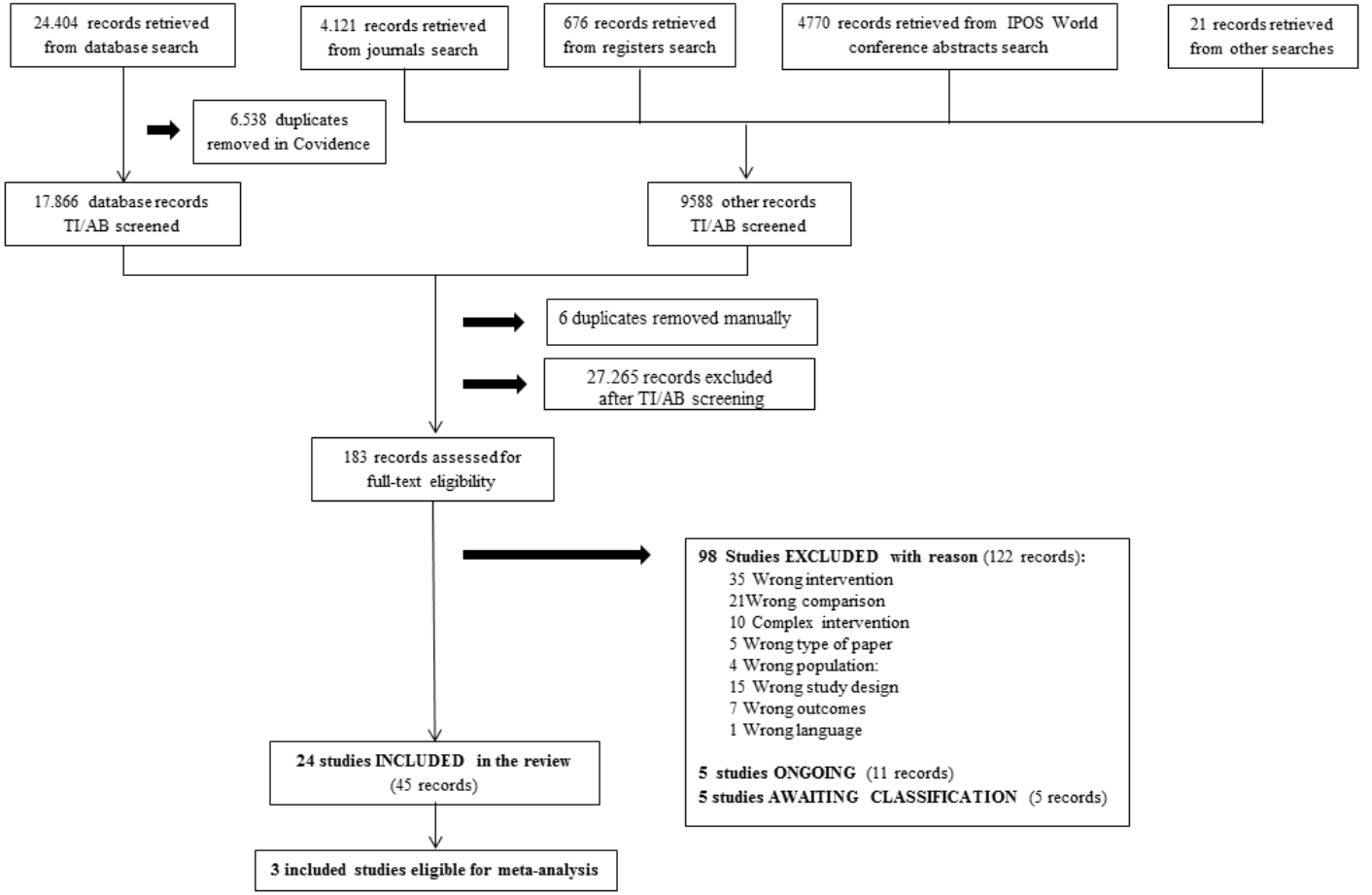


Figure 1 Study flow

Included studies

Details of all included studies are presented in the Characteristics of included studies tables (Appendix 7.4.).

Six studies were conducted in The Netherlands [218, 219, 220, 221, 222, 223], seven in Australia [151, 224, 225, 226, 227, 228, 229], five in the United States [230, 231, 232, 233, 234], three in the United Kingdom [235, 236, 237], two in Canada [238, 239], and one in Denmark [240]. All studies took place between 1990 and 2017, and were described in English.

For 12 studies we contacted the study authors multiple times with the request for more information or data. Three did not respond. Of the nine others, only four provided us with extra data.

Design

We included 16 studies with a RCT-design. Of these, Detmar et al. (2002) [221] used a longitudinal randomized crossover design, and Giesler et al. (2005)[230] used a prospective multisite RCT. Six studies were based on a RCT design with two [222, 224, 226, 231, 235, 238], and three studies on a design with three groups [233, 236, 237]. Four studies were based on a cluster RCT design with two [218, 229, 232, 240] or three groups [225].

We included eight studies with an NRCT-design. Waller worked with a interrupted time series design [151], and Williams et al. (2013) [234] conducted a historically controlled study. Two other studies performed a prospective non-randomized controlled study [220, 228]. Four studies used a sequential cohort design with repeated measures [219, 223, 227, 239].

Settings

Participants were recruited in general hospitals [223, 224, 228, 229, 230, 235, 240], university medical centers [219, 222, 230], radiotherapy and oncology departments of academic medical centers [218, 233], specialized cancer clinics [151, 220, 226, 235, 237, 238], tertiary medicine and care clinics [225, 234, 236], and outpatient clinics of cancer hospitals [221, 227, 232, 239]. Given described the settings in which patients were recruited as 'institutions'. The nature of the institutions remained unclear.

Participants

For all studies, adult cancer patients were recruited, mostly of both sexes. Maunsel et al. (1996)[238] recruited only women, Giesler et al. (2005)[230] and Livingston et al. (2010) [225] recruited only men. Twelve studies focused on one or only some specific cancer types, namely: breast cancer [238]; lung cancer [222, 226, 236, 239]; head-and-neck cancer [220]; colorectal cancer [224, 228, 229]; prostate cancer [230]; prostate and colorectal cancer [225]; breast, lung and colorectal cancer [233]. The other 12 studies defined a broader range of pathologies or made no specifications on type of cancer. In seven studies, patients with metastases or palliative treatment were excluded [218, 220, 222, 230, 231, 235, 238]. However, in four other studies advanced diagnosis or palliative treatment was explicitly part of the inclusion criteria [151, 221, 226, 233]. Nimako et al. (2015) [236] recruited participants after treatment completion. In all other studies patients were recruited at the start of or during active treatment. In 11 studies the eligible types of treatment were specified [218, 221, 222, 223, 226, 228, 229, 230, 231, 233, 234, 235], chemo- and radiotherapy were the most prevalent. Research samples counted between 41 [228] and 955 [240] participants, and a total of 6532 participants was included in this review. A detailed description of participants in each study can be found in the Characteristics of included studies table (Appendix 7.4.).

Interventions

A theoretical basis for the studied intervention was reported for five studies. Giesler et al. (2005) [230] based their assessment of well-being on the proximal-distal framework [241]. Given et al. (2004) [231] used the cognitive behavioral model and Bandura's theory of Self-efficacy to develop their screening intervention [242]. The self-regulation model of adjustment to illness [243] was the theoretical starting point that Young et al. (2010,2013) [224, 228, 229] used for the development of their telephone screening intervention. For two other studies [227, 230], results of a review, written recommendations and guidelines on screening were the basis for the intervention studied.

Intervention content and tools

For eight included studies the content of the screening intervention was (HR)QOL. In five of these the EORTC-QLQ-C30 was used as intervention tool, sometimes with the addition of a cancer type specific module [221, 223, 236, 237, 239]. Rosenbloom et al. (2007) [233] used the Functional Assessment of Cancer Therapy-General (FACT-G), and in the studies of Giesler et al. (2005) [230] and Given et al. (2004) [231] the content was described without a specific QOL-tool name.

Four studies described their intervention as distress screening. In three of them the DT was deployed for this purpose, solely [227], together with the Problem list (PL) [235], or with the PL and the 'referral wish question' [222]. Maunsell et al. (1996)[238] conducted the distress screening with the 20 item-General Health Questionnaire (20-GHQ).

Needs assessment was applied in eight studies. In six of them no specific instrument was used for this purpose, but the content was described [220, 224, 228, 229, 232, 240]. Schofield et al. (2013) [226] used the 38-item Needs Assessment for Advanced Lung Cancer Patients, and Waller et al. (2012) [151] used the Needs Assessment Tool: Progressive Diseased Cancer (NAT:PD-C).

In five studies (bio-)psychosocial symptoms or overall well-being formed the content for the screening intervention. Braeken et al. (2013)[218] used the The Dutch Screening Inventory of Psychosocial Problems (SIPP), Williams et al. (2013) [234] the Therapy-Related Symptom Checklist (TRSC), and in the other three studies no specific instrument was used, but the content of the screening intervention was described.

Intervention mode, frequency and follow-up

In 11 of the included studies the screening intervention took place in the form of self-completion of a screening tool [218, 221, 222, 223, 226, 227, 232, 234, 236, 237, 239], whereas in the other 13 studies an interventionist conducted the screening or assessment. Nurses fulfilled this role in 10 studies [220, 224, 225, 228, 229, 230, 231, 233, 235, 240]. Other interventionists mentioned were psychologists or social workers [219], radiographers [235], and research assistants [238]. In the study of Waller et al. (2012) [151] healthcare professionals of several disciplines used the NAT:PD-C during consultation.

Ten studies explored the effect of a 'solitary screening intervention' of which the insights on patients' well-being were communicated to a treating healthcare professional, to use in further follow-up of the patient [151, 218, 221, 223, 227, 232, 234, 236, 237]. In the other studies [219, 220, 222, 224, 225, 226, 228, 229, 230, 231, 233, 235, 238, 240] the screening intervention was combined with a co-intervention to actively use and respond to screening results: active results-discussion with patients, further assessment of certain problem areas, generation of respond formats, or specified intervention and referral strategies.
There was considerable heterogeneity regarding the number of times that the screening intervention was applied, ranging from one to 12 times. In the intervention of Taenzer et al. (2000) [239] and Kutner et al. (1999) [232] there was no further follow-up of patients after screening. In all other studies follow-up varied between four weeks and 18 months.
Further details on intervention procedures for each study separately are described in the Characteristics of included studies tables (Appendix 7.4.).

Conditions for implementation

A wide variation in conditions was set to implement the screening and assessment interventions studied in the included studies.
In 18 studies training or educational sessions for involved care professionals were provided, to become familiar with the screening instrument and/or the intervention procedures [151, 218, 220, 221, 223, 224, 225, 226, 227, 228, 229, 230, 231, 234, 235, 236, 237, 239]. Staffing was a requirement to be able to implement the face-to-face and telephone screenings in 11 of the included studies [151, 219, 224, 225, 228, 229, 230, 231, 233, 238, 240]. In the 11 studies that worked with a PROM-completion for their screening intervention [218, 221, 222, 223, 226, 227, 232, 234, 236, 237, 239] a person or system for questionnaire management (giving to patient, collecting, data-analysis, giving result-reports to patients and/or healthcare professionals) was needed. Authors of seven studies stated that special documents were developed, like interview manuals, a source directory, standardized clinical protocols, or written material for patients [151, 221, 223, 226, 229, 235, 240]. Detmar et al. (2002) [221] and Taenzer et al. (2000) [239] provided a person (assistant, volunteer) available for patients in case there was a need for extra information.

For detailed information on all of the conditions for implementation in each included study, we refer to the Characteristics of included studies tables (Appendix 7.4.).

Comparative conditions

In 20 of the included studies the intervention of interest was only compared to a usual care control group [151, 218, 219, 220, 221, 222, 223, 224, 226, 227, 228, 229, 230, 231, 232, 234, 235, 238, 239, 240]. In two studies a third condition or 'attention control group' was created, with participants completing screening questionnaires, differing from the intervention condition because the screening results were not shared with the treating doctors [236, 237]. Rosenbloom et al. (2007) [233] used a third condition, called 'assessment control group' with screening and sharing of screening results, but without a structured interview that followed the HRQOL-assessment in the intervention condition. Livingston et al. (2010) [225] also introduced an extra condition in addition to the intervention and control condition, with a less intensive version of the intervention of interest (1 vs 4 outcalls from the Cancer Helpline).

Outcomes

Most of the included studies measured several of the primary and secondary outcomes of our interest.

Outcomes of primary interest

(HR)QOL

Eighteen studies focused on our primary outcome, (HR)QOL, using a wide variety of measurement tools such as the EORTC-QLQ-C30, its subscales or individual items and its cancer type specific modules [151, 218, 219, 220, 222, 226, 235, 236, 240], the SF-36 [221, 223, 230], the EuroQol 5D (EQ-5D) [222, 235], the FLIC [233], the FACT-G or its disease specific versions [223, 224, 228, 229, 237], and two lesser-known tools: the Health-Related Quality of Life Linear Analogue Self-assessment (HRQOL-LASA) [234], and the PCQoL [230].

Distress

The effect of the screening intervention on patients' distress was measured in 14 studies. For this purpose following instruments were used: the Profile of Mood States (POMS) [233, 235, 240]; the HADS [151, 218, 222, 225, 226]; the General Health Questionnaire 12 items version (GHQ-12) [218, 219]; the Center for Epidemiological Studies Depression Scale (CES-D) [230, 231]; the Psychiatric Symptom Index (PSI) [238]; the DT [226, 228, 229]; a modified version of an existing distress-tool for breast cancer patients [225].

Care needs

Care needs were outcomes in seven studies. The SCNS was used to measure these in five studies [151, 224, 227, 228, 229]. In addition, Waller et al. (2012) [151] also used the questions on spiritual needs from the Needs assessment for advanced cancer patients (NA-ACP). Further, care needs were assessed with the CaSUN [224], the Needs Assessment for Advanced Lung Cancer Patients (NA-ALCP) [226], or did not specify a tool for needs assessment, but described the content [240]

Adverse events

None of the included studies specified adverse events as an outcome in their study.

Outcomes of secondary interest

Satisfaction

Satisfaction was measured in ten of the included studies. This concerned satisfaction with the quality of care in general or care from a specific healthcare professional, satisfaction with professional-patient communication, their active involvement, addressment of needs, information and emotional support received. Patients' satisfaction was surveyed with self-constructed questions [218, 237, 240] or with existing tools. The Danish Patients Evaluate General Practice (Dan-PEP) [240], the Patient Satisfaction Questionnaire (PSQ) [221, 222, 223, 233], the Trent patient Views of Cancer Services Questionnaire (TPVCSQ) [235], the five item Medical Outcomes Study Patient Visit Rating Questionnaire [232], and the Patient-Doctor Interaction Scale (PDIS) [239] were used for this purpose.

Psychosocial well-being

Other elements of psychosocial well-being that were addressed in the outcomes of included studies were marital well-being [230, 238], health and activity limitation [238], impact of stressful life events [219], and psychosocial adjustment [220].

Time points

Frequency of outcome measurement in the included studies varied from one to four times for each condition. Following time points for outcome assessment were used: baseline; one week; one month; six weeks; seven weeks; eight weeks; 10 weeks; 12 weeks; three months; four months; 20 weeks; 25 weeks; six, seven, 12 and 14 months. In the interrupted time series study that was included, outcomes were measured seven times, three times before intervention implementation, at baseline, and four times after implementation [151]. The timing of outcome assessment in the study of Williams et al. (2013) [234] was variable, linked to the treatment cycles of radio- and chemotherapy patients' received.

Excluded studies

Ninety-eight studies were excluded for the following reasons:

- Wrong intervention: no psychosocial screening intervention-effect studied;
- Wrong comparison: no usual-care condition without screening to compare with;
- Complex intervention: screening part of complex intervention, not possible to distinguish effect of screening intervention;
- Wrong type of paper: no original research paper, but paper with review, recommendations or letter to the editor;
- Wrong population: no adult cancer patients;
- Wrong study design: other than RCT and controlled NRCT;
- Wrong outcomes, but interesting and related: care outcomes;
- Wrong language: record not in English, French or Dutch.

Several examples of excluded studies are displayed in the Characteristics of excluded studies table (Appendix 7.5.).

Risk of bias in included studies

Risk of bias judgement is described separately for RCT and NRCT, presented for each study in the Risk of Bias tables (Appendix 7.4.) and visualized in the Risk of Bias Summaries (Figure 2 and Figure 3). Subsequently, our judgements about each risk of bias domain, presented as percentages across all included studies, is displayed in the Risk of Bias Graphs (Figure 4).

RANDOMIZED CONTROLLED TRIALS

Results of the Cochrane tool for assessing risk of bias of the 16 included RCT are presented in the Risk of Bias tables (Appendix 7.4.) and Figure 2. Based on 'sequence generation', 'blinding outcome assessors', and 'reporting on outcomes', we labelled six studies as 'high risk of bias study' [225, 231, 232, 236, 237, 240], and five as 'low risk of bias study' [222, 224, 226, 229, 235]. For five of the included RCT no general risk of bias judgement could be made due to unclear risk of bias for several domains [218, 221, 230, 233, 238].

Allocation (selection bias)

Sequence generation

The generation of random sequences was specified for ten RCT. Maunsell et al. (1996) [238] and Velikova et al. (2004) [237] generated the sequence with a random number table. In seven other studies computer generated randomization schedules were used [222, 224, 225, 226, 229, 235, 240]. For the other six studies the method for sequence generation was unclear.

Allocation to conditions

In four studies condition allocation was done by an independent researcher or administrative worker, not involved in the clinical care [222, 224, 237, 238]. In the study of Livingston et al. (2010) [225] there was a risk of bias in allocation, since the study coordinator and referring specialist were aware of group allocation. For the other 11 studies allocation concealment was not specified.

Blinding (performance bias and detection bias)

Blinding of participants and personnel

Due to the nature of the intervention it was difficult to blind participants and personnel, consequently there was high risk of performance bias in all studies.

In three studies [218, 221, 237] patients were blinded, personnel was not. In the other 13 studies patients, neither healthcare professionals were blinded.

Blinding of outcome assessors
Thirteen studies clearly stated the blinding of outcome assessors, or used self-report measures to collect outcome data from patients directly. We labeled these studies with a low risk of detection bias, since there was no extra person aware of the condition that could bias the outcome assessment. Three studies did not provide clear information on blinding of outcome assessors [231, 233, 236].

Incomplete outcome data (attrition bias)

Kutner et al. (1999) [232] did not provide sufficient information to judge on attrition bias. In seven other studies, rated to have a low risk of attrition bias, drop-out rates were low (≤15%) and comparable in both conditions, reasons for drop-out were reported [218, 225, 229, 235, 236, 237, 238]. We considered eight studies to be at high risk of attrition bias due to high drop-out (>15%) [221, 222, 224, 226, 230, 231, 233, 240].

Selective reporting (reporting bias)

In nine studies, judged to have a low risk of reporting bias, all pre-specified outcomes are reported in the results paper or in supplementary files. For several outcomes Kutner et al. [232] and Velikova et al. (1999) [237] only reported on significant subscales with p-values without further information on group outcomes, or spread of data, and were therefore judged as having high risk of bias. Due to the lack of reporting on certain outcomes for one or more conditions, we found indications for selective reporting in four studies [225, 236, 238, 240], which were therefore considered at high risk of reporting bias. In Given et al. (2004) [231] the data on patient-characteristics was limited, there is no clear presentation of the concrete data on patients' depression or severity of problems, and is therefore judged to have a high risk of reporting bias.

Other potential sources of bias

We identified three studies as having other potential sources of bias. In Giesler et al. (2005) [230] no adjustments for multiple testings were made, what implicates that the few positive results have a high risk to be type-I errors. It is

not clear whether the different models composed in Given et al. (2004) [231] are post-hoc analyses, or were rather planned in advance. In case of the first, this induced high risk of bias for this study. Kutner et al. (1999) [232]reported that adjusted p-values were reported to adjust for clustering. However, no information is given on how this adjustment was done. There is a huge difference in baseline characteristics, which are the result of clustering at the physician level according to study authors. These differences become non-significant when clustering is taken into account. In our opinion this is problematic and potentially induces bias.

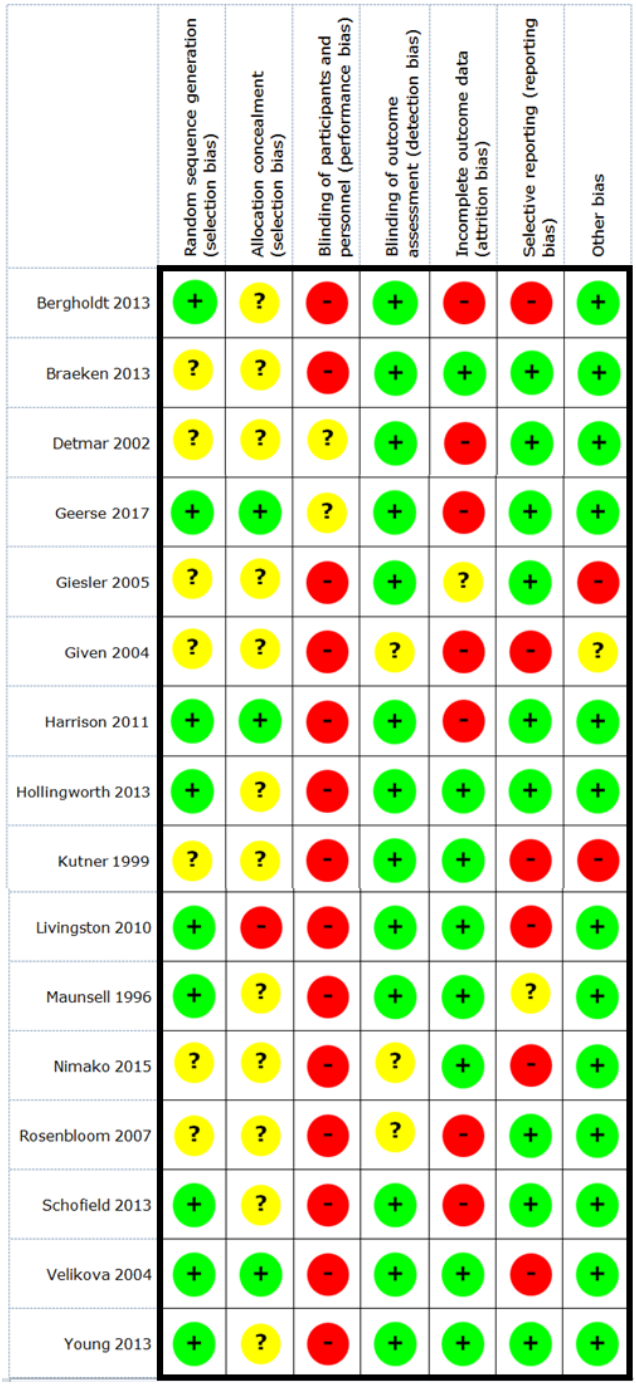


Figure 2 Risk of bias summary: review authors' judgements about each risk of bias item for each included RCT

NON-RANDOMIZED CONTROLLED TRIALS

Results of the ROBINS-I to assess the risk of bias in the eight included NRCT are presented in the Risk of Bias Tables (Appendix 7.4.) and Figure 3. Based on the criteria formulated in the methods section, we labelled one study as 'critical risk study' [151], and six as 'serious risk study' [219, 220, 223, 227, 228, 234]. For the remaining NRCT there was not enough information available to make an overall risk of bias judgement about the study [239].

Bias due to confounding

We labelled only Williams et al. (2013) [234] as a study with low risk of bias due to confounding, since no real confounding was expected and the study design thoroughly controlled for potentially confounding factors. Four studies were judged to have moderate risk since confounding was possible, but not more than we would expect in a RCT on this topic [219, 223, 228, 239]. In de Leeuw et al. (2013) [220] QOL-scores at baseline differed strongly between conditions, making the chance for confounding likely. All nursing and psychosocial staff in Thewes et al. (2009) [227]participated in training sessions before the study started. This potentially influenced the alertness to and management of psychosocial concerns in both conditions. In one study we found evidence for critical risk of bias due to confounding [151]: substantial deviations from the intended intervention are present, and not adjusted for in the analysis; baseline characteristics between the control group and intervention groups differ significantly.

Bias in selection of participants into the study

All included NRCT were judged to have low risk of bias in selection of participants. Sequential recruitment designs were used to include eligible participants. Each time, the same approach for inclusion was used in the intervention and control phase of the studies.

Bias in classification of interventions

Four studies reported no information on whether there is deviation from the intended intervention [219, 220, 223, 239] and were therefore classified as having an unclear risk of bias due to deviations from intended intervention. In

two studies a certain percentage of participants did not receive the screening intervention as planned [151, 227]. Therefore, these studies were judged to have a moderate risk of bias due to deviations from the intended intervention. We found evidence for serious risk of bias in Williams et al. (2013) [234], since problems with implementation fidelity are apparent (amount of screening interventions/outcome measurements ranged from 2 to 11).

Bias due to deviations from intended intervention

Young et al. (2010) [228] did not provide sufficient information to judge on bias due to missing data and was therefore classified as having an unclear risk. In two other studies drop-out rates were low (≤15%) and comparable in both conditions, reasons for drop-out were reported [234, 239]. These studies were judged to have a low risk of bias due to missing data. We considered five NRCT studies to be at high risk of attrition bias due to high drop-out (>15%) [151, 219, 220, 223, 227].

Bias due to missing data

Young et al. (2010) [228] did not provide sufficient information to judge on bias due to missing data and was therefore classified as having an unclear risk. In two other studies drop-out rates were low (≤15%) and comparable in both conditions, reasons for drop-out were reported [234, 239]. These studies were judged to have a low risk of bias due to missing data. We considered five NRCT studies to be at high risk of attrition bias due to high drop-out (>15%) [151, 219, 220, 223, 227].

Bias in measurement of outcomes

The information given on outcome assessment in Williams et al. (2013) [234] and Young et al. (2010) [228] is not clear enough to evaluate risk of this type of bias. Six studies used validated PRO's or trained interviewers (not part of the clinical team) to measure outcomes, leading to a low risk of bias in outcome measurement [151, 219, 220, 223, 227, 239].

Bias in selection of the reported results

In seven studies the outcome measurements, and analyses were clearly defined: there were no indications of selective reporting, data dredging, nor biased selection of the study cohort or subgroups [219, 220, 223, 227, 228, 239]. For Waller et al. (2012) [151] there is concrete evidence that the reporting of results is complete. All these studies were therefore considered to have a low risk of bias for selection of the reporting results. Results of generalized estimating equations analysis of HRQOL-LASA on covariates were mentioned in Williams et al (2013) [234], however, no information about the scores of the HRQOL-LASA items itself was presented, leading to a serious risk of bias in selection for the reported results.

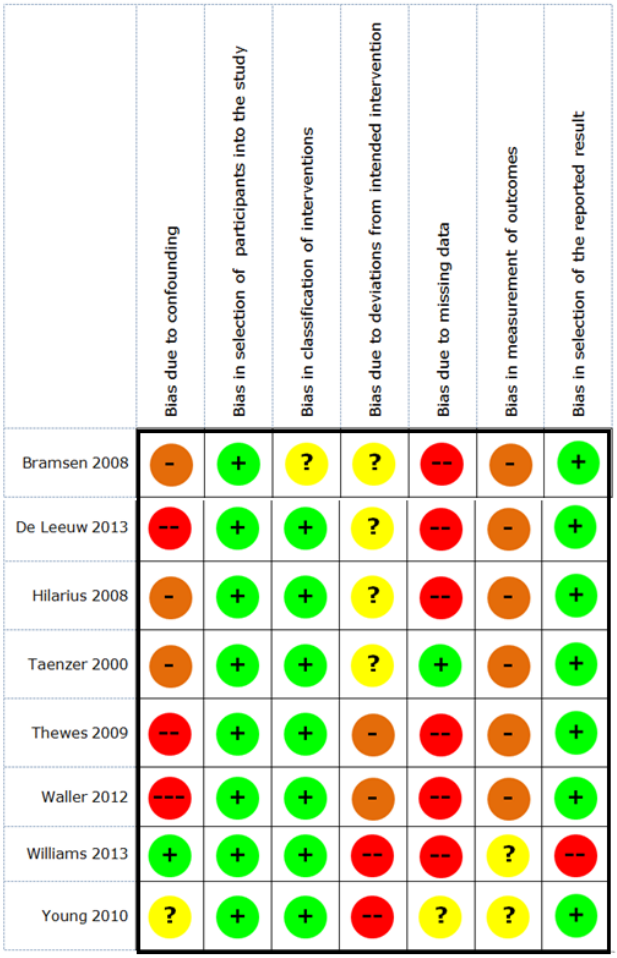


Figure 3 Risk of bias summary: review authors' judgements about each risk of bias item for each included NRCT

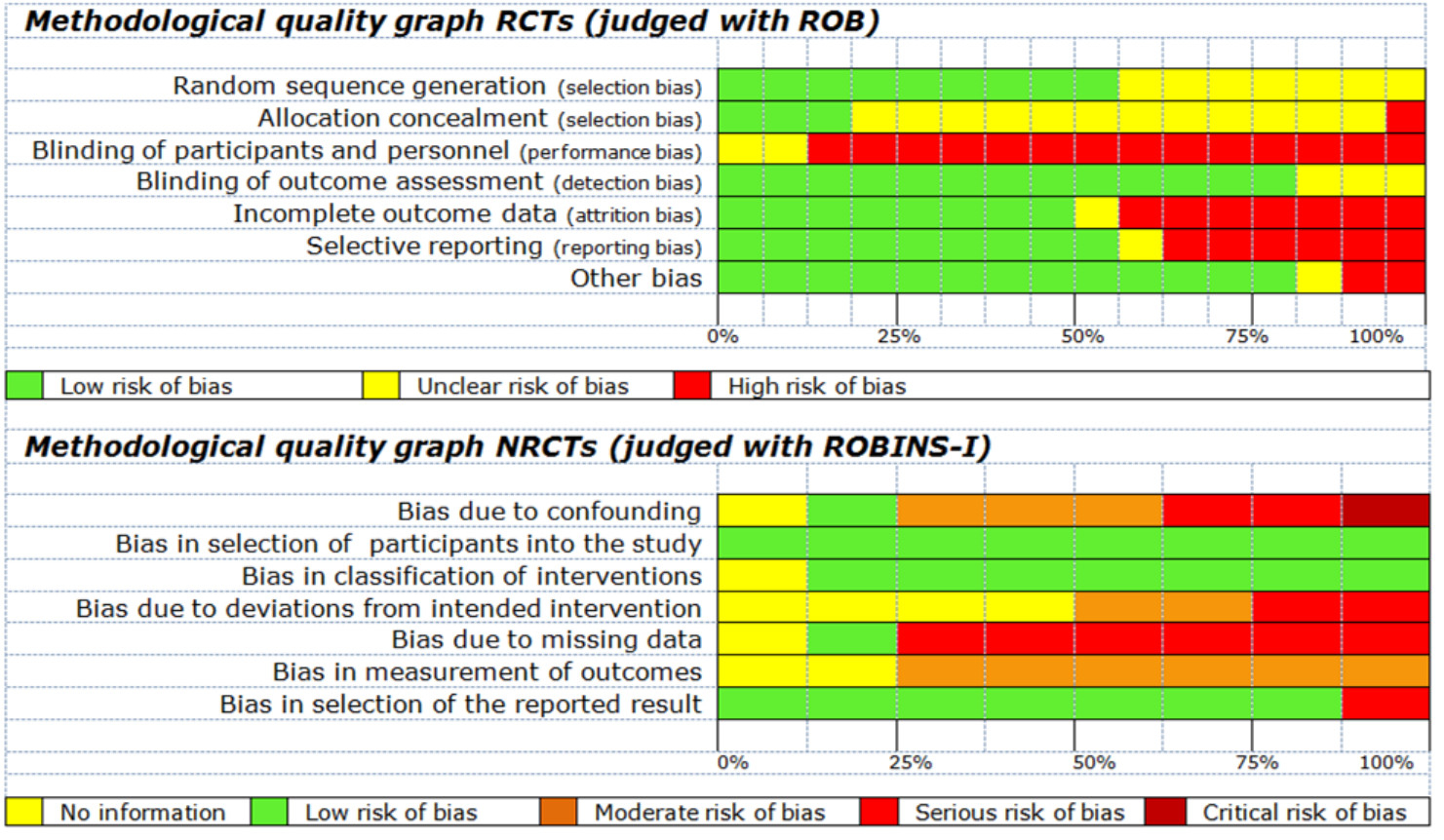


Figure 4 Risk of bias graph: review authors' judgements about each risk of bias item presented as a percentage across all included studies

Effects of interventions

In this section we describe the evidence that resulted from quantitative and qualitative analysis of the included studies. Additionally, we made an Evidence Summary with all the results of these studies for the outcomes that fall within the scope of this review (Appendix 7.8).

Results of meta-analysis

A meta-analysis with all included studies was not possible, due to considerable heterogeneity in intervention characteristics, outcome measures, outcome time points, and variation in methodological quality. Only two RCT studies and one NRCT [224, 228, 229] were considered to be sufficient homogeneous in order to pool.

The studies of which we considered the results eligible to be combined into a meta-analysis concerned a nurse-led intervention where patients who received surgery for colorectal cancer were contacted on a regular basis by phone to discuss their supportive care needs, the so-called CONNECT intervention. The first paper by this research group reports a non-randomized feasibility study [228], followed by a single-center pilot RCT [224], and a large scale multi-center RCT [229]. The outcomes that were investigated in these studies were (HR)QOL (measured with the FACT-C scale in all 3 studies), distress (measured with the distress thermometer in Young et al. (2010) [228] and Young et al. (2013) [229] and supportive care needs (measured with the SCNS in all 3 studies, and at 6 months with the Cancer survivor's unmet needs survey in Harrison et al. (2011) [224]). The NRCT [228] had follow-up measurements at 1 and 3 months after surgery, while the RCT [224, 229] measured their outcomes at 1, 3 and 6 months after surgery.

Unfortunately, due to differences between studies in reporting (e.g. only subscale scores for SCNS reported in the NRCT vs only total scores in the RCT) and timing of outcome measurements (e.g. supportive care needs measured at 1, 3 and 6 months in Harrison et al. (2011) [224] vs only at 3 and 6 months in Young et al. (2013) [229], we were not able to combine all reported outcomes. Therefore, we refer to the Evidence Summary (Appendix 7.8) for full details of all results.

(HR)QOL

All three studies did not find a significant effect of the intervention on global health status, 1 month after surgery, leading to an overall MD of 0.37 (95%CI -2.13 to 2.88; p=0.77; 3 trials; 816 participants – Analysis 1.1) (Figure 5). No important heterogeneity was present (I^2 = 24.9%). Also at 3 months after surgery, we did not find a significant difference in global health status, between the screening intervention and usual care, with a MD of 3.78 (95%CI -3.58 to 11.14; p=0.31; 3 trials, 791 participants – Analysis 1.2) (Figure 6). However, substantial heterogeneity was found (I^2 = 63%), and the subgroup analysis revealed that there was a significant difference between the NRCT and RCT (p=0.02, I^2 = 81.6%), with the NRCT [228] showing a beneficial effect of the screening, while the RCT [224, 229] did not.

(HR)QOL was assessed at 6 months after surgery by the RCT [224, 229] only, and no significant effect of the screening intervention was found, with a MD of 1.65 (95%CI -4.83 to 8.12; p=0.62; 2 trials; 730 participants – Analysis 1.3) (Figure 7). Heterogeneity between the two RCT was moderate (I^2 = 43%).

Analysis 1.1. Forest plot of comparison: 1 Screening vs Usual care, outcome: 1.1 (HR)-QOL: Global health status (1 month).

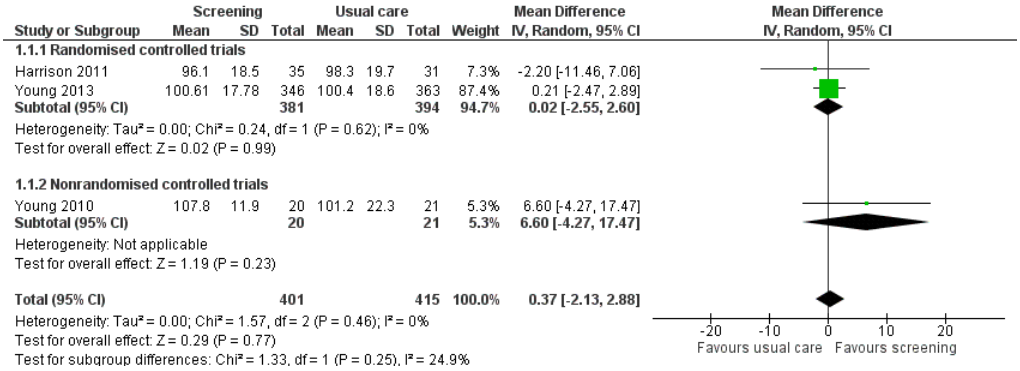


Figure 5 Analysis 1.1

Analysis 1.2. Forest plot of comparison: 1 Screening vs Usual care, outcome: 1.2 (HR)-QOL: Global health status (3 months).

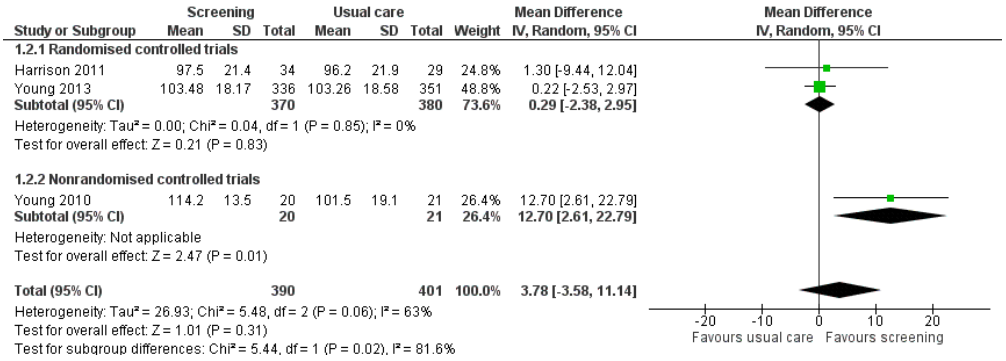


Figure 6 Analysis 1.2

Analysis 1.3. Forest plot of comparison: 1 Screening vs Usual care, outcome: 1.3 (HR)-QOL: Global health status (6 months).

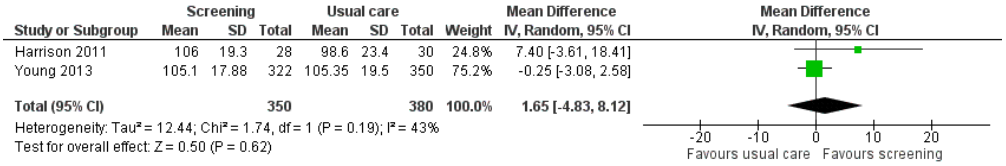


Figure 7 Analysis 1.3

Distress

Psychological distress was assessed by the NRCT [228] and the multi-center RCT [228] and did not differ at 1 month after surgery between the screening intervention and usual care, with a MD in distress thermometer score of -0.14 (95%CI -0.49 to 0.21; p=0.44; 2 trials; 750 participants – Analysis 1.4) (Figure 8), without heterogeneity between studies (I^2 = 0%). Distress was also not different at 3 months, with a MD of 0.0 (95%CI -0.36 to 0.36; p=1; 1 trial; 687 participants – Analysis 1.5) (Figure 9), nor at 6 months, with a MD of 0.0 (95%CI -0.42 to 0.42; p=1; 1 trial; 672 participants – Additional Table 2).

Analysis 1.4. Forest plot of comparison: 1 Screening vs Usual care, outcome: 1.4 Psychological distress (1 month).

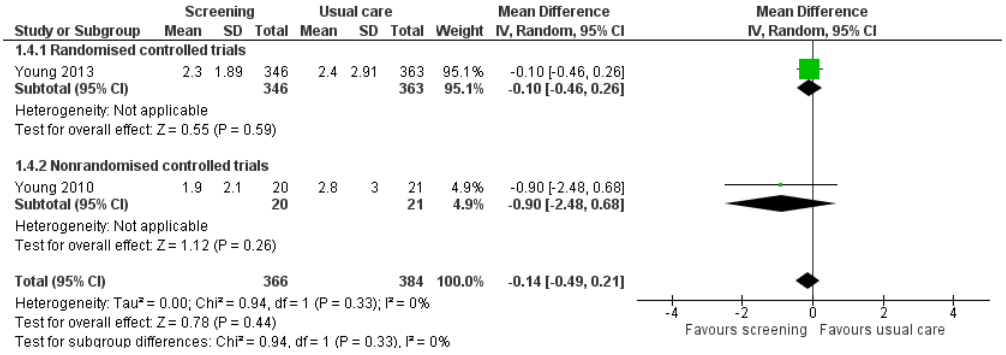


Figure 8 Analysis 1.4

Analysis 1.5. Forest plot of comparison: 1 Screening vs Usual care, outcome: 1.5 Psychological distress (3 months).

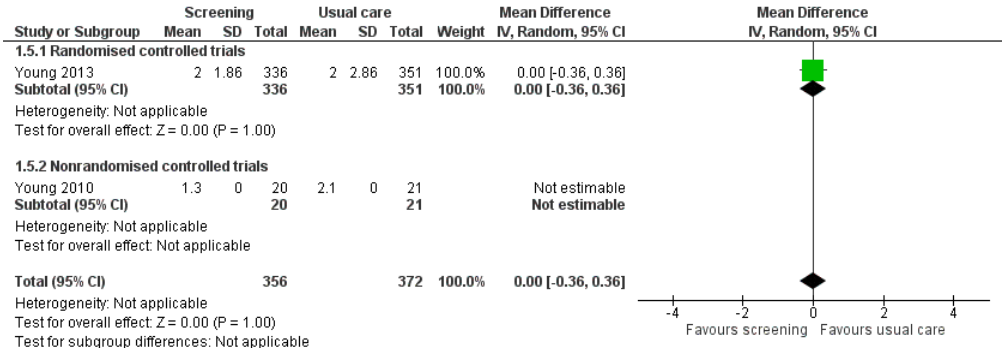


Figure 9 Analysis 1.5

Supportive care needs

The NRCT [228] included in the meta-analysis only reported SCNS sub scores, and could not be pooled with the other two studies. Supportive care needs, assessed 3 months after surgery with the SCNS, were reported as a global level of unmet needs in the two RCT [224, 229], and this level did not differ between screening and usual care, with a MD of 2.32 (95%CI -7.49 to 12.14; p=0.64; 2 trials; 748 participants – Analysis 1.6) (Figure 10). There was no important heterogeneity (I^2 = 0%). At 6 months this global level of unmet needs was

measured with the CaSUN in the pilot RCT [224] and with the SCNS in the multi-center RCT [229], leading to a standardized MD of 0.00 (95%CI -0.22 to 0.22; p=0.99; 2 trials; 732 participants – Analysis 1.7) (Figure 11), without important heterogeneity between studies (I^2 = 19%).

Analysis 1.6. Forest plot of comparison: 1 Screening vs Usual care, outcome: 1.6 Supportive care needs: General unmet needs (3 months).

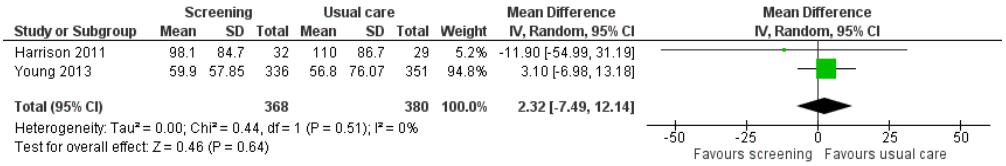


Figure 10 Analysis 1.6

Analysis 1.7. Forest plot of comparison: 1 Screening vs Usual care, outcome: 1.7 Supportive care needs: General unmet needs (6 months).

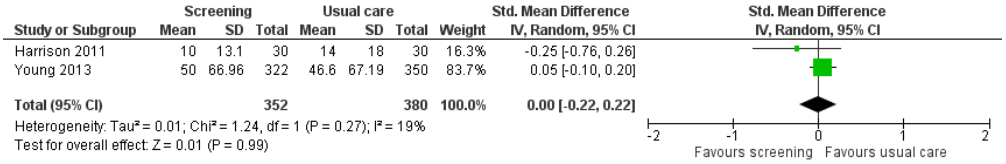


Figure 11 Analysis 1.7

Adverse events

None of the included studies specified adverse events as an outcome, no spontaneous findings on this were reported. However, evidence from the included NRCT [228] shows an unfavorable effect of the intervention on patients' care needs. At 3 months after surgery the intervention group had more unmet care needs in the domains of 'health and system information' (MD14.60; 95%CI 9.12 to 20.08; p= <0.001), and 'patient care and support' (MD9.00; 95%CI 4.09 to 13.91; p= 0.002)

Narrative description of further evidence

The evidence on the studied screening and assessment interventions of the remaining 21 studies is narratively described for all the outcomes of primary and secondary interest for this review (qualitative analysis).

Evidence on outcomes of primary interest

(HR)QOL

Of the 15 studies that focused on (HR)QOL, seven did not detect an effect from the screening intervention on patients' (HR)QOL [151, 221, 222, 223, 233, 236, 240]. Eight other studies did find evidence for negative and/or positive effects on one or more domains of (HR)QOL.

In the study of Braeken et al. (2013) [218] a negative effect was found for 'role functioning' (one of the five EORTC-QLQ-C30 functional scales).

No group difference was found by de Leeuw et al. (2013) [220] in the EORTC-QLQ-C30 and QLQ-H&N36 data at six and 12 months. Nevertheless, study authors claimed to have found a beneficial effect, since changes in time compared to baseline were significantly larger in the intervention group for three out of five functional scales ('physical functioning', 'role functioning', 'social functioning'), for 'global health status/QOL', for six out of nine symptom scales ('fatigue', 'nausea', 'vomiting', 'pain', 'dyspnea', 'appetite loss', 'constipation'), and nine out of 18 H&N scales ('pain', 'swallowing', 'senses, speech', 'social eating', 'opening mouth', 'coughing', 'use of nutritional supplements', 'weight loss') at six and 12 months. However, the intervention condition had significantly worse scores than the control condition at baseline, compromising comparability between groups.

Giesler et al. (2005) [230] found no evidence for effects with the SF-36. However, in the same study positive effects were detected with the PCQOL in one out of 10 domains at each time point: 'sexual functioning' at four months, 'sexual limitations' at seven months, and 'sexual limitations' and 'cancer worry' at 12 months.

A positive effect on 'physical functioning' was measured with the EORTC in the study of Hollingsworth (1 of the 5 EORTC functioning scales). With the EQ-5D-3L no evidence for effects was found.

The tests of group differences on the five EORTC functional scales at follow-up assessments were not significant in the study of Schofield et al. (2013) [226]. Yet, analysis of change scores indicated between group differences on the 'physical functioning scale' at T2, on 'social functioning' at T3, and on 'role functioning' at T3, in favor of the intervention condition.

Velikova et al. (2004) [237] observed positive effects of their screening intervention on the FACT-G total, and on three of four subscales: the physical, emotional, and functional well-being scales.

The EORTC-QLQ-C30 assessment in Bramsen et al. (2008) [219] revealed positive effects for the domain of 'role functioning' (1 out of 5 functioning scales) and 'pain' (1 out of 9 symptom scales) at four weeks post baseline.

Williams et al. (2013) [234] detected a positive effect on (HR)QOL measured with the HRQOL-LASA after four months.

For detailed information we refer to the Evidence Summary (Appendix 7.8).

Distress

In 10 of the 12 studies that included distress as an outcome measure no effect of the intervention on this outcome was detected [151, 218, 222, 225, 230, 231, 233, 235, 238, 240].

At four weeks post baseline Bramsen et al. (2008) [219] found a significant higher score in the intervention condition on the 'positive subscale' of the GHQ-12. No difference in score was found for the 'negative subscale' or the GHQ Total score.

There were no significant group differences on the HADS-Total and DT at follow-up assessments in the study of Schofield et al. (2013) [226]. However, change score analysis indicated better scores for the intervention condition at T2 in both measures.

For detailed information we refer to the Evidence Summary (Appendix 7.8).

Care needs

Of the 4 studies that assessed care needs as an outcome, one did not present any data on this outcome [240], and the remaining three studies detected positive or negative effects of the screening intervention they studied.

The study of Thewes et al (2009) [227] revealed negative effects, since the intervention group reported higher levels of 'overall unmet needs', and of 'psychological needs', 'information needs', and 'physical and daily living needs'(3 out of 5 SCNS-SF scales) compared to the control group after 6 months.
With the same outcome measure Waller et al. (2012) [151] found a positive effect of their intervention in terms of a lower proportion of patients scoring at least one moderate or high need on two out of five subscales: 'health system and information needs', and 'patient care and support needs' after approximately six months of follow-up.
In the study of Schofield et al. (2013) [226] change score analysis of the NA-ALCP data indicated a relative benefit from the intervention for unmet 'symptom needs' at eight and 12 weeks post-assessment (1 out of 6 subscales).
For detailed information we refer to the Evidence Summary (Appendix 7.8).

Adverse events
None of the included studies specified adverse events as an outcome, no spontaneous findings on this were reported. However, evidence from three of the included studies shows an unfavorable effect of the intervention on certain components of (HR)QOL [218], patients' care needs [227], and patients' satisfaction [232].

Evidence on outcomes of secondary interest
Satisfaction
No evidence for an effect of the screening interventions on patients' satisfaction was found in eight of the 10 studies that focused on this outcome [218, 222, 223, 233, 235, 237, 239, 240]. The two remaining studies showed positive or negative effects.
With the PSQ Detmar et al. (2002) [221] detected more 'satisfaction with emotional support received' in the intervention group at the fourth follow-up visit (1 out of 5 domains).
Compared to the control group, the intervention group in the study of Kutner experienced significantly lower levels of 'satisfaction on time spend with the physician', and 'satisfaction on physicians' explanation what was done for the

patient' (The five item Medical Outcomes Study Patient Visit Rating Questionnaire).
For detailed information we refer to the Evidence Summary (Appendix 7.8).

Psychosocial well-being
For other concepts of psychosocial well-being addressed in the included studies, namely marital well-being [230, 238], health and activity limitation [238], impact of stressful life events [219], and psychosocial adjustment [220], no effects of the screening interventions were found.
For detailed information we refer to the Evidence Summary (Appendix 7.8).

Intervention effects and intervention characteristics
From the included studies that found any positive effect of the systematic screening or assessment intervention on one or more of the outcomes of interest in this review (n=9):

- (HR)QOL, distress, care needs, psychosocial problems, and overall well-being was the focus of the screening intervention for three, two, three, one and two of these studies, respectively;
- five had an interventionist for the screening intervention, four worked with patients' completion of a PROM;
- four studied a solitary screening intervention, and five studied the effect of a screening intervention coupled with a co-intervention to use the screening results;
- seven provided training for screening interventionists and/or clinic staff to work interpret or work with the screening results, two did not;
- four were RCT, five were NRCT.

From the included studies that found any negative effect of the systematic screening or assessment intervention on one or more of the outcomes of interest in this review (n=4):

- distress, care needs, and psychosocial problems was the focus in the screening intervention for one, two, and one of these studies respectively;

- one had an interventionist for the screening intervention, three worked with patients' completion of a PROM;
- three studied a solitary screening intervention, and one studied the effect of a screening intervention coupled with a co-intervention to use the screening results;
- three provided training for screening interventionists and/or clinic staff to work interpret or work with the screening results, one did not;
- two were RCT, two were NRCT.

DISCUSSION

Summary of main results

The objective of this review was to assess the effect of screening and assessment of psychosocial well-being and care needs on the well-being of people with cancer. We found 24 studies that were eligible for inclusion in the review, of which 16 RCT and eight NRCT. Five outcomes falling within the scope of this review ((HR)QOL, distress, needs, satisfaction, psychosocial well-being) were addressed in several studies. However, there was considerable heterogeneity in intervention characteristics, measures and time points for outcome assessment. Only three studies could be included in a meta-analysis, and their pooled estimates did not find evidence for the effectiveness of screening and assessment of psychosocial well-being and care needs in cancer patients. The results of the 21 individual studies not suitable for meta-analysis varied (Evidence Summary - Appendix 7.8). Some study authors spoke of clinical significance, however, no statistically significant effects of the screening and assessment interventions were found in 11 studies. The results of 10 studies suggest beneficial effects of screening of cancer patients' psychosocial well-being and care needs on their well-being. Importantly, although none of the studies reported adverse events, four studies reported negative effects of screening such as decreased (HR)QOL, more unmet care needs, and lower patient satisfaction. Five RCT were judged to have low risk of bias. For the remaining studies the risk of bias was judged to be 'high', 'serious' or 'critical',

or there was insufficient information to judge the methodological quality of the study. This undermines the reliability of the results.

Consequently, the evidence found with this review does not support the effectiveness of the studied screening interventions.

Rather than simply asking 'Are psychosocial screening and assessment interventions effective?', we had the objective to identify the circumstances in which these interventions were effective. However, we could not detect systematic consistency of intervention characteristics and intervention results. Also the study designs did not seem to coincide with the evidence found.

Overall completeness and applicability of evidence

Our broad search led to the inclusion of a wide variation of screening interventions, populations and outcomes. Overall, limited indications for positive effects were found.

Firstly, this could mean that the used interventions were not effective. Several reasons could be considered for this. In several studies the adherence to the intervention protocol was verified, in the other studies this did not seem to be the case. Were all interventions performed as intended? Where in all included studies intervention conditions were compared to a usual care condition without any form of psychosocial screening, it often was not clear what 'usual care' implied. There can be a wide variation of 'usual care' in clinical practice. The question arises to what extent the intervention yielded more to psychosocial focus and care actions than already applied in the routine care of the study settings.

Secondly, it could also mean that the interventions need to be targeted to risk populations for experiencing elevated levels of distress or needs. We believe that the results of this review could be a correct reflection of the effectiveness of psychosocial screening interventions in the general population of cancer patients. The included studies recruited newly diagnosed and advanced cancer patients, patients undergoing surgery, chemotherapy, and radiation, or one recruited patients with a specific type of cancer. However, earlier studies demonstrated that patients that were younger, single, female, and patients that had a worse clinical status, lower QOL and socio economic status relatively experienced higher levels of distress and care needs [22, 104, 200, 244, 245,

246]. Application of the studied screening and assessment interventions in these risk populations may provide more insight into the effectiveness of the intervention. This could clarify why de Leeuw et al. (2013) [220] did not found significant difference between both conditions in the mean outcome scores at six and 12 months, but, on the other hand, noted that the change score from baseline was significantly higher for the intervention group: patients in the intervention group initially had a worse clinical status at baseline. We see that only Kutner et al. (1999) [232] recruited a relative young sample of participants (mean 42years). However, no positive effect of the intervention was found in this study. In all the other included studies the mean age was above 50 years, for the majority even above 60 years. Several of the other 'risk characteristics' appear in the description of the study samples, however no subgroup analyses were conducted to study the effect of the intervention in the subgroups of younger females, singles, patients with lower SES,…

Thirdly, it could also mean that the appropriateness of outcome measures (subjective) should be reconsidered. As stated earlier, the use of subjective outcomes can introduce bias. Therefore, it could be valuable to include objective outcomes in the study, in addition to the subjective outcomes. In 11 of the included studies this was done in terms of number and/or types of referral [218, 219], patient-professional communication content and/or length [221, 237, 239], information on psychosocial well-being in patient file [221, 223, 239], healthcare professionals' awareness of the patient's well-being [221, 223], and health service utilization [224, 229, 235, 236, 238]. In several studies evidence was found for a beneficial effect of psychosocial screening on one or more of these aspects [219, 221, 223, 238, 239].

Quality of the evidence

We identified 24 studies with a total of 6532 participants. Due to the nature of the studied intervention blinding of patients was difficult, and the effect of the interventions on subjective outcomes was explored. Both are sensitive to response bias, and so all studies were prone to bias because of this aspect. Another key domain of quality weakness in RCT as well as NRCT was 'bias due to missing data' (>40% of the studies) (Figure 4). In RCT there was a lot of

unclearity on 'selection bias' (>40% of the studies), and for 50% of the NRCT the 'bias due to deviations from intended intervention' was unclear.

Based on the criteria set, only five included studies (RCT) were labelled as 'low risk study' [222, 224, 226, 229, 235]. Six RCT were labelled as 'high risk study' [225, 231, 232, 236, 237, 240], six NRCT as 'serious risk study' [219, 220, 223, 227, 228, 234], and one NRCT as 'critical risk study' [151]. For five RCT [218, 221, 230, 233, 236, 238] and one NRCT [239] there was not enough information to give an overall risk of bias judgement. Consequently, we can state that a slight majority of the studies included in this review (13/24) was of low methodological quality. The results from the five studies with low risk of bias do not provide convincing evidence to support the beneficial value of screening and assessment of cancer patients' psychosocial well-being and care needs on their well-being.

Potential biases in the review process

We conducted a thorough search for this review, in sources of published and unpublished studies, reducing the chance of publication bias. Also a wide range of terms to define psychosocial well-being or distress in the search was used to prevent missing relevant studies.

For the screening of database records one author (BS) screened all records, and was doubled by five other screeners (AVH, BA, GB, JM, PV) for different numbers of records. That not all records were screened by the same two authors could have caused bias, however was necessary because of the large number of database records that needed to be screened. The review authors that were involved in the screening of records often had contact to assure that they were mutually well-tuned with regard of the inclusion and exclusion criteria, in order to limit the risk of bias.

We contacted study authors multiple times in the title-abstract-screening phase for extra information or full texts, to decide on eligibility of studies. In the phase of data-collection we approached study authors multiple times to request additional data where necessary. In this way, for most studies we obtained all the information needed to study them in this review.

The quality of included studies was assessed with the risk of bias tool for RCT [211], and with the ROBINS-I for NRCT [216], both Cochrane tools. The latter

was recommended by the Cochrane review group, and gave the opportunity to assess NRCT' quality in a nuanced way with 'low risk', 'moderate risk', 'serious risk', 'critical risk' and 'no information', in comparison with the 'low', 'high' and 'unclear' rating of the risk of bias tool for RCT. However, we noticed that by following the ROBINS-I strictly, NRCT were assessed more stringently then RCT with Cochrane's standard risk of bias tool [211] (e.g. a RCT did not fulfil the 'high-risk' criteria of the tool and so received a 'low risk' or positive rating, while a NRCT with similar characteristics fulfilled the 'moderate-risk' criteria of the ROBINS-I and so received a more negative rating). Potentially, this has led to bias in the quality judgements of the included studies. We received permission to combine studies with RCT and NRCT design in this review. However, to make general conclusions it should be possible to generate comparable quality evaluations with both Cochrane tools.

Originally, we wanted to study the effect of screening and assessment of psychosocial well-being and care needs on the well-being of cancer patients and on quality of care (measures with care aspects like: referral; consultation length; discussion of problems;…). As this would have resulted in a complex variation of outcomes, we decided to narrow the scope to patients psychosocial well-being. On second thought, it may have been more interesting to work with the double scope, since this would have entailed subjective as well as objective outcomes, of which the latter are not prone to reporting bias.

Agreements and disagreements with other studies or reviews

Prior to our work, several other reviews already studied the effectiveness of screening for distress and care needs on cancer patients outcomes [46, 187, 198, 247, 248]. In contrast to these reviews, our search was more thorough, consulting more sources to find eligible studies in the published as well as the grey literature [46, 198]. We included RCT as well as NRCT based on the belief that RCT are often not available to address questions about the effects of health system interventions and implementation strategies, due to the nature of the field [201], while three other reviews only focused on RCT [187, 198, 248]. We believe that these differences, and the fact that our review was undertaken three to seven years later, resulted in finding more studies eligible for inclusion

in the review. In the current review, we included 24 studies, where Lucket (2009)[248], Bidsdrup (2011)[198], Carlson (2012)[46], Howell (2012)[247] and Meijer (2013)[187] included six, seven, 14, 14 and one, respectively. However, the latter was criticized for its rationale and methodology [249, 250], resulting in very narrow inclusion criteria that enabled them to include relevant studies to answer their research questions.

To confine the heterogeneity in included studies we only included studies with a real usual care condition without screening. This was in contrast to four other reviews [46, 198, 247, 248] that included studies with a control group that underwent screening without the screening results being shared with physicians or nurses (e.g. Boyes (2006)[251]; Carlson (2010)[113]; Grassi (2011)[252]; McLachlan (2001)[253]; Sarna (1998)[254]). In our opinion these studies explored evidence on the effect of making screening results available to care professionals, and not on the effect of the screening on its own.

In previous reviews it was concluded that, due to the lack of unambiguous evidence, it was impossible to draw conclusions on the effect of systematic screening and assessment of psychosocial well-being and care needs in cancer care. Bidsdrup et al. (2001)[198] stated "We find it too early to conclude whether psychological screening improves the psychological well-being of cancer patients". However, now, six years later the evidence is moving into the direction of 'no effect'.

AUTHORS' CONCLUSIONS

Implications for practice

During the last decade several calls have been launched to stimulate the design of psychosocial screening programs in clinical practice, and -to support this- consensus-based guidelines were written [46, 247, 248]. With these guidelines one sought to meet several questions from clinical practice: 'What should be the exact content of the screening or assessment?', 'What tool should be used?', 'What are the appropriate timing and frequency of assessments?', 'Who should conduct these interventions?'. With this review we not only attempted to explore the effect of the interventions. Additionally, we set the objective to add

evidence-based input to the earlier formulated consensus-based recommendations on intervention characteristics which showed consistency with the effectiveness of the screening interventions. Although some of the included studies suggested some benefits of systematic screening (for (HR)QOL, distress, care needs, patients' satisfaction, and psychosocial well-being), some other studies reported no or negative effects. Based on the results of this review, screening of cancer patients' psychosocial well-being and care needs in general does not seem to be meaningful for patients' well-being. Possibly, attention should be paid to more specific forms of screening in risk populations, or by certain healthcare disciplines. Likewise, we did not find any systematic patterns of cohesion between individual study effects and intervention characteristics. Therefore, on the basis of the evidence found, it is difficult to state which intervention elements and characteristics should be used in the development of these interventions. Further research is needed to support the guidelines and recommendations for clinical practice with evidence-based data.

Implications for research

The results of this review plea for more uniformity in outcomes and reporting, for the use of intervention description guidelines, for further improvement of methodological quality in studies, and for combining subjective PRO outcomes with objective outcomes.

We advise researchers to use validated, internationally frequently used tools such as the EORTC-QLQ-C30, SF-36, FACT-G, GHQ-12, HADS, DT, SCNS, and PSQ to measure patients' psychosocial well-being, care needs, and satisfaction. In recent years, there has been pleading for the development of core outcome sets (COS). These are agreed standardized collections of outcomes that should be measured and reported in all trials within a specific field of research [255]. The development, and use of COS could reduce heterogeneity in outcomes.

As well, it is important that study authors clearly describe the intervention content, tools, procedure, and conditions for implementation, so that other researcher could construct and study comparable interventions in other patient populations. This way homogeneity can be pursued, and meta-analysis could be possible in the future. For example, the TIDieR [256], and the CReDECI 2-guidelines [213] were developed to support this.

Although improvement is already being seen, we believe further efforts should be made to improve the methodological quality of studies, to reduce the risk of bias and obtain more reliable and less ambiguous evidence. This review provides several points of attention for this purpose. We believe that well developed RCT as well as NRCT can have a valuable role in future research on the effectiveness of screening and assessment of psychosocial well-being and care needs in cancer patients.

Finally, we recommend for future studies to include the subjective PROM together with more objective outcomes, such as biomedical indicators of distress, or care outcomes to detect possible effects in care processes. The latter are less prone to response bias, and care outcomes have shown promising results in several studies [219, 221, 223, 238, 239]. At the same time, the use of PROM ensures that insights from patient-perspective are obtained, which is of great importance to support the patient-centered approach in care and research [257].

The evidence of the studies that took place so far did not result in conclusive evidence on the effect of the studied intervention, but suggest the absence of a general intervention effect. We think that future studies in this field should focus on patients that belong to risk populations for experiencing increased levels of distress and care needs (e.g. younger, single, female, worse clinical status, lower QOL, lower socio economic status). In this way, it can be studied whether the intervention may have an effect in vulnerable subgroups.

As well, we wonder why some of the interventions in the included studies resulted in negative effects on patients (HR)QOL, care needs and satisfaction. No explanation for this could be found in the intervention characteristics. Possibly, the intervention makes some patients more dependent, resulting in an increased expression of problems and care needs. In future studies, more attention needs to be paid to the 'how' and 'why' of negative intervention effects in case they occur.

ACKNOWLEDGEMENTS

This review is part of a PhD funded by Limburg Sterk Merk (LSM). We are grateful to Elke van Hoof for her contribution to the review protocol, and thank Nick Van Campenhout for his practical support in the screening of IPOS-conference abstracts. We would like to thank Noémie Aubert-Bonn for her linguistic advice, and the Cochrane Gynaecological, Neuro-oncology and Orphan Cancers for their support and guidance in conducting this review.

This project was supported by the National Institute for Health Research, via infrastructure funding to Cochrane Gynaecological, Neuro-oncology and Orphan Cancers. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

CONTRIBUTIONS OF AUTHORS

- Conceptualizing the topic for the review: BS, AVH, JH, and PV.
- Coordinating the review: BS.
- Development of search strategies: BS and AVH.
- Undertaking searches: BS.
- Screening search results: BS paired by AVH, BA, GB, JM and PV.
- Contacting study authors for retrieving papers or additional information: BS and BA.
- Screening retrieved papers and data against eligibility criteria: BS, AVH, BA.
- Data collection of included studies: BS, AVH and BA.
- Quality assessments of included studies: BS, AVH and BA.
- Entering data into Review Manager: BS and BA.
- Evidence collection and meta-analysis: BA.
- Narrative analysis: BS.
- Results discussion: BS, BA, AVH, GB, PV.
- Providing a methodological perspective: BA, GB, AVH.
- Providing a clinical perspective: PV, JM.

- Providing a policy perspective: JH.
- Drafting the review text: BS.
- Editing the review text: BS, BA, AVH
- Reviewing the review text: PV, JM, JH.

DECLARATIONS OF INTEREST

All authors have none to declare.

DIFFERENCES BETWEEN PROTOCOL & REVIEW

DT out of search strategy

Protocol: The abbreviation for the distress tool Distress Thermometer (DT) was included in the MEDLINE search strategy published in the Cochrane Protocol.

Review: The abbreviation for distress thermometer (DT) was not used as a search term in the search strategy for the databases.

Explanation: When the search in Embase was conducted , we noticed that in a large number of records 'DT' was not used as an abbreviation of 'distress thermometer', but of something not related to our review. Following the advice of the Cochrane Gynaecological, Neuro-oncology and Orphan Cancers Review Group, we did not include 'DT' in our search strategy at the time the review was conducted.

Outcome (HR)QOL

Protocol: We specified QOL and HRQOL as separate primary outcomes.

Review: We addressed both in one outcome, namely (HR)QOL).

Explanation: In the included studies, both terms were used by each other alternately, even when the same outcome instruments were used. We chose to take them together in one outcome.

Time span studied

Protocol: We described that we would include records up to the end of 2015.

Review: we included records up to the end of 2016.

Explanation: Due to the length of time passed over the submission, review, revision and acceptance of our Cochrane Protocol, it was possible to add an additional year to the search.

Management database records

Protocol: We planned to import and screen all database records in Endote X6.

Review: We imported and screened all database records in Covidence.

Explanation: Covidence was introduced to Cochrane members as a new and promising tool that would facilitate screening and data extraction. Covidence was chosen, considering that we would be screening with multiple review authors at the same time, and with Covidence a good overview could be maintained.

More than two screeners

Protocol: We described that all the screening work would be done by the two same screeners (BS and AVH).

Review: Six review authors were involved in the Title & Abstract-screening of database records. BS screened all records, and was doubled for different numbers of records by a second independent screener (AVH, BA, TB, JM, PV).

Explanation: Because of the large number of database records it was not possible for AVH to screen all records, so more review authors were involved in this phase of screening.

More than two data extractors

Protocol: We described that all the data extraction would be done by the two same authors (BS and AVH).

Review: Three review authors were involved in the activities of data extraction and management (BS, AVH, BA).

Explanation: Compared to the Cochrane Protocol, an extra review author was involved (BA). He participated in data extraction and management.

Dropout rates calculation

Protocol: We had no specific plan to compute the dropout rates for all included studies.

Review: We computed the dropout rates for all included studies.

Explanation: The dropout rates were important in estimating the extent of missing data in the studies, and so these were computed. Based on the literature a dropout of 15% was set as cut-off to distinguish between low (≤15%) and high dropout (>15%).

Appendix 7.1.

Search strategy MEDLINE (Ovid)

1. exp Neoplasms/
2. (cancer* or tumor* or tumour* or neoplas* or carcinoma* or adenocarcinoma* or malignan* or oncolog* or psycho-oncolog*).mp.
3. 1 or 2
4. "Quality of Life"/
5. exp Health Status/
6. Stress, Psychological/
7. exp Adaptation, Psychological/
8. exp Anxiety/
9. Depression/
10. Social Support/
11. (quality of life or QOL or HQOL or HRQOL).mp.
12. (cope or coping).mp.
13. (social support or care need*).mp.
14. ((psychosocial or psycho-social or psychological or social or emotion* or cogniti* or marital or relational or sexual or financial or spiritual or famil*) adj5 (wellbeing or well-being or difficult* or function* or dysfunction*)).mp.
15. (health adj status).mp.
16. (distress* or stress* or anxiety or anxious* or depress*).mp.
17. ((psychiat* or adjustment) adj5 disorder).mp.
18. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. "Outcome Assessment (Health Care)"/
20. patient outcome assessment/
21. (PROM or PRO).mp.
22. patient reported outcome*.mp.
23. interview/
24. Interview, Psychological/
25. exp Questionnaires/
26. (questionnaire* or interview*).mp.
27. ((psychosocial or psycho-social or psychological) adj5 (screen* or assess* or report* or survey* or scale* or instrument*)).mp.
28. exp Psychiatric status rating scales/
29. (systemat* adj5 assess*).mp.
30. Screen*.mp.
31. (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30).mp.
32. EORTC-QLQ-C30.mp.
33. (Short Form Health Survey or SF36).mp.
34. ((Hospital Anxiety and Depression Scale) or HADS).mp.
35. (Distress Thermometer).mp.
36. (Beck Depression Inventory or BDI).mp.
37. (Supportive Care Needs Survey or Cancer Survivors Unmet Needs or CaSUN).mp.
38. EORTC IN-PATSAT32.mp.
39. ((Patient Satisfaction and Quality in Oncological Care) or PASQOC).mp.
40. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39
41. 3 and 18 and 40
42. randomized controlled trial.pt.
43. controlled clinical trial.pt.
44. randomized.ab.
45. placebo.ab.
46. clinical trials as topic.sh.
47. randomly.ab.

48. trial.ti.
49. ((before-after or (before and after)) adj (study or studies)).mp.
50. (CBA adj (study or studies)).mp.
51. interrupted time series.mp.
52. (ITS adj (study or studies)).mp.
53. (repeated measure adj (study or studies)).mp.
54. ((RMS or rms) adj (study or studies)).mp.
55. (historical* control* adj5 (study or studies)).mp.
56. ((HCT or hct) adj (study or studies)).mp.
57. 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56
58. 41 and 57
59. exp animals/ not humans.sh.
60. 58 not 59

Search strategy CENTRAL

#1. MeSH descriptor: [Neoplasms] explode all trees
#2. cancer* or tumor* or tumour* or neoplas* or carcinoma* or adenocarcinoma* or malignan* or oncolog* or psycho-oncolog*
#3. #1 or #2
#4. MeSH descriptor: [Quality of Life] this term only
#5. MeSH descriptor: [Health Status] explode all trees
#6.MeSH descriptor: [Stress, Psychological] this term only
#7. MeSH descriptor: [Adaptation, Psychological] explode all trees
#8. MeSH descriptor: [Anxiety] explode all trees
#9. MeSH descriptor: [Depression] this term only
#10. MeSH descriptor: [Social Support] this term only
#11. quality of life or QOL or HQOL or HRQOL
#12. cope or coping
#13. social support or care need*
#14. ((psychosocial or psycho-social or psychological or social or emotion* or cogniti* or marital or relational or sexual or financial or spiritual or famil*) near/5 (wellbeing or well-being or difficult* or function* or dysfunction*))
#15. health near/2 status
#16. distress* or stress* or anxiety or anxious* or depress*
#17. ((psychiat* or adjustment) near/5 disorder)
#18. #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17
#19. MeSH descriptor: [Outcome Assessment (Health Care)] this term only
#20. MeSH descriptor: [Patient Outcome Assessment] this term only
#21. PROM or PRO
#22. patient reported outcome*
#23. MeSH descriptor: [Interview] this term only
#24. MeSH descriptor: [Interview, Psychological] this term only
#25. MeSH descriptor: [Surveys and Questionnaires] explode all trees
#26. questionnaire* or interview*
#27. ((psychosocial or psycho-social or psychological) near/5 (screen* or assess* or report* or survey* or scale* or instrument*))
#28. MeSH descriptor: [Psychiatric Status Rating Scales] explode all trees
#29. systemat* near/5 assess*
#30. Screen*
#31. European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30
#32. EORTC-QLQ-C30
#33. Short Form Health Survey or SF36
#34. ((Hospital Anxiety and Depression Scale) or HADS)
#35. (Distress Thermometer)

#36. (Beck Depression Inventory or BDI)
#37. (Supportive Care Needs Survey or Cancer Survivors Unmet Needs or CaSUN)
#38. EORTC IN-PATSAT32
#39. ((Patient Satisfaction and Quality in Oncological Care) or PASQOC)
#40. #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39
#41. #3 and #18 and #40

Search strategy Embase (Ovid)

1. exp neoplasm/
2. (cancer* or tumor* or tumour* or neoplas* or carcinoma* or adenocarcinoma* or malignan* or oncolog* or psycho-oncolog*).mp.
3. 1 or 2
4. "quality of life"/
5. exp health status/
6. mental stress/
7. exp adaptive behavior/
8. exp anxiety/
9. depression/
10. social support/
11. (quality of life or QOL or HQOL or HRQOL).mp.
12. (cope or coping).mp.
13. (social support or care need*).mp.
14. ((psychosocial or psycho-social or psychological or social or emotion* or cogniti* or marital or relational or sexual or financial or spiritual or famil*) adj5 (wellbeing or well-being or difficult* or function* or dysfunction*)).mp.
15. (health adj status).mp.
16. (distress* or stress* or anxiety or anxious* or depress*).mp.
17. ((psychiat* or adjustment) adj5 disorder).mp.
18. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. outcome assessment/
20. patient outcome assessment.mp.
21. (PROM or PRO).mp.
22. patient reported outcome*.mp.
23. interview/
24. psychologic test/
25. exp questionnaire/
26. (questionnaire* or interview*).mp.
27. ((psychosocial or psycho-social or psychological) adj5 (screen* or assess* or report* or survey* or scale* or instrument*)).mp.
28. exp psychological rating scale/
29. (systemat* adj5 assess*).mp.
30. Screen*.mp.
31. (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30).mp.
32. EORTC-QLQ-C30.mp.
33. (Short Form Health Survey or SF36).mp.
34. ((Hospital Anxiety and Depression Scale) or HADS).mp.
35. Distress Thermometer.mp.
36. (Beck Depression Inventory or BDI).mp.
37. (Supportive Care Needs Survey or Cancer Survivors Unmet Needs or CaSUN).mp.
38. EORTC IN-PATSAT32.mp.
39. ((Patient Satisfaction and Quality in Oncological Care) or PASQOC).mp.
40. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39
41. 3 and 18 and 40

42. crossover procedure/
43. double-blind procedure/
44. randomized controlled trial/
45. single-blind procedure/
46. random*.mp.
47. factorial*.mp.
48. (crossover* or cross over* or cross-over*).mp.
49. placebo*.mp.
50. (double* adj blind*).mp.
51. (singl* adj blind*).mp.
52. assign*.mp.
53. allocat*.mp.
54. volunteer*.mp.
55. ((before-after or (before and after)) adj (study or studies)).mp.
56. (CBA adj (study or studies)).mp.
57. interrupted time series.mp.
58. (ITS adj (study or studies)).mp.
59. (repeated measure adj (study or studies)).mp.
60. ((RMS or rms) adj (study or studies)).mp.
61. (historical* control* adj5 (study or studies)).mp.
62. ((HCT or hct) adj (study or studies)).mp.
63. 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62
64. 41 and 63
65. (exp Animal/ or Nonhuman/ or exp Animal Experiment/) not Human/
66. 64 not 65
67. limit 66 to embase

Search strategy PsycInfo (Ovid)

1	exp Neoplasms/
2	(cancer* or tumor* or tumour* or neoplas* or carcinoma* or adenocarcinoma* or malignan* or oncolog* or psycho-oncolog*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
3	1 or 2
4	"Quality of Life"/
5	Well Being/
6	Psychological Stress/
7	Psychosocial Rehabilitation/
8	Psychosocial Readjustment/
9	exp Anxiety/
10	"Depression (Emotion)"/
11	Distress/
12	Stress/
13	Social Stress/
14	Social Support/
15	Needs/
16	Health Service Needs/

17	Psychological Needs/
18	(quality of life or QOL or HQOL).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
19	(cope or coping).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
20	(social support or care need*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
21	((psychosocial or psycho-social or psychological or social or emotion* or cogniti* or marital or relational or sexual or financial or spiritual or famil*) adj5 (wellbeing or well-being or difficult* or function* or dysfunction*)).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
22	(distress* or stress* or anxiety or anxious* or depress*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
23	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
24	exp Measurement/
25	exp Screening/
26	(PROM or PRO).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
27	patient reported outcome*.mp.
28	Interviews/
29	exp Questionnaires/
30	(questionnaire* or interview*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
31	((psychosocial or psycho-social or psychological) adj5 (screen* or assess* or report* or survey* or scale* or instrument*)).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
32	((European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30) or EORTC-QLQ-C30).mp.
33	((Short Form Health Survey) or SF36).mp.
34	((Hospital Anxiety and Depression Scale) or HADS).mp.
35	(Distress Thermometer).mp.
36	((Beck Depression Inventory) or BDI).mp.
37	((Supportive Care Needs Survey or SCNS or Cancer Survivors Unmet Needs) or CaSUN).mp.
38	EORTC IN-PATSAT32.mp.
39	((Patient Satisfaction and Quality in Oncological Care) or PASQOC).mp.
40	24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 r 35 or 36 or 37 or 38 or 39
41	3 and 23 and 40
42	randomized controlled trial.mp.
43	controlled clinical trial.mp.
44	randomized.ab.
45	randomized.ab.
46	placebo.ab.
47	exp Clinical Trials/
48	randomly.ab.

49	trial.ti.
50	((before-after or (before and after)) adj (study or studies)).mp.
51	(CBA adj (study or studies)).mp.
52	interrupted time series.mp.
53	(ITS adj (study or studies)).mp.
54	(repeated measure adj (study or studies)).mp.
55	42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53
56	41 and 54
57	limit 56 to human

Search strategy CINAHL (EBSCO)

S56	S54 not S55
S55	(MH "Animals") not (MH "Human")
S54	S39 and S53
S53	S40 or S41 or S42 or S43 or S44 or S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52
S52	(repeated measure N (study or studies))
S51	(ITS N (study or studies))
S50	"interrupted time series"
S49	(CBA N (study or studies))
S48	((before-after or (before and after)) N (study or studies))
S47	TI trial
S46	AB randomly
S45	AB placebo
S44	AB randomized
S43	"controlled clinical trial"
S42	"randomized controlled trial"
S41	(MH "Clinical Trials+")
S40	(MH "Randomized Controlled Trials")
S39	S7 and S21 and S38
S38	S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34 or S35 or S36 or S37

S37	((European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30) or EORTC-QLQ-C30)
S36	((Short Form Health Survey) or SF36)
S35	((Hospital Anxiety and Depression Scale) or HADS)
S34	(Distress Thermometer)
S33	((Beck Depression Inventory) or BDI)
S32	((Supportive Care Needs Survey) or SCNS) or ((Cancer Survivors Unmet Needs) or CaSUN)
S31	EORTC IN-PATSAT32
S30	((Patient Satisfaction and Quality in Oncological Care) or PASQOC)
S29	((psychosocial or psycho-social or psychological) N5 (screen* or assess* or report* or survey* or scale* or instrument*))
S28	(questionnaire* or interview*)
S27	(MH "Questionnaires+")
S26	(MH "Interviews")
S25	"patient reported outcome*"
S24	(PROM or PRO)
S23	(MH "Outcome Assessment")
S22	(MH "Needs Assessment")
S21	S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20
S20	(distress* or stress* or anxiety or anxious* or depress*)
S19	((psychosocial or psycho-social or psychological or social or emotion* or cogniti* or marital or relational or sexual or financial or spiritual or famil*) N5 (wellbeing or well-being or difficult* or function* or dysfunction*))
S18	(social support or care need*)
S17	(cope or coping)
S16	(quality of life or QOL or HQOL)
S15	(MH "Information Needs")
S14	(MH "Health Services Needs and Demand")
S13	(MH "Social Support (Iowa NOC)")
S12	(MH "Support, Psychosocial")
S11	(MH "Depression")

S10	(MH "Anxiety+")
S9	(MH "Adaptation, Psychological") OR (MH "Psychosocial Adaptation (Iowa NOC)")
S8	(MH "Stress") or (MH "Stress, Psychological")
S7	S1 or S2 or S3 or S4 or S5 or S6
S6	(cancer* or tumor* or tumour* or neoplas* or carcinoma* or adenocarcinoma* or malignan* or oncolog* or psycho-oncolog*)
S5	(MH "Carcinoma")
S4	(MH "Oncologic Care")
S3	(MH "Cancer Patients")
S2	(MH "Oncology")
S1	(MH "Neoplasms+")

Appendix 7.2.

Search strategy Clinical Trials Gov.

Accessed true: https://clinicaltrials.gov/
Search with indication of conditions:

- Study type: Interventional Studies
- Condition: cancer
- Search terms: 'psychosocial', 'screening'

Search strategy ISRCTN registry

Accessed true: http://www.isrctn.com/
Search with advanced search-option:

- Within text search: ('distress' OR 'quality of life') AND ('screening' OR 'assessment')
- Condition: 'cancer'

Search strategy Nederlands Trial Register (NRT)

Accessed true: http://www.trialregister.nl/trialreg/index.asp
Several searches with individual terms (no combination possible in this register):
'Psychosocial', 'Distress', 'Quality of life', 'Screening'

Search strategy RePORTER querry tool

Accessed true: https://projectreporter.nih.gov/reporter.cfm
Search with advanced search-option:
'cancer' AND 'psychosocial' AND 'screening'

Search strategy UK National Research Register

Accessed true: http://www.journalslibrary.nihr.ac.uk/news/the-nihr-journals-library-one-year-on.
Search terms: 'cancer' AND 'psychosocial' AND 'screening'

Appendix 7.3

Data collection and quality assessment file

An Excel file with following subdivisions was used to collect data and assess methodological quality:

1. Study ID
- 1st Author
- Year

2. METHODS
- Study design
- Duration study
- Source

3. PARTICIPANTS
- Country
- Participants
- Setting
- Inclusion criteria
- Exclusion criteria

4. INTERVENTION
- Type Randomization
- Aim study
- Content Of Screen
- Interventionist
- Intervention
- Conditions Intervention Implementation
- Theoretical Basis
- Comparative Condition
- Protocol adherence
- Length follow-up

5. OUTCOMES
- Primary Outcome
- Secondary outcome
- Outcome time points

6. STUDY RESULTS
- Sample size
- Number analyzed
- Age
- Gender
- Results Primary Outcome
- Results Secondary Outcome

7. REVIEWERS CONCLUSION
- Our Primary Outcomes
- Our Secondary Outcomes

8a. QUALITY ASSESSMENT - RCT
- Funding info
- Conflicts of interest
- Sample Size Calculation
- Sequence Generation
- Allocation Concealment
- Blinding Patients & Staff
- Blinding Outcome Assessors
- Completeness Outcome data
- Reporting on outcome data
- Other sources of bias
- Overall RISK OF BIAS in study
- Notes

8b. QUALITY ASSESSMENT - NRCT
- Bias due to confounding
- Bias in selection of participants into the study
- Bias in classification of interventions
- Bias due to deviations from intended intervention
- Bias due to missing data
- Bias in measurement of outcomes
- Bias in selection of the reported result
- Overall RISK OF BIAS in study
- Notes

Appendix 7.4.

Table A7.4. Characteristics of included studies & risk of bias tables

[ordered by study ID]

Bergholdt 2013	
Methods	Cluster RCT - with intervention group (IG) and control group (CG).
Participants	Adult patients with cancer treated for incident cancer at the public regional hospital. *Country:* Denmark. *Age:* CG: mean 63.6years(62.5-64.6); IG: mean 63.2years(62.2-64.3). *Sex:* CG: 71.4% female; IG: 72.6% female. *Inclusion criteria:* 1) ≥18 years, 2) admitted to Vejle Hospital between 12 May 2008 and 28 February 2009, 3) newly diagnosed with cancer, 3) new cancer diagnosis within the previous 3 months, 4) listed with a general practice. *Exclusion criteria:* 1) Patients with carcinoma in situ or non-melanoma skin cancers. *N randomized:* Patients: N=955, IG: n=486, CG: n=469; GP: N=775; IG: n=377; CG: n=398. *N in analysis:* Patients-baseline: N=955; IG: n=486; CG: n=469; GP-baseline: /; Patients-6months: N=565; IG: n=273; CG: n=292; GP-6months: /; Patients-14months: N=318; IG: n=159; CG: n=159; GP: 14months: N=775; IG: n=377; CG: n=398.
Interventions	*Content of screen:* CARE NEEDS: Individual needs for physical, psychological, sexual, social, work-related and finance-related rehabilitation (interview guide based on information from studies on needs). *Interventionist:* Two RCs to conduct the needs assessment. (both nurses with oncological experience, assigned exclusively to the project and not taking part in the daily routines at the hospital ward). *Intervention procedure:* SI with co-intervention to use screening results: RC interviews patient about rehabilitation needs, then information about the patient's individual rehabilitation needs is send to the GP + the rehabilitation needs of patients with cancer in general, and GP is encouraged to proactively contact the patient to facilitate the rehabilitation process.. *Conditions for implementation*: 1) professionals needed who conduct the rehabilitation needs interviews and inform the GP; 2) An interview manual needed to facilitate the structured screening interview. *Comparative condition:* Usual care group. *Length of follow-up:* 14 months following admission to the hospital after new cancer diagnosis .
Outcomes	*Primary outcomes:* 1) General Health at 6 months (General Health –item EORTC-QLQ-C30) *Secondary outcomes:* 1) HRQOL at 6 and14 months (all items EORTC-QLQ-C30); 2) psychological distress (POMS-SF) at 14 months; 3) number of working days lost to sickness at 14 months; 4) patient satisfaction with the GP: (Dan-PEP) at 14 months; 5) evaluation of the GP's contribution to rehabilitation estimated at 14 months; 6) Locus of control (MHLC scale Form B); religious and spiritual beliefs: part of the FACIT-sp questionnaire at 14 months; 7) rehabilitation needs (somatic, psychological, social and occupational), and how and where these needs were addressed at 14 months; 8) satisfaction with the rehabilitation provided by the healthcare system in general and the GP in particular at 14 months; 9) social support at 14 months; 10) GP's satisfaction on own contribution in rehabilitation of the patient at 14 months. *Outcome time points:* 6 and 14 months after inclusion (= admission to the hospital after a new cancer diagnosis).
Notes	

Risk of bias table *(judged with RoB)*		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence	Low risk	Computerized random-number generator.

generation (selection bias)		
Allocation concealment (selection bias)	Unclear risk	Danish GP practices allocated to conditions, patients automatically allocated to condition of the GP. Unclear if the person that includes the patients is aware of the randomization condition of the GP/patient.
Blinding of participants and personnel (performance bias)	High risk	1) No blinding of RC that managed the intervention; 2) The staff at the involved departments of the hospital was informed about the study; 3) GP allocated to the control condition were not informed about the study.
Blinding of outcome assessment (detection bias)	Low risk	Validated self-report questionnaires were used for data-collection, "data were collected in the same way, irrespective of the allocation status". No extra person for outcome assessment aware of condition allocation.
Incomplete outcome data (attrition bias)	High risk	Drop-out from baseline to 12 months assessment at both patient (+/- 30%) and GP level(+/- 20%), drop-out in both conditions equally distributed.
Selective reporting (reporting bias)	High risk	There seems to be adequate reporting on every outcome except on 'patients rehabilitation needs' (outcome mentioned in protocol, not mentioned elsewhere).
Other bias	Low risk	Computerized random-number generator.

Braeken 2013	
Methods	Stratified cluster RCT - with intervention group (IG) and control group (CG).
Participants	Adult cancer patients receiving radiotherapy. *Country:* The Netherlands. *Age:* Patients: CG: mean 63.6years(62.5-64.6); IG: mean 63.2years(62.2-64.3); GP: CG: mean 53.3years (52.5-54.1); IG: mean 53.3years(52.4-54.1). *Sex:* Patients: CG: 71.4% female; IG: 72.6% female; GP: CG: 30.2% female; IG: 36.1% female. *Inclusion criteria:* 1) cancer type: lung, prostate, bladder, rectum, breast, cervix, skin, endometrium, Non-Hodgkin lymphoma; 2) age ≥ 18 yrs; 3) no metastases; 4) provide written informed consent. *Exclusion criteria:* 1) receiving palliative treatment; 2) have ≤10 fractions of RT; 3) unable to read and speak Dutch; 4) unable to complete the questionnaires (e.g. too sick). *N randomized:* N=568; IG: n=268 (n=136 with baseline assessment, n=132 without baseline assessment); CG: n=300 (n=144 with baseline assessment, n=156 without baseline assessment) *N in analysis:* 3 months: N=640 (IG: n=356, CG: n=284); 12 months: N=491 (IG: n=230, CG: n=261).
Interventions	*Content of screen:* PSYCHOSOCIAL PROBLEMS*:* tool=The Dutch SIPP: 24 items; physical complaints (n=7), psychological complaints (n=10), social/financial problems (n=4) and sexual problems (n=3). *Interventionist:* No interventionist for screening act (self-reported measure). *Intervention procedure:* solitary SI; patients received SIPP twice: before the first consultation with the radiotherapist and before the consultation at the end of the RT; radiotherapists checked the scores (manual provided with cut-off scores SIPP); SIPP + judgement radiotherapist -> referral for psychosocial support. *Conditions for implementation*: 1)A system/person is needed to deliver and collect questionnaires and to control data management; 2) Someone has to mail the follow-up measurements (at 3 and 12 months after baseline); 3) training of radiotherapists in using and interpreting the SIPP. *Comparative condition:* Usual care group. *Length of follow-up:* 12 months following the start of RT.
Outcomes	*Primary outcomes:* 1) Number and types of referrals of patients with psychosocial problems

	to psychosocial caregivers. *Secondary outcomes:* 1) Patients' satisfaction with radiotherapist-patient communication during the first consultation. 2)Psychosocial distress (HADS, GHQ-12); 3) (HR)QOL (EORTC-QOL-C30). *Outcome time points:* Baseline = start of RT (patients on odd weeks received a pre-measurement, patients on even weeks received no pre-measurement); 3 and 12 months post-baseline.
Notes	

Risk of bias table *(judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not clear what method was used to generate the sequence.
Allocation concealment (selection bias)	Unclear risk	Radiotherapists allocated to conditions, patients automatically allocated to condition of the radiotherapist. Unclear if the person that includes the patients is aware of the randomization condition of the radiotherapist/patient.
Blinding of participants and personnel (performance bias)	High risk	Single blinding: participants; radiotherapist: not blinded (note: asked not to discuss the study with their colleagues of the control group).
Blinding of outcome assessment (detection bias)	Low risk	Outcomes were collected with mailed questionnaires. No extra person for outcome assessment aware of condition allocation.
Incomplete outcome data (attrition bias)	Low risk	Drop-out of patients from baseline to 12 months assessment +/- 14%;, equally distributed between both conditions.
Selective reporting (reporting bias)	Low risk	The study protocol is not available but it is clear that the published reports include all expected outcomes.
Other bias	Low risk	/

Bramsen 2008

Methods	Sequential cohort study with repeated measures - first a control cohort (UCG), sequentially an experimental cohort (IG), a medical records control group from patients admitted to the department in the 4 months preceding the control cohort (MRCG).
Participants	Inpatients in department medical oncology. *Country:* The Netherlands. *Age:* IG: mean 53years(13.1sd); RealCG: mean 55years(9.9sd); MedicalRecordCG: mean 56years(14.1sd). *Sex:* IG: 54% female; RealCG: 43% female; MedicalRecordCG: 47% female. *Inclusion criteria:* 1) inpatient in the department medical oncology; 2) fist admission or readmission after > 24 months. *Exclusion criteria:* 1) extremely poor physical condition; ; 2) severe cognitive impairment; 3) not have basic fluency in Dutch language. *N recruited:* N =262; IG: n=109; RealCG: n=64; MedicalRecordCG: n=89. *N in analysis:* N =218; IG: n=79; RealCG: n=50; MedicalRecordCG: n=89.
Interventions	*Content of screen:* OVERALL WELL-BEING: Current overall situation of the patient, physical condition and treatment, emotional condition, social network and living circumstances, religion or philosophy of life, medical history, life events, personality and coping, history of psychosocial care, future perspective, any other issues. *Screenings interventionist:* A psychologist or social worker (intaker) conducted the semi-structured screening interview with the patient. *Intervention procedure:* Face-to-face psychosocial SI with co-intervention to use screening results: a semi-structured interview with a psychologist or social worker guided by a checklist, afterwards rating the presence of problems and needs on 4-point likert scale(no

	special attention needed, mild problems, problems that require attention, serious problems), need for follow-up contact discussed with patient, if follow-up requested conclusion summary placed in the medical patient record. *Conditions for implementation*: 1) Availability and competence of an intaker to conduct screening interviews. *Comparative condition:* 1) UCG: usual care without screening intervention; 2) MRCG: record data collection of period without screening intervention. *Length of follow-up:* 4 weeks following discharge of hospital.
Outcomes	*Primary outcomes:* 1) uptake of the face-to-face psychosocial screening intervention (interview); 2) referral for psychosocial care; 3) attrition from baseline to follow-up, 4) QOL at follow-up (EORTC-QOL-C30); 5) mental health at follow-up (GHQ-12); 6) emotional impact of the illness at follow-up (IES). *Secondary outcomes: /* *Outcome time points:* baseline (=discharge of hospital); 4 weeks post-baseline.
Notes	For bias judgement on NRCT we refer to the ROBINS-I tables in the 'Additional Tables-section'.

***Risk of bias table** (judged with ROBINS-I)*

Bias	Authors' judgement	Support for judgement
Bias due to confounding	SERIOUS RISK	Confounding possible, QOL scores at baseline differ a lot between conditions.
Bias in selection of participants into the study	LOW RISK	The study employed a sequential cohort design with an initial cohort consecutive patients that formed the control group with usual care, and after a 'wash out' period of 5 months the cohort of the experimental arm was recruited.
Bias in classification of interventions	LOW RISK	The classification of interventions is clear.
Bias due to deviations from intended intervention	NO INFORMATION	There were no deviations in the screening interview intervention mentioned.
Bias due to missing data	SERIOUS RISK	Drop-out of patients from baseline to 12 months assessment +/- 22%; non-responses evenly distributed between both conditions. It is unclear on what number of participants the analysis for each outcome is based.
Bias in measurement of outcomes	MODERATE RISK	Validated PRO's are used to measure the subjective outcomes in both conditions. No extra person for outcome assessment aware of condition allocation.
Bias in selection of the reported result	LOW RISK	The outcome measurements and analyses are clearly defined and there is no indication of selection of the reported analysis from among multiple analyses; no indication of selection of the cohort or subgroups for analysis and reporting on the basis of the results.
OVERALL RISK OF BIAS	*SERIOUS RISK study*	

de Leeuw 2013

Methods	Quasi-experimental prospective single-center study - with intervention group (IG) and control group (CG).
Participants	Head and neck cancer patients. *Country:* The Netherlands. *Age:* IG: mean 58.4years(22-86); CG: mean 59.2years(30-83). *Sex:* IG: 32.5% female; CG: 25% female. *Inclusion criteria:* 1) HNC diagnosis (but no other cancer); 2) treated with curative intent; 3) able to speak, write and understand Dutch; 4) cognitively able to provide informed consent.

	Exclusion criteria: 1) overt psychopathology or alcohol addiction; 2) a life expectancy < 6 months. *N recruited:* N= 160; IG: n=80; CG: n= 80. *N in analysis:* N= 160; IG: n=80; CG: n= 80.
Interventions	*Content of screen:* CARE NEEDS and PSYCHOSOCIAL PROBLEMS*:* 1) a needs assessment based on the biopsychosocial model (13-item checklist completed by patients prior to each consultation); 2) psychosocial problem area's. *Screenings interventionist:* A nurse to conduct the needs assessment. *Intervention procedure:* SI with co-intervention to use screening results: 6 30-minute nursing follow-up consultations in the 1st year posttreatment, conducted in parallel with and preceding the medical routine control visits and included a biopsychosocial needs assessment (13-item checklist) prior to each consultation. Every 3 months, patients were screened for psychosocial problem areas using a specific questionnaire. *Conditions for implementation*: 1) Training sessions for nurses on the biopsychosocial model and using exploratory communication skills; 2) 2 head and neck surgeons delivered a 2-hour training session on performing simple medical checks; 3) Nursing supervision meetings were planned every 2 months led by a clinical psychologist. *Comparative condition:* UCG: Usual care: 5-year routine control with 6 bimonthly 10-minute visits to a head and neck surgeon in the 1st year posttreatment + nursing follow-up care (ad hoc problem-based contacts). Exceptions: 1) patients who underwent a laryngectomy: standard nursing consultations during the first 6 months posttreatment in parallel with the medical control visits; 2) patients treated with surgery alone: 1 standard wound control visit with a nurse; 3) patients treated with radiotherapy: 1-6 ad hoc nursing contacts during the first 6 months posttreatment. *Length of follow-up:* 12 months following treatment.
Outcomes	*Primary outcomes:* 1) psychosocial adjustment (PAIS-SR); 2) QOL (EORTC QLQ-C30 and QLQ-H&N35). *Secondary outcomes: /* *Outcome time points:* Baseline (=1 month post-treatment), 6 and 12 months post-treatment.
Notes	For bias judgement on NRCT we refer to the ROBINS-I tables in the 'Additional Tables-section'.

Risk of bias table *(judged with ROBINS-I)*

Bias	Authors' judgement	Support for judgement
Bias due to confounding	SERIOUS RISK	Confounding possible, QOL scores at baseline differ a lot between conditions.
Bias in selection of participants into the study	LOW RISK	The study employed a sequential cohort design with an initial cohort consecutive patients that formed the control group with usual care, and after a 'wash out' period of 5 months the cohort of the experimental arm was recruited.
Bias in classification of interventions	LOW RISK	The classification of interventions is clear.
Bias due to deviations from intended intervention	NO INFORMATION	There were no deviations in the screening interview intervention mentioned.
Bias due to missing data	SERIOUS RISK	Drop-out of patients from baseline to 12 months assessment +/- 22%; non-responses evenly distributed between both conditions. It is unclear on what number of participants the analysis for each outcome is based.
Bias in measurement of outcomes	MODERATE RISK	Validated PRO's are used to measure the subjective outcomes in both conditions. No extra person for outcome assessment aware of condition allocation.
Bias in selection of the reported result	LOW RISK	The outcome measurements and analyses are clearly defined and there is no indication of selection of the reported analysis from among multiple analyses; no indication of selection of

		the cohort or subgroups for analysis and reporting on the basis of the results.
OVERALL RISK OF BIAS	*SERIOUS RISK study*	

Detmar 2002

Methods	Longitudinal randomized crossover design - with intervention group (IG) and control group (CG).
Participants	Cancer patients undergoing outpatient palliative chemotherapy, and oncologists working in the department of medical oncology. *Country:* The Netherlands. *Age:* Patients: IG: mean 58 years(25-84) ; CG: mean 55 years (24-81) - p=0.24; Oncologists: mean 44 years (35-53). *Sex:* Patients: IG: 73% female; CG: 81% female - p=0.15; Oncologists: 40% female. *Inclusion criteria:* 1)receiving outpatient palliative chemotherapy; 2) recruited after receiving 2 cycles of chemotherapy. *Exclusion criteria:* 1) lacking proficiency in Dutch; 2) ≤ 18 years; 3) participation in concurrent HRQOL study. *N randomized:* Patients: N= 273; IG: n=131; CG: n=172; Oncologists: n=10. *N in analysis:* Patients: N= 214; IG: n=100; CG: n=144; Oncologists: n=10.
Interventions	*Content of screen:* (HR)QOL: tool=EORTC-QOL-C30: 5 functional scales, 9 symptom scales, and 2 General Health- and QOL-items, no total score can be computed. *Interventionist:* No interventionist for screening act, self-completion of screening tool. *Intervention procedure:* solitary SI: Patients in IG had a first standard follow-up visit with oncologist,. At 3 following outpatient visits, patients completed HRQL-questionnaire on paper in waiting room immediately before their visit, the responses were optically scanned, scored and transformed into a graphic summary. Physicians and patients received a copy of the summary before the consultation. *Conditions for implementation*: 1) Half-hour educational session for oncologists on how to interpret the QOL-summary scores; 2) Development of information pamphlet for (intervention)patients; 3) A system/person is needed to deliver and collect questionnaires and to control data management; 4) A research assistant was available for further explanation. *Comparative condition:* Usual care group. *Length of follow-up:* from the 1st to the 4th visit for follow-up of palliative chemotherapy (1st study medical visit: baseline assessment for both groups - intervention introduced at 2nd study visit and continued through the 4th study visit).
Outcomes	*Primary outcomes:* 1) Patients' sociodemographic and clinical characteristics; 2) Patient-Physician Communication: content, total length; 3) Physicians' awareness of patients' HRQL: fatigue, physical fitness, feelings, daily and social activities, pain, and overall health (COOP and WONCA); 4) Patient Management: notes and comments relating to HRQL-related in patients' medical record, prescription of medication, ordering of tests, referrals to other health care practitioners, and counseling; 5) Patient and Physician Satisfaction: patients were asked how their needs were addressed, their active involvement during the visit, patient-physician interaction, and information and emotional support received (PSQ). Oncologists were asked "How satisfied were you with the communication with your patient during this visit?"; 6) Patients' Self-Reported HRQL (SF-36), 7) Patient and Physician Evaluation of the Intervention. *Secondary outcomes: /* *Outcome time points:* At the end of the 1st and 4th follow-up visit.
Notes	

Risk of bias table (judged with RoB)

Bias	Authors' judgement	Support for judgement
Random sequence	Unclear risk	Not clear what method was used to generate a sequence.

generation (selection bias)		
Allocation concealment (selection bias)	Unclear risk	Unclear which method was used to conceal the allocation of physicians to conditions.
Blinding of participants and personnel (performance bias)	Unclear risk	Patients: blinded; oncologists: not blinded, act as their own control in a other period of the study. Potentially a bias for the oncologists who first had to undertake the intervention period and afterwards the control period (were they providing 'usual care'?)
Blinding of outcome assessment (detection bias)	Low risk	Outcomes of interest were collected with self-report questionnaires, no extra person for outcome assessment aware of condition allocation. Raters for content coding of audiotaped medical consultations were blinded.
Incomplete outcome data (attrition bias)	High risk	Drop-out of patients from baseline to 4th study visit +/- 22%; equally distributed between both conditions, explained by death, change of physician, change of hospital.
Selective reporting (reporting bias)	Low risk	Adequate: conclusions made on the basis of their outcomes of interest, but other outcome results also available in supplementary.
Other bias	Low risk	/

Geerse 2017	
Methods	RCT - with intervention group (IG) and control group (CG).
Participants	Newly diagnosed or recurrent lung cancer patients starting systemic therapy. *Country:* The Netherlands. *Age:* IG: mean 60.6 years(sd10.5); CG: mean 62.3years (sd9.7). *Sex:* IG: 46% female; CG: 39% female. *Inclusion criteria:* 1) newly diagnosed or recurrent lung cancer; 2) starting (adjuvant) chemo-(radio)therapy or treatment with biologicals; 3) Eastern Cooperative Oncology Group performance score 0-2. *Exclusion criteria:* 1) actual psychiatric co-morbidity, 2) receiving care from palliative team. *N randomized:* N=223, IG: n=110 ; CG: n=113. *N in analysis:* N= 111; IG: n=61; CG: n=50 completed all four assessments.
Interventions	*Content of screen:* DISTRESS: tool= DT, PL and the referral wish question (yes, may be, no): PL 47 items covering five life domains: practical (7 items), social (3 items), emotional (10 items), spiritual (2 items) and physical (25items). *Interventionist:* Self-completion of screening tool, but psychosocial nurse needed for discussion response patterns. *Intervention procedure:* SI with co-intervention to use screening results: Patients completed DT/PL before their outpatient clinic appointment at baseline - T4 (min. 4 times). After completion face-to-face with psychosocial nurse to discuss response pattern. Referral DT score was≥4 or if referral wish. *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires and to control data management; 2) nurse available to discuss screening results. *Comparative condition:* Usual care group. *Length of follow-up:* +/- 6,5 months following start of treatment (=randomization)
Outcomes	*Primary outcomes:* 1) (HR)QOL: EORTC-QLQ-C30. *Secondary outcomes:* 1a) lung cancer specific QOL (EORTC-LC13); 1b) QOL (EQ-5D), 2) Distress (HADS), 3) Satisfaction (PSQ-III), 4) end of life care; 5) survival. *Outcome time points:* 1, 7, 13, 25 weeks after randomization.
Notes	

***Risk of bias table** (judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization schedule generated by a validated system (PMX CTM, release 3.3.0 HP2, Propack Data) with use of pseudorandom number generator and supplied seed number.
Allocation concealment (selection bias)	Low risk	Randomisation, questionnaire distribution and data management performed by the independent Netherlands Comprehensive Cancer Organization (IKNL).
Blinding of participants and personnel (performance bias)	Unclear risk	No blinding of patients or psychosocial nurses.
Blinding of outcome assessment (detection bias)	Low risk	All outcomes collected with self-report questionnaires, no extra person for outcome assessment aware of condition allocation.
Incomplete outcome data (attrition bias)	High risk	Drop-out from baseline to 24 weeks post baseline: 56% in control group, 45% in intervention group ; reasons for drop-out: death, discontinued participation.
Selective reporting (reporting bias)	Low risk	All outcome data available in paper or in supplementary file.
Other bias	Low risk	/

Giesler 2005	
Methods	Prospective multisite RCT - with intervention group (IG) and control group (CG).
Participants	Adult patients with prostate carcinoma and their partners. *Country:* United States. *Age:* IG: mean 66,7years; CG: mean 61,1years. *Sex:* All male. *Inclusion criteria:* 1) Diagnosed with stage T1a-T2c prostate carcinoma; 2) Scheduled to undergo or have undergone surgery, external beam radiation or brachytherapy; 3) Partner willing to participate within 2 weeks after conclusion of the therapy; 4) ≥ 18 years; 5) Fluent English. *Exclusion criteria: /* *N randomized:* N=99; IG: n48; CG: n=52. *N in analysis:* N=99; IG: n48; CG: n=51 (sample sizes at baseline,4,7,12months fluctuated slightly due to missing answers), n=85 at 12months drop-out equal in IG and CG.
Interventions	*Content of screen:* (HR)QOL: Quality of life problems (sexual functioning, cancer worry, dyadic adjustment, depression and other cancer-related problems). *Interventionist:* A nurse to conduct the screening/assessment. *Intervention procedure:* SI with co-intervention to use screening results: 6 intervention visits in first 6 months after end treatment, 1st visit (end therapy): assessment of bowel and urinary function problems; 2nd visit (1 month later): assessment guided by computer assessment program; contacts 3-6 (each month on phone): asks to discuss issues and concerns. Menu-driven computer program provided standardized questions and response formats that the nurse used to elicit and document information concerning QOL problems. If score exceeded threshold for a problem, program prompted to assess the problem in greater detail and helped identify strategies. *Conditions for implementation*: 1) Development of computer assessment program with specific and general strategies linked to the assessment outcome; 2) Laptop needed; 3) Training of the nurse in use of the system; 4) A nurse to monthly contact the prostate cancer patient and his partner. *Comparative condition:* Usual care group. *Length of follow-up:* 6 months following end of treatment.
Outcomes	*Primary outcomes:* 1) Specific QOL: Urinary, sexual, bowel and cancer worry outcomes (PCQoL); 2) Depression (CES-D); 3) Dyadic adjustment (DAS); 4) General QOL (SF-36).

	Secondary outcomes: / *Outcome time points:* Baseline (= end of treatment); 4, 7, and 12 months past treatment.
Notes	

Risk of bias table *(judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not clear what method was used to gererate the sequence.
Allocation concealment (selection bias)	Unclear risk	Unclear which method was used to conceal the allocation to conditions.
Blinding of participants and personnel (performance bias)	High risk	Patients, partners and nurses not blinded.
Blinding of outcome assessment (detection bias)	Low risk	Outcome data collected with computer-assisted telephone interviews, interviewers were blind to the group.
Incomplete outcome data (attrition bias)	High risk	Drop-out of patients from baseline to 12 months assessment +/- 15%; equally distributed between both conditions, “attriters did not differ from those who completed the study”; reason for drop-out: inconvenience. "Because some respondents occasionally failed to answer all items during the interviews, the sample sizes fluctuated slightly", nowhere stated how much this is.
Selective reporting (reporting bias)	Low risk	All prespecified data reported.
Other bias	High risk	No adjustments for multiple testing implicate that the few positive results have a high risk to be type II errors.

Given 2004

Methods	RCT – with an intervention group (IG) and control group (CG).
Participants	Patients diagnosed with a solid tumor and within 56 days of undergoing a first cycle of chemotherapy.. *Country:* United States. *Age:* unclear. *Sex:* Almost 80% of the total sample female. *Inclusion criteria:* 1) diagnosed with a solid tumor; 2) Within 56 days of undergoing a first cycle of chemotherapy; 3) Having a family member who agreed to be the informal caregiver of record; 4) caregiver and patient need to be able to speak and read English; 5) Cognitively intact. *Exclusion criteria:* 1) undergone a previous course of chemotherapy or receiving radiation. *N randomized:* N=237; IG: n=118; CG: n=119. *N in analysis:* baseline: N=237, IG: n=118, CG: n=199; 10 weeks: N=191, IG: n=97, CG: n=94; 20 weeks: N=167, IG: n=80, CG: n=87.
Interventions	*Content of screen* HRQOL*:* Assessment of severity of problems and extent to which each of these problems impacted QOL-dimensions. Problems assessed: alopecia, anxiety, constipation, depression, diarrhea, nausea, dyspnea, fatigue, fever, anorexia, insomnia, mucositis, pain, skin problems, lack of concentration, and physical and work role functioning; QOL dimensions assessed: emotions, relationships with others, sleep, appetite, daily activity, and concentration. *Interventionist:* A nurse to conduct the screening/assessment and broader intervention. *Intervention procedure:* SI with co-intervention to use screening results: A 10 contact, 20 week intervention with symptom assessment, The computer documentation system provided up to 4 intervention strategies for each detected problem selected from the categories: information, counseling and support, coordination of care, and prescribing

	therapeutic activities. Nurse discussed and entered patients' choice into computer-guided protocol. At all subsequent contacts, patients rated the severity and impact on symptoms for each specific intervention. Evaluation of each problem classified as: resolved, improving, no change or deteriorating. Each of the in person sessions took approximately 1 hour . *Conditions for implementation*: 1) Development of a computer system with pre-defined roster of interventions related to detected problems; 2) Training of intervention nurses in assessing patients and use of computer system. *Comparative condition:* Usual care group. *Length of follow-up:* 20 weeks following a first cycle of chemotherapy.
Outcomes	*Primary outcomes:* Depression (CES-D). *Secondary outcomes: /* *Outcome time points:* baseline (=within 56 days of undergoing 1st cycle of chemo); 10 and 20 weeks.
Notes	

Risk of bias table (judged with RoB)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Sequence generation not specified.
Allocation concealment (selection bias)	Unclear risk	Unclear which method was used to conceal the allocation to conditions.
Blinding of participants and personnel (performance bias)	High risk	Patients, partners and nurses not blinded.
Blinding of outcome assessment (detection bias)	Unclear risk	No information on blinding of telephone (outcome) interviewers.
Incomplete outcome data (attrition bias)	High risk	Drop-out from baseline to 20 weeks post baseline: 32% in control group, 27% in intervention group.
Selective reporting (reporting bias)	High risk	Data on patient-characteristics is very limited, no clear presentation on the concrete depression data (CES-D scores) or severity of problems data, only a lot of visuals and text on the assessed interactions. There is also no referral to a supplementary file for the concrete data.
Other bias	Unclear risk	Not clear whether the different composed models are post-hoc analyses or were rather planned in advance.

Harrison 2011

Methods	RCT - with an intervention group (IG) and a control group (CG).
Participants	Adult colorectal cancer patients that underwent surgery. *Country:* Australia. *Age:* IG: mean 67.2 years ; CG: mean 61.8 years. *Sex:* CG: IG: 42% female; CG: 36% female. *Inclusion criteria:* 1) ≥18 years, 2) admitted for surgery for colorectal cancer (any stage), 3) telephone access, family member or caregiver as interpreter for telephone intervention if not English speaking. *Exclusion criteria: /* *N randomized:* N= 75, IG: n=38, CG: n=36. *N in analysis:* baseline: N= 73, IG: n=37, CG: n=36; 1 month: N=70, IG: n=36, CG: n=34; 3 months: N= 65, IG: n=34,CG: n=31; 6 months: N=60, IG: n= 30, CG: n=30.
Interventions	*Content of screen:* CARE NEEDS: A set of questions acting as a screening tool, designed to address common problems experienced by patients throughout this period. Physical, psychosocial, information, supportive care, and rehabilitation needs are assessed and

	addressed during each call. *Interventionist:* Colorectal cancer nurse who conducts the telephone screenings. *Intervention procedure:* SI part of a more complex intervention: The CONNECT intervention comprises 5 calls of a nurse following the patients initial discharge from hospital after surgery (days 3 and 10 and then at 1, 3, and 6months). Needs are assessed and addressed during each call. Patients also have the opportunity to raise any additional concerns. If the nurse identifies a need, relevant information is provided. Emotional support is given when necessary. Where further clinical advice, or referral, is required, the nurse directs patients back to the appropriate clinical team member to make the relevant appointments and referrals.. *Conditions for implementation*: 1) training for nurse that conducts the telephone screening, 2) availability of nurse to conduct all screening calls. *Comparative condition:* Usual care: included a recommended follow- up appointment with a general practitioner and surgeon. *Length of follow-up:* 6 months following initial discharge from hospital.
Outcomes	*Primary outcomes:* 1) Unmet needs (SCNS-SF34), At 6months, the SCNS-SF34 was replaced with the Ca-SUN, more relevant to the majority of participants (assesses unmet need in 4 areas: information, quality of life, emotional, and life perspective.). *Secondary outcomes:* 1)QOL (FACT-C), 2) Cancer-related postoperative health service utilization, including presentations to emergency departments, hospital readmissions, appointments/contacts with hospital based staff (ward staff, cancer care coordinators), specialists (surgeons, oncologists), general practitioners, stoma therapists, and community services (community nurse, pharmacist, support groups). *Outcome time points:* 1, 3, and 6 months after discharge from hospital.
Notes	

***Risk of bias table** (judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sequences were created using a Computer generated randomization schedule.
Allocation concealment (selection bias)	Low risk	Independent researcher randomly allocated patients to intervention or control groups.
Blinding of participants and personnel (performance bias)	High risk	Study authors stated: "blinding of either patients or researchers was not possible".
Blinding of outcome assessment (detection bias)	Low risk	Care needs and QOL data were collected with self-report tools for patients, no extra person for outcome assessment aware of condition allocation. Health service utilization data were collected blind to participants' group status.
Incomplete outcome data (attrition bias)	High risk	Drop-out of patients from baseline to 6 months assessment +/- 20%; equally distributed between both conditions for care needs and QOL measurement. Completeness of data on health service utilization seems to be adequate.
Selective reporting (reporting bias)	Low risk	The study protocol is not available but it is clear that the published reports include all expected outcomes.
Other bias	Low risk	/

Hilarius 2008

Methods	Sequential cohort design with repeated measures - with intervention group (IG) and control group (CG).
Participants	Cancer patients who were to begin adjuvant or palliative chemotherapy treatment. *Country:* The Netherlands. *Age:* Patients: IG: mean 57 years ; CG: mean 55 years - p=0.17; Nurses: mean 36 years (26-48).

	Sex: Patients: IG: 61% female; CG: 67% female - p=0.54; Nurses: 100% female. *Inclusion criteria:* 1) cancer patient; 2) to begin adjuvant or palliative chemotherapy treatment. *Exclusion criteria:* Patients: 1) aged < 18 years; 2) lack basic proficiency in Dutch; 3) exhibit overt psychopathology or serious cognitive problems; 4) participating in a concurrent HRQL study. *N recruited:* Patients: N=298; IG: n=148; CG: n=150; Nurses: N=10. *N in analysis:* Patients: N=219; IG: n=111; CG: n=108; Nurses: N=10.
Interventions	*Content of screen:* (HR)QOL: tool= EORTC-QLQ-C30: validated HRQOL-measure with 5 functional scales, 9 symptom scales, and 2 General Health- and QOL-items, no total score can be computed. If applicable a specific module for breast cancer (QLQ-BR23), colorectal cancer (QLQ-CR38), or lung cancer (QLQ-LC13) was added. *Screenings interventionist:* No interventionist for screening act, self-completion of screening tool. *Intervention procedure:* Solitary SI: Patients completed the EORTC questionnaire on touch screen computer in outpatient clinic, a graphic results summary was generated and given to patient and nurse before consultation (outpatient visit 2, 3, 4,5 = study visit 1,2,3,4). No specific guidelines were provided on how the HRQL summary data could/should be used during consultations. *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires and to control data management; 2) A group educational session and written information for nurses on how to interpret the HRQL summary scores; 3) Development of written materials for (intervention)patients. *Comparative condition:* CG: usual care. *Length of follow-up:* 4 consecutive outpatient visits.
Outcomes	*Primary outcomes:* 1) Nurse-patient communication: self-report questionnaire for patients; 2) Nurses' awareness of patients' HRQL: COOP and WONCA completed by nurses and patients ; 3) Patient management: notations relating to HRQL-related topics coverd by the EORTC questionnaires abstracted form medical and nursing records, and abstracted with a checklist; 4) Patient satisfaction: modified PSQ, Form II with 4 subscales (perceived technical quality of care, interpersonal manner, communication, and continuity of care); 5) Patients' HRQOL: SF-36, and if applicable FACT-BCS, FACT-C, and FACT-L; 6) patient and nurse evaluation of the intervention. *Secondary outcomes: /* *Outcome time points:* Baseline *(*=2nd outpatient visit=1st study visit), and 5th outpatient visit (4th study visit).
Notes	For bias judgement on NRCT we refer to the ROBINS-I tables in the 'Additional Tables-section'.

Risk of bias table *(judged with ROBINS-I)*

Bias	Authors' judgement	Support for judgement
Bias due to confounding	MODERATE RISK	Confounding possible, but not more than we would expect in a RCT on this topic.
Bias in selection of participants into the study	LOW RISK	The study employed a sequential cohort design with an initial cohort of 100 consecutive patients that formed the control group with usual care, and after a 'wash out' period of 2 months the cohort of the experimental arm was recruited.
Bias in classification of interventions	LOW RISK	The classification of interventions is clear.
Bias due to deviations from intended intervention	NO INFORMATION	There were no deviations in the screening interview intervention mentioned.
Bias due to missing data	SERIOUS RISK	Drop-out of patients from baseline to 13 and 14 months assessment +/- 27%; non-responses evenly distributed between both conditions; 2 most common reasons for dropout were death and cessation of treatment.

Bias in measurement of outcomes	MODERATE RISK	For both conditions subjective outcomes were measured with validated and self-adjusted PRO's. No extra person for outcome assessment aware of condition allocation.
Bias in selection of the reported result	LOW RISK	The outcome measurements and analyses are clearly defined and there is no indication of selection of the reported analysis from among multiple analyses; no indication of selection of the cohort or subgroups for analysis and reporting on the basis of the results.
OVERALL RISK OF BIAS	*SERIOUS RISK study*	

Hollingworth 2013

Methods	RCT - with intervention group (IG) and usual care control group (UCG).
Participants	Patients undergoing outpatient chemo- or radiotherapy. *Country:* United Kingdom. *Age:* IG: mean 61years(12.2sd); CG: mean 62years(11.5sd). *Sex:* IG: 67.9% female; CG: 59.3% female. *Inclusion criteria:* 1) age ≥18 yrs and < 85yrs; 2) primary solid tumor diagnosis within previous 12 months; 3) outpatient external radiotherapy over period of ≥2weeks, or outpatient chemotherapy of ≥ 2 cycles; 4) ability to read and communicate in English. *Exclusion criteria:* 1) receiving neoadjuvant chemotherapy; 2) diagnosed with ductal carcinoma in situ or skin carcinoma. *N randomized:* N=220; IG: n=112; CG: n=108. *N in analysis:* N=220; IG: n=112; CG: n=108.
Interventions	*Content of screen:* DISTRESS: tool= DT, distress by self-report of patients on a 11-point scale ranging from 0('none') to 10 ('extreme'). PL of physical, practical, family, emotional, and spiritual concerns ('yes'-'no') refined in this study to a 42-item list. *Interventionist:* A radiographer or nurse to conduct the screening conversation. *Intervention procedure:* SI with co-intervention to use screening results: During 2nd week of radiotherapy or 2nd cycle of chemo, patients completed the DT&PL as basis of a therapeutic conversation with the radiographer/nurse: concerns identified, potential solutions discussed, staff actions/patient actions/referral taken. At the discretion of the patient, a 2nd DT&PL meeting could be arranged toward the end of therapy. *Conditions for implementation*: 1) All staff received training: audiovisual example of DT&PL administration, role playing, advice on dealing with strong emotions; 2)A source directory was developed providing info on self-management techniques, information sources, support groups and guidance for staff on when to refer patients. *Comparative condition:* Usual care group. *Length of follow-up:* 12 months following 2nd week of radiotherapy or 2nd cycle of chemo.
Outcomes	*Primary outcomes:* 1) psychological well-being (POMS) *Secondary outcomes:* 1) QOL (EORTC-QLQ-C30); 2) EQ-5D-3L; 3) patient satisfaction: (TPVCSQ) at 6months only; 4) cost of the DT&PL: pretrial training costs, cost of staff time; 5) health service use: medical record review on inpatients and ambulatory hospital care and patient questionnaires on 1, 6, 12months detailing community health care and medications. *Outcome time points:* Baseline (=2nd week of radiotherapy or 2nd cycle of chemo); 1, 6, and 12months after baseline.
Notes	

Risk of bias table (judged with RoB)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer based 1:1 allocation, stratified by site.
Allocation concealment	Unclear risk	Unclear which method was used to conceal the allocation to

(selection bias)		conditions.
Blinding of participants and personnel (performance bias)	High risk	Patients and therapists were aware of group allocation.
Blinding of outcome assessment (detection bias)	Low risk	Researcher/outcome assessor was blinded for group allocation.
Incomplete outcome data (attrition bias)	Low risk	Drop-out from baseline to 12 months post baseline +/- 5%; equally distributed between both conditions; reasons for drop-out: death, withdrawal, lost contact.
Selective reporting (reporting bias)	Low risk	The study protocol is not available but it is clear that the published reports include all expected outcomes.
Other bias	Low risk	/

Kutner 1999	
Methods	Cluster RCT - with an intervention group (IG) and a control group (CG).
Participants	Cancer patients scheduled for a follow-up visit in a ambulatory cancer clinic. *Country:* United States. *Age:* Physicians: IG: 41.7±6.9, CG: 42.2±6.3; Patients: IG: 51.5±16.4, CG: 55.6±13.3. *Sex:* Physicians: IG: 33% female, CG: 20% female; Patients: IG: 44% female, CG: 66% female. *Inclusion criteria:* 1) ≥18 years, 2) had a scheduled follow-up visit, 3) English-speaking, 4) able and willing to consent and to read and complete the questionnaires. *Exclusion criteria:* / *N randomized:* Physicians: N=11, IG: n=6, CG: n=5, Patients: N=282, IG: n=149, CG: n=133. *N in analysis:* baseline: Physicians: N=11, IG: n=6 CG: n=5; Patients: N=282, IG: n=149, CG: n=133.
Interventions	*Content of screen:* CARE NEEDS: needs assessment questionnaire adapted from published instruments, exploring needs in 13 domains: intensive care, financial, self-care, future, symptom relief, treatment, emotional, spiritual, test, prevention, diagnosis, referral and advance directives. *Interventionist:* No interventionist for screening act, self-completion of screening tool. *Intervention procedure:* Solitary SI: Patients completed a pre-visit needs assessment questionnaire, completed forms were attached to the patient charts prior to the clinic visit. Physicians were aware of this information, but not instructed in use of the information provided. *Conditions for implementation*: A person or system that gives/sends the pre-visit questionnaire to patients and attaches it to patients files. *Comparative condition:* Usual care: not further specified. *Length of follow-up:* No follow-up.
Outcomes	*Primary outcomes:* 1) items discussed at the clinical encounter, 2) Visit specific patient satisfaction: five item Medical Outcomes Study Patient Visit Rating Questionnaire, 3) Visit specific physician satisfaction: Relation and Demand subscales + one-item satisfaction measure from Suchmans' Physician Satisfaction Questionnaire, 4) Physician participatory decision-making style: a three item scale. *Secondary outcomes:* / *Outcome time points:* only 1: post-visit
Notes	

***Risk of bias table** (judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear what method was used to randomize the physicians.
Allocation concealment	Unclear risk	Unclear which method was used to conceal the allocation to

(selection bias)		conditions.
Blinding of participants and personnel (performance bias)	High risk	No blinding of physicians or patients.
Blinding of outcome assessment (detection bias)	Low risk	Outcome data were collected with post-visit questionnaires in both conditions. No extra person for outcome assessment aware of condition allocation.
Incomplete outcome data (attrition bias)	Low risk	Only 1 outcome time point, so no potential missing data due to loss in follow-up. No indication for other missing data.
Selective reporting (reporting bias)	High risk	Incomplete reporting of outcomes (only significant subscales reported for patient satisfaction, without a measure of the spread of the data).
Other bias	High risk	Adjusted p-values reported everywhere, to adjust for clustering, but no information on how this adjustment was done It is clear that these is a huge difference in baseline characteristics, which are the result of clustering at the physician level, but there become non-significant when "clustering is taken into account". Nevertheless remains problematic.

Livingston 2010	
Methods	Cluster RCT - with two intervention groups (IG-4 and IG-1) and one control group (CG).
Participants	Newly diagnosed prostate cancer and male colorectal cancer patients *Country:* Australia *Age:* IG-4 Outcalls: mean 65,3years (sd8,9); IG-1 Outcall: mean 64,2years (sd8,8); CG-passive referral: mean 63,9years (sd9,0). *Sex:* All male *Inclusion criteria:* 1) male, 2) newly diagnosed prostate or colorectal cancer. *Exclusion criteria:* 1) limited English, 2) have a psychiatric illness, 3) prognosis less than 52 weeks.. *N randomized:* N 571; IG-4: n=209; IG-1: 197; CG: n=165. *N in analysis:* Variety in sample size according to timing outcome measurement; IG-4 Outcalls: n-baseline=209, n-4mo=136, n-7mo=194, n-12mo: 194; IG-1 Outcall: n-baseline=225, n-4mo=183, n-7mo=174, n-12mo: 166; CG-Passive Referral: n-baseline=165, n-4mo=157, n-7mo=153, n-12mo: 147.
Interventions	*Content of screen:* BIOPSYCHOSOCIAL WELL-BEING*:* Discussion of 10 topics during outcall: the cancer diagnosis; treatment /management issues; what to expect from surgery; management of side effects; communication with the specialist; partner/family issues; psychological/ emotional and communication concerns; understanding cancer language; diet and nutrition; other support services and availability of written resources. If the patients did not mention a topic, the cancer nurse raised the topic. *Interventionist:* A Cancer Helpline nurse to conduct the screening/assessment. *Intervention procedure:* SI with co-intervention to use screening results: IG-Active Referral-4 outcalls (IG-4): a specialist referral to the Helpline with 4 outcalls to the participant (telephone assessment) within 1 week of diagnosis, 6 weeks, 3 and 6 months post-diagnosis; IG-Active Referral-1 outcall (IG-1): a specialist referral to the Helpline and 1 outcall (telephone assessment) within 1 week of diagnosis. If topics(of content of screen) not mentioned by patient, raised by the nurse. *Conditions for implementation*: 1) Availability of a Cancer Telephone Helpline; 2)Professionals trained in communication and listening skills, counseling qualifications and experience in clinical oncology; 3) Training of specialists to discuss the Cancer Helpline en use the referral slips. *Comparative condition:* Usual care group, with suggestion to patient to call the Cancer

	Helpline in case of needs/questions. *Length of follow-up:* 12 months following the specialist consultation on cancer diagnosis.
Outcomes	*Primary outcomes:* 1) Cancer specific distress: modified version of an existing distress-tool for breast cancer patients; 2) Anxiety and depression (HADS). *Secondary outcomes: /* *Outcome time points:* baseline (= diagnosis); 4, 7 and 12 months post-diagnosis.
Notes	

Risk of bias table *(judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated random numbers produced by the project coordinator.
Allocation concealment (selection bias)	High risk	Both study coordinator and referring specialist were aware of intervention group.
Blinding of participants and personnel (performance bias)	High risk	Patients were aware of intervention group. Blinding of personnel not reported.
Blinding of outcome assessment (detection bias)	Low risk	Outcome assessors were not aware of intervention/control group.
Incomplete outcome data (attrition bias)	Low risk	Drop-out from baseline to 12 months post baseline +/- 12%; equally distributed between both conditions ; reasons for drop-out: death, withdrawal, refused.
Selective reporting (reporting bias)	High risk	Incomplete reporting of the data of intervention group 1 outcall.
Other bias	Low risk	/

Maunsell 1996

Methods	RCT - with intervention group (IG) and control group (CG).
Participants	Women with newly diagnosed localized or regional stage breast cancer. *Country:* Canada. *Age:* IG: mean 54.6 years(sd12.4); CG: mean 56.3years (sd13.2). *Sex:* All female. *Inclusion criteria:* 1) diagnosis with localized or regional stage breast cancer; 2) pathological report of breast cancer confirmation available; 3) first treatment at the Saint-Sacrement Breast Disease Clinic, Quebec. *Exclusion criteria:* 1) previous treatment for cancer, 2) distant disease at diagnosis, 3) participating in National Surgical Adjuvant Breast Project protocol B-18 and randomized to receive chemotherapy before surgery, 4)without a telephone, 5) hearing or other health problems so severe that an interview was not possible. *N randomized:* N = 261, IG: n=131, CG: n=130. *N in analysis:* N=250; IG: n=123; CG: n=127.
Interventions	*Content of screen:* DISTRESS: tool= GHQ-20 measuring increases in psychologic symptoms (somatic items not used for this purpose). GHQ ≥ 5 were considered symptomatic *Interventionist:* Telephone screener (research assistant) and Social worker to discuss results and give support. *Intervention procedure:* SI with co-intervention to use screening results: Systematic telephone screening of psychologic distress, starting at 21days after randomization, repeated at 28-day intervals, for 12 times. Patients with high scores called by social worker to discuss reasons for increased distress, desire for further contact with social worker and tailored approach. *Conditions for implementation*: 1) Person needed who conducts the telephone screenings, 2) Social worker needed who contacts and works with patients with high GHQ scores.

	Comparative condition: Usual care group. *Length of follow-up:* 12 months following hospitalization for initial treatment.
Outcomes	*Primary outcomes:* 1) Psychologic distress (PSI). *Secondary outcomes:* 1) Social support: six-item Social Support Questionnaire, 2) Impact of stressful life events (LES): 3) Marital satisfaction (LWMAT). 4) questions on participants' general perception of her health= QOL-parameters, extent to which her health worried her, performance of usual home, social, leisure and physical activities, return to payd employment (based on Canada Health and Activitey Limitation Survey); 5) visits to healthcare professionals in the past year and other distress alleviating co-interventions; 6) degree and nature of exposure to contacts with social workers. *Outcome time points:* Baseline (=hospitalization for initial treatment), 3&12 months after baseline.
Notes	

***Risk of bias table** (judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization using a random numbers table.
Allocation concealment (selection bias)	Unclear risk	Randomization communication by the clinic secretary with sealed envelopes prepared by the principal investigator, but not clearly stated if the envelopes are opaque and opened sequentially.
Blinding of participants and personnel (performance bias)	High risk	The research nurse who carried out the baseline interview was blinded to patients' treatment assignment, further no blinding.
Blinding of outcome assessment (detection bias)	Low risk	The research nurse who conducted the baseline and all following interviews was blinded.
Incomplete outcome data (attrition bias)	Low risk	Adequate, drop-out from baseline to 12 months post baseline +/- 5%.
Selective reporting (reporting bias)	Unclear risk	It seems that data of some outcomes is not given (e.g. LES).
Other bias	Low risk	/

Nimako

Methods	RCT - with intervention group (IG), usual care control group (UCG) and attention control group (ACG).
Participants	Patients of all ages with a diagnosis of a thoracic cancer that recently completed treatment. *Country:* United kingdom. *Age:* IG: mean 64.6years; ACG: mean 64.7years; UCG: 62.9years. *Sex:* IG: 44% female; ACG: 45% female; UCG: 46% female. *Inclusion criteria:* 1) attending the Royal Marsden Hospital, 2) diagnosis of a thoracic cancer (NSCLC, SCLC and mesothelioma), 3) able to understand written and spoken English, 4) recently completed treatment. *Exclusion criteria:* 1) a plan in to commence treatment (chemotherapy, targeted therapies, radiotherapy, surgery) within 6 weeks, 2) taking part in any other studies that required the completion of a QoL questionnaire, 3) had received any anti-cancer treatment (chemotherapy, radiotherapy, surgery or targeted therapies) within the previous 3 week, 4)had any ongoing toxicities from their treatment, which had not been stabilised (i.e. required intervention within last 7 days). *N randomized:* N=138; IG: n=45; ACG: n=47; UCG: n=46. *N in analysis:* baseline measures: N=138; IG: n=45; ACG: n=47; UCG: n=46; 6 weeks measures: N=131; IG: n=42; ACG: n=45; UCG: n=44.
Interventions	*Content of screen:* (HR)QOL: tool= EORTC-QOL-C30: 5 functional scales, 9 symptom scales,

	and 2 General Health- and QOL-items, no total score can be computed. *Interventionist:* No interventionist for screening act, self-completion of screening tool. *Intervention procedure:* Solitary SI: 1) IG: patients completed EORTC QLQ-C30 and LC13 on paper in waiting room before clinic visit, this questionnaire was given to the reviewing doctor. The doctor provided feedback to the patient and conducted the consultation with the aid of the questionnaire; 2) Attention CG: patients also completed the EORTC-QLQ-C30 on paper and LC13 in waiting room before clinic visit, the questionnaire was filed and not shared with the doctor. *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires and to control data management; 2)Training of reviewing doctors in the use and interpretation of the questionnaire. *Comparative condition:* Usual care group. *Length of follow-up:* 6 weeks following completion of treatment.
Outcomes	*Primary outcomes:* 1) Global Health at six weeks : General Health Status (item from EORTC-QLQ-C30). *Secondary outcomes:* 1) changes in QOL from baseline to 6 weeks between intervention and control groups, 2) improvement in 5 functional scales of EORTC-QLQ-C30, 3) improvement in symptom scales of EORTC-QLQ-LC13 , 4) number of QOL issues identified at baseline, 5) number of management actions at baseline, 6) number of contacts with healthcare professionals outside clinic during study. *Outcome time points:* baseline (after completion of treatment) and 6 weeks after baseline.
Notes	

Risk of bias table (judged with RoB)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Electronic randomization is mentioned, however exact method of sequence generation is unclear.
Allocation concealment (selection bias)	Unclear risk	Not mentioned how and who allocated the participants to the 3 conditions, unclear if this was concealed.
Blinding of participants and personnel (performance bias)	High risk	Patients and doctors not blinded.
Blinding of outcome assessment (detection bias)	Unclear risk	1) QOL-assessments: were completed on paper and over the phone, unclear if the telephone assessor was blinded , 2) QOL issues identification and management: outcome assessment by the principal investigator based on the record chart completed by the unblinded doctor and the GP letter.
Incomplete outcome data (attrition bias)	Low risk	Outcome data seem to be complete, drop-out from baseline to 6 weeks post baseline +/- 7%.
Selective reporting (reporting bias)	High risk	Only data on global health question of the EORTC-QLQ-C30 was used/reported for CG, while whole questionnaire was administered by patients in the control group.
Other bias	Low risk	/

Rosenbloom 2007

Methods	Stratified 3-arm RCT - with intervention group (IG), usual care control group (UCG) and assessment control group (ACG).
Participants	Adult patients with advanced cancer. *Country:* United States. *Age:* IG: mean 57.3 years (11.8sd); ACG: mean 60.2 years (11.0sd); UCG: mean 60.6 years (9.3sd). *Sex:* IG: 67% female; ACG: 70% female; UCG: 64% female. *Inclusion criteria:* 1) age 18-75 years; 2) advanced breast, lung or colorectal cancer with regional or distant spread of disease; 3) receiving chemotherapy at time of enrollment; 4)

	life expectancy of at least 6 months (estimated by their attending physician). *Exclusion criteria:* 1) having brain metastases or other major central nervous system complication; 2) current psychosis, mania or severe depression with overt psychotic symptomatology; 3) inability to speak or read English. *N randomised:* unclear: there was drop-out due to worsening illness (n=10) and death(n=46), analysis techniques were chosen with non-random missing data in mind. *N in analysis:* N=213; IG: n=69; ACG: n=73; UCG: n=71.
Interventions	*Content of screen:* (HR)QOL: tool= FACT-G: 5 subscales measuring physical, functional, social-familial and emotional well-being, and relation with the physician. Scores on the subscales can be summed to produce a total QOL-scale; 9 breast/lung/colon cancer specific items; question if experience of particular symptom was better than/worse than expected. *Interventionist:* An interviewer to conduct the screening. *Intervention procedure:* SI with co-intervention to use screening results: 1) IG: HRQL patient assessments at baseline and 1, 2, 3 and 6 months. At baseline, 1 and 2 month visits patients' HRQL assessment was followed by a structured interview of 20-30minutes with the research nurse in case symptoms 'worse than expected'. Patients concerns and comments shared with the treating nurse prior to visits; 2) AssessmentCG: completed HRQL assessments at the same time points without a following interview. HRQL scores were shared with the treating nurse. *Conditions for implementation*: 1) An interviewer needed to conduct the semi-structured interviews and communicate HRQL-scores to the treatment nurse. *Comparative condition:* UCG: usual care *Length of follow-up:* 6 months following recruitment during chemotherapy treatment.
Outcomes	*Primary outcomes:* 1) HRQL (FLIC); 2) Distress (Brief POMS, negative affect items); 3) Patient satisfaction: PSQ-III general satisfaction subscale (GENSAT), PSQ-III, communication satisfaction subscale (COMSAT); 4) Clinical treatment changes (total score of supportive care changes; referral to supportive services; 'other' clinical changes; and changes in the standard dose of chemotherapy as a result of patient-reported side effects or treatment toxicity). *Secondary outcomes: /* *Outcome time points:* baseline (recruitment during chemotherapy treatment); 3, and 6 months after baseline.
Notes	

Risk of bias table *(judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not clear what method was used to generate the sequence.
Allocation concealment (selection bias)	Unclear risk	Unclear which method was used to conceal the allocation to conditions.
Blinding of participants and personnel (performance bias)	High risk	Patients and treatment staff not blinded to treatment assignment.
Blinding of outcome assessment (detection bias)	Unclear risk	No information on blinding of outcome assessors.
Incomplete outcome data (attrition bias)	High risk	Drop-out from baseline to 6 months assessment +/- 28%.
Selective reporting (reporting bias)	Low risk	Adequate.
Other bias	Low risk	/

Schofield 2013	
Methods	RCT - with intervention group (IG) and control group (CG).
Participants	Adult patients with inoperable lung cancer. *Country:* Australia. *Age:* IG: mean 62.3years(9.2sd); CG: mean 63.8years(11.4sd). *Sex:* IG: 43.6% female; CG: 35.8% female. *Inclusion criteria:* 1) diagnosis of inoperable lung or pleural (including mesothelioma) cancer; 2) scheduled to receive palliative external beam radiotherapy, palliative chemotherapy or radical radiotherapy and chemotherapy; 3) able to understand English. *Exclusion criteria:* 1) psychiatric disorder or serious cognitive impairment, 2) ECOG performance status [18] score≥3 or 2 months or less since a previous treatment regimen. *N randomized:* N= 108; IG: n=55; CG: n= 53. *N in analysis:* N= 108; IG: n=55; CG: n= 53.
Interventions	*Content of screen:* CARE NEEDS: The 38-item Needs Assessment for Advanced Lung Cancer Patients with subscales: Medical communication/information, Psychological/emotional, Daily living, Financial, Symptoms and Social. *Interventionist:* Self completion of the needs assessment, but a trained cancer health professional needed for the results discussion. *Intervention procedure:* SI with co-intervention to use screening results: 2 sessions (treatment commencement and completion): self-completed needs assessment+ intervention with active listening, self-care education and communication of unmet psychosocial and symptom needs to the multidisciplinary team for management and referral. *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires and to control data management; 2) Training of a cancer health professional in the intervention-action; 3) development of consultation materials: 6 standardized, manualized modules, with a take-home self-care leaflet, to address unmet needs reported by patients during consultations ('Communicating with your Health Professional', 'Communicating with your Family and Friends', 'Dealing with Emotional Distress', 'Dealing with Sleeplessness', 'Dealing with Breathlessness' and 'Goals for the Future'.) *Comparative condition:* Usual care group. *Length of follow-up:* from start of treatment to 12 weeks post-treatment completion: length depends on length of treatment.
Outcomes	*Primary outcomes:* 1) unmet needs: Needs Assessment for Advanced Lung Cancer Patients, 2) psychological morbidity (HADS), 3) distress (DT) and 4) (HR)QOL (EORTC-QLQ-C30). *Secondary outcomes: /* *Outcome time points:* baseline (=start of treatment); 8, and 12 weeks post-treatment completion.
Notes	

Risk of bias table *(judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated, weighted-biased coin method, including stratification according to scheduled treatment (palliative chemotherapy, radical radiotherapy and pallia-tive radiotherapy).
Allocation concealment (selection bias)	Unclear risk	Unclear which method was used to conceal the allocation of physicians to conditions.
Blinding of participants and personnel (performance bias)	High risk	No blinding: very involved multidisciplinary team, IG and CG may not have been sufficiently different. Tape-recorded consultations run by two individuals not involved in providing usual care to ensure that there was no contamination between both conditions
Blinding of outcome assessment (detection bias)	Low risk	All outcomes collected with self-report questionnaires, no extra person for outcome assessment aware of condition allocation.

Incomplete outcome data (attrition bias)	High risk	Drop-out from baseline to 12 weeks post treatment completion +/- 27%; missing intervention consultations and/or outcome assessment due to scheduling issues, withdrawal, worsened health, death.
Selective reporting (reporting bias)	Low risk	Adequate.
Other bias	Low risk	/

Taenzer 2000	
Methods	Sequential cohort study - first a control cohort (CG), sequentially an experimental cohort (IG).
Participants	Outpatient lung clinic of specialized cancer center. *Country:* Canada. *Age:* IG: mean 65.6 years(10.5sd); CG: mean 64.4(9.7sd). *Sex:* IG: 37% female; CG: 35%. *Inclusion criteria:* 1) diagnosis of primary, secondary or metastatic lung cancer of any stage; 2) attendance at the outpatient cancer clinic; 3) fluency in the English language; 4) eyesight sufficient to use the computer. *Exclusion criteria:* unclear. *N recruited:* N=57; IG: n=29; CG: n=28. *N in analysis:* N= 53; IG: n=27; CG: n=26.
Interventions	*Content of screen:* (HR)QOL: tool= EORTC-QLQ-C30: validated HRQOL-measure with 5 functional scales, 9 symptom scales, and 2 General Health- and QOL-items, no total score can be computed. *Screenings interventionist:* No interventionist for screening act, self-completion of screening tool. *Intervention procedure:* solitary SI: Participants completed the computerized EORTC-QOL-C30 before their clinic appointment (if needed with help of a trained volunteer), a report was generated and given to the nurse and physician. *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires and to control data management; 2) Demonstration for clinic staff: demonstrate the computer program, explain the report and instructions were given how to read the report and to use it to guide discussions with patients regarding QOL issues; 3) A trained volunteer available to support patients with the completion of the computer EORTC. *Comparative condition:* CG: Usual care: after completion of the clinic appointment participants completed a paper-and-pencil version of the EORTC-QOL-C30. There was no EORTC-report generated for the clinical staff. *Length of follow-up:* no follow-up.
Outcomes	*Primary outcomes:* 1) Patient satisfaction (modified PDIS): items about feeling listened to, feeling well informed, feel comfortable talking about personal issues, contacting the staff about concerns, feeling treated respectfully, feeling the staff was rushed; 2) adressing of QOL concerns during clinic appointment (exit interview); 3) QOL registration in the medical record (medical record audit): concerns indicated by patients, interventions or referrals related to these. *Secondary outcomes: /* *Outcome time points:* one single outcome measurement, after the clinical appointment.
Notes	For bias judgement on NRCT we refer to the ROBINS-I tables in the 'Additional Tables-section'.

***Risk of bias table** (judged with ROBINS-I)*

Bias	**Authors' judgement**	**Support for judgement**
Bias due to confounding	MODERATE RISK	Confounding possible, but not more than we would expect in a RCT on this topic.

Bias in selection of participants into the study	LOW RISK	A sequential recruitment design was used to recruit participants during the study period, first for the control group (approximately 25), then for the experimental group (approximately 25).
Bias in classification of interventions	LOW RISK	The classification of interventions is clear.
Bias due to deviations from intended intervention	NO INFORMATION	No information is reported on whether there is departure from the intended intervention.
Bias due to missing data	LOW RISK	Only 1 outcome time point, so no potential missing data due to loss in follow-up. "Complete data for 26 participants in the control group and 27 in the experimental group, which were used for all analyses."
Bias in measurement of outcomes	MODERATE RISK	The outcomes were measured by an independent research assistant for both conditions, not by clinic staff.
Bias in selection of the reported result	LOW RISK	The outcome measurements and analyses are clearly defined and there is no indication of selection of the reported analysis from among multiple analyses; no indication of selection of the cohort or subgroups for analysis and reporting on the basis of the results.
OVERALL RISK OF BIAS	*NO INFORMATION enough to estimate the risk of the study (highest is 'moderate risk').*	

Thewes 2009	
Methods	Sequential cohort study - first a control cohort (CG), sequentially an experimental cohort (IG).
Participants	Rural oncology patients. *Country:* Australia. *Age:* mean age (sd) total sample: 60 years (10.5). *Sex:* 45.7% woman in the total sample. *Inclusion criteria:* 1) newly diagnosed with malignant disease; 2) ≥ 18years; 3) able to give informed consent; 4) able to read English proficiently. *Exclusion criteria: /* *N recruited:* n= 83; IG: n=43; CG: n= 40. *N in analysis:* baseline: N=83; after six-month follow-up: 83-2 withdrew -16 died, n= 65; follow-up questionnaires fully completed n= 52.
Interventions	*Content of screen:* DISTRESS: tool= DT, a single-item screening measure that identifies level of distress by self-report of patients on a 11-point scale ranging from 0('none') to 10 ('extreme'). *Screenings interventionist:* No interventionist for screening act, self-completion of screening tool. *Intervention procedure:* solitary SI: Completion of DT at baseline before an initial oncologist rural clinical appointment or chemotherapy education session. Staff was encouraged to discuss problems and concerns for individuals who scores above the cut-off score. *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires and to control data management, 2)Training session for nursing and psychosocial staff on the rationale for screening, the screening instrument and the study procedure. *Comparative condition:* CG: usual care without DT-screening. *Length of follow-up:* 6 months following an initial oncologist rural clinical appointment or chemotherapy education session.
Outcomes	*Primary outcomes:* 1) Common psychological and somatic distress (PSYCH-6: subscale psychological health) at baseline; 2) Patient attitudes in the intervention group towards screening (six purpose-designed statements about DT-screening); 3) Unmet psychosocial needs (SCNS-short): psychological needs, health information needs, physical and daily living

	needs, patients care and support needs, and sexuality needs. *Secondary outcomes: /* *Outcome time points:* baseline (before an initial oncologist rural clinical appointment or chemotherapy education session); 6 months after baseline.
Notes	For bias judgement on NRCT we refer to the ROBINS-I tables in the 'Additional Tables-section'.

Risk of bias table *(judged with ROBINS-I)*

Bias	Authors' judgement	Support for judgement
Bias due to confounding	SERIOUS RISK	All nursing and psychosocial staff participated in a two-hour training session on the rationale for screening, the screening instrument and the study procedure before the study started. This potentially influenced the alertness to and management of psychosocial concerns in both conditions, with the potential to influence outcomes for both conditions.
Bias in selection of participants into the study	LOW RISK	Study authors mention 2 waves of data collection from consecutive patients: an unscreened cohort and a screened cohort.
Bias in classification of interventions	LOW RISK	The classification of interventions is clear
Bias due to deviations from intended intervention	MODERATE RISK	7 out of 19 participants that reported scores on the DT above the cut-off id not receive referral because of vacancies of social workers or psychologists 'n=4), clinic staff not being able to contact the patient (n=1), or unstated reason(n=2). Possibly these people were left with unmet care needs despite the use of screening, because there was no action in response to the screening results, while for 10 of the 19 participants in the experimental condition this was the case.
Bias due to missing data	SERIOUS RISK	Drop-out of patients from baseline to 6 months assessment +/- 22%; reasons for dropout: withdrawal and death. Patient characteristics are based on n=83, However, 16 participants died and 2 withdrew during the study period/follow up. Since no numbers of participants are specified where the outcomes are based on, we assume that they included the records from participants with missing data.
Bias in measurement of outcomes	MODERATE RISK	Validated PRO's are used to measure the subjective outcomes in both conditions. No extra person for outcome assessment aware of condition allocation.
Bias in selection of the reported result	LOW RISK	The outcome measurements and analyses are clearly defined and there is no indication of selection of the reported analysis from among multiple analyses; no indication of selection of the cohort or subgroups for analysis and reporting on the basis of the results.
OVERALL RISK OF BIAS	*SERIOUS RISK study*	

Velikova 2004

Methods	Stratified 3-arm RCT - with intervention group (IG), usual care control group (UCG) and attention control group (ACG).
Participants	Cancer patients with different tumor types and treatments, and oncology consultants and physicians in training. *Country:* United Kingdom. *Age:* IG: mean 55.1 years (13.02SD); ACG: mean 54.8 years (12.49SD); UCG: mean 54.7 years (11.67SD). *Sex:* IG: 75% female; ACG: 70% female; UCC: 74% female.

	Inclusion criteria: Patients: 1) commencing treatment, 2)attend the clinic at least three times, 3)fluent in English. *Exclusion criteria:* Patients: 1)participating in other HRQL studies, 2) exhibiting psychopathology ; P *N randomized:* N=286; IG: n= 144; ACG: n=70; UCG: n=72. (article 2010: n = 258, IG: n = 129, attentionCG: n=62, CG: n=67). *N in analysis:* Sample size for analysis (baseline-6mo): Total (286-164); IG (144-84); ACG (70-35); UCG (72-45).
Interventions	*Content of screen:* (HR)QOL: tool= EORTC-QOL-C30: measure with 5 functional scales, 9 symptom scales, and 2 General Health- and QOL-items, no total score can be computed; DISTRESS: tool =HADS: 14 items, Anxiety (n=7), Depression (n=7), total score can be computed. *Interventionist:* No interventionist for screening act, self-completion of screening tool. *Intervention procedure:* Solitary SI: 1) IG: patients completed EORTC and HADS on touch screen computer before each clinic encounter, graphic result-printouts given to physicians asked to review and use the HRQOL results during all intervention encounters. No recommendations for specific responses were made. The physician discussed the screening results with patients if he thought this was necessary; 2) AttentionCG: patients also completed screening questionnaires via touch-screen computer before clinic encounters, there was no feedback to physicians. *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires and to control data management; 2)Physicians were trained in interpretation EORT- and HADS-scores; 3) A manual was developed with description of scales, interpretation of scores and explanations of the graphs. *Comparative condition:* UCG: usual care; *Length of follow-up:* 6 months following start of treatment.
Outcomes	*Primary outcomes:* 1) (HR)QOL (FACT-G); 2) Process-of-care outcome: whether HRQOL issues were discussed, medical and nonmedical actions taken, length of encounters; 3) Continuity and coordination of care (MCQ; 4) Satisfaction with care: measured with the questions 'How would you rate the overall quality of your medical care?' (very poor, poor, fair, good very good, excellent), and 'How well do doctors in this clinic meet your expectations?' (not at all, not so well, to some extent, very well, extremely well); 5) Patients' and physicians' evaluation of the intervention. *Secondary outcomes: /* *Outcome time points:* baseline (start of treatment); after three on-study encounters (approximately 2-3 months); 4 and 6 months after baseline.
Notes	

Risk of bias table *(judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Adequate: randomization at the level of the patients following an allocation ratio of 2:1:1 in favor of IC and stratified by cancer site.
Allocation concealment (selection bias)	Low risk	Adequate: the random assignment was carried out by telephone, by the Administrative Office at Cancer Research UK.
Blinding of participants and personnel (performance bias)	High risk	participants were blinded, physicians were not. It is possible that the experience with the HRQOL-profiles given in the IC influenced physicians' practice when seeing patients in the control arms.
Blinding of outcome assessment (detection bias)	Low risk	Outcome assessors were blinded.
Incomplete outcome data (attrition bias)	High risk	Drop-out of patients from baseline to 6 months assessment +/- 43% and not equally distributed between conditions (42%, 50%, and 38% for the IG, ACG and UCG, respectively).
Selective reporting (reporting bias)	High risk	Not adequate: means(sd) over time for the FACT-G scores are given visually, only the exact p-values are given.

Other bias	Low risk	/

Waller 2012

Methods	Quasi-experimental interrupted time series design - first a control group (CG), sequentially intervention group (IG).
Participants	Patients with advanced cancer. *Country:* Australia. *Age:* At T0: mean 66.1years (SD10.7; range 31-89). *Sex:* At T0: 47% female. *Inclusion criteria:* 1) diagnosis advanced cancer, no longer amenable to cure, with extensive local, regional, or metastatic disease; 2) ≥18 years; 3) understand English sufficiently to complete questionnaires and telephone interviews; 4) emotionally and cognitively capable of participating, as judged by clinic staff. *Exclusion criteria: /* *N recruited:* N=219 consented, n=195 completed baseline measurement. *N in analysis:* Variable according to time-point: T-3 (n=70); T-2 (n=122); T-1 (n=160); T0 (n=192); T1 (n=103); T2 (n=85); T3 (n=67).
Interventions	*Content of screen:* CARE NEEDS: tool= NAT:PD-C: 1) 3 items: patient has a caregiver available; patient or caregiver has requested a referral; health professional needs assistance in managing care, 2) 7 items: patient's well-being: physical, daily living, psychological, information, spiritual/existential, cultural and social, financial, and legal domains; 3) 6 items: ability of caregiver/family to care for the patient: physical, daily living, psychological, information, financial, and legal, and family and relationship domains; 4) 2 items: caregiver's well-being in relation to their own physical, psychological, and bereavement issues. *Screenings interventionist:* Healthcare professionals (several disciplines) use the tool to assess the issues in the consult with the patient. *Intervention procedure:* Solitary SI: healthcare professionals complete the NAT-PD-C during consultation and use the resulting insights in their discussion of and referral for patients' specific care needs or issues. *Conditions for implementation*: 1) Palliative care needs assessment guidelines & NAT: PD-C available; 2) Medical staff, trained in using the NAT: PD-C tool. *Comparative condition:* CG: usual care without use of the NAT:PD-C or training of the professionals on the Palliative Care needs Assessment Guidelines. *Length of follow-up:* 18 months.
Outcomes	*Primary outcomes:* 1) Care needs (SCNS) 2) Needs assessment for advanced cancer patients (NA-ACP): questions on spiritual needs. *Secondary outcomes:* 1) depression and anxiety (HADS); 2) QOL: 2 general questions of the EORTC-QLQ-C30. *Outcome time points:* 7 times: 6, 4 and 2 months before intervention implementation (T-3, T-2, T-1); at start, 2, 4 and 6 months past intervention implementation (T0, T1, T2, T3).
Notes	For bias judgement on NRCT we refer to the ROBINS-I tables in the 'Additional Tables-section'.

Risk of bias table *(judged with ROBINS-I)*

Bias	Authors' judgement	Support for judgement
Bias due to confounding	CRITICAL RISK	Substantial deviations from the intended intervention are present and are not adjusted for in the analysis: "control group" (baseline) is a much unhealthier group (QOL, depression) than "intervention groups" (2 months, 4 months, 6 months follow-up).
Bias in selection of participants into the study	LOW RISK	A sequential recruitment design was used to include eligible participants. The same approach for inclusion was used in the two study phases (first 3 months as intervention group-phase,

		and second 3 months as control group-phase).
Bias in classification of interventions	LOW RISK	The classification of interventions is clear.
Bias due to deviations from intended intervention	MODERATE RISK	A separate publication reports a fidelity (NAT: PD-C due that were actually completed) of 83%.
Bias due to missing data	SERIOUS RISK	A strong variation in sample size across all time points: T-3 (n=70); T-2 (n=122); T-1 (n=160); T0 (n=192); T1 (n=103); T2 (n=85); T3 (n=67), so results are nog always based on the same sample (dropout of+/-30%). Proportions of missing data differ substantially between "control" and "intervention" AND the nature of the missing data means that risk of bias cannot be removed.
Bias in measurement of outcomes	MODERATE RISK	Trained interviewers (so not part of the clinical team) telephoned participants every 2 months during the study period to undertake a computer assisted interview on the subjective outcome variables.
Bias in selection of the reported result	LOW RISK	There is clear evidence that all reported results correspond to all intended outcomes, analyses and sub-cohorts (Waller 2010).
OVERALL RISK OF BIAS	*CRITICAL RISK study*	

Williams 2013	
Methods	Quasi-experimental historically controlled study - with control group (CG) and intervention group (IG).
Participants	Adult cancer patients that started chemo- and/or radiotherapy. *Country:* United States. *Age:* IG: mean 58.24 years(sd9.14), CG: mean 62.33years (sd10.49). *Sex:* IG: 55.2% female; CG: 63.6% female. *Inclusion criteria:* 1) at least 1 day of treatment (radio- or chemotherapy, or both); 2) not participating in ongoing clinical trial; 3) no diagnosed psychopathology; 4) ≥18 years; 5) spoke/read English; 6) Eastern Cooperative Oncology Group score ≤ 3 or Karnofsky score ≥ 60. *Exclusion criteria: /* *N recruited:* N= 128, IG: n= 64, CG: n= 64. *N in analysis:* N= 113; IG: n=58; CG: n=55.
Interventions	*Content of screen:* PHISICAL AND PSYCHOLOGICAL SYMPTOMS: *tool=* TRSC: PROM; 25 symptoms (taste change, loss of appetite, nausea, vomiting, weight loss, sore mouth, cough, sore throat, difficulty swallowing, jaw pain, shortness of breath, numbness of fingers/toes, feeling sluggish, depression, difficulty concentrating, fever, bruising, bleeding, hair loss, skin changes, soreness in vein where chemotherapy was given, difficulty sleeping, pain, decreased interest in sexual activity, constipation) rated using a 5-point scale; 0 (not present) to 4 (very severe); scores indicate occurrence and severity. *Screenings interventionist:* No interventionist for screening act, self-completion of screening tool. *Intervention procedure:* Solitary SI: patients completed TRSC prior to clinical consultation. Clinicians received results of the completed screening intervention form prior to consultation, but however did not receive any training on how to use the form. *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires and to control data management; 2) Training of clinic staff in the use of the study instruments and the importance of complete and consistent follow-up to accrue at least 5 complete sets of instruments from each patient, and advised that on the patients' completion of the form the provider was to be given a copy. *Comparative condition:* CG: usual care: Chemo and radiotherapy, with a wide range of supportive therapies available. Documentation and management of symptoms is done by clinicians and nurses using the standard clinic interview and medical record. *Length of follow-up:* 4 months following the start of chemo- and/or radiotherapy.

Outcomes	*Primary outcomes:* 1) (HR)QOL (HRQOL-LASA). *Secondary outcomes:* 1) Number of symptoms identified and managed. *Outcome time points:* variable: RT patients completed instruments once weekly on the same day each week. CT patients completed them on the day of provider evaluation prior to receiving CT on day 1 of each cycle. # RT and CT cycles varied, depending on treatment protocol.
Notes	For bias judgement on NRCT we refer to the ROBINS-I tables in the 'Additional Tables-section'.

Risk of bias table *(judged with ROBINS-I)*

Bias	Authors' judgement	Support for judgement
Bias due to confounding	LOW RISK	Non-randomized design, but no real confounding expected + thoroughly controlled for potentially confounding factors.
Bias in selection of participants into the study	LOW RISK	A sequential recruitment design was used to include eligible participants. The same approach for inclusion was used in the two study phases.
Bias in classification of interventions	LOW RISK	The classification of interventions is clear.
Bias due to deviations from intended intervention	SERIOUS RISK	Problems with implementation fidelity are apparent (amount of screening interventions/outcome measurements ranged from 2 to 11).
Bias due to missing data	SERIOUS RISK	Dropout of +/-12%.
Bias in measurement of outcomes	NO INFORMATION	Unclear information on outcome assessment (even the six items of the HRQOL-tool are never mentioned), only tools and timing are mentioned, not who assesses it, paper/digital,…
Bias in selection of the reported result	SERIOUS RISK	Results of generalized estimating equations analysis of HRQOL-LASA on covariates is mentioned, no information about the scores of the HRQOL-LASA items itself.
OVERALL RISK OF BIAS	*SERIOUS RISK study*	

Young 2010

Methods	Prospective non-randomized controlled study – first an intervention group (IG), sequentially an usual care control group (UCG).
Participants	Adult colorectal cancer patients that underwent surgery. *Country:* Australia. *Age:* IG: mean 66.9 years ; CG: mean 64.5 years. *Sex:* IG:40% female; CG: 50% female. p = 0.4. *Inclusion criteria:* 1) age ≥18 yrs; 2)underwent surgery in the hospital for colorectal cancer; 3) admitted to Royal Prince Alfred Hospital, Sydney between 25 July and 21 December 2006. *Exclusion criteria:* 1) discharged to another hospital; 2) died during admission; 3) be cognitively impaired and not able to give informed consent or complete questionnaires. *N recruited:* n=41; IG: n=20; CG: n=21. *N in analysis:* n=41; IG: n=20; CG: n=21.
Interventions	*Content of screen:* CARE NEEDS*:* Checklist with 6 areas of potential need (general health, wound, bowel function, investigations/appointments, psychosocial and information needs). *Screenings interventionist:* Intervention nurse to conduct the telephone screening. *Intervention procedure:* SI with co-intervention to use screening results: 5 calls in 6 months following patient's discharge, on days 3 and 10 and at 1, 3 and 6 months. At each timepoint the nurse enquires each aspect of need on checklist If a need identified, she provides information, checks understanding and provides emotional support and advice. If further clinical advice or referral warranted, the patient directed back to the clinical team. *Conditions for implementation*: 1) Training for nurse that conducts the screening; 2)

	Availability of a nurse to conduct all screening calls. *Comparative condition:* CG: Usual care: CG recruited in month 4-6 of the study, receiving usual care following discharge from hospital. *Length of follow-up:* 6 months following discharge from hospital for surgery.
Outcomes	*Primary outcomes:* 1) number of completed and refused calls at each time point, duration of calls, needs identified and data on action taken; 2) proportion of consent, characteristics of participants and those who declined; 3) participants' views of the content, and timing of the intervention; 4) Unmet supportive care needs (SCNS); 5) Psychological Distress (DT); 6) Disease-specific QOL (FACT-C). *Secondary outcomes: /* *Outcome time points:* 1 and 3 months following discharge from hospital for surgery.
Notes	For bias judgement on NRCT we refer to the ROBINS-I tables in the 'Additional Tables-section'.

***Risk of bias table** (judged with ROBINS-I)*

Bias	Authors' judgement	Support for judgement
Bias due to confounding	NO INFORMATION	No information on missing data, but also no smaller numbers of participants mentioned at the outcome tables than the 20 intervention- and 21 control participants mentioned in the section on participants.
Bias in selection of participants into the study	LOW RISK	A sequential recruitment design was used to include eligible participants. The same approach for inclusion was used in the two study phases (first 3 months as intervention group-phase, and second 3 months as control group-phase).
Bias in classification of interventions	LOW RISK	The classification of interventions is clear.
Bias due to deviations from intended intervention	SERIOUS RISK	1) the control condition followed in time after the intervention condition. The routine of screening and discussion patients' needs during the 'intervention phase', can influence the behavior and way of working of the interventionist in the 'control phase'. Consequently the 'usual care' in the control phase possibly is influenced by that and is no usual care anymore; 2) not all follow-up calls of the CONNECT intervention could be done successfully for all participants.
Bias due to missing data	NO INFORMATION	No information on missing data, but also no smaller numbers of participants mentioned at the outcome tables than the 20 intervention- and 21 control participants mentioned in the section on participant characteristics, so outcomes are probably based on all participants.
Bias in measurement of outcomes	NO INFORMATION	Risk of bias seems to be low, the outcomes were measured by an independent researcher that differs from the intervention nurse, but not clear if the independent researcher is aware of participants allocation to the intervention- or the control condition.
Bias in selection of the reported result	LOW RISK	*Reporting of the results is rather complete, only p-values were missing in the results section on psychological distress.* The outcome measurements and analyses are clearly defined and there is no indication of selection of the reported analysis from among multiple analyses; no indication of selection of the cohort or subgroups for analysis and reporting on the basis of the results.
OVERALL RISK OF BIAS	*SERIOUS RISK study*	

Young 2013	
Methods	Cluster RCT - with an intervention group (IG) and a control group (CG).
Participants	Adult patients undergoing surgery for primary colorectal cancer. *Country:* Australia. *Age:* IG: mean 68.6 years ; CG: mean 67.0 years. *Sex:* IG: 43.2% female; CG: 45.8% female. *Inclusion criteria:* 1) adult (≥18years), 2) newly diagnosed with colorectal cancer. *Exclusion criteria:* 1) receiving end-of-life care, 2) cognitively impaired or deaf, 3) no telephone access, 4) insufficient English language skills to participate. *N randomized:* N=775; IG: n=398; CG: n=377. *N in analysis:* Baseline: N=756 , IG: n= 387, CG: n= 369; 1 month: N=709 , IG: n=363, CG: n=346; 3 months: N=687 , IG: n=336, CG: n=351; 6 months: N= 672, IG: n=350, CG: n=322.
Interventions	*Content of screen:* CARE NEEDS: Each call includes 22 standardized screening questions about common physical, psychosocial, information, supportive care, and rehabilitation/follow-up needs. At 1 month, for cancer patients with type C colon cancer topic of adjuvant chemo was raised. *Interventionist:* Colorectal cancer nurse who conducts the telephone screenings, employed specially for this study. *Intervention procedure:* SI with co-intervention to use screening results: 5 scheduled, structured telephone calls on days 3 and 10 and at 1, 3, and 6 months after hospital discharge to screen for needs. Identified needs were addressed by the intervention nurse using detailed, standardized clinical protocols according to the nature and severity of the need and level of clinical risk posed. For low-risk needs, the nurse provided relevant information and advice so that the patients could seek appropriate assistance from their local care providers. For a serious or potentially high-risk problem (e.g, suicidal ideation), the intervention nurse contacted a member of the patient's local health care team directly. No independent referrals to other health professionals were made. *Conditions for implementation*: 1) training for nurse that conducts the telephone screening, 2) availability of nurse to conduct all screening calls, 3) development of detailed, standardized clinical protocols to respond on detected needs. *Comparative condition:* Usual care group. *Length of follow-up:* 6 months following hospital discharge after surgery.
Outcomes	*Primary outcomes:* 1) (HR)QOL at 1,3,6 months (FACT-C). *Secondary outcomes:* 1) Distress at 1,3,6 months (DT), 2) post-operative service utilization at 1,3,6 months, 3) experience of cancer care coordination(20-item questionnaire generating one total and 2 subscale (communication & navigation) scores) at 3 and 6 months, 5) care needs at 3 and 6 months (SCNS). *Outcome time points:* 1, 3, and 6 months after discharge from hospital for surgery.
Notes	

***Risk of bias table** (judged with RoB)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Using a computer-generated random-number list.
Allocation concealment (selection bias)	Unclear risk	Unclear which method was used to conceal the allocation to conditions.
Blinding of participants and personnel (performance bias)	High risk	Patients and staff were not blinded, intervention group patients experienced the telephone calls, and hospital staff was contacted by the intervention nurse (not part of clinical team) in case of problems or needs in patients.
Blinding of outcome assessment (detection bias)	Low risk	Outcomes were measured with self-report questionnaires, no extra person for outcome assessment aware of condition allocation.
Incomplete outcome data (attrition bias)	Low risk	Study authors state "Follow-up participation rates at 1, 3, and 6 months were 91.5%, 88.6%, and 86.7%, respectively." Drop-out of patients from baseline to 6 months assessment +/- 13%;

		equally distributed between both conditions.
Selective reporting (reporting bias)	Low risk	The study protocol is not available but it is clear that the published reports include all expected outcomes.
Other bias	Low risk	/

Appendix 7.5.

Table A7.5. Characteristics of excluded studies tables *[ordered by study ID]*

Study	Reason for exclusion
Bauwens 2014	Wrong outcomes, care outcomes.
Boyes 2006	Wrong comparison, no usual care condition without screening.
Carlson 2010	Wrong comparison, no usual care condition without screening.
Carter 2012	Wrong study design, longitudinal study without control condition.
Girgis 2014	Wrong outcomes, care outcomes.
Hoekstra-Weebers 2012	Wrong comparison, no usual care condition without screening.
Mlachlan 2001	Wrong comparison, no usual care condition without screening.
Sarna 1998	Wrong comparison, no usual care condition without screening.
Stanciu 2015	Wrong comparison, no usual care condition without screening.
Waller 2012a	Wrong outcomes, care outcomes.

Appendix 7.6.

Table A7.6. Characteristics of ongoing studies tables *[ordered by study ID]*

Amstel 2016	
Study name	Registered as 'Nurse Intervention Project (VIP)' in ClinicalTrials.gov (NCT01091584).
Methods	RCT - with intervention group (IG) and control group (CG).
Participants	Patients treated with curative intent for breast cancer. *Country:* The Netherlands. *Age:* results not yet available, ≥18years (inclusion criteria). *Sex:* 100% female (inclusion criteria). *Inclusion criteria:* 1) women with histology proven malignancy of the breast; 2) treatment with curative intent, 3) written and oral fluency in the Dutch language; 4) aged ≥ 18 years. *Exclusion criteria:* 1) men; 2) treated previously for a malignancy (except adequately treated cervix carcinoma in situ and basal cell carcinoma of the skin); 3) women with psychiatric problems that impair adherence to this study. *N randomized:* based on power calculations a total number of 193 patients needs to be included to have sufficient power for the primary and secondary outcomes. *N in analysis:* results not yet available.
Interventions	*Content of screen:* DISTRESS: tool= Distress Thermometer (DT): consists of a thermometer ranging from 0 (no distress) to 10 (extreme distress). In addition the tool contains 47 questions (yes / no answers) related to different issues, called Problem List (PL). The issues have been categorized into: practical issues, family / social issues, emotional issues, religious / spiritual issues, physical issues. The DT concludes with the question: "Would you like to talk with a professional about your problems?" (yes/no/maybe). Interventionist: No interventionist for screening act (self-reported measure). *Interventionist:* use of a self-completion tool, no interventionist for the screening act. *Intervention procedure:* SI with co-intervention to use screening results: The patient will fill out out the DT in the outpatient clinic a few minutes before the appointment, a trained oncology nurse will discuss the DT results with the patient and ask for desire of referral. Time allocated to these meetings will last between 5– 30 min, depending on the severity of the distress and the nature of the problems.5. If the patient reports a DT score of <5 the nurse will inquire whether the patient is sufficiently in control of her situation. The low distress score and the issues marked on the problem list are discussed briefly. At a score ≥5 on the DT, an extensive exploratory conversation between the nurse and the patient will take place. The outcome of this conversation will be discussed in a psychosocial Multi-Disciplinary Team (MDT). *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires and to control data management; 2) A nurse to actively discuss the DT results with patients. *Comparative condition:* Usual care, without using the DT. *Length of follow-up:* two years.
Outcomes	*Primary outcomes:* 1) quality of life (the global quality of life item of the EORTC QLQ-C30). *Secondary outcomes:* 1) functional and symptom scales of the EORTC QLQ-C30 and BR23; 2) anxiety and depression (HADS); 3) coping (Impact of Event Scale); 4) illness cognition (Illness Cognition Questionnaire); 5) distress (DT) (baseline and final measurement only). *Outcome time points:* Questionnaires are obtained in both arms at baseline, after completion of each type of cancer treatment modality and during follow up, with a three and six months' interval during the first and second year respectively.
Starting date	March 2010.
Contact information	Principal Investigator: P. B. Ottevanger, Dr University Medical Centre Nijmegen.
Notes	Information from conference abstract and protocol paper available, no further data received from study authors. Results paper in progress.

Bernacki 2015	
Study name	Registered as 'Serious Illness Communication Project' in ClinicalTrials.gov (NCT01786811).
Methods	Cluster RCT - with intervention group (IG) and control group (CG).
Participants	Patients with advanced, incurable cancer and life expectancy of <12 and their surrogate. *Country:* United States. *Age:* results not yet available, ≥18years (inclusion criteria). *Sex:* results not yet available. *Inclusion criteria:* 1) age >18 years; 2) English-speaking; 3) able to consent and complete periodic Surveys; 4) an adult (≥18years) and English-speaking friend or family member willing to answer surveys as surrogate of the patient; 5) high risk of dying within a year; 6) receiving ongoing primary oncology care at Dana-Farber Cancer Institute. *Exclusion criteria: /* *N randomized:* based on power calculations a total of 426 patients (213 per group) will be accrued at an estimated accrual rate of 200 patients per year. *N in analysis:* results not yet available.
Interventions	*Content of screen:* Overall well-being, information and care preferences: tool = Serious Illness Conversation Guide (SICG): addresses eliciting illness understanding, eliciting decision-making preferences, sharing prognostic information according to preferences, understanding goals and fears, exploring views on trade-offs and impaired function, and wishes for family involvement. *Interventionist:* the treating clinician (oncologists) uses the SICG in the outpatient encounter with the patient. *Intervention procedure:* SI with co-intervention to use screening results: Patients are send a letter to encourage them to think about some of the topics raised in the SICG to prepare them for the conversation with their doctor. During the clinical encounter clinicians use the SICG to conduct patients' values and goals, document outcomes of the discussion in a structured format in the EMR and (7) provide patients with a Family Communication Guide to help them continue the discussion at home with their loved ones. *Conditions for implementation*: 1) development of the SICG; 2) training program for intervention clinicians to develop their competencies in using the SICG; 3) development of a electronic medical record module documentation to register the SICG results in the patient record; 4) development of a Family Guide that suggests an approach for patients to discuss their illness and care preferences with their family *Comparative condition:* usual care control group. *Length of follow-up:* at least 1 year or until death.
Outcomes	*Primary outcomes:* 1) patient receipt of goal-concordant care; 2) peacefulness at the end of Life (PEACE-scale); 3) Key process measures: acceptability of the SICG conversation to patients, acceptability of training to clinicians, number of triggers required to complete SICG, and frequency, timing, and quality of documentation of goals of care discussion. *Secondary outcomes:* anxiety (GAD-7), depression (PHQ-9), quality of life (SF-12 V2 health survey), therapeutic alliance (Human Connection Scale), quality of communication (QOC), and quality of dying (Brief R-COPE) and death . *Outcome time points:* baseline, and a following survey every 2 months.
Starting date	June 2012.
Contact information	Principal Investigator: Rachelle Bernacki, MD, MS Dana-Farber Cancer Institute. Principal Investigator: Atul Gawande, MD, MPH Harvard T.H. Chan School of Public Health. Principal Investigator: Susan Block, MD Dana-Farber Cancer Institute.
Notes	Information from conference abstract and protocol paper available, no further information received from study authors. Results paper in progress.

Singer 2014	
Study name	Registered as 'Stepped Care - Optimizing Psycho-oncological Care Provision by Structured Screening and Diagnosis (STEPPEDCARE)' in ClinicalTrials.gov (NCT01859429).
Methods	Cluster RCT - with intervention group (IG) and control group (CG).
Participants	Adult patients with cancer treated admitted to the University Medical Center Leipzig. *Country:* Germany. *Age:* results not yet available, ≥18years (inclusion criteria). *Sex:* results not yet available. *Inclusion criteria:* 1) patients admitted to University Medical Center Leipzig for diagnosis or treatment of cancer; 2) aged ≥18years; 3) ability to complete questionnaires. *Exclusion criteria:* 1) insufficient command of German; 2) no written informed consent. *N randomized:* based on sample size calculations a total of 800 patients (400 per group) is aimed for. *N in analysis:* results not yet available.
Interventions	*Content of screen:* DISTRESS: no further information on screening tool or exact content. *Interventionist:* Presumably use of a self-completion tool, no interventionist for the screening act. ("the results of this screening are electronically computed, graphically visualized and fed back to the clinician in charge") *Intervention procedure:* SI with co-intervention to use screening results: Step 1: Screening for psychosocial distress Step 2: If a patient is moderately or highly distressed according to step 1, the physician performs a brief structured interview and arranges, if necessary, appropriate psychosocial care Step 3: psychosocial care as indicated by step 2. *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires, to automatically analyze data and generate graphically visualized feedback information for clinicians; 2) Training for clinicians in the use of screening results, and in communication with patients about their emotional problems. *Comparative condition:* usual care without screening. *Length of follow-up:* 6 months.
Outcomes	*Primary outcomes:* 1) Mental health (HADS). *Secondary outcomes:* 1) Social functioning (Role Functioning Subscale, EORTC QLQ-C30); 2) Satisfaction with treatment (QPP); 3) Comorbid mental (SCID); 4) Use of healthcare services (Bundesgesundheitssurvey). *Outcome time points:* at beginning (=baseline) and end of hospital stay, 3 and 6 months after baseline.
Starting date	April 2012.
Contact information	Study Chair: Susanne Singer, Prof. PhD MSc Epidemiology Johannes Gutenberg University of Mainz
Notes	Information from protocol paper available, no further data received from study authors. Results paper in progress.

Sussman 2012	
Study name	Title conference abstract: "Results of a cluster randomized trial to evaluate a nursing lead supportive care intervention in newly diagnosed breast and colorectal cancer patients."
Methods	Cluster RCT - with intervention group (IG) and control group (CG).
Participants	Newly diagnosed breast and colorectal cancer patients. *Country:* Canada. *Age:* results not yet available for the large group, unclear for the subgroup presented with the preliminary results. *Sex:* results not yet available for the large group, unclear for the subgroup presented in the preliminary results record. *Inclusion criteria:* 1) patients newly diagnosed with breast and colorectal cancer; 2) enrolled through surgical practices within 7 days of cancer surgery. *Exclusion criteria:* unclear.

	N randomized: results not yet available for the large group, 193 enrolled when preliminary results were presented at the conference. *N in analysis:* results not yet available for the large group, unclear for the subgroup presented in the preliminary results record.
Interventions	*Content of screen:* CARE NEEDS: no further information on assessment tool and exact content. *Interventionist:* a person that conducts the in person supportive care assessment. *Intervention procedure:* SI with co-intervention to use screening results: an in person supportive care assessment is conducted followed by ongoing supportive care by telephone or in person including linkage to community services using protocol specified guidelines according to identified needs. *Conditions for implementation*: 1) an interventionist to conduct the needs assessment; 2) the development of protocol specified guidelines to respond on the identified needs. *Comparative condition:* a control group involving usual care practices. *Length of follow-up:* 8 weeks.
Outcomes	*Primary outcomes:* 1) unmet need (SCNS); 2) continuity of care (CCCQI). Secondary outcomes: 1) quality of life (EORTC QLQ-C30); 2) health resource utilization; 3) level of uncertainty with care trajectory (MUIS). *Outcome time points:* at 8 weeks.
Starting date	Unclear.
Contact information	First author conference abstract: Dr. Jonathan Sussman, Juravinski Cancer Centre, Hamilton, Ontario.
Notes	Information from conference abstract available, no further data received from study authors. Only preliminary results were presented at conference, full results paper in progress.

Cooley	
Study name	Title conference abstract: "Point-of-care clinical decision support for cancer symptom management: Results of a group randomized trial."
Methods	RCT - with intervention group (IG) and control group (CG).
Participants	Cancer patients (no further specification in conference abstract). *Country:* United States. *Age:* mean age of 63 years. *Sex:* 58% female. *Inclusion criteria:* unclear. *Exclusion criteria:* unclear. *N randomized:* n=179, number of patients in each condition unclear. *N in analysis:* unclear.
Interventions	*Content of screen:* BIOPSYCHOSOCIAL WELL-BEING: The symptom assessment resulted in insight on patients' pain, fatigue, depression, anxiety and/or dyspnea. *Interventionist:* Presumably use of a self-completion tool, no interventionist fort he screening act. ("patients completed the web based symptom assessment") *Intervention procedure:* SI with co-intervention to use screening results: Prior to each visit for 6 months, patients completed the symptom assessment. A tailored report provided a longitudinal symptom report, and suggestions for management were provided to clinicians in the SAMI arm prior to the visit. *Conditions for implementation*: 1) A system/person is needed to deliver and collect questionnaires, to automatically analyze and manage data, and generate the feed back information for clinicians, including suggestions for management. 2) The development of the electronic system generating problem management suggestions. *Comparative condition:* usual care condition. *Length of follow-up:* 6 months.
Outcomes	*Primary outcomes:* 1) Communication about symptoms; 2) the treatment outcome index (TOI) was the primary outcome for HR-QOL.

	Secondary outcomes: Management of the target symptoms (chart review). *Outcome time points:* baseline, 2, 4 and 6 months.
Starting date	Unclear.
Contact information	First author conference abstract: Prof. dr. Mary E. Cooley, Dana-Farbe/ Harvard Cancer Institute, Boston.
Notes	Information from conference abstract available, no further information received from study authors. Results paper in preparation.

Appendix 7.7.

Table A7.7. Characteristics of studies awaiting classification table

[ordered by study ID]

Frennet 2011	
Methods	Multicenter phase II RCT (ONGOING)
Participants	Frail elderly patients with newly diagnosed cancer. *Country:* not reported. *Age:* mean 79.3 yrs (SD 5.8). *Sex:* 57.7% women. *Inclusion criteria:* 1) patients aged over 70 yrs, 2) newly diagnosed with cancer for which initiation of therapy was considered, 3) frail patients (VES-13, score >3/10). *Exclusion criteria:* 1) VES-13, score <3/10. *N randomized:* (ongoing): IG: 53; CG: 58. *N in analysis:* not applicable (ongoing).
Interventions	*Content of screen:* Comprehensive geriatric assessment. Exact content of screen unclear. *Interventionist:* not reported. *Intervention procedure:* not reported. *Conditions for implementation*: not reported. *Comparative condition:* conventional oncological management. *Length of follow-up:* unclear, 6 months?
Outcomes	*Primary outcomes:* Functional decline at 6 months (change in ADL-score) *Secondary outcomes:* unclear. *Outcome time points:* one at 6 months.
Notes	Information from conference abstract available, no further information received from study authors.

Mehanna 2010	
Methods	RCT.
Participants	Adult patients with neck and head cancer in follow-up clinic. *Country:* United Kingdom. *Age:* adult. *Sex:* men and women. *Inclusion criteria:* 1) early or advanced oral/oropharyngeal and laryngeal cancer with completed curative treatment 1 - 12 months previously; 2) attend head and neck follow-up clinic; 3) male and female patients ≥18 years; 4) ability to communicate in and read English; 5) ability to give informed consent. *Exclusion criteria:* 1) undergoing treatment for palliation; 2) cancers that are not laryngeal or oral/oropharyngeal. *N randomized:* Targeted n= 44. *N in analysis:* unclear.

Interventions	*Content of screen:* (HR)QOL: tool= the FACT HN *Interventionist:* no interventionist for the screening act, self-completion on a touch screen computer. *Intervention procedure:* solitary SI: patients complete the screening on a tablet touch screen computer before their clinic visit, then take a print out of the results when they see the doctor or nurse. (doctor and nurse led clinics). *Conditions for implementation*: not reported. *Comparative condition:* not reported. *Length of follow-up:* unclear, probably no follow-up..
Outcomes	*Primary outcomes:* 1) Improvement in the Consultation and Relational Skills Questionnaire. *Secondary outcomes:* 2) Patient Enablement Instrument; 2) Perceived Involvement in Care Scale; 3) EORTC QLQ-C30; 4) EORTC QLQ-HN35. *Outcome time points:* baseline and 4-6 weeks following the intervention.
Notes	Information from ISRCTN registry available, no further information received from study authors.

Munro 1994

Methods	RCT – with intervention group (IG) and control group (CG).
Participants	Outpatients attending for radiotherapy. *Country:* United Kingdom. *Age:* CG: median 65 years (37-88); IG: median 63 years (30-87). *Sex:* CG: 58.8% female, 41.2% male; IG: 57.1% female, 42.9% male. *Inclusion criteria:* 1) outpatients attending for radiotherapy under the care of one consultant. *Exclusion criteria:* 1) patients who did not understand English; 2) patients who did not have a telephone; 3) patients with HIV related malignancies; 4) patients treated with less than five fractions of radiotherapy; 5) hospital inpatients. *N randomized:* n=100; IG: n=49; CG: n=51. *N in analysis:* IG: n=44; CG: n=51.
Interventions	*Content of screen:* OVERALL WELL-BEING: questions to be asked: 'How are you feeling?' 'Are you having any problems?' 'Have you any further side effects from treatment?' 'Do you need to make an appointment to be seen in the Radiotherapy department before your outpatient appointment?' Patients were asked if they had any additional worries or concerns. Wherever possible, the appropriate action was taken. *Interventionist:* The telephone calls were made by a member of staff, radiographer, nurse, or doctor who was known to the patient. *Intervention procedure:* solitary SI: semi structured telephone calls to the patient on days 4, 8, 14 and 18 after completing radiotherapy. *Conditions for implementation*: A simple log form needed to record the responses to the set questions and any other relevant information for each telephone call. *Comparative condition:* Usual care group (i.e. having once a week a consultation in the clinic by a doctor during treatment + no contact between completing treatment and the first follow-up visit) *Length of follow-up:* last phone call 18 days after completing radiotherapy, probably no further follow-up provided as part of the study intervention
Outcomes	*Primary outcomes:* Adequacy of support (CG + IG): 'How adequate do you describe the support after treatment?'. *Secondary outcomes:* Helpfulness of telephone calls (IG): 'How helpful do you find the telephone calls?'. *Outcome time points:* 4 weeks after completing radiotherapy treatment (i.e. at the first follow-up visit).
Notes	Information from a journal article (Clinical Oncology, 1994) available, no futher information received from study authors.

Powell 2008	
Methods	RCT – with intervention group with completion (IGC), intervention without completion (IGWC), and control group (CG).
Participants	Gynecologic cancer patients. *Country:* United States. *Age:* IGC: mean 52.2 years (30-78); IGWC: mean 47.2 years (27-76); CG: mean 49.8 years (24-79). *Sex:* 100% women. *Inclusion criteria:* 1) new patients attending a tertiary care gynecological cancer center for the first time with the new diagnosis or high suspicion of a gynecologic cancer. *Exclusion criteria:* 1) not understanding English; 2) women who are deemed too ill or confused to participate. *N randomized:* n=100; IG (IGC + IGWC): n=49; CG: n=50; *N in analysis:* IGC: n=21; IGWC: n=28 (however, for IG only n=45 completed baseline); CG: n=51.
Interventions	*Content of screen:* OVERALL WELL-BEING: issues and concerns that the woman may have about her symptoms and potential cancer diagnosis. *Interventionist:* psychologist. *Intervention procedure:* solitary SI: patients received a single counseling session of 1 hour with a psychologist. This meeting focused on discussing issues and concerns that the woman may have about her symptoms and potential cancer diagnosis. *Conditions for implementation*: 1) having a psychologist in the setting that is available to conduct the counseling sessions with every patient. *Comparative condition:* control group (usual care). *Length of follow-up:* 3 months.
Outcomes	*Primary outcomes/ Secondary outcomes:* 1) (HR)QOL (FACIT-II); 2) Mood (POMS); 3) coping style (Index of Coping Responses); 4) Satisfaction with the clinic (questionnaire with Likert scale) *Outcome time points:* baseline (at the time of the counseling session); 2 weeks and 3 months after baseline.
Notes	Information from a journal article (Gynecologic Oncology, 2008) available, no futher information received from study authors.

Skorstengaard 2014	
Methods	RCT.
Participants	Patients from oncology, cardiology and respiratory departments. *Country:* Denmark. *Age:* not reported. *Sex:* not reported. *Inclusion criteria:* patients from oncology, cardiology and respiratory departments. *Exclusion criteria:* not reported *N randomized:* not reported *N in analysis:* not reported
Interventions	*Content of screen:* well-being and preferences for end-of-life care. *Interventionist:* a health care professional conducts the discussion with the patient and if possible a relative. *Intervention procedure:* unclear. *Conditions for implementation*: not reported. *Comparative condition:* usual care. *Length of follow-up:* unclear.
Outcomes	*Primary outcomes/ Secondary outcomes:* 1) QOL; 2) satisfaction with health care services; 3) meeting preferences for place of care and death; 4) anxiety, and 5) psychological distress in patients and relatives *Outcome time points:* unclear, after death of patients, relatives are questioned.

Notes	Information from conference abstract available, no further information received from study authors.

Appendix 7.8.

Table A7.8.1. Evidence Summary: continuous outcomes

Main outcome	Sub-outcome	Time post intervention	Scale used	Intervention (screening)			Control (usual care)			MD (95%CI)	Study ID
				Mean	SD	N	Mean	SD	N		
HRQOL (cont)	Global health status	1 month	EORTC-QLQ-C30	65.18	17.43	28	51.49	26.16	28	13.69 [2.05, 25.33]	Bramsen 2008
				61.8	20.9	109	61.2	18.2	103	0.60 [-4.67, 5.87]	Hollingworth 2013
			EQ-5D	0.739	0.223	109	0.74	0.249	103	-0.00 [-0.06, 0.06]	
			FACT-C	107.8	11.9	20	101.2	22.3	21	6.60 [-4.27, 17.47]	Young 2010
				96.1	18.5	35	98.3	19.7	31	0.21 [-2.47, 2.89]	Harrison 2011
				100.61	17.78	346	100.4	18.6	363	0.01 [-0.14, 0.16]	Young 2013
		6 weeks	EORTC-QLQ-C30	63.1	25	42	65.5	25	44	-0.10 [-0.52, 0.33]	Nimako 2015
				65.4	20.825	45	65.5	25	44	-0.00 [-0.42, 0.41]	
		2 months		57.5	4.74	103	58	4.75	192	-0.11 [-0.34, 0.13]	Waller 2012
		3 months	EORTC-QLQ-C30	72.61	20.08	268	71.48	19.62	300	0.06 [-0.11, 0.22]	Braeken 2013
			FLIC	116.5	21.1	60	114.1	24.7	60	0.10 [-0.23, 0.44]	Rosenbloom 2007
				112.1	20.6	60	114.1	24.7	60	-0.09 [-0.41, 0.24]	
			FACT-C	114.2	13.5	20	101.5	19.1	21	0.75 [0.11, 1.39]	Young 2010

				97.5	21.4	34	96.2	21.9	29	0.06 [-0.44, 0.55]	Harrison 2011
				103.48	18.17	336	103.26	18.58	351	0.01 [-0.14, 0.16]	Young 2013
		4 months	EORTC-QLQ-C30	56.5	5.09	85	58	4.75	192	-0.31 [-0.56, -0.05]	Waller 2012
		6 months		69.3	22.14	281	68	21.89	297	0.06 [-0.10, 0.22]	Bergholdt 2013
				77	16	80	80	18	80	-0.18 [-0.49, 0.14]	de Leeuw 2013
				68.6	17.7	108	68.3	18.2	101	0.02 [-0.25, 0.29]	Hollingworth 2013
				57.5	5.39	67	58	4.75	192	-0.10 [-0.38, 0.18]	Waller 2012
			EQ-5D	0.783	0.217	108	0.79	0.246	103	-0.03 [-0.30, 0.24]	Hollingworth 2013
			FLIC	115.8	22.9	51	112.2	21.4	52	0.16 [-0.17, 0.49]	Rosenbloom 2007
				113.3	24.5	51	112.2	21.4	52	0.05 [-0.28, 0.37]	
			FACT-C	106	19.3	28	98.6	23.4	30	0.34 [-0.18, 0.86]	Harrison 2011
				105.1	17.88	322	105.35	19.5	350	-0.01 [-0.16, 0.14]	Young 2013
		12 months	EORTC-QLQ-C30	75.95	18.7	268	76.09	17.53	300	-0.01 [-0.17, 0.16]	Braeken 2013
				81	18	80	80	17	80	0.06 [-0.25, 0.37]	de Leeuw 2013
				68.5	20.2	106	69.6	20.4	103	-0.05 [-0.33, 0.22]	Hollingworth 2013
			EQ-5D	0.742	0.268	106	0.788	0.257	103	-0.17 [-0.45, 0.10]	

		14 months	EORTC-QLQ-C30	72.1	19.66	240	72.8	19.71	246	-0.04 [-0.21, 0.14]	Bergholdt 2013
		4th follow-up visit	SF-36	46	N/A	108	47	N/A	110	N/E	Hilarius 2008
	Physical functioning	1 month	EORTC-QLQ-C30	80.48	20.84	28	63.63	23.42	28	16.85 [5.24, 28.46]	Bramsen 2008
				81.9	20.5	109	80.7	20.5	103	1.20 [-4.32, 6.72]	Hollingworth 2013
			FACT-C	22.8	3.3	20	21.8	5.1	21	1.00 [-1.62, 3.62]	Young 2010
		6 weeks	EORTC-QLQ-C30	74.6	21.675	42	72.2	21.675	43	2.40 [-6.82, 11.62]	Nimako 2015
				73.8	25	43	72.2	21.675	43	1.60 [-8.29, 11.49]	
		2 months		57.21	30.33	55	60.2	29.99	53	-2.99 [-14.37, 8.39]	Schofield 2013
		3 months		79.63	21.02	268	81.78	17.83	300	-2.15 [-5.38, 1.08]	Braeken 2013
				63.49	27.66	55	59.09	26.57	53	4.40 [-5.83, 14.63]	Schofield 2013
			FLIC	45.9	12	69	45.7	11.9	71	0.20 [-3.76, 4.16]	Rosenbloom 2007
				44.5	10.4	60	45.7	11.9	60	-1.20 [-5.20, 2.80]	
			FACT-C	24.4	3.2	20	22.1	5.2	21	2.30 [-0.33, 4.93]	Young 2010
		6 months	EORTC-QLQ-C30	79.7	22.1	280	79	22.65	294	0.70 [-2.96, 4.36]	Bergholdt 2013
				83	17	80	86	16	80	-3.00 [-8.12, 2.12]	de Leeuw 2013

				84.2	19	108	83.8	18.6	101	0.40 [-4.70, 5.50]	Hollingworth 2013
			FLIC	46.7	11.6	51	45.2	9.8	52	1.50 [-2.65, 5.65]	Rosenbloom 2007
				45	20.6	51	45.2	9.8	52	-0.20 [-6.45, 6.05]	
		12 months	EORTC-QLQ-C30	81.99	18.06	268	85	17.76	300	-3.01 [-5.96, -0.06]	Braeken 2013
				86	17	80	87	16	80	-1.00 [-6.12, 4.12]	de Leeuw 2013
				83.8	19.3	106	85.5	17.8	103	-1.70 [-6.73, 3.33]	Hollingworth 2013
		14 months		82	20.19	234	81.9	20.45	240	0.10 [-3.56, 3.76]	Bergholdt 2013
		4th follow-up visit	SF-36	53	28	104	52	26	95	1.00 [-6.50, 8.50]	Detmar 2002
				69	N/A	108	62	N/A	110	N/E	Hilarius 2008
	Role functioning	1 month	EORTC-QLQ-C30	57.14	27.75	28	39.88	35.35	28	17.26 [0.61, 33.91]	Bramsen 2008
				69.4	31.3	109	68	28.8	103	1.40 [-6.69, 9.49]	Hollingworth 2013
			FACT-C	13.8	6.1	20	12.1	5.8	21	1.70 [-1.95, 5.35]	Young 2010
		6 weeks	EORTC-QLQ-C30	70.63	25	42	69.7	25	44	0.93 [-9.64, 11.50]	Nimako 2015
				62.5	25	44	69.7	25	44	-7.20 [-17.65, 3.25]	
		2 months		57.03	36.71	55	56.82	35.82	53	0.21 [-13.47, 13.89]	Schofield 2013

		3 months		72.77	29.77	268	72.87	27.52	300	-0.10 [-4.83, 4.63]	Braeken 2013
				58.48	36.86	55	65.01	35.16	53	-6.53 [-20.11, 7.05]	Schofield 2013
			FACT-C	21.4	4.8	20	17.4	7.3	21	4.00 [0.24, 7.76]	Young 2010
		6 months	EORTC-QLQ-C30	72.5	31.28	277	71.3	31.2	291	1.20 [-3.94, 6.34]	Bergholdt 2013
				79	26	80	81	24	80	-2.00 [-9.75, 5.75]	de Leeuw 2013
				79.2	24.9	108	79.7	27.6	101	-0.50 [-7.64, 6.64]	Hollingworth 2013
		12 months		80.26	26.65	268	82.44	24.7	300	-2.18 [-6.42, 2.06]	Braeken 2013
				81	27	80	85	25	80	-4.00 [-12.06, 4.06]	de Leeuw 2013
				80.5	26.4	106	84.1	21.9	103	-3.60 [-10.17, 2.97]	Hollingworth 2013
		14 months		78.8	29.57	235	78	28.25	239	0.80 [-4.41, 6.01]	Bergholdt 2013
	Role functioning (emotional)	4th follow-up visit	SF-36	69	44	104	60	44	95	9.00 [-3.24, 21.24]	Detmar 2002
				66	N/A	108	68	N/A	110	N/E	Hilarius 2008
	Role functioning (physical)			36	42	104	31	41	95	5.00 [-6.54, 16.54]	Detmar 2002
				30	N/A	108	33	N/A	110	N/E	Hilarius 2008

	Emotional functioning	1 month	EORTC-QLQ-C30	78.28	15.93	28	65.87	20.51	28	12.41 [2.79, 22.03]	Bramsen 2008
				79.1	21.1	109	77.8	21.4	103	1.30 [-4.42, 7.02]	Hollingworth 2013
			FACT-C	21.2	2	20	19.4	3.7	21	1.80 [-0.01, 3.61]	Young 2010
		6 weeks	EORTC-QLQ-C30	74.2	22.925	42	76.4	20.825	43	-2.20 [-11.52, 7.12]	Nimako 2015
				76.6	25	43	76.4	20.825	43	0.20 [-9.53, 9.93]	
		2 months		81.43	24.62	55	73.23	24.1	53	8.20 [-0.99, 17.39]	Schofield 2013
		3 months		78.38	22.75	268	79.46	20.68	300	-1.08 [-4.67, 2.51]	Braeken 2013
				75.31	26.7	55	75.51	25.26	53	-0.20 [-10.00, 9.60]	Schofield 2013
			FACT-C	21.8	1.9	20	19.2	3.2	21	2.60 [1.00, 4.20]	Young 2010
		6 months	EORTC-QLQ-C30	81.6	21.17	278	80.5	20.87	293	1.10 [-2.35, 4.55]	Bergholdt 2013
				84	19	80	85	19	80	-1.00 [-6.89, 4.89]	de Leeuw 2013
				81.2	18	108	80.3	20.7	101	0.90 [-4.37, 6.17]	Hollingworth 2013
		12 months		83.66	20.8	268	81.23	20.6	300	2.43 [-0.98, 5.84]	Braeken 2013
				82	23	80	85	18	80	-3.00 [-9.40, 3.40]	de Leeuw 2013

				78.7	21.6	106	80.3	21.4	103	-1.60 [-7.43, 4.23]	Hollingworth 2013
		14 months		80.8	21.93	238	80.7	22	240	0.10 [-3.84, 4.04]	Bergholdt 2013
	Cognitive functioning	1 month		85.12	19.43	28	75	25.46	28	10.12 [-1.74, 21.98]	Bramsen 2008
				79.8	20.5	109	78.2	21.8	103	1.60 [-4.10, 7.30]	Hollingworth 2013
		6 weeks		76.6	25	42	81.4	25	43	-4.80 [-15.43, 5.83]	Nimako 2015
				83.7	25	41	81.4	25	43	2.30 [-8.40, 13.00]	
		2 months		80.45	26.25	55	75.34	25.7	53	5.11 [-4.69, 14.91]	Schofield 2013
		3 months		83.92	19.73	268	84.27	19.49	300	-0.35 [-3.58, 2.88]	Braeken 2013
				80.4	27.51	55	77.73	26.21	53	2.67 [-7.46, 12.80]	Schofield 2013
		6 months		83.9	22.02	278	83	21.63	290	0.90 [-2.69, 4.49]	Bergholdt 2013
				88	17	80	87	17	80	1.00 [-4.27, 6.27]	de Leeuw 2013
				81	20.3	108	80.7	19.7	101	0.30 [-5.12, 5.72]	Hollingworth 2013
		12 months		82.46	22.11	268	82.82	19.98	300	-0.36 [-3.84, 3.12]	Braeken 2013

				87	20	80	86	21	80	1.00 [-5.35, 7.35]	de Leeuw 2013
				82.9	18.6	106	79.8	22.5	103	3.10 [-2.51, 8.71]	Hollingworth 2013
		14 months		85.1	23.49	238	82.6	23.04	245	2.50 [-1.65, 6.65]	Bergholdt 2013
	Social functioning	1 month		66.07	26.64	28	61.63	29.06	28	4.44 [-10.16, 19.04]	Bramsen 2008
				69	31.7	109	67.3	29.7	103	1.70 [-6.57, 9.97]	Hollingworth 2013
			FACT-C	23.4	3.8	20	22.6	5.4	21	0.80 [-2.05, 3.65]	Young 2010
		6 weeks	EORTC-QLQ-C30	73.8	25	42	75.8	25	42	-2.00 [-12.69, 8.69]	Nimako 2015
				75.8	25	44	75.8	25	42	0.00 [-10.57, 10.57]	
		2 months	EORTC-QLQ-C30	68.28	31.96	55	70.58	31.16	53	-2.30 [-14.20, 9.60]	Schofield 2013
		3 months		83.46	23.57	268	81.81	22.37	300	1.65 [-2.14, 5.44]	Braeken 2013
				65.03	34.11	55	71.29	32.61	53	-6.26 [-18.84, 6.32]	Schofield 2013
			FLIC	11.6	2.4	60	11.4	2.3	60	0.20 [-0.64, 1.04]	Rosenbloom 2007
				11.2	2.4	60	11.4	2.3	60	-0.20 [-1.04, 0.64]	
			FACT-C	24.1	3.7	20	22.8	4.4	21	1.30 [-1.18, 3.78]	Young 2010
		6 months	EORTC-QLQ-C30	86	23.8	280	85.7	23.56	295	0.30 [-3.57, 4.17]	Bergholdt 2013

				91	15	80	90	16	80	1.00 [-3.81, 5.81]	de Leeuw 2013
				78.3	26.8	108	78.2	28.2	101	0.10 [-7.37, 7.57]	Hollingworth 2013
			FLIC	11.4	2.3	51	11.5	1.8	52	-0.10 [-0.90, 0.70]	Rosenbloom 2007
				11.1	2.3	51	11.5	1.8	52	-0.40 [-1.20, 0.40]	
		12 months	EORTC-QLQ-C30	86.99	20.73	268	87.55	19.1	300	-0.56 [-3.85, 2.73]	Braeken 2013
				90	19	80	91	21	80	-1.00 [-7.21, 5.21]	de Leeuw 2013
				81.3	27.5	106	84	23.4	103	-2.70 [-9.62, 4.22]	Hollingworth 2013
		14 months		87.4	21.93	238	88.2	22.11	242	-0.80 [-4.74, 3.14]	Bergholdt 2013
		4th follow-up visit	SF-36	65	30	104	63	29	95	2.00 [-6.20, 10.20]	Detmar 2002
				69	N/A	108	65	N/A	110	N/E	Hilarius 2008
	Fatigue	1 month	EORTC-QLQ-C30	58.33	23.55	28	43.25	28.74	28	15.08 [1.32, 28.84]	Bramsen 2008
		3 months		66.93	26.64	268	67.06	25.18	300	-0.13 [-4.41, 4.15]	Braeken 2013
		6 months		65.8	28	279	62.6	26.92	292	3.20 [-1.31, 7.71]	Bergholdt 2013
				76	21	80	75	23	80	1.00 [-5.82, 7.82]	de Leeuw 2013

		12 months		74.07	24.15	268	76.29	22.63	300	-2.22 [-6.08, 1.64]	Braeken 2013
				81	25	80	78	24	80	3.00 [-4.59, 10.59]	de Leeuw 2013
		14 months		67.7	26.4	234	67.9	26.17	244	-0.20 [-4.91, 4.51]	Bergholdt 2013
	Nausea/vomiting	1 month		82.14	22.19	28	74.4	27.02	28	7.74 [-5.21, 20.69]	Bramsen 2008
		3 months		92.85	18.51	268	95.77	12.2	300	-2.92 [-5.53, -0.31]	Braeken 2013
			FLIC	11.6	2.7	60	11.4	2.7	60	0.20 [-0.77, 1.17]	Rosenbloom 2007
				11.5	2.7	60	11.4	2.7	60	0.10 [-0.87, 1.07]	
		6 months	EORTC-QLQ-C30	92	17.12	284	91.9	17.6	300	0.10 [-2.72, 2.92]	Bergholdt 2013
				97	13	80	96	13	80	1.00 [-3.03, 5.03]	de Leeuw 2013
			FLIC	11.8	2.7	51	11.1	2.9	52	0.70 [-0.38, 1.78]	Rosenbloom 2007
				11.6	3	51	11.1	2.9	52	0.50 [-0.64, 1.64]	
		12 months	EORTC-QLQ-C30	96.86	10.43	268	96.23	12.9	300	0.63 [-1.29, 2.55]	Braeken 2013
				97	13	80	96	10	80	1.00 [-2.59, 4.59]	de Leeuw 2013
		14 months		94.4	13.26	236	94.5	12.69	244	-0.10 [-2.42, 2.22]	Bergholdt 2013

	Pain	1 month		84.52	21.24	28	63.69	33.96	28	20.83 [5.99, 35.67]	Bramsen 2008
		3 months		82.09	25.44	268	81.34	23.49	300	0.75 [-3.29, 4.79]	Braeken 2013
		6 months		78	26.91	274	77	27.35	283	1.00 [-3.51, 5.51]	Bergholdt 2013
				85	22	80	86	23	80	-1.00 [-7.97, 5.97]	de Leeuw 2013
			EORTC-QLQ-H&N35	85	16	80	85	14	80	0.00 [-4.66, 4.66]	
		12 months	EORTC-QLQ-C30	85.16	22.02	268	86.33	23.22	300	-1.17 [-4.89, 2.55]	Braeken 2013
				88	22	80	85	22	80	3.00 [-3.82, 9.82]	de Leeuw 2013
			EORTC-QLQ-H&N35	86	17	80	86	18	80	0.00 [-5.43, 5.43]	
		14 months	EORTC-QLQ-C30	78.6	27.95	234	78.1	26.79	241	0.50 [-4.43, 5.43]	Bergholdt 2013
		4th follow-up visit	SF-36	68	28	104	66	28	95	2.00 [-5.79, 9.79]	Detmar 2002
				74	N/A	108	75	N/A	110	N/E	Hilarius 2008
	Dyspnea	1 month	EORTC-QLQ-C30	82.14	21.24	28	77.78	22.65	28	4.36 [-7.14, 15.86]	Bramsen 2008
		3 months		82.41	25.44	268	81.44	27.52	300	0.97 [-3.39, 5.33]	Braeken 2013
		6 months		82.1	27.49	286	83	27.15	297	-0.90 [-5.34, 3.54]	Bergholdt 2013

				90	20	80	86	23	80	4.00 [-2.68, 10.68]	de Leeuw 2013
		12 months		85.9	20.73	268	84.95	24.97	300	0.95 [-2.81, 4.71]	Braeken 2013
				88	21	80	88	19	80	0.00 [-6.21, 6.21]	de Leeuw 2013
		14 months		84.6	27.12	233	86.8	25.43	245	-2.20 [-6.92, 2.52]	Bergholdt 2013
	Insomnia	1 month		88.1	18.62	28	69.05	29.99	28	19.05 [5.97, 32.13]	Bramsen 2008
		3 months		73.39	30.19	268	71.83	30.13	300	1.56 [-3.41, 6.53]	Braeken 2013
		6 months		72.7	31.73	285	72.5	30.91	302	0.20 [-4.87, 5.27]	Bergholdt 2013
				80	28	80	82	25	80	-2.00 [-10.23, 6.23]	de Leeuw 2013
		12 months		75.73	30.27	268	77.95	28.42	300	-2.22 [-7.07, 2.63]	Braeken 2013
				81	30	80	82	25	80	-1.00 [-9.56, 7.56]	de Leeuw 2013
		14 months		71.5	32.24	240	70.4	31.98	248	1.10 [-4.60, 6.80]	Bergholdt 2013
	Appetite loss	1 month		75	30.93	28	61.9	33.6	28	13.10 [-3.82, 30.02]	Bramsen 2008
		3 months		85.96	26	268	91.43	21.36	300	-5.47 [-9.41, -1.53]	Braeken 2013

		6 months		84.1	27.59	288	85.9	27.33	301	-1.80 [-6.24, 2.64]	Bergholdt 2013
				87	23	80	91	19	80	-4.00 [-10.54, 2.54]	de Leeuw 2013
		12 months		94.01	17.37	268	93.36	18.22	300	0.65 [-2.28, 3.58]	Braeken 2013
				93	17	80	92	21	80	1.00 [-4.92, 6.92]	de Leeuw 2013
		14 months		92.1	19.62	239	90.4	19.91	246	1.70 [-1.82, 5.22]	Bergholdt 2013
	Constipation	1 month		83.33	26.45	28	79.76	24.58	28	3.57 [-9.80, 16.94]	Bramsen 2008
		3 months		91.6	18.73	268	89.63	21.98	300	1.97 [-1.38, 5.32]	Braeken 2013
		6 months		88.7	25.68	284	87.4	25.48	299	1.30 [-2.85, 5.45]	Bergholdt 2013
				92	21	80	94	14	80	-2.00 [-7.53, 3.53]	de Leeuw 2013
		12 months		95.03	14.5	268	92.54	17.73	300	2.49 [-0.16, 5.14]	Braeken 2013
				93	18	80	94	15	80	-1.00 [-6.13, 4.13]	de Leeuw 2013
		14 months		91.1	23.39	236	88.1	23.19	248	3.00 [-1.15, 7.15]	Bergholdt 2013
	Diarrhea	1 month		90.48	19.99	28	83.33	23.13	28	7.15 [-4.17, 18.47]	Bramsen 2008
		3 months		90.29	19.71	268	88.53	22.29	300	1.76 [-1.69, 5.21]	Braeken 2013

		6 months		88.6	22.26	284	88.7	21.97	299	-0.10 [-3.69, 3.49]	Bergholdt 2013
				95	15	80	94	16	80	1.00 [-3.81, 5.81]	de Leeuw 2013
		12 months		92.22	17.55	268	92.41	17.8	300	-0.19 [-3.10, 2.72]	Braeken 2013
				96	11	80	92	18	80	4.00 [-0.62, 8.62]	de Leeuw 2013
		14 months		90	23.49	238	88.6	23.28	250	1.40 [-2.75, 5.55]	Bergholdt 2013
	Financial difficulties	1 month		90.48	21.96	28	88.1	22.62	28	2.38 [-9.30, 14.06]	Bramsen 2008
		3 months		94.88	15.54	268	93.14	17.34	300	1.74 [-0.96, 4.44]	Braeken 2013
		6 months		92	19.69	284	92.4	19.27	297	-0.40 [-3.57, 2.77]	Bergholdt 2013
				93	17	80	92	20	80	1.00 [-4.75, 6.75]	de Leeuw 2013
		12 months		92.98	17.96	268	93.23	19.42	300	-0.25 [-3.32, 2.82]	Braeken 2013
				92	22	80	93	15	80	-1.00 [-6.83, 4.83]	de Leeuw 2013
		14 months		93.3	20.27	236	93.5	20.53	242	-0.20 [-3.86, 3.46]	Bergholdt 2013
	Swallowing	6 months	EORTC-QLQ-H&N35	96	18	80	89	16	80	7.00 [1.72, 12.28]	de Leeuw 2013
		12 months		91	19	80	90	15	80	1.00 [-4.30, 6.30]	

	Senses	6 months		83	24	80	86	21	80	-3.00 [-9.99, 3.99]
		12 months		82	26	80	85	23	80	-3.00 [-10.61, 4.61]
	Speech	6 months		88	21	80	92	15	80	-4.00 [-9.66, 1.66]
		12 months		89	19	80	90	19	80	-1.00 [-6.89, 4.89]
	Social eating	6 months		85	18	80	91	19	80	-6.00 [-11.74, -0.26]
		12 months		90	19	80	91	17	80	-1.00 [-6.59, 4.59]
	Social contact	6 months		94	10	80	96	9	80	-2.00 [-4.95, 0.95]
		12 months		95	12	80	97	8	80	-2.00 [-5.16, 1.16]
	Less sexuality	6 months		81	26	80	80	29	80	1.00 [-7.53, 9.53]
		12 months		81	27	80	85	23	80	-4.00 [-11.77, 3.77]
	Teeth problems	6 months		85	28	80	83	27	80	2.00 [-6.52, 10.52]
		12 months		89	24	80	88	24	80	1.00 [-6.44, 8.44]
	Opening mouth	6 months		83	29	80	86	23	80	-3.00 [-11.11, 5.11]
		12 months		89	21	80	90	21	80	-1.00 [-7.51, 5.51]
	Dry mouth	6 months		59	33	80	62	35	80	-3.00 [-13.54, 7.54]
		12 months		62	34	80	67	33	80	-5.00 [-15.38, 5.38]
	Sticky saliva	6 months		66	32	80	77	32	80	-11.00 [-20.92, -

											1.08]
		12 months		75	32	80	78	29	80	-3.00 [-12.46, 6.46]	
	Coughing	6 months		84	23	80	80	30	80	4.00 [-4.28, 12.28]	
		12 months		80	26	80	85	25	80	-5.00 [-12.90, 2.90]	
	Feeling ill	6 months		94	17	80	88	24	80	6.00 [-0.44, 12.44]	
		12 months		93	22	80	91	18	80	2.00 [-4.23, 8.23]	
	Use of pain killers	6 months		71	46	80	76	43	80	-5.00 [-18.80, 8.80]	
		12 months		78	42	80	78	42	80	0.00 [-13.02, 13.02]	
	Use of nutritional supplements	6 months		78	42	80	87	34	80	-9.00 [-20.84, 2.84]	
		12 months		91	28	80	92	27	80	-1.00 [-9.52, 7.52]	
	Use of feeding tube	6 months		97	18	80	100	0	80	N/E	
		12 months		97	18	80	97	12	80	0.00 [-4.74, 4.74]	
	Weight loss	6 months		84	37	80	83	38	80	1.00 [-10.62, 12.62]	
		12 months		85	36	80	87	33	80	-2.00 [-12.70, 8.70]	
	Weight gain	6 months		74	44	80	65	48	80	9.00 [-5.27, 23.27]	
		12 months		73	45	80	66	48	80	7.00 [-7.42,	

										21.42]	
	Vitality	4th follow-up visit	SF-36	51	25	104	49	25	95	2.00 [-4.95, 8.95]	Detmar 2002
				56	N/A	108	51	N/A	110	N/E	Hilarius 2008
	Mental health			70	19	104	68	21	95	2.00 [-3.58, 7.58]	Detmar 2002
				72	N/A	108	72	N/A	110	N/E	Hilarius 2008
	Hardship	3 months	FLIC	15.3	3.5	60	15.1	4.2	60	0.20 [-1.18, 1.58]	Rosenbloom 2007
				14.2	3.9	60	15.1	4.2	60	-0.90 [-2.35, 0.55]	
		6 months		15.2	4.1	51	14.6	3.8	52	0.60 [-0.93, 2.13]	
				15.4	3.6	51	14.6	3.8	52	0.80 [-0.63, 2.23]	
	Psychological wellbeing	3 months		32.1	4.7	60	30.4	6.5	60	1.70 [-0.33, 3.73]	
				30.3	6.3	60	30.4	6.5	60	-0.10 [-2.39, 2.19]	
		6 months		30.6	5.9	60	29.7	6.1	60	0.90 [-1.25, 3.05]	
				30.1	6.9	60	29.7	6.1	60	0.40 [-1.93, 2.73]	
	Colorectal cancer symptom-related wellbeing	1 month	FACT-C	21.4	3.3	20	20.7	5.3	21	0.70 [-1.99, 3.39]	Young 2010
		3 months		22.8	3.7	20	19.8	4.1	21	3.00 [0.61, 5.39]	
Distress (cont)	Tension/Anxiety	1 month	POMS	4.4	4.5	109	4.4	4.4	103	0.00 [-1.20, 1.20]	Hollingworth 2013
		3 months	HADS	4.66	3.68	268	4.86	3.81	300	-0.20 [-0.82, 0.42]	Braeken 2013
		6 months	POMS	4.1	4.3	108	4.1	4.4	101	0.00 [-1.18, 1.18]	Hollingworth 2013
		12 months	HADS	4.57	3.90	268	4.98	4.24	300	-0.41 [-1.08, 0.26]	Braeken 2013

			POMS	4.1	4.2	106	3.7	4.4	103	0.40 [-0.77, 1.57]	Hollingworth 2013
		14 months		3.56	4.12	226	3.82	4.12	226	-0.26 [-1.02, 0.50]	Bergholdt 2013
	Depression/dejection	1 month		4.4	6.1	109	4	5.3	103	0.40 [-1.14, 1.94]	Hollingworth 2013
		3 months	HADS	3.68	4.11	268	3.72	3.76	300	-0.04 [-0.69, 0.61]	Braeken 2013
		6 months	POMS	3.7	5	108	3.8	5.4	101	-0.10 [-1.51, 1.31]	Hollingworth 2013
		12 months	HADS	3.45	3.78	268	3.7	4.08	300	-0.25 [-0.90, 0.40]	Braeken 2013
			POMS	3.9	5.5	106	2.9	4.5	103	1.00 [-0.36, 2.36]	Hollingworth 2013
		14 months		3.26	4.99	229	3.85	4.93	223	-0.59 [-1.50, 0.32]	Bergholdt 2013
	Psychological distress (+ subscale)	1 month	GHQ-12	1.54	1.57	28	3.31	1.7	28	-1.77 [-2.63, -0.91]	Bramsen 2008
	Psychological distress (- subscale)			1.55	1.43	28	2.5	1.86	28	-0.95 [-1.82, -0.08]	
	Psychological distress (total score)			3.09	2.8	28	5.81	3.29	28	-2.72 [-4.32, -1.12]	
			DT	1.9	2.1	20	2.8	3	21	-0.90 [-2.48, 0.68]	Young 2010
				2.3	1.89	346	2.4	2.91	363	-0.10 [-0.46, 0.26]	Young 2013
		2 months		2.46	2.7	55	2.91	2.62	53	-0.45 [-1.45, 0.55]	Schofield 2013
			HADS	10.77	8.4	55	11.15	8.23	53	-0.38 [-	

										3.52, 2.76]	
		3 months	GHQ-12	2.74	3.26	268	2.85	3.38	300	-0.11 [-0.66, 0.44]	Braeken 2013
			PSI	15	12.7	123	15.5	13.1	127	-0.50 [-3.70, 2.70]	Maunsell 1996
			DT	2.85	2.9	55	2.99	2.77	53	-0.14 [-1.21, 0.93]	Schofield 2013
				1.3	N/A	20	2.1	N/A	21	N/E	Young 2010
				2	1.86	336	2	2.86	351	0.00 [-0.36, 0.36]	Young 2013
			HADS	11.52	8.8	55	10.34	8.52	53	1.18 [-2.09, 4.45]	Schofield 2013
			POMS (negative affect items)	6.6	6	60	8.5	9.3	60	-1.90 [-4.70, 0.90]	Rosenbloom 2007
				7.2	7.7	60	8.5	9.3	60	-1.30 [-4.36, 1.76]	
		6 months		8.1	8.5	51	8.3	8.2	52	-0.20 [-3.43, 3.03]	
				8.1	9.5	51	8.3	8.2	52	-0.20 [-3.63, 3.23]	
			DT	1.8	2.74	322	1.8	2.85	350	0.00 [-0.42, 0.42]	Young 2013
		12 months	GHQ-12	1.96	3.14	268	2.14	3.22	300	-0.18 [-0.70, 0.34]	Braeken 2013
			PSI	13.5	12.1	123	14.6	12.3	127	-1.10 [-4.12, 1.92]	Maunsell 1996
	Anger/hostility	1 month	POMS	3	4.4	109	2.9	4	103	0.10 [-1.03, 1.23]	Hollingworth 2013
		6 months		2.8	3.7	108	2.6	3.3	101	0.20 [-0.75, 1.15]	
		12 months		3.5	5	106	2.5	3.7	103	1.00 [-0.19, 2.19]	
		14 months		1.88	3.46	230	2.03	3.33	223	-0.15 [-0.78, 0.48]	Bergholdt 2013
	Confusion/bewilderment	1 month		3.2	3.4	109	3.6	3.6	103	-0.40 [-1.34, 0.54]	Hollingworth 2013

		6 months		3.1	3.3	108	3.6	3.6	101	-0.50 [-1.44, 0.44]	
		12 months		3.1	3.3	106	3	3.2	103	0.10 [-0.78, 0.98]	
		14 months		2.11	3.24	231	2.45	3.15	229	-0.34 [-0.92, 0.24]	Bergholdt 2013
	Fatigue/inertia	1 month		7.2	6.4	109	7.8	6	103	-0.60 [-2.27, 1.07]	Hollingworth 2013
		6 months		6.6	5.4	108	6.7	5.8	101	-0.10 [-1.62, 1.42]	
		12 months		6.1	5.4	106	5.1	4.7	103	1.00 [-0.37, 2.37]	
		14 months		4.14	8.7	234	4.56	4.35	226	-0.42 [-1.67, 0.83]	Bergholdt 2013
	Vigor/activity	1 month		8.2	5.6	109	8.1	5.5	103	0.10 [-1.39, 1.59]	Hollingworth 2013
		6 months		3.1	3.3	108	3.6	3.6	101	-0.50 [-1.44, 0.44]	
		12 months		3.1	3.3	106	3	3.2	103	0.10 [-0.78, 0.98]	
		14 months		10.09	5.98	228	10.28	5.77	218	-0.19 [-1.28, 0.90]	Bergholdt 2013
	Total mood disturbance	1 month		38.09	23.5	109	38.6	21.99	103	-0.51 [-6.63, 5.61]	Hollingworth 2013
		6 months		34.46	20.87	108	34.87	22	101	-0.41 [-6.23, 5.41]	
		12 months		35.1	22.85	106	31.13	20.52	103	3.97 [-1.91, 9.85]	
		14 months		4.19	18.89	210	4.87	18.5	200	-0.68 [-4.30, 2.94]	Bergholdt 2013
Psychosocial well-being	Emotional impact of the intervention (total)	1 month	IES	15.77	14.53	28	25.91	12.49	28	-10.14 [-17.24, -3.04]	Bramsen 2008
	Emotional impact of the intervention (re-experiencing)			8	8.04	28	12.5	6.61	28	-4.50 [-8.36, -0.64]	
	Emotional impact of the intervention (avoidance)			6.19	6.64	28	11.09	7.7	28	-4.90 [-8.67, -1.13]	
	Psychosocial adjustment (healthcare orientation)	6 months	PAIS-SR	51	8	80	49	9	80	2.00 [-0.64, 4.64]	de Leeuw 2013

		12 months		52	9	80	48	8	80	4.00 [1.36, 6.64]	
	Psychosocial adjustment (vocational environment)	6 months		57	7	80	56	7	80	1.00 [-1.17, 3.17]	
		12 months		54	7	80	54	7	80	0.00 [-2.17, 2.17]	
	Psychosocial adjustment (domestic environment)	6 months		43	9	80	42	9	80	1.00 [-1.79, 3.79]	
		12 months		42	9	80	41	9	80	1.00 [-1.79, 3.79]	
	Psychosocial adjustment (sexual relations)	6 months		46	8	80	47	9	80	-1.00 [-3.64, 1.64]	
		12 months		46	8	80	47	9	80	-1.00 [-3.64, 1.64]	
	Psychosocial adjustment (extended family relations)	6 months		49	7	80	52	8	80	-3.00 [-5.33, -0.67]	
		12 months		49	7	80	49	7	80	0.00 [-2.17, 2.17]	
	Psychosocial adjustment (social environment)	6 months		43	15	80	43	13	80	0.00 [-4.35, 4.35]	
		12 months		42	14	80	42	13	80	0.00 [-4.19, 4.19]	
	Psychosocial adjustment (psychological distress)	6 months		45	10	80	45	10	80	0.00 [-3.10, 3.10]	
		12 months		45	11	80	43	10	80	2.00 [-1.26, 5.26]	
	Psychosocial adjustment (total adjustment)	6 months		44	12	80	44	13	80	0.00 [-3.88, 3.88]	
		12 months		43	13	80	42	12	80	1.00 [-2.88, 4.88]	
	Physical functioning (number of arm problems reported)	3 months	LES	1.6	1.3	122	1.6	1.4	126	0.00 [-0.34, 0.34]	Maunsell 1996
		12 months		1.3	1.4	122	1.1	1.4	126	0.20 [-0.15, 0.55]	
	Role functioning (household activities performed without help)	3 months		1.5	1.1	123	1.6	1.2	127	-0.10 [-0.39, 0.19]	
		12 months		2.1	1.2	123	2	1.3	127	0.10 [-0.21, 0.41]	
	Role functioning (hours worked per week)	3 months		22.1	15.1	123	22.4	14	127	-0.30 [-3.91, 3.31]	

		12 months		32.1	12.3	123	31.4	16.1	127	0.70 [-2.84, 4.24]	
	Social functioning (times per week engaged in social activities)	3 months		7.4	5.8	123	6.1	4.7	127	1.30 [-0.01, 2.61]	
		12 months		7.5	5.3	123	6.3	5	127	1.20 [-0.08, 2.48]	
	Social functioning (Hours per day devoted to leisure activities)	3 months		4.5	3	123	4.3	2.4	127	0.20 [-0.47, 0.87]	
		12 months		4.1	2.6	123	4.5	3.1	127	-0.40 [-1.11, 0.31]	
	Social functioning (Times per week engaged in physical activities/sports)	3 months		3	4.4	123	4.3	5.3	127	-1.30 [-2.51, -0.09]	
		12 months		3.7	4.6	123	3.6	4.2	127	0.10 [-0.99, 1.19]	
	Marital satisfaction	3 months	LWMAT	46.6	21	76	50.5	25.3	82	-3.90 [-11.13, 3.33]	
		12 months		48.5	25.1	74	48.5	24.4	78	0.00 [-7.88, 7.88]	
Supportive care needs	General unmet need	1 month	SCNS-SF34	128.7	75.4	35	140.3	96.6	32	-11.60 [-53.36, 30.16]	Harrison 2011
		3 months		98.1	84.7	32	110	86.7	29	-11.90 [-54.99, 31.19]	
				59.9	57.85	336	56.8	76.07	351	3.10 [-6.98, 13.18]	Young 2013
		6 months		50	66.96	322	46.6	67.19	350	3.40 [-6.75, 13.55]	
				N/A	N/A	N/A	N/A	N/A	N/A	N/E	Thewes 2009
			CaSUN	10	13.1	30	14	18	30	-4.00 [-11.97, 3.97]	Harrison 2011
	Medical communication	2 months	NA-ALCP	2.37	1.3	55	2.21	1.24	53	0.16 [-0.32, 0.64]	Schofield 2013
		3 months		2.14	1.2	55	2.03	1.16	53	0.11 [-0.34, 0.56]	

	Psychological/emotional	1 month	SCNS	16.6	11.2	20	19.6	20.4	21	-3.00 [-13.01, 7.01]	Young 2010
		2 months	NA-ALCP	2.04	0.9	55	1.94	0.87	53	0.10 [-0.23, 0.43]	Schofield 2013
		3 months		2.03	0.9	55	1.84	0.80	53	0.19 [-0.13, 0.51]	
			SCNS	8.2	8.1	20	17.7	18.7	21	-9.50 [-18.25, -0.75]	Young 2010
		6 months	SCNS-SF34	N/A	N/A	N/A	N/A	N/A	N/A	N/E	Thewes 2009
	Daily living	1 month	SCNS	22.8	16.3	20	25.8	19	21	-3.00 [-13.82, 7.82]	Young 2010
		2 months	NA-ALCP	1.69	0.8	55	1.56	0.80	53	0.13 [-0.17, 0.43]	Schofield 2013
		3 months		1.75	0.9	55	1.57	0.87	53	0.18 [-0.15, 0.51]	
			SCNS	11.8	15.6	20	24.4	20.3	21	-12.60 [-23.65, -1.55]	Young 2010
		6 months	SCNS-SF34	N/A	N/A	N/A	N/A	N/A	N/A	N/E	Thewes 2009
	Financial	2 months	NA-ALCP	1.76	1.1	55	1.78	1.09	53	-0.02 [-0.43, 0.39]	Schofield 2013
		3 months		1.7	1.1	55	1.64	1.02	53	0.06 [-0.34, 0.46]	
	Symptoms	2 months		1.65	0.7	55	1.9	0.73	53	-0.25 [-0.52, 0.02]	
		3 months		1.67	0.8	55	1.86	0.73	53	-0.19 [-0.48, 0.10]	
	Social	2 months		1.49	0.7	55	1.43	0.66	53	0.06 [-0.20, 0.32]	
		3 months		1.54	0.7	55	1.38	0.73	53	0.16 [-0.11, 0.43]	
	Health system and information	1 month	SCNS	22.6	10.3	20	23.1	18	21	-0.50 [-9.42, 8.42]	Young 2010
		3 months		19.4	10	20	4.8	7.7	21	14.60 [9.12, 20.08]	

		6 months	SCNS-SF34	N/A	N/A	N/A	N/A	N/A	N/A	N/E	Thewes 2009
	Patient care and support	1 month	SCNS	18.5	7.4	20	14.4	14.9	21	4.10 [-3.05, 11.25]	Young 2010
		3 months		10.8	9.5	20	1.8	6.1	21	9.00 [4.09, 13.91]	
		6 months	SCNS-SF34	N/A	N/A	N/A	N/A	N/A	N/A	N/E	Thewes 2009
	Sexuality	1 month	SCNS	7.9	11.9	20	8.8	22.9	21	-0.90 [-12.00, 10.20]	Young 2010
		3 months		5.7	17.8	20	3.9	9.4	21	1.80 [-6.98, 10.58]	
		6 months	SCNS-SF34	N/A	N/A	N/A	N/A	N/A	N/A	N/E	Thewes 2009
Patient satisfaction	Needs addressed	After clinical visit	PDIS	4.4	0.4	27	4.2	0.7	26	0.20 [-0.11, 0.51]	Taenzer 2000
		4th follow-up visit	PSQ-C	N/A	N/A	104	N/A	N/A	95	N/E	Detmar 2002
				N/A	N/A	108	N/A	N/A	110	N/E	Hilarius 2008
	Active involvement			N/A	N/A	104	N/A	N/A	95	N/E	Detmar 2002
				N/A	N/A	108	N/A	N/A	110	N/E	Hilarius 2008
	Patient-physician interaction	After clinical visit	PDIS	4.5	0.4	27	4.5	0.5	26	0.00 [-0.24, 0.24]	Taenzer 2000
		4th follow-up visit	PSQ-C	N/A	N/A	104	N/A	N/A	95	N/E	Detmar 2002
				N/A	N/A	108	N/A	N/A	110	N/E	Hilarius 2008
	Information received	After clinical visit	PDIS	4.4	0.5	27	4.5	0.6	26	-0.10 [-0.40, 0.20]	Taenzer 2000
			MOSPVRQ	3.65	0.67	147	3.81	0.45	130	-0.16 [-0.29, -0.03]	Kutner 1999
		4th follow-up visit	PSQ-C	N/A	N/A	104	N/A	N/A	95	N/E	Detmar 2002
				N/A	N/A	108	N/A	N/A	110	N/E	Hilarius

											2008
	Support received			4.3	0.72	104	4	0.89	95	0.30 [0.07, 0.53]	Detmar 2002
				N/A	N/A	108	N/A	N/A	110	N/E	Hilarius 2008
	General satisfaction	After clinical visit	MOSPVRQ	3.63	0.68	149	3.76	0.52	133	-0.13 [-0.27, 0.01]	Kutner 1999
		3 months	PSQ-III (gensat)	23.2	3.7	60	24.6	4.2	60	-1.40 [-2.82, 0.02]	Rosenbloom 2007
				23	4.1	60	24.6	4.2	60	-1.60 [-3.09, -0.11]	
		6 months		22.4	4.2	51	24.4	4.1	52	-2.00 [-3.60, -0.40]	
				23.1	4.2	51	24.4	4.1	52	-1.30 [-2.90, 0.30]	
			TPVCSQ	70.7	17.1	108	71.2	16.1	101	-0.50 [-5.00, 4.00]	Hollingworth 2013
	Communication satisfaction	After clinical visit	MOSPVRQ	3.82	0.53	149	3.87	0.36	133	-0.05 [-0.15, 0.05]	Kutner 1999
		3 months	PSQ-III (comsat)	21.2	2.8	60	21.4	2.3	60	-0.20 [-1.12, 0.72]	Rosenbloom 2007
				21.1	3	60	21.4	2.3	60	-0.30 [-1.26, 0.66]	
		6 months		21.2	2.8	51	20.8	3.2	52	0.40 [-0.76, 1.56]	
				21.2	3	51	20.8	3.2	52	0.40 [-0.80, 1.60]	
	Time spent with MD satisfaction	After clinical visit	MOSPVRQ	3.53	0.78	149	3.7	0.59	133	-0.17 [-0.33, -0.01]	Kutner 1999
	Skills of the MD satisfaction			3.78	0.54	149	3.85	0.40	133	-0.07 [-0.18, 0.04]	

Abbreviations: CaSUN (Cancer Survivors' Unmet Needs Measure); DT (Distress thermometer); EORTC-QLQ-C30 (European Organisation for Research and Treatment of Cance-Quality of Life Questionnaire-Core 30); EQ-5D (EuroQol 5D); FACT-C (Functional Assessment of Cancer Therapy-Colorectal); FLIC (Functional Living Index-Cancer); GHQ-12 (General Health Questionnaire 12-tems version); HADS (Hospital Anxiety and Depression Scale); LES (Life Experiences Survey); LWMAT (Locke Wallace Marital Adjustment Scale); MOSPVRQ (Medical Outcomes Study Patient Visit Rating Questionnaire); NA-ALCP (Needs Assessment for Advanced Lung Cancer Patients); POMS (Profile of Mood States); (PAIS-SR (Psychosocial Adjustment to Illness Scale – Self Reported); PDIS (Patient Doctor Interaction Scale); PSI (Psychiatric Symptom Index); PSQ-III (Patient Satisfaction Questionnaire III); PSQ-C (Patient Satisfaction Questionnaire C); SCNS (Supportive Care Needs Survey); SCNS-SF34 (Supportive Care Needs Survey-Short Form); SF-36 (36-Item Short Form Health Survey); TPVCSQ (Trent Patient Views of Cancer Services Questionnaire).

Table A7.8.2. Evidence Summary: continuous outcomes (change from baseline)

Main outcome	**Sub-outc**ome	**Time post intervention**	**Scale used**	**Intervention (screening)**			**Control (usual care)**			**MD [95%CI]**	**Study ID**
				Mean	**SD**	**N**	**Mean**	**SD**	**N**		
HRQOL (cont)	Global health status	+/- 6 months	EORTC-QLQ-C30	3.3	25.56	58	5.8	25.2	44	0.42 [-7.64, 8.48]	Geerse 2017
			EQ-5D	-0.78	23.61	59	-1.2	17.91	47	-2.50 [-12.22, 7.22]	
	Physical functioning	4 months	SF-36	18.24	20.12	48	21.14	22.31	51	-2.90 [-11.26, 5.46]	Giesler 2005
		+/- 6 months	EORTC-QLQ-C30	-3.5	22.46	60	-1.2	21.21	50	-2.30 [-10.48, 5.88]	Geerse 2017
		7 months	SF-36	17.43	23.5	41	17.47	24.64	44	-0.04 [-10.27, 10.19]	Giesler 2005
		12 months		18.39	21.69	41	19.47	23.97	44	-1.08 [-10.79, 8.63]	
	Role functioning	+/- 6 months	EORTC-QLQ-C30	6.9	37.18	60	0.7	33.6	49	6.20 [-7.10, 19.50]	Geerse 2017
	Role functioning (emotional)	4 months	SF-36	13.44	34.33	48	5.7	34.87	51	7.74 [-5.89, 21.37]	Giesler 2005
		7 months		11.41	27.74	41	12.33	35.1	44	-0.92 [-14.32, 12.48]	
		12 months		12.09	30.61	41	1.34	42.05	44	10.75 [-4.81, 26.31]	
	Role functioning (physical)	4 months		55.44	43.63	48	40.38	49.84	51	15.06 [-3.36, 33.48]	
		7 months		50.33	51.87	41	33.61	54.24	44	16.72 [-5.84, 39.28]	
		12 months		51.6	47.56	41	35.4	52.08	44	16.20 [-4.98, 37.38]	
	Emotional functioning	+/- 6 months	EORTC-QLQ-C30	6.4	20.14	60	1.7	24.5	49	4.70 [-3.85, 13.25]	Geerse 2017
	Cognitive functioning	+/- 6 months		2.5	20.14	60	2	23.1	49	0.50 [-7.73, 8.73]	
	Social functioning	4 months	SF-36	18.84	30.06	48	15.95	24.35	51	2.89 [-7.93, 13.71]	Giesler 2005
		+/- 6 months	EORTC-QLQ-C30	6.1	28.66	60	4.4	23.8	49	1.70 [-8.15, 11.55]	Geerse 2017
		7 months	SF-36	15.07	36.02	41	14.99	25.65	44	0.08 [-13.30, 13.46]	Giesler 2005
		12 months		18.51	27.56	41	12.45	30.33	44	6.06 [-6.25, 18.37]	
	Pain	4 months		22.9	26.08	48	16.37	27.91	51	6.53 [-4.11, 17.17]	
		7 months		23.96	34.75	41	16.32	27.63	44	7.64 [-5.77, 21.05]	
		12 months		24.49	29.16	41	17.48	31.62	44	7.01 [-5.91, 19.93]	
	Global QOL	+/- 6 months	EQ-5D	-0.01	0.31	59	-0.0004	0.21	47	-0.01 [-0.11, 0.09]	Geerse 2017

	Sexual function	4 months	PC-QOL	14.63	21.29	48	5.23	20.16	51	9.40 [1.22, 17.58]	Giesler 2005
		7 months		21.9	22.72	41	12.6	26.33	44	9.30 [-1.14, 19.74]	
		12 months		25.26	26.6	41	15.32	27.77	44	9.94 [-1.62, 21.50]	
	Sexual limitation	4 months		7.75	16.81	48	0.41	20.56	51	7.34 [-0.04, 14.72]	
		7 months		10.68	15.93	41	3.8	15.05	44	6.88 [0.28, 13.48]	
		12 months		12.35	17.28	41	3.11	19.61	44	9.24 [1.39, 17.09]	
	Sexual bother	4 months		-0.95	22.12	48	-3.55	24.23	51	2.60 [-6.53, 11.73]	
		7 months		5.54	23.74	41	-0.2	19.67	44	5.74 [-3.57, 15.05]	
		12 months		9.21	29.63	41	3.3	25.35	44	5.91 [-5.85, 17.67]	
	Urinary function	4 months		13.68	16.89	48	19.51	17.56	51	-5.83 [-12.62, 0.96]	
		7 months		18.86	19.71	41	22.35	19.32	44	-3.49 [-11.80, 4.82]	
		12 months		19.55	23.57	41	23.09	22.34	44	-3.54 [-13.32, 6.24]	
	Urinary limitation	4 months		24.17	26.48	48	20.26	25.75	51	3.91 [-6.39, 14.21]	
		7 months		23.05	23.26	41	17.58	24.17	44	5.47 [-4.61, 15.55]	
		12 months		23.4	24.14	41	17.19	26.72	44	6.21 [-4.60, 17.02]	
	Urinary bother	4 months		21.16	29.16	48	19.15	22.66	51	2.01 [-8.32, 12.34]	
		7 months		27.55	21.91	41	20.51	21.72	44	7.04 [-2.24, 16.32]	
		12 months		21.76	30.93	41	25.84	24.48	44	-4.08 [-15.99, 7.83]	
	Bowel function	4 months		4.81	15.56	48	9.19	17.58	51	-4.38 [-10.91, 2.15]	
		7 months		6.79	13.97	41	11.42	19.26	44	-4.63 [-11.75, 2.49]	
		12 months		4.8	16.91	41	8.35	15.71	44	-3.55 [-10.50, 3.40]	
	Bowel limitation	4 months		4	13.36	48	3.25	10.66	51	0.75 [-4.03, 5.53]	
		7 months		6.01	11.62	41	5.04	13.88	44	0.97 [-4.46, 6.40]	
		12 months		2.8	10.99	41	3.27	10.6	44	-0.47 [-5.07, 4.13]	
	Bowel bother	4 months		15.84	27.81	48	7.21	24.15	51	8.63 [-1.66, 18.92]	
		7 months		15.56	24.51	41	12.18	23.96	44	3.38 [-6.94, 13.70]	
		12 months		14	23.67	41	10.22	25.49	44	3.78 [-6.67, 14.23]	
	Cancer worry	4 months		12.64	23.52	48	6.34	17.65	51	6.30 [-1.93, 14.53]	
		7 months		13.9	26.12	41	8.97	21.46	44	4.93 [-5.27, 15.13]	
		12 months		14.15	25.12	41	3.07	17.68	44	11.08 [1.78, 20.38]	
	Vitality	4 months	SF-36	17.7	18.65	48	18.71	23.86	51	-1.01 [-9.42, 7.40]	
		7 months		16.04	22.48	41	11.88	24.16	44	4.16 [-5.76, 14.08]	
		12 months		17.02	22.37	41	13.53	21.33	44	3.49 [-5.82, 12.80]	
	Mental health	4 months		0.45	14.19	48	1.98	13.74	51	-1.53 [-7.04, 3.98]	
		7 months		4.56	12.6	41	2.34	13.48	44	2.22 [-3.32, 7.76]	
		12 months		1.62	11.31	41	2.43	14.57	44	-0.81 [-6.33, 4.71]	
	Health perception	4 months		7.15	17.47	48	6.69	18.44	51	0.46 [-6.61, 7.53]	
		7 months		7.88	16.88	41	7.08	18.76	44	0.80 [-6.78, 8.38]	
		12 months		3.21	19.41	41	4.82	17.59	44	-1.61 [-9.50, 6.28]	
	Health	4 months		-0.4	1.13	48	-0.63	1	51	0.23 [-0.19, 0.65]	

	transition	7 months		-0.76	1.3	41	-0.61	1.03	44	-0.15 [-0.65, 0.35]	
		12 months		-1.3	1.19	41	-1.35	1.28	44	0.05 [-0.48, 0.58]	
Distress	BreastCancer-specific distress	4 months	Adaptation of breast-cancer distress tool	-2.16	4.4	196	-1.7	4.38	157	-0.46 [-1.38, 0.46]	Livingston 2010
		12 months		-2.74	3.46	194	-2.96	3.5	147	0.22 [-0.53, 0.97]	
	Overall distress	+/- 6 months	HADS	-2.1	7.68	59	-2.4	8.91	47	0.30 [-2.91, 3.51]	Geerse 2017
	Tension/Anxiety	4 months		-2.33	3.05	196	-2.34	3.04	157	0.01 [-0.63, 0.65]	Livingston 2010
		+/- 6 months		-1.3	3.87	60	-1.3	4.80	47	0.00 [-1.69, 1.69]	Geerse 2017
		12 months		-2.91	3.74	194	-3.1	3.8	147	0.19 [-0.62, 1.00]	Livingston 2010
	Depression/ dejection	4 months		-0.29	2.84	196	-0.18	2.85	157	-0.11 [-0.71, 0.49]	
		+/- 6 months		-0.6	4.61	59	-0.9	4.9	49	0.30 [-1.51, 2.11]	Geerse 2017
		12 months		-0.92	2.47	194	-0.76	2.45	147	-0.16 [-0.69, 0.37]	Livingston 2010
Psychosocial well-being	Dyadic cohesion	4 months	DAS	-0.35	4.29	48	-0.27	3.42	51	-0.08 [-1.61, 1.45]	Giesler 2005
		7 months		-0.75	4.52	41	0.07	4.12	44	-0.82 [-2.66, 1.02]	
		12 months		-0.41	3.62	41	-0.12	4.26	44	-0.29 [-1.97, 1.39]	
	Dyadic satisfaction	4 months		-0.45	2.72	48	0.51	4.13	51	-0.96 [-2.33, 0.41]	
		7 months		-0.55	3.75	41	0.36	3.72	44	-0.91 [-2.50, 0.68]	
		12 months		-0.36	3.54	41	1.01	3.87	44	-1.37 [-2.95, 0.21]	
	Depression	2,5 months	CES-D	N/A	N/A	97	N/A	N/A	94	N/E	Given 2004
		4 months		-2.16	6.86	48	-1.89	7.08	51	-0.27 [-3.02, 2.48]	Giesler 2005
		5 months		N/A	N/A	80	N/A	N/A	87	N/E	Given 2004
		7 months		-2.99	4.69	41	-0.69	7.57	44	-2.30 [-4.96, 0.36]	Giesler 2005
		12 months		-3	5.58	41	-1.51	6.76	44	-1.49 [-4.12, 1.14]	
Patient satisfaction	Total satisfaction	+/- 6 months	PSQ-III	-0.3	12.61	55	3.4	11.65	47	-3.70 [-8.41, 1.01]	Geerse 2017
	Overall satisfaction	+/- 6 months		-1.4	22.99	55	4.6	18.01	48	-6.00 [-13.93, 1.93]	
	Accessibility	+/- 6 months		1.2	13.96	54	5.4	13.71	47	-4.20 [-9.61, 1.21]	
	Interpersonal manner	+/- 6 months		-1.2	14.97	56	3.1	14.55	48	-4.30 [-9.98, 1.38]	
	Technical	+/- 6 months		-0.9	17.06	55	1.2	13.71	47	-2.10 [-8.07, 3.87]	

	quality										

Abbreviations: CES-D (Center for Epidemiological Studies Depression Scale);DAS (Dyadic Adjustment Scale); EORTC-QLQ-C30 (European Organisation for Research and Treatment of Cancer-Quality of Life Questionnaire-Core 30); EQ-5D (EuroQol 5D); FACT-C (Functional Assessment of Cancer Therapy-Colorectal); FLIC (Functional Living Index-Cancer); HADS (Hospital Anxiety and Depression Scale); PC-QOL (Prostate Cancer-Related Quality of Life Scales); PSQ-III (Patient Satisfaction Questionnaire 3rd update); SF-36 (36-Item Short Form Health Survey).

Table A7.8.3. Evidence Summary: binary outcomes

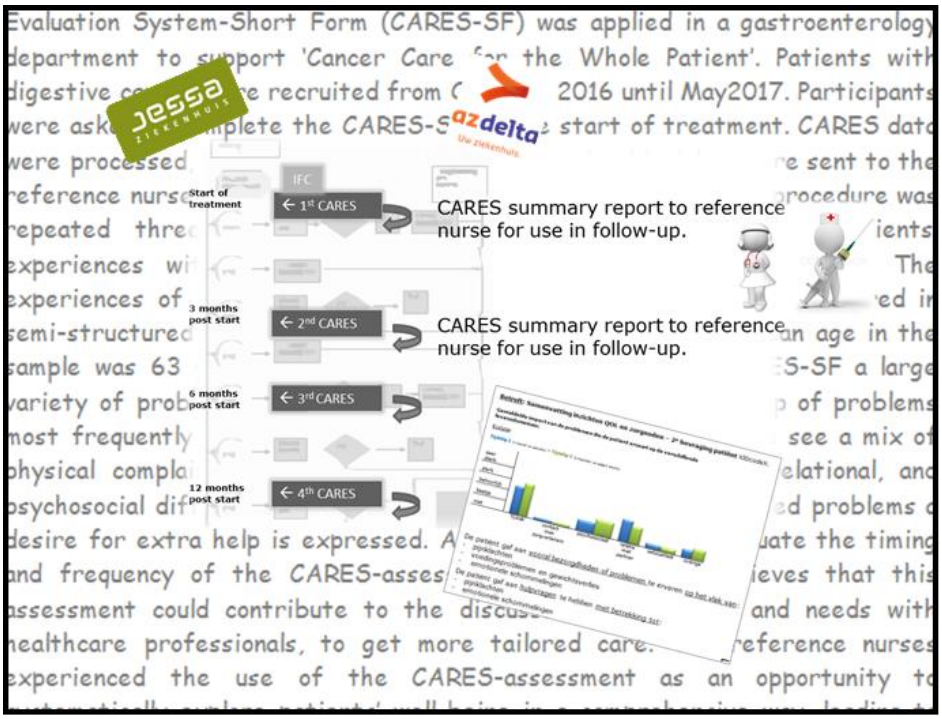
Main outcome	Sub-outcome	Time post intervention	Scale used	Intervention (screening)		Control (usual care)		RR [95%CI]	Study ID
				Events	Total	Events	Total		
Distress (proportion yes)	Anxiety	2 months	HADS	9	103	18	192	0.93 [0.43;2]	Waller 2012
		3 months		57	268	64	300	1 [0.73;1.37]	Braeken 2013
		4 months		11	85	18	192	1.38 [0.68;2.79]	Waller 2012
		6 months		5	67	18	192	0.8 [0.31;2.06]	
		12 months		42	268	61	300	0.77 [0.54;1.1]	Braeken 2013
			DIS/DSM	0	123	0	127	N/E	Maunsell 1996
	Depression	2 months	HADS	10	103	26	192	0.72 [0.36;1.43]	Waller 2012
		3 months		17	268	23	300	0.83 [0.45;1.51]	Braeken 2013
		4 months		9	85	26	192	0.78 [0.38;1.6]	Waller 2012
		6 months		9	67	26	192	0.99 [0.49;2.01]	
		12 months		46	268	46	300	1.12 [0.77;1.63]	Braeken 2013
			DIS/DSM	22	123	15	127	1.51 [0.82;2.78]	Maunsell 1996
	Psychological distress	3 months	GHQ-12	103	268	117	300	0.99 [0.8;1.21]	Braeken 2013
		12 months		65	268	74	300	0.98 [0.74;1.31]	
Psychosocial wellbeing	Physical health (rated good or excellent)	12 months	LES	98	123	101	127	1 [0.88;1.14]	Maunsell 1996
	Physical health (do not worry moderately or a lot)			87	123	85	127	1.06 [0.89;1.25]	
	Physical health (no arm problems)	3 months		27	122	31	126	0.9 [0.57;1.41]	
		12 months		49	122	63	126	0.8 [0.61;1.06]	
	Role functioning (working at interview)	3 months		11	55	7	56	1.6 [0.67;3.82]	
		12 months		41	55	43	56	0.97 [0.79;1.2]	
	Marital relation (still with	3 months	LWMAT	76	78	82	83	0.99 [0.94;1.03]	
		12 months		74	78	78	83	1.01 [0.94;1.09]	

	spouse)								
	Marital relation (marriage not rated as unhappy)	3 months		69	78	71	83	1.03 [0.92;1.17]	
		12 months		70	78	75	83	0.99 [0.9;1.1]	
	Marital relation (had sexual relationship with spouse)	3 months		59	78	61	83	1.03 [0.86;1.23]	
		12 months		55	78	55	83	1.06 [0.86;1.31]	
Supportive care needs (proportion yes)	Physical symptom and daily living	2 months	SCNS	47	103	98	192	0.89 [0.69;1.15]	Waller 2012
		4 months		40	85	98	192	0.92 [0.71;1.2]	
		6 months		33	67	98	192	0.96 [0.73;1.28]	
	Psychological	2 months		39	103	74	192	0.98 [0.72;1.33]	
		4 months		30	85	74	192	0.92 [0.65;1.28]	
		6 months		22	67	74	192	0.85 [0.58;1.25]	
	Health system and information	2 months		19	103	54	192	0.66 [0.41;1.1]	
		4 months		16	85	54	192	0.67 [0.41;1.1]	
		6 months		11	67	54	192	0.58 [0.32;1.05]	
	Patient care and support	2 months		13	103	26	192	0.93 [0.50, 1.73]	
		4 months		9	85	26	192	0.78 [0.38, 1.60]	
		6 months		3	67	26	192	0.33 [0.10, 1.06]	
	Sexuality	2 months		9	103	12	192	1.40 [0.61, 3.21]	
		4 months		6	85	12	192	1.13 [0.44, 2.91]	
		6 months		4	67	12	192	0.96 [0.32, 2.86]	
	Spirituality	2 months	NA-ACP	9	103	17	192	0.99 [0.46, 2.13]	
		4 months		7	85	17	192	0.93 [0.40, 2.16]	
		6 months		6	67	17	192	1.01 [0.42, 2.46]	
Patient satisfaction (proportion yes)	Doctor-patient relationship	6 months	DanPEP (top-evaluation)	N/A	N/A	N/A	N/A	N/E	Bergholdt 2013
	Medical care			N/A	N/A	N/A	N/A	N/E	
	Information and support			N/A	N/A	N/A	N/A	N/E	
	Organization of care			N/A	N/A	N/A	N/A	N/E	
	GP's accessibility			N/A	N/A	N/A	N/A	N/E	
	Patient satisfaction with GP's contribution to the	14 months	Ad-hoc question	109	159	105	159	1.04 [0.89, 1.21]	

	rehabilitation course								

Abbreviations: DIS/DSM (Diagnostic Interview Schedule according to Diagnostic and Statistical Manual criteria); GHQ-12 (General Health Questionnaire 12-tems version); HADS (Hospital Anxiety and Depression Scale); LES (Life Experiences Survey); LWMAT (Locke-Wallace martial adjustment test); NA-ACP (Needs Assessment for Advanced Cancer patients); SCNS (Supportive Care Needs Survey); N/A: Not available; N/E: Not estimable

8
Chapter



Systematic CARES-assessment in a gastroenterology department

This chapter is based on:

Schouten Bojoura; de Jonckheere, Dominiek; Aerts, Marc; Decaestecker, Jochen; Walgraeve, Daan; Vankrunkelsven, Patrick; Hellings, Johan. *An explorative study on systematic assessment of QOL and care needs with the CARES-SF in the follow-up of patients with digestive cancer. – Under review.*

ABSTRACT

BACKGROUND Systematic assessment of QOL and care needs with the Cancer Rehabilitation Evaluation System-Short Form (CARES-SF) was applied in two gastroenterology departments to support 'Cancer Care for the Whole Patient'.

METHODS Patients with digestive cancer were asked to complete the CARES-SF at the start of treatment and three months later. Each time CARES data were processed, and summary reports were sent to the reference nurse for use in further follow-up. Patients' and reference nurses' experiences with the systematic CARES-assessment were explored.

RESULTS Fifty one patients participated. The mean age in the sample was 63 years(SD11.17), 52.9% was male. With the CARES-SF a large variety of problems and care needs was detected. The subgroup of problems most frequently experienced, and most burdensome for QOL are a mix of physical complaints, side effects from treatment, practical, relational, and psychosocial difficulties. Only for a limited number of experienced problems a desire for extra help was expressed. All patients positively evaluate the timing and frequency of the CARES-assessment. The majority believes that this assessment could contribute to the discussion of problems and needs with healthcare professionals, to get more tailored care. The reference nurses experienced the use of the CARES-assessment as an opportunity to systematically explore patients' well-being in a comprehensive way, leading to detection and discussion of specific problems or needs in greater depth, and more efficient involvement of different disciplines in care.

CONCLUSION Both patients and reference nurses had positive experiences with the systematic CARES-assessment. The tool provided a broad insight on the well-being and care needs of patients, and facilitated the communication between patients and healthcare professionals.

KEYWORDS: digestive cancer, systematic assessment quality of life, care needs, CARES

INTRODUCTION

Colorectal cancer is the third most common cancer worldwide. Other types of cancer that affect the digestive system are cancers of the esophagus, stomach, liver, gallbladder and pancreas. Worldwide 4.065.000 new cases of digestive cancer were diagnosed in 2012, accounting for 29% of all cancers [1]. Depending on the type of cancer, the prognosis and other health factors digestive cancers are mostly treated with surgery, chemotherapy or radiation, or a combination of these. Due to the disease and these related treatments cancer patients can suffer from physical, psychosocial and practical problems. There is a large interpersonal variability in the resulting supportive care needs [15, 130, 153]. When confronted with digestive cancer, patients often face specific challenges such as frequent constipation or diarrhea, weight loss, loss of appetite, stoma care, incontinence, changed body image, problems in sexual and social functioning [258, 259].

In the pursuit for high quality care, it is important that the care offered adequately matches with the problems and care needs that patients experience. In this context, the Institute Of Medicine (IOM) recommended routine assessment of experiences, needs, preferences and values in all cancer patients [33]. Use of a patient reported outcome measure (PROM) could support standardization of this routine assessment, and so several studies reviewed the available needs assessment instruments, their characteristics, and psychometric qualities [46, 134, 135]. The Cancer Rehabilitation Evaluation System (CARES) was described as a psychometric robust and feasible instrument for the measurement of quality of life (QOL) and care needs. The instrument was developed in the early ’90 [80, 85, 138], and subsequently used in clinical practice and in several studies [142, 260, 261, 262, 263, 264, 265].

This article describes an explorative pilot study in which systematic assessment of QOL and care needs with the CARES is applied in the follow-up of patients with digestive cancer. The objectives are to explore: 1) the value of the insights that can be obtained with the routine application of this tool in clinical practice; 2) the management of detected problems and care needs; 3) the feasibility of the systematic QOL and needs assessment intervention for patients and professionals.

MATERIAL AND METHODS

Participants and setting

For this study participants were recruited from October 2016 until April 2017 in the gastroenterology departments of two general hospitals. Two reference nurses (clinical nurse specialist in one hospital, head nurse of the department in the other) actively worked with the researcher to recruit participants, and received the needs assessment output for use in patient follow-up.

Patients were eligible if they (1) were diagnosed with digestive cancer, (2) started treatment in the gastroenterology department (no former experience with follow-up in this department), (3) were aged 18 years or older, and (4) provided written informed consent. Exclusion criteria were: a lack of proficiency in Dutch, cognitive or other impairment that hinders the person from completing questionnaires.

Instruments

QOL and needs assessment instrument

The CARES-Short Form (CARES-SF) was used in this study for the systematic assessment of QOL and care needs. This is a PROM with good psychometric qualities, that was developed with great involvement of patients and professionals from the clinical field [80, 85, 138]. The instrument was translated and validated for the Dutch speaking population [77, 125, 144, 158]. With addition of two items, requested for by participants in the validation study, the CARES-SF used in this study counts 61 items (min of 34, and maximum of 59 applicable per person). For each statement patients are asked to answer the question “How much does this apply to you?” on a 5-point ordinal scale with following answer-options: “not at all” (no problem); “a little”, “a fair amount”, “much”; “very much” (severe problem). Additionally, for any problem experienced patients are asked to answer the question "Do you want help?' by ticking “yes” or “no”. The tool has an average completion time of 10 minutes. Based on all items a CARES-SF-total score and 6 domain scores (physical, medical interaction, psychosocial, relational, sexual, miscellaneous) can be computed.

Assessment output report

This CARES-report is a short summary of the insights obtained from the patients' CARES-SF completion. The CARES-SF-total score is given as an indication for patients' QOL disruption, followed by a visual overview of the average severity of problems in the 6 domains, a list of the problems that are indicated as applicable in 'a fair amount' to 'very much', and a list of the indicated care needs. For the visual overview in subsequent reports, the data of previous assessments is maintained to display the evolution.

Study survey and semi-structured interviews

To explore patients' experiences with the systematic CARES-assessment intervention, a short survey was constructed with multiple choice questions on completion time, frequency and timing of the assessment intervention, and value of the CARES for the discussion of problems with healthcare professionals. Six months after the start of the study, semi-structured interviews were conducted with both reference nurses to explore their experiences with the implementation of the CARES in their daily work. One semi-structured interview was conducted face-to-face, the second by phone, following several key questions (for the interview guide see Appendix 8.1). These interviews took approximately 30 minutes.

Procedure

Participants were recruited by the reference nurses at the start of their treatment (T_0). After informed consent they received a paper version of the CARES-SF, and asked if they preferred to complete following assessments on paper or digitally. This choice, patients' diagnosis and treatment regimen were registered. Patients were asked to return their filled out questionnaire on socio-demographic characteristics and the CARES-SF with the stamped and addressed envelope provided. The researcher processed the CARES data, set up the output report, and sent it coded to the reference nurse for use in patient follow-up. We choose not to work with reminders when patients did not return the completed CARES-SF, as this would probably not be feasible in the eventual implementation of systematic needs assessment in clinical practice in the future. At three months post start of treatment (T_1) a second CARES-SF was sent to

participants, by post or with a Qualtrics survey-link by e-mail, according to the preference for paper or digital version. Again, returned questionnaires were processed and an output report was sent to the reference nurse. The full procedure is visualized in Figure 1. Only the first two CARES assessments are in the scope of this article.

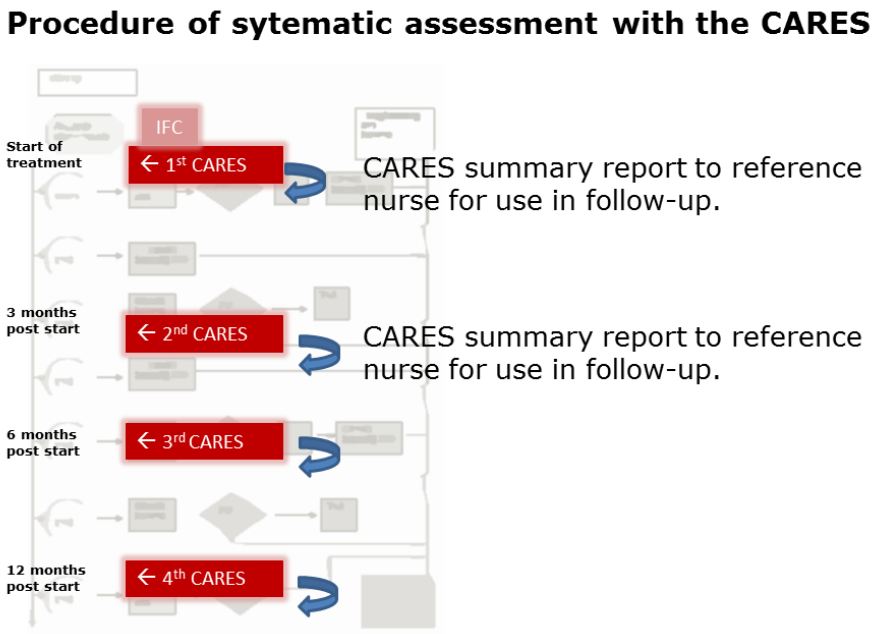


Figure 1. Procedure systematic CARES-assessment

Ethical considerations and study registration

Participant data was treated confidentially. Participant codes were used on CARES-SF forms, in data collection and for all correspondence. Only the researcher and reference nurse had access to the file that linked the patients' name with their participant code.

The study procedure and all study materials were submitted to the ethical committees of both hospitals (Committee Medical Ethics AZ Delta and Ethical Review Commission Jessa Hospital) and the university (Medical Ethical

Committee Hasselt University). Ethical approval was given by the leading ethical committee (Committee Medical Ethics AZ Delta) on 14th of March 2016 (B117201627823). The leading ethical committee also reviewed and approved amendments. This pilot study was registered with ClinicalTrialsGov. (ID. NCT02282696).

Data analysis

The Statistical Package for Social Sciences (SPSS;Chicago, IL) version 22.0 was used for calculation of CARES scores and further data analysis. Simple descriptive statistics were used to analyze all data.

RESULTS

Participants

Patients

Sixty seven patients consented to participate in this study. Eight of them were lost due to death (n=6) or worsened health condition (n=2) before they returned any questionnaire. With 51 participants of the remaining 59 actually returning one or both completed CARES forms, the response rate was 86.4%. The mean age in the study sample was 63years (SD11.17), and for 82.4% the digestive cancer was the first cancer diagnosis they were treated for. Further socio-demographic and medical characteristics are displayed in Table 1.

Professionals

The reference nurse in AZ Delta was a female clinical nurse specialist, working as the central contact person for the follow-up of cancer patients in the gastroenterology department. She had 21 years of job experience, of which 18 years in oncology. The reference nurse in the other site of this pilot study was the male head nurse of the oncology outpatient clinic in the gastroenterology department in the Jessa Hospital. He had 28.5 years of job experience, all in the field of oncology.

Table 1. Socio-demographic and medical characteristics patients (N=51).

Socio-demographic characteristics	**n**	**%**	**Medical characteristics**	**n**	**%**
Sex			*Type of cancer* [c]		
Men	27	52.9	Colorectal	31	60.8
Woman	24	47.1	Pancreas	7	13.9
Relational status			Esophagus	1	2.0
Single	7	13.7	Stomach	3	5.9
Partner, married or living together	39	76.5	Liver, gallbladder	7	13.9
Partner, not married or living together	2	3.9			
Widowed	3	5.9			
Having children	46	90.2	*Type of treatment* [c]		
Graduation level [a]			Surgery	2	3.9
Elementary school	7	13.7	Surgery + Palliative CT	1	2.0
High school	27	52.9	CT + RT	5	9.8
Graduate school	9	17.6	Adjuvant CT	18	35.3
University	4	7.8	Neoadjuvant CT	5	9.8
Job occupation [b]			Palliative CT	18	35.3
Employed	5	9.8			
Work interruption/on sick leave	6	11.8			
Unemployed	1	2.0			
Disabled	2	3.9	*Intention of treatment* [a]		
Housewife/houseman	2	3.9	Curative	29	56.9
Retired	34	66.7	Palliative	18	35.3

Abbreviations: CT (chemo therapy); n (number of participants); RT (radio therapy).
[a] percentages do not count up to 100%, due to missing data of 4 participants.
[b] percentages do not count up to 100%, due to missing data of 1 participant.
[c] percentages do not count up to 100%, due to missing data of 2 participants.

Quality Of Life

In this study sample all participants experienced problems to a greater or a lesser extent, at the start of treatment, as well as three months after start of treatment. For both time points, the frequency and severity rating of all 61 problems stated in the CARES-SF are presented in Appendix 8.2. The average and total number of problems that are experienced by patients in the several life domains are presented in Table 2.

Table 2. Severity scores for problems and impact on QOL in the CARES domains.

	Number of problems				**Severity of problems**[a]				**Impact on QOL**[a,b]			
	At T_0		**At T_1**		**At T_0**		**At T_1**		**At T_0**		**At T_1**	
CARES domains	M	Range	M	Range	M	SD	M	SD	M	SD	M	SD
Physical	5	0-10	5	1-10	1.55	0.57	1.66	0.56	0.89	0.68	1.00	0.76
Medical Interaction	1	0-4	1	0-4	1.21	0.42	1.23	0.42	0.24	0.38	0.20	0.40
Psychosocial	8	1-18	7	0-15	1.45	0.53	1.53	0.58	0.76	0.64	0.75	0.61
Marital	1	0-5	2	0-6	1.50	0.71	1.55	0.57	0.44	0.46	0.58	0.65
Sexual	1	0-3	1	0-3	2.12	0.98	1.87	0.83	0.93	1.08	1.00	1.09
Miscellaneous	3	0-10	3	0-10	1.44	0.58	1.70	0.80	0.40	0.38	0.51	0.48
CARES-SF Total	19	2-37	19	1-41	1.45	0.46	1.51	0.49	0.61	0.43	0.67	0.43

Abbreviations: M (mean), SD (standard deviation), T_0 (at start of treatment); T_1 (3 months after start of treatment).
[a] QOL-score range of each CARES-SF item from 0 - 4: 0= "not at all" (no problem); 1= "a little", 2= "a fair amount", 3= "much"; 4= "very much", on the question "How much does this apply to you?".
[b] This score is weight on the number of items applicable for a person.

At the start of treatment the *mean severity of problems* was highest in the domain of sexual functioning, followed by physical, marital and psychosocial functioning, miscellaneous aspects, and medical interaction (Table 2). At T_1 this sequence was relatively sexual functioning, miscellaneous aspects, physical, marital and psychosocial functioning, and medical interaction (Table 2).

The *relative impact of the cancer experience on QOL* at T_0 was highest for sexual, physical and psychosocial functioning, followed by marital functioning, miscellaneous aspects, and medical interaction (Table 2). Three months after start of treatment the impact was highest in the domains of physical and sexual functioning, followed by psychosocial, and marital functioning, miscellaneous aspects, and medical interaction.

The *problems most frequently experienced* by patients *(*by more than half of the sample) at both time points are displayed in Table 3, as well as the *problems that have the highest impact on patients' QOL*.

Care needs

The percentage of participants indicating to be in need for additional support or assistance was limited with 34.8 % and 25.6% at T_0 and T_1, respectively. At the start of treatment there were 40 type of problems for which participants desire help, three months after start of treatment 36 types of problems (Appendix 8.2).

The number of problems for which patients desire help at the start of treatment ranges from 0-7, 0-2, 0-7, 0-2, 0-2, and 0-3, for the physical, medical interaction, psychosocial, marital, sexual and miscellaneous domain, respectively. This is similar at T_1. The problems for which additional care or support is desired the most at both time points are presented in Table 3.

TABLE 3 Main problems and care needs in this population of digestive cancer patients (N=51).

PROBLEMS MOST FREQUENTLY EXPERIENCED

At the start of treatment (T_0)			At 3 months post start of treatment (T_1)		
Problem	**n[a]**	**%**	**Problem**	**n[a]**	**%**
Worry whether cancer progresses	43	93.5	Reduction in energy	40	93.0
Reduction in energy	39	84.8	Worry whether cancer progresses	37	86.1
Difficulties planning activities	32	69.6	Difficulties planning activities	31	72.1
Worry how loved ones are coping	30	65.2	Uncomfortable with body changes	30	69.8
Uncomfortable with body changes	30	65.2	Cancer interferes ability to work	26	60.5
Cancer interferes ability to work	29	63.0	Food unappealing	25	58.1
Nervous when waiting to see doctor	29	63.0	Worry not being able to care for self	25	58.1
Difficulties sleeping	27.00	58.7	Frequently anxious	24	55.8
Frequently having pain	26.00	56.5	Nervous when waiting to see doctor	24	55.8
Difficulties doing household chores	25.00	54.3	Difficulties to bend or lift	23	53.5
Difficulties asking frnd/rel. for help	25.00	54.3	Difficulties sleeping	23	53.5
Worry not being able to care for self	27.00	58.7	Difficulties concentrating	23	53.5
			Difficulties asking frnd/rel. help	23	53.5

PROBLEMS WITH THE HIGHEST IMPACT ON PATIENTS' QOL

At start of treatment (T_0)		At 3 months post start of treatment (T_1)	
Problem	**Av.sev.[b]**	**Problem**	**Av.sev.[b]**
Difficulties telling a date about cancer[c]	3.00	Vomit after chemo[c]	2.67
Nauseous/vomit after radiotherapy[c]	3.00	Difficulties telling date about cancer[c]	2.50
Difficulties initiating dates[c]	2.60	Cannot gain weight	2.38
Difficulties to talk about cancer at work[c]	2.50	Not gets along as usual with partner[c]	2.38
Cannot gain weight	2.20	Difficulties initiating dates[c]	2.25
Not interested in having sex	2.16	Other side effect from chemo[c]	2.21
Frequency of sex decreased[c]	2.14	Cancer interferes ability to work	2.19
Doesn't feel sexually attractive	2.13	Frequency of sex decreased[c]	2.18
Worry whether cancer progresses	2.02	Clothes do not fit	2.11
Not gets along as usual with partner[c]	2.00	Reduction in energy	2.05
Problems ostomy care/maintenance[c]	2.00	Frequent diarrhea	2.00

CARE NEEDS MOST FREQUENTLY EXPRESSED

At start of treatment (T_0)			At 3 months post start of treatment (T_1)		
Wish for help with...	**n[a]**	**%**	**Wish for help with...**	**n[a]**	**%**
Difficulties doing household chores	8	17.4	Difficulties planning activities	5	11.6
Worry whether cancer progresses	5	10.9	Food unappealing	4	9.3
Reduction in energy	4	8.7	Cancer interferes ability to work	4	9.3
Cannot gain weight	4	8.7	Uncomfortable with body changes	4	9.3
Difficulties sleeping	4	8.7	Difficulties concentrating	4	9.3
Worry how loved ones are coping	4	8.7	Worry how loved ones are coping	4	9.3
Food unappealing	3	6.5	Difficulties doing household chores	3	7.0
Frequent diarrhea	3	6.5	Cannot gain weight	3	7.0
Cancer interferes ability to work	3	6.5	Frequent diarrhea	3	7.0
Frequently has pain	3	6.5	Frequently anxious	3	7.0
Uncomfortable with body changes	3	6.5	Difficulties sleeping	3	7.0
Difficulties concentrating	3	6.5	Worry whether cancer progresses	3	7.0
			Nauseated after chemo[c]	3	7.0

Abbreviations: Av.sev (average severity); n (number of participants); QOL (quality of life).
[a] n_{T0} = 46; n_{T1} = 43.
[b] QOL-score range of each item from 0 - 4: 0= "Not at all", 1= "A little", 2= "A fair amount", 3= "Much", 4= "Very Much".
[c] Item not applicable for every participant.

Feasibility and Acceptability intervention

Questionnaire return

Of the 51 participants returning their questionnaire, 46 (90.2%) completed the first CARES-SF at start of treatment, 43 (84.3%) completed the second CARES-SF three months later. Reasons for non-return mentioned to the nurse were lack of time, not feeling into completing a questionnaire, or forgetting. For example because of these reasons, there were five patients who did not complete the CARES-SF at the start of the treatment, but did so three months later.

Patients' experience (quantitative data)

All participants that completed the questionnaire at the start of treatment judged the completion time of the CARES-SF to be acceptable. At the start of treatment 42 participants (91.3%) indicated that repeated assessment with the CARES-SF could contribute to the discussion of problems and needs with healthcare professionals, to get support that was more tailored to their individual needs. One person (2.2%) indicated 'no' for this question. After the CARES-SF completion at three months, participants were asked to evaluate the frequency and timing of the CARES-assessments. Almost 91 percent indicated that this was good and had no suggestions for other frequency or timing. After this second CARES-assessment 65.1% of the participants indicated that the use of the CARES-assessment in follow-up could contribute to problems and needs discussions with healthcare professionals. Eight participants (18.6%) thought this was not the case.

Professionals' experience (qualitative data)

Both reference nurses used the CARES-results on needs as action points in care. The QOL information was used in follow-up for the discussion of patients well-being and their way of coping with disease and treatment. In AZ Delta the CARES-report was scanned and placed in the electronic patient file, in Jessa Hospital the reference nurse included information on detected problems and needs in his discipline specific section of the electronic patient record.

The CARES-SF was experienced by the references nurses as a tool that provides support in patient-communication and follow-up of patients' overall well-being, including medical and psychosocial. On the one hand, the CARES-information

confirmed their clinical insights, on the other hand in several cases it added extra insights.

> *"The information is rich…. One of the great strengths of the CARES is that the CARES questionnaire gives a reflection of how people are doing, and that you can use it as a starting point for communication." (Reference Nurse 1).*
>
> *"Putting patients on the IV line is one thing…but everything going beyond that…the questionnaire is perfect for that… the experience, the side effects, and what makes the patient feel comfortable. And the CARES gives you input to address all of these aspects." (Reference Nurse 2).*

The semi-structured interviews with the two reference nurses revealed that use of the CARES can support the completeness, efficiency and customization of follow-up. Besides, it could contribute to the relationship of trust that a care professional has with the patient.

> *"I think, if you have to get all of that information that you collect with the CARES, you would need a conversation of three or four hours…and we don't have that time." (Reference Nurse 1).*
>
> *"I think you can navigate care actions a lot better. Plus, I also think that it is a great advantage for the patient, or your trust relationship with that patient, that the patient experiences 'he understands me', "he is aware of the problems I have to face" (Reference Nurse 2).*
>
> *"Your conversations are going to have a larger variety in topics, because there are actually many different classes of questions answered. (Sums up a series of CARES topics) A huge divergence of opportunities for discussion topics is addressed." (Reference Nurse 1).*
>
> *"You can work a lot more proactively ... so that's the benefit." (Reference Nurse 2).*

During the interview, the reference nurse of the Jessa Hospital stated 'We also should have a questionnaire like that for the patients' partners'. In AZ Delta the reference nurse already asked for such a version during the study period, and used a partner-version of the CARES (not part of the scope in this study, but developed and added on her request), and experienced this as valuable. Problems that remained unnamed before between partners, were now exposed. In response to this the concern not to strain each other, and the problem could be discussed, sometimes resulting in a relief of relational tension.
According to the reference nurses healthcare professionals can be involved in a more efficient and focused way, better prepared with self-reported problems and needs that are important to patients. Outcomes of the CARES-assessment were discussed with several disciplines.

"I have already called a general practitioner with issues from the CARES questionnaire, a treating physician, because there were some questions or patients who indicated "I want more information, but I do not get that ". Social services, especially for problems of finance, insurance, practical help at home ... a dietician for nutritional and weight problems." (Reference Nurse 1).

A physician of the gastroenterology department not actively involved in the study spontaneously sent an email with the message 'A lot of our patients complete the CARES, often we get valuable insights from this'. A psychologist asked if there was a cut-off value for the CARES to determine whether further care was required.

In reference nurses' experience, most patients were willing to complete the CARES. What struck them was that many problems were indicated in the CARES, but that few patients pointed out that they were in need for help. However, in conversations about these issues, help questions did emerged sometimes. According to both reference nurses the use of the CARES could contribute to a patient-centered approach in care.

"The patient will complete the questions from his perspective…and then care will be targeted more to individual needs" (Reference Nurse 2).

"The patient has his responsibility there too ... he completes those questions, but in the end it provides him with more tailored support." (Reference Nurse 2).

"You're going to do something with that (insights from the CARES) in collaboration with them…in the end it's all about them." (Reference Nurse 1).

"If they refuge things or don't want it, well…it's their way" (Reference Nurse 1).

After recruitment fort his pilot study the reference nurse in AZ Delta kept on using the CARES-SF in the follow-up of patients, and encouraged colleagues and managers to use the instrument for the wider group of cancer patients in the hospital.

The other reference nurse is also positive about a future implementation of the instrument in practice. And this not only for the benefit of the individual patient, but also because of the value of big data that could be collected in case of larger scale implementation.

"50% of our care for the patient is treatment, and the other 50% is the attention for the thing we're talking about… patients' quality of life… and that is important! I'm not sure if all doctors are aware of that. Ours are, because they gave me the chance to do this PAN-function and take time for the people, but…other doctors… And with an instrument like this you can indicate what kind of problems and needs patients experience. This is also important for the organization of the healthcare system." (Reference Nurse 2).

DISCUSSION

With the CARES-SF a comprehensive overview of each patients' overall well-being was obtained in the study sample. The problems most common in the sample, and most stressing to patients' QOL consist of a mix of disease symptoms or treatment side effects, physical, practical, relational, and psychosocial problems. As in other studies, only a small group of patients experiencing problems also expressed related care needs (34.8% at T_0; 25.6% at T_1), or is willing to accept a referral [266, 267]. This can be explained by the fact that patients want to cope with the problems and distress on their own, they do not experience their levels of distress as high enough, or they have sufficient social support in their personal context to deal with the situation [268]. This emphasizes that the QOL insights require attention in follow-up, but not necessarily ask for action. However, the indicated care needs do. As in other studies [269], some patients who initially did not experience considerable problems or care needs did report significant problems or care needs in the CARES assessment at three months after start of treatment. This emphasizes the value of repeated needs assessment, to enable us to timely identify and address patients QOL issues.

All participants were positive on the frequency and timing of the CARES-assessment, and the majority indicated that this could have an additional value in the patient-professional communication and receiving tailored care. That some of the patients do not share this opinion may be in person's personal coping, physical and social surroundings. As well, communication needs and preferences can change along the care trajectory[270].

The reference nurses experienced the CARES data as a valuable starting point to discuss patients well-being, and in detecting potential problems and care needs [271]. It stimulates patients to reflect on potential problems and their impact, and supports them in determining for which they desire further discussion or support [272]. The obtained insights provided the nurses guidance in conversations on patients' well-being, enabled them to 'come to the point' in less time and to involve other disciplines more effectively in care [273]. However, they emphasized that the tool should be used for its' supportive value and not to replace clinical contacts.

In addition to these findings, several critical reflections on this study should be mentioned. Firstly, in comparison with other intervention studies, our sample size was rather small. However, this study was set up with an explorative purpose to study the acceptability and feasibility from patients' and professionals' perspective. In subsequent studies more participants will be recruited. As well, outcome measures will be used to study the concrete effectiveness of the intervention. Secondly, as we worked with two reference nurses that were willing to collaborate for this explorative pilot study, there might have been a bias in their judgements. In studies following on this explorative pilot, more hospitals and departments should be involved in a broader evaluation, with inclusion of additional objective outcomes. Also, it would be interesting to evaluate the clinical use of CARES compared to the European Organization for Research and Treatment of Cancer (EORTC) QOL-schemes frequently used in clinical trials. Thirdly, at the point of data processing we had some doubts about the question on patients' experience with the potential value of the CARES-assessment for the discussion of problems, and for receiving tailored care. This question was accompanied by the answer options: 'yes' and 'no'. Perhaps it would have been better to use a rating scale, as this would have allowed more nuance in patients' responses.

In conclusion, it is still challenging to implement a systematic assessment with the CARES in daily cancer care. Healthcare professionals have to get acquainted in introducing the CARES in the most appropriate way, and to work with the obtained insights, in good collaboration with other team members. Mutual agreements must be made regarding data processing, inclusion of the obtained insights in the patient file, and the actions that have to be taken (and by whom) when certain problems or needs are detected. Also for patients it requires an effort in terms of time investment to complete the CARES. However, both patients and reference nurses positively evaluated the CARES-assessment. The tool supports patients in providing valuable information on their well-being and care needs, and stimulates the comprehensiveness in professionals' follow-up. The obtained insights can be used in clinical conversations, and to efficiently take action in care, in line with patients' preferences and needs.

ACKNOWLEDGEMENTS

We would like to acknowledge the gastroenterology departments who were willing to work with us for this pilot study. Also we would like to thank Limburg Sterk Merk for funding the PhD-project of Bojoura Schouten.

DISCLOSURE OF INTEREST

The authors report no conflicts of interest.

Appendix 8.1.

Interview guide semi-structured interview with reference nurses

1. Do you notice any influence from the use of the systematic CARES assessment on the detection of problems or issues in patients? In case you do, what kind of influence?

2. Do you notice any influence from the use of the systematic CARES assessment on your follow-up of patients? In case you do, what kind of influence?

3. Do you notice any influence from the use of the systematic CARES assessment on the referral of patients? In case you do, what kind of influence?

4. With which colleagues (disciplines) did you share information from the CARES-reports? How do they react on your use of the CARES?

5. What do you concretely do with the CARES reports after you receive them?

6. How do patients react on the use of the systematic CARES assessment?

7. What is your general experience with the use of these systematic assessment of QOL and care needs in the follow-up of patients?

Appendix 8.2.

Table A8.2.1. Number of participants with problem rating and desire for help at start of treatment (T_0).

CARES-SF items	Patients' problem rating and desire for help (N=46)[a]							
	0	1	2	3	4	Mean[b]	No[b]	Yes[b]
1.Diff. bend or lift	24	15	6	0	1	1.41	34	2
4.Reduction in energy	7	17	13	7	2	1.85	33	4
6.Diff. household chores	20	16	6	3	1	1.58	30	8
7.Diff. bathe. brush. groom	36	9	1	0	0	1.10	35	0
12.Diff. planning active.	14	20	9	1	2	1.53	36	2
13.Cannot gain weight	25	7	5	5	3	2.20	31	4
85.Gain too much weight	39	5	0	0	0	1.00	29	1
15.Food unappealing	27	8	5	4	1	1.89	29	3
87.Fequent diarrhea	21	15	3	3	3	1.75	29	3
88.Poor bladder control	35	9	2	0	0	1.18	31	1
19.Cancer interferes work	13	11	11	4	3	1.97	28	3
20.Frequently has pain	19	17	8	2	0	1.44	30	3
25.Clothes not fit	30	8	6	1	1	1.69	32	1
28.Doctors don't explain what do	41	4	1	0	0	1.20	32	1
30.Diff. ask doctors questions	38	5	3	0	0	1.38	31	1
34.Diff. understand doctors' explanation	34	9	2	0	0	1.18	32	1
36.Wants more control over doctor	35	10	0	0	1	1.27	31	1
40.Uncomfor. with body changes	15	17	8	4	1	1.63	31	3
41.Frequently anxious	24	13	7	1	1	1.55	30	2
41b. Frequently lonely	36	5	4	1	1	1.82	32	1
46.Diff. sleep	18	14	8	4	1	1.70	30	4
47.Diff. concentrating	21	15	5	1	2	1.57	29	3
54.Diff. ask frnd/rel. help	21	13	9	1	2	1.68	31	1
55.Diff. tell frnd/rel. about cancer	31	9	3	2	1	1.67	32	0
57.Frnd/rel. say look well when not	29	11	4	1	1	1.53	321	0
60.Frnd/rel. do not visit enough	38	6	2	0	0	1.25	32	0
63.Frnd/rel. diff. talk about cancer	30	11	5	0	0	1.31	33	0
63b. Worry how loved ones are coping	16	14	12	3	1	1.70	31	4
66.Nervous wait to see doctor	17	22	4	1	2	1.41	32	1
69.Nervous get blood drawn	35	9	1	1	0	1.27	32	0
71.Worry whether cancer progress	3	19	11	6	7	2.02	29	5
72.Worry not able to care for self	21	15	5	2	3	1.72	32	2
74.Doesn't feel sex. attractive	27	6	5	2	3	2.13	31	0
76.Not interested in having sex	24	5	8	4	2	2.16	28	2
81.Doesn't follow MD's instructions	36	7	0	2	1	1.70	31	1
82.Financial problems	39	4	2	1	0	1.57	31	2
83.Insurance problems	41	4	1	0	0	1.20	31	2
84.Diff. with transport	42	3	1	0	0	1.25	31	1
90.Diff help children cope [c]	27	11	2	1	1	1.47	29	1
93.Diff. talk people at work [c]	5	1	0	0	1	2.50	5	0
95.Diff. ask time off for treatments [c]	4	2	0	1	0	1.67	6	0
96.Worried about being fired [c]	5	2	0	0	0	1.00	5	0
97. Diff. finding new job [c]	44	0	0	0	0	-	2	0

99.Frequency of sex decreased [c]	1	1	5	0	1	2.14	9	1
103.Diff. talk feelings with partner [c]	23	9	4	0	0	1.31	27	1
108.Diff. talk wills/financial matters with partner [c]	26	4	4	1	0	1.67	25	0
109.Doesn't feel like embrace. etc. partner [c]	28	3	4	0	0	1.57	26	0
113.Not get along as well usual with partner [c]	31	2	1	0	1	2.00	26	0
118.Partner provides too much care [c]	19	10	4	1	1	1.56	25	0
120.Diff. ask partner to take care [c]	22	8	3	1	1	1.62	25	1
121.Diff. initiating dates [c]	1	1	2	0	2	2.60	5	1
124. Diff. tell date about cancer [c]	2	0	2	0	2	3.00	5	0
126.Nervous get chemo [c]	15	10	4	1	0	1.40	19	0
127.Nauseated during/before chemo [c]	21	8	1	0	0	1.11	18	1
130.Nauseated after chemo [c]	18	10	2	0	0	1.17	18	1
131.Vomit after chemo [c]	28	2	0	0	0	1.00	21	0
133.Other side effect chemo [c]	12	10	5	3	0	1.61	20	2
136.Nervous to get radiotherapy [c]	3	5	1	0	0	1.17	10	0
137.Nauseous/vomit after radiotherapy [c]	7	0	0	1	0	3.00	7	0
138.Problems ostomy care/maintenance [c]	1	0	1	0	0	2.00	4	1
139.Diff. with prosthesis [c]	3	1	1	0	0	1.50	4	0

Note: QOL-score range of each item from 0 - 4: 0= Not at all, 1= A little, 2= A fair amount, 3= Much, 4= Very Much, on the question 'Does this apply to you?', Need for help-score is retrieved by the indication 'Yes' or 'No' on the question 'Do you want help?'.
[a] Number of participants do not always count up to 46 due to missing values for some participants.
[b] Mean = mean problem severity in case a problem is experienced; No/Yes = participants answer on the question 'Do you want help?'.
[c] Item not applicable for every participant.

Table A8.2.2. Number of participants with problem rating and desire for help 3months post start of treatment (T_1).

CARES-SF items	Patients' problem rating and desire for help (N=43)[a]							
	0	1	2	3	4	Mean[b]	No[b]	Yes[b]
1.Diff. bend or lift	20	13	9	0	1	1.52	29	0
4.Reduction in energy	2	12	19	4	5	2.05	30	2
6.Diff. household chores	19	10	6	5	0	1.76	23	3
7.Diff. bathe. brush. groom	35	6	1	0	0	1.14	27	0
12.Diff. planning active.	11	21	4	4	2	1.58	25	5
13.Cannot gain weight	22	6	6	4	5	2.38	24	3
85.Gain too much weight	36	4	1	0	1	1.67	26	0
15.Food unappealing	17	11	12	2	0	1.64	26	4
87.Fequent diarrhea	25	7	6	1	3	2.00	24	3
88.Poor bladder control	34	6	2	0	0	1.25	27	0
19.Cancer interferes work	14	8	8	7	3	2.19	24	4
20.Frequently has pain	27	9	4	2	0	1.53	26	1
25.Clothes not fit	23	7	7	1	4	2.11	25	2
28.Doctors don't explain what do	37	1	2	1	0	2.00	27	0
30.Diff. ask doctors questions	36	5	1	0	0	1.17	26	0
34.Diff. understand doctor about cancer	36	4	1	0	0	1.20	24	2
36.Wants more control over doctor	32	8	2	0	0	1.20	25	1
40.Uncomfor. with body changes	12	16	7	3	4	1.83	23	4

41.Frequently anxious	18	12	7	4	1	1.75	27	3
41b. Frequently lonely	32	2	4	0	1	2.00	26	1
46.Diff. sleep	19	10	11	1	1	1.70	26	3
47.Diff. concentrating	18	10	8	4	1	1.83	23	4
54.Diff. ask frnd/rel. help	19	11	10	2	0	1.61	24	2
55.Diff. tell frnd/rel. about cancer	31	8	2	1	0	1.36	27	0
57.Frnd/rel. say look well when not	23	13	4	2	0	1.42	26	1
60.Frnd/rel. do not visit enough	35	4	2	0	0	1.33	25	1
63.Frnd/rel. diff. talk about cancer	27	12	3	0	0	1.20	28	0
63b. Worry how loved ones are coping	20	13	7	0	2	1.59	25	4
66.Nervous wait to see doctor	18	17	4	3	0	1.42	26	2
69.Nervous get blood drawn	30	7	3	1	0	1.45	27	0
71.Worry whether cancer progress	5	18	10	4	5	1.89	26	3
72.Worry not able to care for self	16	17	5	2	1	1.48	26	1
74.Doesn't feel sex. attractive	24	9	5	2	2	1.83	26	1
76.Not interested in having sex	20	9	7	2	3	1.95	24	2
81.Doesn't follow MD's instructions	35	4	1	1	1	1.86	26	0
82.Financial problems	34	6	1	0	0	1.14	26	1
83.Insurance problems	38	0	2	0	0	2.00	26	1
84.Diff. with transport	37	4	0	0	0	1.00	26	0
90.Diff help children cope [c]	22	9	3	1	0	1.38	23	2
93.Diff. talk people at work [c]	4	1	0	0	0	1.00	3	0
95.Diff. ask time off for treatments [c]	5	0	0	0	0	0.00	2	0
96.Worried about being fired [c]	5	0	0	0	0	0.00	3	0
97. Diff. finding new job [c]	1	0	0	0	0	0.00	2	0
99.Frequency of sex decreased [c]	0	2	5	4	0	2.18	7	0
103.Diff. talk feelings with partner [c]	21	6	5	0	0	1.45	21	2
108.Diff. talk wills/financial matters with partner [c]	20	5	5	2	0	1.75	21	0
109.Doesn't feel like embrace. etc. partner [c]	22	7	1	0	1	1.44	20	0
113.Not get along as well usual with partner [c]	24	2	3	1	2	2.38	19	2
118.Partner provides too much care [c]	20	5	6	1	0	1.67	19	1
120.Diff. ask partner to take care [c]	18	8	5	1	0	1.50	21	1
121.Diff. initiating dates [c]	1	2	0	1	1	2.25	4	0
124. Diff. tell date about cancer [c]	2	1	0	3	0	2.50	4	0
126.Nervous get chemo [c]	13	10	3	1	2	1.69	15	2
127.Nauseated during/before chemo [c]	15	9	0	2	1	1.58	18	0
130.Nauseated after chemo [c]	14	6	4	1	2	1.92	15	3
131.Vomit after chemo [c]	25	0	2	0	1	2.67	17	0
133.Other side effect chemo [c]	7	6	5	6	2	2.21	19	1
136.Nervous to get radiotherapy [c]	1	1	0	0	0	1.00	4	1
137.Nauseous/vomit after radiotherapy [c]	4	0	0	0	0	0.00	2	0
138.Problems ostomy care/maintenance [c]	2	0	1	0	0	2.00	4	0
139.Diff. with prosthesis [c]	1	0	0	0	0	0.00	3	0

Note: QOL-score range of each item from 0 - 4: 0= Not at all. 1= A little. 2= A fair amount. 3= Much. 4= Very Much. on the question 'Does this apply to you?'. Need for help-score is retrieved by the indication 'Yes' or 'No' on the question 'Do you want help?'.

[a] Number of participants do not always count up to 43 due to missing values for some participants.

[b] Mean = mean problem severity in case a problem is experienced; No/Yes = participants answer on the question 'Do you want help?'.

[c] Item not applicable for every participant.

9
Chapter

General discussion and conclusions

When confronted with cancer and related treatments, patients and their relatives often experience consequences of physical, psychological, social and practical nature, that can lead to a variation of care needs [8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 274, 275, 276]. To adequately address the 'cancer experience', cancer care should be comprehensive, and driven by a holistic, biopsychosocial approach [38]. Besides, in order to achieve more patient-centeredness and a higher quality of care, the Institute Of Medicine (IOM) advised to focus more on patients' experiences, values, preferences and needs, and to use these to guide all clinical decisions [33].

As described in the introduction, the objective of this PhD-project was to contribute to the research on the psychosocial aspects and patient-centeredness in Flemish cancer care. This gave rise to several consecutive research questions, and led to the various studies described in this dissertation. In this last chapter, the evidence retrieved from these studies is shortly discussed and recommendations for clinical practice and future research are formulated.

MAIN FINDINGS FROM THIS RESEARCH PROJECT

Research question 1: 'How can we support the detection and monitoring of cancer patients' psychosocial care needs, in order to improve the comprehensive and patient-centered approach in cancer care?'

This question has led to an exploration of the literature on needs assessment and psychosocial aspects of cancer care. When this PhD project started in 2013 already three reviews on needs assessment tools were available, with the most recent published in 2012 [46, 134, 135]. These reviews explored available needs assessment tools, and evaluated the conceptual and measurement models, the psychometric qualities, the feasibility and acceptability to patients. In all these reviews the Cancer Rehabilitation Evaluation System (CARES) was discussed as a needs assessment instrument that was developed with a thorough procedure and involvement of important stakeholders. The instrument was rather complete and covers patients' biopsychosocial well-being and care needs, possessed relatively good psychometric qualities, and was judged to be feasible and

acceptable for patients. Consequently, from this finding several research questions about the CARES followed.

'Is the Flemish translation of the CARES eligible to measure quality of life (QOL) and care needs of cancer patients in our population?'. After all, a simple translation of a validated instrument does not suffice. Due to cross-cultural and linguistic differences, the validity of an instrument is not necessarily applicable to any population [78, 277, 278, 279]. Therefore, frequently studies are conducted to examine the cross-cultural validity of already validated patient reported outcome measures (PROM) in different languages and populations[92, 280, 281, 282, 283, 284, 285, 286, 287, 288].

A first sub question, ***'Is the Flemish CARES psychometrically robust?'***, lead to the quantitative questionnaire study described in **Chapter 2 and 3**. The CARES was translated into Flemish following a translation-back translation process, with involvement of sworn translators. With cooperation of four hospitals 192 cancer patients were recruited and asked to complete two questionnaire bundles. A first bundle contained questions on socio-demographic characteristics, the CARES, and seven other validated and frequently used instruments of QOL (EORTC-QLQ-C30), distress (DT), physical functioning (KPS), depression and anxiety (HADS), social support (SSL), sexual and marital functioning (MMQ). The data collected with this first bundle were used to explore internal consistency, construct and concurrent validity. About a week later participants received a second questionnaire bundle with the CARES and questions on the feasibility and their experiences with the questionnaire. With this additional data test-retest reliability and feasibility of the instrument could be explored. Data of 176 participants was eligible for analysis. The results demonstrated excellent reliability with high internal consistency (range .87-.96) and test-retest ratings (range .70-.91) for all summary scales of the Flemish CARES. Factor analysis replicated the original factor solution of five higher order factors with factor loadings of .325-.851. Correlations with the other seven instruments ranged from |.43| - |.75|, and confirmed concurrent validity. This is in line with other studies, however in our study even better reliability and validity ratings were found [77, 85, 138, 148, 289]. The CARES assessment resulted in a clear overview of cancer patients' frequently experienced problems,

QOL disruption, and care needs. Patients mainly gave positive feedback on the instrument.

From this study, it could be concluded that the Flemish CARES has strong psychometric properties, and it can as such be used as a valid tool to assess cancer patients' QOL and needs.

A second sub question, ***'Is the CARES an acceptable and feasible instrument, and is the content relevant and complete for patients in our population?***', was explored in the qualitative study addressed in **Chapter 4**. Quantitative research enables researchers to collect data of a large group of patients. However, due to the format of the questions most often used (multiple choice (MPC) and matrix questions), an in depth exploration of participants' reasoning and experiences that can be obtained with qualitative design is not possible [290]. Since the patient-perspective was of considerable importance in this project, focus groups were organized to discuss the CARES content, acceptability and feasibility of the instrument with patients. Data were gathered in four focus groups with 26 (ex-)patients that were treated for different cancers, in different hospitals. The focus group discussions were facilitated with key questions, conducted an followed by a moderator and an observer. Thematic analysis of the transcribed audio file revealed that participants experienced concerns and needs in a wide range of life domains. According to participants, the items of the CARES are all relevant and able to give a good impression on the biopsychosocial impact that cancer and related treatments can have in a persons' live. However, the theme of 'well-being of loved ones' and 'loneliness' was missing in the CARES. These could be a valuable addition according to participants, since attention for these aspects was often also missing in cancer care. The completion time of the CARES was judged to be feasible, and for only a few items a reformulation was requested.

In conclusion, the results of these focus group discussions support the content validity and feasibility of the Flemish CARES version. This is in line with the research on the original instrument [80, 85]. Additionally, we obtained the insights that little adjustments in formulation and a few extra item in the CARES were needed for an even better match of the CARES content with patients experiences. This was not found in earlier studies. The final Flemish CARES

versions are presented in Appendix 9.1. There are available at request at University Hasselt, and can be used in research and clinical practice with approval of the authors of the original instrument.

Research question 2: 'How do patients experience cancer care, and the match of the care offer with their care needs?'

The Belgian National Cancer Plan that was launched in 2008, contained several actions and objectives to stimulate the psychosocial approach in cancer care [57]. After a few years, however, several actions were not executed yet or limited progress was made [58, 291]. Besides, most actions were rather supply-driven instead of demand-driven, while the latter is needed to achieve more patient-centeredness in care [37, 292]. No actions were planned to actively involve patients in the improvement plans, and evaluations of actions. As well, there were no actions in line with the international guidelines and recommendations on systematically screening of cancer patients distress and care needs. However, it is of great importance to know 'where you stand', when you want to plan 'where you are going'. Therefore in **chapter 5** of this thesis the experiences of (ex-)cancer patients with the care they received, the detection of, and response to their care needs was addressed. Data were collected in four focus groups, 26 (ex-)patients participated. The focus group discussions gave insights in the positive and negative experiences that participants had in cancer care. These seemed to be influenced by several aspects: the accessibility; comprehensiveness; multidisciplinary cooperation and referral; continuity and timing of care on the one hand. On the other hand, interpersonal aspects like trust, holistic and personal approach, availability/time, professionals' communication style, clarity of information, shared decision-making and health care professionals' familiarity with patients' medical or personal situation played an important role in participants' experiences of care. Several specific and important needs were repeatedly mentioned: the need for clear information on their medical condition; treatment and supportive care options; a desire for involvement in care choices and decisions; initiation about psychosocial topic by care professionals; support in rehabilitation; the availability of a central contact person in care to discuss questions and needs.

In summary, interpersonal and organizational aspects seem to play an important role in the establishment of the (mis)match between cancer care and cancer patients' care needs. Healthcare policy and organization differs between countries. The focus group study of this project provided input on points of attention for the pursuit of comprehensive, patient-centered cancer care in Belgian practice.

Research question 3: 'How does the multidisciplinary group of HCP involved in cancer care manage patients' psychosocial issues?

A wide variety of healthcare professionals (HCP) from different medical, paramedical, psychosocial and spiritual disciplines can be involved in patients' cancer care trajectory. In other words, cancer care is a multidisciplinary affair. Since all these HCP together contribute the available care offer, it seemed important to also explore their perspective regarding the psychosocial approach in their work with cancer patients. In **Chapter 6** the cross-sectional survey that was conducted to explore professionals' perspective on the approach of psychosocial issues in cancer care is described. Oncology specialists, other physicians, nurses, social workers, spiritual workers, psychologists, dieticians, GP, physical-, occupational- and lymphedema therapists working in the in-hospital or in ambulatory care context were invited to participate. Recruiting took place in collaboration with heads of departments, team leaders, discipline specific networks or associations. These decided to provide us with the mailing lists of their team members, or forwarded our message, or placed a message about the study in the newsletter for their members. Consequently, there was a variation in the way the potential participants were invited to participate in the study. Three hundred and sixty eight HCP successfully completed the online survey with MPC, matrix, and open questions. The majority of these participants did not use a systematic approach to discuss psychosocial concerns with patients, 37.5% indicated to use the general question 'How are you?', and 65.0% percent spontaneously addresses various psychosocial aspects. Only 1.9% uses a PROM or checklist to assure that potential psychosocial issues are discussed. A large range of psychosocial topics is 'sometimes' or 'often' discussed. Thoughts about disease, treatment and recovery, and related

emotions are discussed more often. However, sexuality and return to work are rarely mentioned. About 50% of the participants were convinced that they pay enough attention to the psychosocial well-being of cancer patients: by merely listening, engaging in a deeper conversation, providing advice, and through referral. On the other hand, there is the other 50% that is not satisfied with the (amount) of psychosocial support they can provide. Referrals are most often made to psychologists, general practitioners (GP), social workers, specialized nurses, or centers for well-being and mental health. The barriers in providing psychosocial support that were most mentioned are the lack of time, the desire for appropriate background knowledge and education, insufficient interdisciplinary communication and cooperation on psychosocial issues, difficulties with referrals, and lack of reimbursement for psychosocial care.

The data collected with this cross-sectional survey revealed that only half of the participating HCP is satisfied with the support or care they provide when cancer patients suffer from psychosocial issues, problems or needs. In general psychosocial issues are not systematically addressed. The barriers that need to be addressed according to them are mainly related to education, communication, healthcare policy and organization.

Research question 4: 'What is the effect of systematic screening and assessment of cancer patients psychosocial well-being and care needs, and which specific characteristics of these interventions potentially contribute to this effect?'

In the last decades, several calls and consensus-based guidelines were launched to implement systematic screening of cancer patients' distress and care needs [46, 247, 248, 293]. These guidelines are based on the belief that this intervention can stimulate (1) detection of, (2) communication on, and (3) tailored referral for psychosocial concerns [114, 188, 189]. This could contribute to a more efficient and effective healthcare delivery, and in the end is expected to improve cancer patients' well-being [191]. To explore the potential benefits of these interventions for patients' psychosocial well-being, a Cochrane Systematic review was conducted and described in **Chapter 7** of this thesis. With a combination of controlled vocabulary and free text terms for 'cancer', 'psychosocial', 'screening', 'assessment', 'quality of life', 'distress' and 'care

needs' a consecutive search for randomized controlled trials (RCT) and non-randomized controlled trials (RCT) studies was conducted in five databases (CENTRAL; MEDLINE; PsycInfo; Embase; CINAHL), and five trial registers (the National Research Register; the ISRCTN registry; the Dutch trial register; the RePORTER query tool) from inception to November 2016. All records of two journals important in the research field (Psycho-Oncology; Supportive Care in Cancer), and the conference abstracts of the yearly World Conference of Psycho-Oncology were searched from 2010-2016. Twenty four studies were eligible for inclusion in the review, of which 16 RCT and 8 NRCT. There was considerable heterogeneity in intervention characteristics, outcome measurements and methodological quality. Only three studies could be included in a meta-analysis. This analysis did not affirm the beneficial effect of the studied intervention. In nine individual studies a beneficial effect was found in the intervention group, compared to the usual care control group. However, negative effects were also found in four studies. Nor was there any coherence observed between the intervention characteristics, and the effectiveness of the interventions.
In conclusion, the evidence found in this Cochrane Review does not support the effectiveness of screening and assessment of psychosocial well-being and care needs on cancer patients' well-being, neither on the intervention characteristics that could be determinative in the effectiveness of the intervention.

Research question 5: 'How do patients and HCP experience the implementation of systematic QOL and needs assessment with the CARES in patients' care pathway?'

After the validation of the Flemish CARES, an exploration of patients' and professionals' perspective, and the systematic review that did not result in conclusive evidence, further research on the application of systematic needs assessment seemed appropriate. Two gastroenterology departments, in two different hospitals, were willing to cooperate in an exploratory pilot study regarding the systematic application of the CARES-assessment in their patients' care process. In **Chapter 8**, the pilot study for which 51 patients with a digestive cancer diagnosis were included was described.
The CARES-Short Form, that was also validated for the Flemish population in this research project, supported in detection and discussion of a large variety of

problems and care needs. The problems most frequently experienced, and most burdensome for QOL, are a mix of physical complaints, side effects from treatment, practical, relational, and psychosocial difficulties. Patients desire help for a limited number of problems that were experienced. All patients positively evaluate the timing and frequency of the CARES-assessment. The majority believes that this assessment could contribute to the discussion of problems and needs with healthcare professionals, to get more tailored care. The reference nurses experienced the use of the CARES-assessment as an opportunity to systematically explore patients' well-being in a comprehensive way, leading to detection and discussion of specific problems or needs in greater depth, and more efficient involvement of different disciplines in care.

In conclusion, both patients and reference nurses had positive experiences with the systematic CARES-assessment in daily routine. The tool provided a broad insight on the well-being and care needs of patients, and facilitated patient-HCP communication, and efficient referral.

General reflections

Several studies in this dissertation demonstrate the large individual variation, and biopsychosocial mix of the concerns, problems, short-, long term- and late-effects which affect the well-being of cancer patients. This emphases that achieving high quality cancer care needs so much more than the excellent cancer treatment that increases the survival among cancer patients in Belgium [294] (Figure 1).

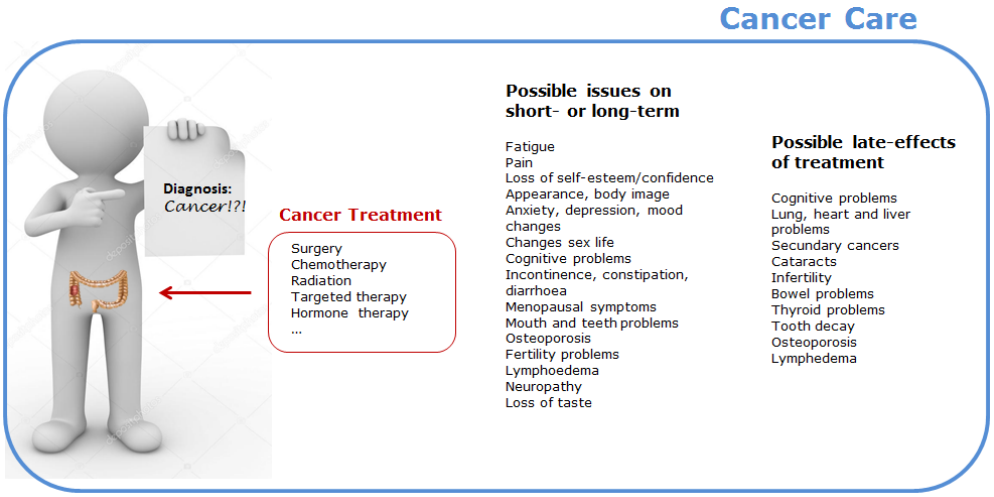


Figure 1. The scope of cancer treatment and cancer care

Due to increased survival and prolongation of cancer patients' life, future cancer care will have to face challenges of new long-term and late effects, to meet cancer patients care needs.

Although the Belgian Cancer Plan that the federal government launched in 2008 included actions with psychosocial content [57], findings from this research project show that both patients and professionals experience similar barriers and needs in relation to the integration of the psychosocial approach in cancer care. Limited time and contact, medical focus, shortage of information, difficulties with communication, interdisciplinary collaboration and referral are seen by both patients and HCP as barriers to delivery of psychosocial cancer care [160, 179, 295, 296, 297]. Like psycho-oncological care is experienced and provided in current practice, it appears to be fragmented and situationally determined by the affinity of healthcare providers, available resources and patient assertiveness. Consequently, some patients and HCP have positive experiences, others feel less comfortable or satisfied with the care they receive or provide. There is a need for a central stakeholder that coordinates each patients' care across the boundaries of in hospital and ambulatory care. Participants, both patients and HCP, in our studies desire for more clarity about rehabilitation options, psychosocial support and care, structural and budgetary anchoring of psychosocial services in routine cancer care.

The use of PROM to support monitoring and follow-up of cancer patients overall well-being seems limited in our clinical practice. Only few patients in our validation studies previously completed such a tool for clinical purposes. Likewise, only few participants in our HCP-survey indicated to use a checklist or PROM to support monitoring and follow-up of patients' well-being.

Not everyone has a positive attitude towards systematic screening and assessment of patients' psychosocial well-being and care needs, because there may be some barriers to use these [298]. However, the majority of patients participating in our studies think that it may have a positive effect on the sensitization, and on timely discussion of potential psychosocial problems that are now often discussed to little or not at all.

For the references nurses that participated in our pilot study, working with the systematic CARES-assessment required some adjustments, in terms of introducing the questionnaire, and using the summary report in clinical encounters. Nevertheless, they experienced a supporting value of the CARES-assessment on the content of their conversations with patients, the efficiency of problem and need of care detection, and sharing of relevant information with other HCP. This is in line with the experiences and satisfaction of participating HCP in several studies that were included in the Cochrane Review of this dissertation [221, 223, 229].

METHODOLOGICAL CONSIDERATIONS

The doctoral research project described in this dissertation contains five studies: a quantitative validation study, a focus group study, a survey, a systematic review, and an exploratory longitudinal pilot study. Here we discuss the considerations on the strengths, as well as some limitations of the research.

Strengths

A major strength of this research project is the ***methodological triangulation***. For the validation of the Flemish CARES version the psychometric robustness of the instrument was thoroughly explored with the collection and analysis of quantitative data. Additionally, focus groups were organized since qualitative

subject input is of utmost importance to assure that questionnaire items have meaning and relevance to the target population [299]. Next to answering the research question regarding the CARES content validity, these focus group discussions also provided additional insights on the experiences of (ex-) patients with cancer care. With the CARES studies and the survey new evidence was collected in our Flemish population. On the other hand, with the systematic review a research synthesis was made of multiple studies conducted all over the world [300, 301]. In this way, this dissertation combines insights from new and best available evidence on related topics.

A second strength is that the ***patient-perspective as well as the professional-perspective*** are addressed in this dissertation. In our patient-centered approach the patient-perspective is of primary importance. However, to complete 'the bigger picture', the input from several stakeholders is also important. With the HCP and patients that were recruited, the people that provide, as well as the people that make use of cancer care were involved in the project. Insights were obtained on (ex)patients' experiences with the impact of the disease, related treatment and cancer care. Besides, healthcare professionals' perspective on their psychosocial approach in cancer care was explored. This resulted in commonly experienced barriers that need to be addressed in order to improve cancer care.

Thirdly, for the recruitment of the study samples of patients as well as HCP a ***multicenter approach*** was used. This kind of approach can improve recruitment, and generalizability of the results.

The ***systematic literature review*** described in this dissertation was registered with, and conducted ***following the methodology of the Cochrane Collaboration***. A systematic review can lead to the wrong conclusions if relevant studies are missed, and data collection and analysis are conducted improperly. Cochrane Reviews are deemed to be robust against this sort of bias, due to the rigorous and analytic methodology, and standardization of approaches that is prescribed by the Cochrane Collaboration [302, 303]. Although time consuming, following this golden methodological standard in conducting the systematic review can be seen as another strength of this research project.

A last strength of the research project are the ***published protocols*** of the validation study as well as the systematic review. This contributed to the transparency of our studies, and to the replicability for other researchers.

Limitations

Although a multicenter approach was used for the recruitment in all studies of this project, ***most participants were recruited in Limburg***. This may limit generalizability of the findings. However, studies described elsewhere in the international literature show similar findings. This applies to the studies with patients as well as with HCP. To avoid this limitation in the explorative pilot study, this was conducted in two sites: the Jessa Hospital in Hasselt (Limburg), and AZ Delta in Roeselare (West Flanders).

In all of the studies the ***response rates were moderate to low***. The response rate in the quantitative CARES validation study was moderate (61%), and recruitment for the FG had to be broadened with calls through local media to obtain a sample of 26 participants. However, the number of participants reached in these studies is acceptable for this field of research. The response rate in the HCP survey was low (12%). We could have achieved a higher response rate by working with a more focused recruitment of healthcare professionals working with cancer patients, for example through the Cedric Hélène Instituut (Flemish institute for Psycho-Oncology), and patient advocacy organizations. However, this could have led to bias by recruiting professionals who already have more affinity with the psychosocial approach in cancer care, not representing the general group of HCP that surround cancer patients in daily practice. This is why we chose to use an exhaustive approach in recruiting through discipline specific networks and associations, and heads of departments in hospitals. Each of these chose to provide us with the contact details of the individual HCP, or forwarded our message about the study by e-mail, or placed our message in a newsletter to their members. Of course, our exhaustive approach and the ways in which HCP were approached about our study has determined the response rate. However, the survey had an exploratory purpose.

A third limitation is the ***potential of self-selection bias of participants*** in our CARES studies, and survey in the multidisciplinary group of HCP. However, this is a known vulnerability in this type of research [304]. As far as possible, the

participating patients were compared to the general population of cancer patients, and agreed in terms of medical characteristics. The response distribution on our HCP survey corresponded with the responses we expected from the several professional disciplines that were invited to participate.

In the quantitative validation study of the CARES we set the ***age criterion on 25-60 years*** in order to capture adult cancer patients, assuming that the lifestyles, impact of cancer and related treatments, as well as the rehabilitation of young adults (<25years) and the elderly (>60years) would differ. However, this limited the evidence of the Flemish CARES validity to the group of adult cancer patients, while other studies with the CARES also included young adults and elderly [140, 264, 265, 305, 306]. In response to this insight, we adapted the age criterion for the focus group and pilot studies. The further and future data collection will allow to reexamine the reliability and validity ratings with inclusion of elderly patients.

IMPLICATIONS FOR CLINICAL PRACTICE

The landscape of healthcare is changing in Belgium. The increase in chronic diseases, aging of the population, and the increased pressure on healthcare resources causes an increased need for more integrated and patient-centered care (Figure 2).

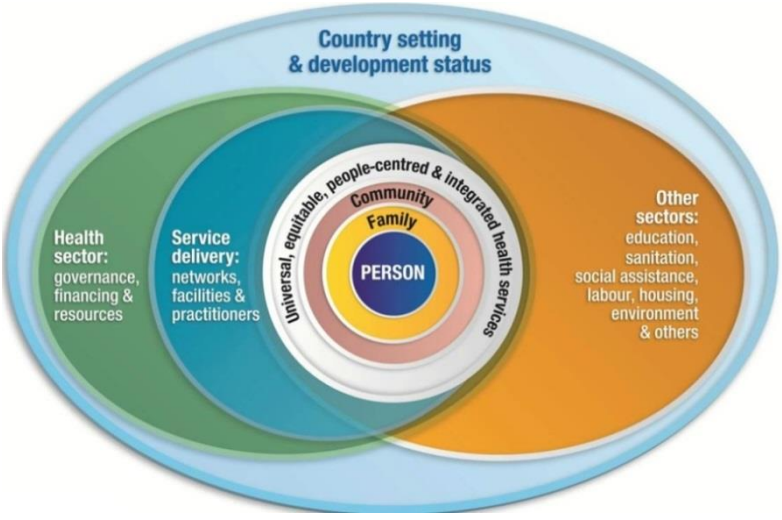


Figure 2. WHO framework on integrated patient-centered care

At the federal level there is an ongoing reformation in the organization, as well as in the funding of hospital care [307, 308]. In the meantime the Flemish government is working on reformations in primary care which should be complimentary [309, 310]. Quality care should be guided by patients' needs and will increasingly be organized with transmural care trajectories or pathways. Hospitals will play an important role in this transmural care organization, since the care trajectory of chronical diseases like cancer mostly starts in these acute care settings [311]. However, in the pursuit of quality care, it is crucial to come to a good transfer from in-hospital to primary care. Only this makes it possible for primary care givers like the GP, home nursing, other healthcare professionals, community services and informal caregivers to continue providing good care and follow-up.

There is strong variation in the psychosocial care offer for cancer patients within Flemish hospitals, and in the extent to which the psychosocial approach is part of day-to-day cancer care [312]. Consequently, the care that patients receive differs depending on the hospital where they are treated, and according to local initiatives in the primary or ambulatory care context. Findings in this dissertation show that patients as well as professionals prefer to anchor the psychosocial approach in routine cancer care. In this way basic psychosocial support can be timely provided to prevent serious psychosocial problems that require more specialized (and more expensive) psychological or psychiatric care when patients for example have already developed clinical levels of depression or anxiety.
The current efforts to achieve change in healthcare organization offer opportunities to anchor new initiatives that would benefit the quality of care, the interdisciplinary data sharing, communication, and collaboration in the support and care for patients with cancer.
Following the findings of this dissertation and working towards more patient-centered care we recommend to implement systematic comprehensive screening of cancer patients overall well-being and care needs with PROM in clinical practice. This can have advantages for patients as well as for cancer care.

1) At the level of patients, screening with the CARES stimulates patients in reflecting on their situation, potential problems, and needs. In addition, it

provides broad information from patients' perspective on their overall well-being and care needs, valuable for the follow-up of each individual patient.

2) At the level of HCP, it was found to stimulate the comprehensiveness in follow-up, addressing potential physical, psychological, and social consequences and concerns. Besides, the use of such systematic screening could increase HCP's confidence and understanding of patient-centered care [313].

3) At the level of care organization it can make a contribution to quality of care. In response to the screening results of each individual patient the different disciplines of HCP can be involved in the patient's care trajectory, which contributes to the effectivity, efficiency, timeliness, equitability and patient-centeredness of care [314]. More comprehensive monitoring of patients, timely detecting and addressing psychosocial issues could even contribute to patient safety. After all, it is known that (ex)cancer patients are at increased risk of suicidality [315, 316].

We cannot make a general statement on which professional or stakeholder is best placed to be involved in this screening intervention, since the background or discipline of interventionists differ between studies (physician, nurses, psychologists, social workers, volunteers) [221, 230, 234, 317]. Patients and HCP in our studies do emphasize the importance of actively using and discussing the screening results.

Of course, this systematic screening and assessment with PROM should not be seen as a goal on its own, but as a supportive intervention to be able 'to make connections'. With an improvement in addressing and detecting psychosocial issues and needs, so that more tailored support or care that meets patients' needs can be offered [24]. However, to achieve the added value of this systematic screening, it is of utmost importance that the required referral and care can be provided [38, 273]. Therefore, HCP should be confident and able to address psychosocial issues, and place adequate referral. Hereto, recognition of and communication on psychosocial issues, and the ways to multidisciplinary complement each other in cancer care should be a standard part of education. The Belgian National Cancer Plan included an objective for the education of psycho-oncologists. However, this two year post-graduate study in psycho-

oncology only holds place for 25 psychologists per cycle, which is limited compared to the number of psychologists working in the field. Further training and information sessions accessible for other disciplines do not seem to be known to the large group of HCP. The knowledge of these courses must therefore be increased.

The implementation of the multidisciplinary oncological consult (MOC) already provided favorable developments in the field of multidisciplinary cooperation in cancer diagnosis and treatment. To increase transmural collaboration and information exchange, GP have the possibility to participate in these meetings. Although so far, this rarely is the case. In particular, time constraints, lack of invitation to participate, and complexity of the patient's (medical) situation are experienced as thresholds for their participation [60, 318]. We believe that psychosocial care needs should also be part of the content in such a MOC. Electronic data sharing could support this. However, this 'care MOC' would have another content, and time dimension, linked to the phase of recovery or further follow-up

Supported by electronic data sharing, the multidisciplinary group of involved HCP (intramural and extramural) could combine their findings with regard to the biopsychosocial well-being and care needs of the patient, which gives input for tailored and comprehensive oncological rehabilitation. This is important, since with the growing population of cancer survivors the need for this kind of rehabilitation will increase. Developments in this area can provide important opportunities, for individual patients, as well as for the community in the context of re-integration.

Besides the clinical value of systematic PRO use for individual patients, it can also provide the opportunity for collecting 'big data'. If PRO data would be integrated in the electronic patient files, and combined with all medical information on disease and treatment characteristics, this would provide a wealth of data for retrospective research to answer biopsychosocial and even health economic related research questions. Several successful examples abroad are the Patient-Reported Outcomes Measurement Information System (PROMIS) which was set up in the USA [319], and the Dutch Patient Reported Outcomes

Following Initial treatment and Long term Evaluation of Survivorship (PROFILES) registry [76].

FUTURE PERSPECTIVES FOR RESEARCH

The research domain of psycho-oncology is dynamic and challenging, in many perspectives. There are still several difficulties and questions arising in practice, for which solutions or answers are sought in national and international studies.

Following the CARES studies in this project it seems appropriate to further collect CARES-data from patients aged older than 60 years in our population. In this way reliability and validity assessments can be repeated to also explore the psychometric robustness of the Flemish version in the population of elderly cancer patients. After all, this subgroup was part of the study sample in the validation studies of the original English instrument. Likewise, it would be valuable to focus a research line specifically on the validation of the instrument in the subgroup of immigrants and patients with low levels of education.
Currently, the follow-up of patients in the explorative pilot study with a CARES-assessment at six and 12 months after start of treatment is still running. These longitudinal data will be valuable (1) to obtain insights in the QOL, potential problems and care needs of patients with digestive cancer throughout the further course of disease, treatment and rehabilitation, (2) to study patients' and HCP's experiences with, efficiency and feasibility of the repeated and long-term use of the CARES.

The findings from the studies in this dissertation plea for further research on the development and implementation of systematic screening and assessment of patients psychosocial well-being and care needs, for there is a strong belief that this would contribute to patient-centeredness of care [38, 320].
In the development and implementation phase, consideration should be given to a number of aspects.
Firstly, we recommend for these interventions to be implemented as a part of transmural clinical pathways that combine the medical and psychosocial follow-up of patients to achieve a holistic approach. Clinical pathways are used to

reduce care variability, support efficient use of resources, and inter-professional transparency and collaboration [67, 68], and because of that could stimulate the transmural multidisciplinary teamwork that cancer care needs.

HCP should be actively involved in the development of these interventions to ensure feasibility for the clinical work force, sense of mastery and co-responsibility for implementing the new approach in daily routine [257].

In the development phase, a clear overview should be created of the support and care options provided in the transmural multidisciplinary care context. This supports the increase of HCP familiarity with each other's care offer, possibilities of collaboration and referral.

Though there is variation in patients' preference for paper-and-pencil questionnaires or electronic versions [144, 321], the future of PROM collection lies in electronic data collection and processing. This facilitates real time output and use of screening results, inclusion of the obtained information in electronic patient files, interdisciplinary information sharing, and makes it possible to link screening results to potential referral and care options via pre-developed algorithms [322, 323].

To combine both, allow patients to choose the format of their preference, and limit workload there is a possibility to work with paper questionnaires that can be scanned to obtain the data in an electronic database (e.g. Teleform®, IBM® SPSS® Data Collection Paper - Scan Add-on, Captricity®).

It would be preferable that patients as well as HCP standardly receive the PROM-outcomes. In the in-hospital context the latter can be a physician or reference nurse responsible for follow-up of the patient, in ambulatory care this should be the GP. Nowadays, GP often experience 'a gap' in their follow-up of patients when they are in active cancer treatment [324]. Moreover, the information received from the hospital in interim reports is primarily medical and lacks insights about the patient's psychosocial well-being. Sharing the PROM-outcomes with patients' permission can meet this limitation. This is consistent with the current movement in digitalization, plans for the electronic patient file, and eHealth ambitions of the Belgian governments at the federal- and community level [307, 308, 309, 310, 325]. Despite the obstacles that exist today, both in the context of care organization, safe data sharing, and the often shredded computer science applications in healthcare, there is a great potential

for a so-called "patient portal". Such a portal provides patients the possibility to enter specific questions and care needs in an electronic patient file that interacts with the general medical record of the GP. At the Primary care Conference (February 2017), the potential of electronic data sharing in care was emphasized, and further developments are being pursued in this area.

With the efforts to work towards a more society based, and patient-centered care model, it is increasingly important to assure that is there is attention for the well-being of patients' partners or informal care givers in cancer care. These people live through the phase of diagnosis and treatment with the patients and often suffer from feelings of uncertainty, anxiety, and grief. Due to the confrontation with the cancer diagnosis of their loved one, the consequences, supporting and caring for the patient, partner's and informal care givers physical, psychological, and social well-being is put to the test as well [274, 275, 276]. On the one hand, because of the well-being of these people, on the other hand, because they are the primary source of support for patients in their daily life (Figure 2), it is very important that there is support available for these people as well.

In future studies exploring the effectiveness of the interventions containing systematic screening of cancer patients psychosocial well-being and care needs, consideration should be given to risk populations. In the studies that already took place, participants were mainly recruited on the basis of criteria regarding diagnosis, prognosis, treatment, or care process phase [151, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240], and not due to risk variables such as being younger, single, female, having a worse clinical status, lower QOL, or socio economic status [22, 104, 200, 244, 246]. However, the possibility of (sub) analyzes for these risk populations could provide us with valuable insights about the effectiveness of the interventions.

When designing intervention studies, it would be interesting to include variables as personality, coping and resilience more [314]. These concepts are related to valuable psychological theories, which are currently insufficiently used in the field of psycho-oncology (discussed at the IPOS World Conference of Psycho Oncology 2017). Patients' personality or coping style can be valuable variables

to estimate the way in which people will handle the confrontation with cancer and related treatments [326, 327, 328, 329]. We believe it would also be valuable for psycho-oncology research, next to care variables and subjective PRO, to integrate biomedical parameters of distress (e.g. high blood pressure, high cortisol levels) in study designs. It is known that, for example, cortisol has a negative effect on immune processes, increasing the risk of cancer progression [330]. In this way, subjective and objective signals of patients overall well-being can be studied together, and medical and psychosocial interventions can be bundled to achieve optimal cancer care that adequately addressed cancer patients overall health.

Despite that the findings in this dissertation plea for a more patient-centered, comprehensive and transmural approach, the challenge remains to find the best approach to operationalize this in daily clinical practice.

The exact approach for each individual will vary according to the patient's care needs, and will be determined by the models of inter-professional collaboration in the extramural, intramural and as well transmural care context. However, we have to make sure that the 'minimal standard' is the same for all patients. Each patient's overall well-being and care needs, including the psychosocial, should be addressed and adequately matched with the available care or support. In this way, patients are optimally supported in dealing with their disease and treatment, in their recovery, and in their re-integration in life.

'What could support the detection and monitoring of cancer patients' psychosocial care needs?', 'Who is informed, in what way, and what is the potential of electronic data sharing in this regard?', 'Who coordinates the different phases of the transmural care pathway, and how can the GP be optimally involved in the whole care process?', 'How can oncological rehabilitation be tailored to the steps taken in the earlier phases of the care process?',…

These are all important questions focusing on 'making connections': connections between cancer patients' needs and cancer care, connections between involved HCP, connections between care contexts and care phases. The first question can

be covered with findings from this dissertation. The other questions imply suggestions for future research that, given the complexity and intertwining of the different perspectives, would best be developed within multidisciplinary collaborations. The evolutions in care that are stimulated, both from the level of the federal and the Flemish government, provide opportunities for making these essential connections.

Appendix 9.1.

CARES

Cancer Rehabilitation Evaluation System

Oorspronkelijk instrument

Ontwikkeling en validatie door Schag CA & Heinrich RL:

Schag CA, Heinrich RL. *Cancer Rehabilitation Evaluation System (CARES) Manual*, ed. 1. Los Angeles: CARES Consultants; 1989.

Schag CA, Heinrich RL. *Development of a comprehensive quality of life measurement tool: CARES.*Oncology (Williston Park, NY). 1990 May;4(5):135-8;discussion 47. PubMed PMID: 2143399. Epub 1990/05/01. eng.

Vlaamse CARES

Vertaling en validatie door Schouten B et al.:

Schouten B, Hellings J, Van Hoof E, Vankrunkelsven P, Bulens P, Buntinx F, et al. *Validation of the flemish CARES, a quality of life and needs assessment tool for cancer care*.BMC cancer. 2016;16:696. PubMed PMID: 27576341. Pubmed Central PMCID: PMC5006609. Epub 2016/09/01. eng.

Schouten B, Van Hoof E, Vankrunkelsven P, Schrooten W, Bulens P, Buntinx F, et al. *Assessing cancer patients' quality of life and supportive care needs: Translation-revalidation of the CARES in Flemish and exhaustive evaluation of concurrent validity*.BMC health services research. 2016;16(1):86. PubMed PMID: 26969509. Pubmed Central PMCID: PMC4788884. Epub 2016/03/13. eng.

Schouten, Bojoura; Hellings, Johan; Vankrunkelsven, Patrick; Mebis, Jeroen; Bulens, Paul; Buntinx, Frank; Vandijck, Dominique & Van Hoof, Elke (2017) Qualitative research on the Belgian Cancer Rehabilitation Evaluation System (CARES): An evaluation of the content validity and feasibility. In: Journal for Evaluation in Clinical Practice, doi: 10.1111/jep.12681. [Epub ahead of print].

1

Vlaamse CARES

Instructies

Hierna volgt een **overzicht met stellingen** die situaties en ervaringen beschrijven van personen die kanker hebben of hadden. Lees elke stelling en **DUIDT HET ANTWOORD AAN** dat het **BESTE OMSCHRIJFT IN HOEVERRE ELKE STELLING VOOR U VAN TOEPASSING IS** gedurende **afgelopen maand**, vandaag inbegrepen.
Gelieve **BIJ ELKE PROBLEEMSTELLING DIE VOOR U VAN TOEPASSING IS**, **AAN TE GEVEN OF** dit een probleem is waarbij **U HULP WENST OF NIET**.

De stellingen zijn onderverdeeld in blokken. Sommige onderdelen, ingeleid door een vraag, zijn niet voor u van toepassing. Gelieve deze over te slaan en over te gaan naar het volgende onderdeel.

VOORBEELD

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik heb problemen met wandelen.	❍	❍	❍	❍	❍	❍	❍
Ik vind dat eten slecht smaakt.	❍	❍	❍	❍	❍	❍	❍

VRAGENLIJST

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
1. Ik heb problemen met bukken of tillen.	❍	❍	❍	❍	❍	❍	❍
2. Ik heb problemen met wandelen en/of bewegen.	❍	❍	❍	❍	❍	❍	❍
3. Ik heb problemen met fysieke activiteiten zoals lopen en sporten.	❍	❍	❍	❍	❍	❍	❍
4. Ik heb niet dezelfde energie als vroeger.	❍	❍	❍	❍	❍	❍	❍
5. Ik heb problemen met autorijden.	❍	❍	❍	❍	❍	❍	❍
6. Ik heb problemen met huishoudelijke taken.	❍	❍	❍	❍	❍	❍	❍
7. Ik heb problemen om me te wassen, mijn tanden te poetsen of mijn haar te kammen.	❍	❍	❍	❍	❍	❍	❍
8. Ik heb problemen om eten klaar te maken.	❍	❍	❍	❍	❍	❍	❍
9. Ik heb niet dezelfde interesse in ontspanningsactiviteiten als vroeger.	❍	❍	❍	❍	❍	❍	❍
10. Ik doe niet dezelfde ontspanningsactiviteiten die ik vroeger deed.	❍	❍	❍	❍	❍	❍	❍
11. Ik heb onvoldoende leuke dingen om mijn dag te vullen.	❍	❍	❍	❍	❍	❍	❍
12. Ik heb moeite om activiteiten te plannen door de kanker of door de behandelingen.	❍	❍	❍	❍	❍	❍	❍

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
13. Ik kom niet bij in gewicht.	❍	❍	❍	❍	❍	❍	❍
14. Ik blijf vermageren.	❍	❍	❍	❍	❍	❍	❍
15. Ik vind eten niet aantrekkelijk.	❍	❍	❍	❍	❍	❍	❍
16. Ik vind dat eten slecht smaakt.	❍	❍	❍	❍	❍	❍	❍
17. Ik heb problemen met slikken.	❍	❍	❍	❍	❍	❍	❍
18. De kanker of de behandelingen verhinderen me te werken.	❍	❍	❍	❍	❍	❍	❍
19. Door de kanker of de behandelingen heb ik het moeilijk om te werken.	❍	❍	❍	❍	❍	❍	❍
20. Ik heb vaak/regelmatig pijn.	❍	❍	❍	❍	❍	❍	❍
21. Ik heb chronische pijn door littekens of door de ingreep.	❍	❍	❍	❍	❍	❍	❍
22. Ik heb pijn die niet met pijnstillers onder controle kan worden gehouden.	❍	❍	❍	❍	❍	❍	❍
23. Ik heb pijn die met pijnstillers onder controle blijft.	❍	❍	❍	❍	❍	❍	❍
24. Ik vind dat ik niet goed sta met mijn kleren.	❍	❍	❍	❍	❍	❍	❍
25. Ik vind dat mijn kleren me niet passen.	❍	❍	❍	❍	❍	❍	❍
26. Ik heb moeite om kleren te vinden die me passen.	❍	❍	❍	❍	❍	❍	❍
27. Ik vind dat het medische team informatie achterhoudt over de kanker.	❍	❍	❍	❍	❍	❍	❍
28. Ik vind dat dokters niet uitleggen wat ze met me doen.	❍	❍	❍	❍	❍	❍	❍
29. Ik vind dat verpleegkundigen niet uitleggen wat ze met me doen.	❍	❍	❍	❍	❍	❍	❍
30. Ik heb moeite om aan dokters vragen te stellen.	❍	❍	❍	❍	❍	❍	❍
31. Ik heb moeite om aan verpleegkundigen vragen te stellen.	❍	❍	❍	❍	❍	❍	❍
32. Ik heb moeite om mijn gevoelens duidelijk te maken aan dokters en verpleegkundigen.	❍	❍	❍	❍	❍	❍	❍
33. Ik heb moeite om mijn dokter over nieuwe symptomen te vertellen.	❍	❍	❍	❍	❍	❍	❍
34. Ik heb problemen met de uitleg van dokters over de kanker of over de behandeling.	❍	❍	❍	❍	❍	❍	❍
35. Ik heb problemen met de uitleg van verpleegkundigen over de kanker of over de behandeling.	❍	❍	❍	❍	❍	❍	❍
36. Ik zou meer inspraak willen in wat de dokters met me doen.	❍	❍	❍	❍	❍	❍	❍

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
37. Ik zou meer inspraak willen in wat de verpleegkundigen met me doen.	❍	❍	❍	❍	❍	❍	❍
38. Door mijn ziekte ben ik beschaamd om mijn lichaam aan anderen te tonendoktersafspraken en/of andere plaatsen.	❍	❍	❍	❍	❍	❍	❍
39. Ik heb moeite om mijn littekens aan anderen te tonen.	❍	❍	❍	❍	❍	❍	❍
40. Ik heb moeite met de veranderingen die mijn lichaam ondergaat.	❍	❍	❍	❍	❍	❍	❍
41. Ik voel me vaak angstig.	❍	❍	❍	❍	❍	❍	❍
41b. Ik voel me vaak eenzaam.	❍	❍	❍	❍	❍	❍	❍
42. Ik voel me vaak neerslachtig/depressief.	❍	❍	❍	❍	❍	❍	❍
43. Ik ben vaak kwaad.	❍	❍	❍	❍	❍	❍	❍
44. Ik ben vaak van streek/ontdaan.	❍	❍	❍	❍	❍	❍	❍
45. Ik word vaak overmand door emoties en gevoelens over de kanker.	❍	❍	❍	❍	❍	❍	❍
46. Ik heb moeite om te slapen.	❍	❍	❍	❍	❍	❍	❍
47. Ik heb moeite om me te concentreren.	❍	❍	❍	❍	❍	❍	❍
48. Ik heb moeite om me dingen te herinneren.	❍	❍	❍	❍	❍	❍	❍
49. Ik heb moeite om helder te denken.	❍	❍	❍	❍	❍	❍	❍
50. Ik heb moeite om vrienden of familieleden te vertellen dat ze minder vaak hoeven te komen.	❍	❍	❍	❍	❍	❍	❍
51. Ik heb moeite om vrienden of familieleden te vertellen dat ze moeten weggaan als ik me niet goed voel.	❍	❍	❍	❍	❍	❍	❍
52. Ik heb moeite om mijn vrienden of familieleden te vragen om iets leuks met me te doen.	❍	❍	❍	❍	❍	❍	❍
53. Ik weet niet wat ik tegen mijn vrienden of familieleden moet zeggen.	❍	❍	❍	❍	❍	❍	❍
54. Ik heb moeite om mijn vrienden of familieleden te vragen om dingen voor mij te doen.	❍	❍	❍	❍	❍	❍	❍
55. Ik heb moeite om mijn vrienden of familieleden over de kanker te vertellen.	❍	❍	❍	❍	❍	❍	❍
56. Ik heb moeite om mijn vrienden of familieleden te vragen om vaker te komen.	❍	❍	❍	❍	❍	❍	❍
57. Ik heb het gevoel dat mijn vrienden en familieleden me zeggen dat ik er goed uitzie als dat niet het geval is.	❍	❍	❍	❍	❍	❍	❍
58. Ik heb het gevoel dat mijn vrienden of familieleden informatie achterhouden.	❍	❍	❍	❍	❍	❍	❍
59. Ik heb het gevoel dat mijn vrienden of familieleden vermijden om met mij over de kanker te praten.	❍	❍	❍	❍	❍	❍	❍
60. Ik vind dat mijn vrienden of familieleden me niet vaak genoeg komen bezoeken.	❍	❍	❍	❍	❍	❍	❍

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
61. Ik vind dat mijn vrienden of familieleden me niet vaak genoeg bellen.	❍	❍	❍	❍	❍	❍	❍
62. Ik heb het gevoel dat mijn vrienden of familieleden op hun ongemak zijn als ze me bezoeken.	❍	❍	❍	❍	❍	❍	❍
63. Ik heb het gevoel dat mijn vrienden of familieleden moeite hebben om met mij over mijn ziekte te praten.	❍	❍	❍	❍	❍	❍	❍
63b. Ik maak me zorgen over de manier waarop mijn dierbaren (partner/kinderen/ouders) omgaan met het feit dat ik een kankerdiagnose kreeg.	❍	❍	❍	❍	❍	❍	❍
64. Ik voel me ongemakkelijk als ik andere patiënten zie die behandeld worden.	❍	❍	❍	❍	❍	❍	❍
65. Ik word nerveus als ik naar het ziekenhuis moet gaan.	❍	❍	❍	❍	❍	❍	❍
66. Ik word nerveus terwijl ik op de dokter wacht.	❍	❍	❍	❍	❍	❍	❍
67. Ik word nerveus terwijl ik op de testresultaten wacht.	❍	❍	❍	❍	❍	❍	❍
68. Ik word nerveus als ik diagnostische tests moet ondergaan.	❍	❍	❍	❍	❍	❍	❍
69. Ik word nerveus bij een bloedafname.	❍	❍	❍	❍	❍	❍	❍
70. Ik maak me zorgen of de behandeling werkt.	❍	❍	❍	❍	❍	❍	❍
71. Ik maak me zorgen dat de kanker uitbreidt.	❍	❍	❍	❍	❍	❍	❍
72. Ik maak me zorgen dat ik niet voor mezelf kan zorgen.	❍	❍	❍	❍	❍	❍	❍
73. Ik maak me zorgen of mijn gezin het zal redden in het geval ik zou overlijden.	❍	❍	❍	❍	❍	❍	❍
74. Ik voel me seksueel niet aantrekkelijk.	❍	❍	❍	❍	❍	❍	❍
75. Ik denk dat anderen me niet seksueel aantrekkelijk vinden.	❍	❍	❍	❍	❍	❍	❍
76. Ik heb geen zin in seks.	❍	❍	❍	❍	❍	❍	❍
77. Ik denk dat mijn (eventuele) partner geen zin heeft in seks met mij.	❍	❍	❍	❍	❍	❍	❍
78. Ik ga soms niet naar een afspraak met de dokter.	❍	❍	❍	❍	❍	❍	❍
79. Ik ga soms niet naar een behandeling.	❍	❍	❍	❍	❍	❍	❍
80. Ik neem soms mijn voorgeschreven geneesmiddelen niet.	❍	❍	❍	❍	❍	❍	❍
81. Ik houd me soms niet aan wat de dokter me zegt.	❍	❍	❍	❍	❍	❍	❍
82. Ik heb financiële problemen.	❍	❍	❍	❍	❍	❍	❍
83. Ik heb problemen met mijn verzekering.	❍	❍	❍	❍	❍	❍	❍
83. Ik heb problemen met mijn verzekering.	❍	❍	❍	❍	❍	❍	❍
84. Ik heb problemen met vervoer van en naar doktersafspraken en/of andere plaatsen.	❍	❍	❍	❍	❍	❍	❍
85. Ik kom te veel bij in gewicht.	❍	❍	❍	❍	❍	❍	❍
86. Ik vind sommige onderzoeken uitermate pijnlijk.	❍	❍	❍	❍	❍	❍	❍

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
87. Ik heb vaak diarree.	❍	❍	❍	❍	❍	❍	❍
88. Ik heb soms geen controle over mijn blaas.	❍	❍	❍	❍	❍	❍	❍

Heeft u kinderen?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
89. Ik heb moeite om voor de kinderen en/of kleinkinderen te zorgen.	❍	❍	❍	❍	❍	❍	❍
90. Ik heb moeite om mijn kinderen te helpen om met mijn ziekte om te gaan.	❍	❍	❍	❍	❍	❍	❍
91. Ik heb moeite om mijn kinderen te helpen om over mijn ziekte te praten.	❍	❍	❍	❍	❍	❍	❍

Werkt u of was u tewerkgesteld gedurende de laatste maand?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
92. Ik heb moeite om met mijn baas over de kanker te praten.	❍	❍	❍	❍	❍	❍	❍
93. Ik heb moeite om met mijn collega's over de kanker te praten.	❍	❍	❍	❍	❍	❍	❍
94. Ik heb moeite om mijn werkgever te vertellen dat ik bepaalde dingen niet kan doen door mijn ziekte.	❍	❍	❍	❍	❍	❍	❍
95. Ik heb moeite om (sociaal) verlof te vragen op het werk voor behandelingen.	❍	❍	❍	❍	❍	❍	❍
96. Ik ben bang te worden ontslagen.	❍	❍	❍	❍	❍	❍	❍

Was u de afgelopen maand op zoek naar werk?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
97. Ik heb problemen om opnieuw werk te vinden na mijn kanker.	❍	❍	❍	❍	❍	❍	❍
98. Ik vind dat werkgevers minder snel geneigd zijn om mensen met een kankerverleden in dienst te nemen.	❍	❍	❍	❍	❍	❍	❍

Hebt u seksuele gemeenschap gehad sinds uw kankerdiagnose?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
99. Ik vind dat we minder seks hebben dan vroeger.	❍	❍	❍	❍	❍	❍	❍
100. Ik heb moeite om seksueel opgewonden te raken.	❍	❍	❍	❍	❍	❍	❍
101.a. Ik heb moeite om een erectie te krijgen/te houden (mannen).	❍	❍	❍	❍	❍	❍	❍
101b. Ik heb moeite om nat/vochtig te worden (vrouwen).	❍	❍	❍	❍	❍	❍	❍
102. Ik heb moeite om een orgasme te bereiken.	❍	❍	❍	❍	❍	❍	❍

Bent u getrouwd of heeft u een vaste relatie?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
103. Mijn partner en ik hebben moeite om samen over onze gevoelens te praten.	❍	❍	❍	❍	❍	❍	❍
104. Mijn partner en ik hebben moeite om samen over onze angsten te praten.	❍	❍	❍	❍	❍	❍	❍
105. Mijn partner en ik hebben moeite om samen te praten over wat er zal gebeuren indien ik zou overlijden.	❍	❍	❍	❍	❍	❍	❍
106. Mijn partner en ik hebben moeite om samen over onze toekomst te praten.	❍	❍	❍	❍	❍	❍	❍
107. Mijn partner en ik hebben moeite om samen te praten over de kanker en over wat er kan gebeuren.	❍	❍	❍	❍	❍	❍	❍

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
108. Mijn partner en ik hebben moeite om samen te praten over een testament en financiële regelingen.	❍	❍	❍	❍	❍	❍	❍
109. Ik heb geen zin om mijn partner te omhelzen, te kussen of te knuffelen.	❍	❍	❍	❍	❍	❍	❍
110. Mijn partner heeft geen zin om mij te omhelzen, te kussen of te knuffelen.	❍	❍	❍	❍	❍	❍	❍
111. Ik heb geen zin om mijn partner aan te raken.	❍	❍	❍	❍	❍	❍	❍
112. Mijn partner heeft geen zin om mij aan te raken.	❍	❍	❍	❍	❍	❍	❍
113. Mijn partner en ik komen niet zo goed overeen als we gewend zijn.	❍	❍	❍	❍	❍	❍	❍
114. Mijn partner en ik ergeren ons vaker aan elkaar dan we gewend zijn.	❍	❍	❍	❍	❍	❍	❍
115. Mijn partner en ik brengen zoveel tijd met elkaar door dat we op elkaars zenuwen werken.	❍	❍	❍	❍	❍	❍	❍
116. Mijn partner en ik zijn afstandelijker dan gewoonlijk.	❍	❍	❍	❍	❍	❍	❍
117. Mijn partner wil me geen dingen laten doen die ik aankan.	❍	❍	❍	❍	❍	❍	❍
118. Mijn partner besteedt teveel tijd aan mijn zorg.	❍	❍	❍	❍	❍	❍	❍
119. Mijn partner zorgt niet genoeg voor me.	❍	❍	❍	❍	❍	❍	❍
120. Ik heb moeite om mijn partner te vragen om voor mij te zorgen.	❍	❍	❍	❍	❍	❍	❍

Bent u vrijgezel? (niet in een vaste relatie)
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
121. Ik heb moeite om contacten te leggen met leuke mannen/vrouwen.	❍	❍	❍	❍	❍	❍	❍
122. Ik heb moeite om leuke mannen/vrouwen te ontmoeten.	❍	❍	❍	❍	❍	❍	❍
123. Ik ben bang om naar die plekken te gaan waar ik vroeger afspraakjes ontmoette.	❍	❍	❍	❍	❍	❍	❍
124. Ik heb moeite om een afspraakje te vertellen over de kanker of over de behandeling.	❍	❍	❍	❍	❍	❍	❍
125. Ik heb moeite om met iemand een seksuele relatie te beginnen.	❍	❍	❍	❍	❍	❍	❍

Heeft u chemotherapie-behandelingen gehad in de laatste maand?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
126. Ik word nerveus als ik chemotherapie krijg.	❍	❍	❍	❍	❍	❍	❍
127. Ik word misselijk tijdens en/of voor chemotherapie.	❍	❍	❍	❍	❍	❍	❍
128. Ik moet braken tijdens en/of voor chemotherapie.	❍	❍	❍	❍	❍	❍	❍
129. Ik voel me misselijk als ik aan chemotherapie denk.	❍	❍	❍	❍	❍	❍	❍
130. Ik voel me misselijk nadat ik chemotherapie krijg.	❍	❍	❍	❍	❍	❍	❍
131. Ik moet braken na chemotherapie.	❍	❍	❍	❍	❍	❍	❍
132. Ik voel me moe na mijn chemotherapie.	❍	❍	❍	❍	❍	❍	❍
133. Ik heb andere nevenwerkingen na mijn chemotherapie.	❍	❍	❍	❍	❍	❍	❍
134. Mijn haar viel uit en/of groeit nu langzaam terug als gevolg van mijn chemotherapie.	❍	❍	❍	❍	❍	❍	❍

Heeft u radiotherapie-behandelingen (bestralingen) gehad in de laatste maand?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
135. Ik voel me moe na mijn radiotherapie-behandelingen (bestralingen).	❍	❍	❍	❍	❍	❍	❍
136. Ik word nerveus als ik radiotherapie-behandelingen (bestralingen) krijg.	❍	❍	❍	❍	❍	❍	❍
137. Ik voel me misselijk of ik moet braken na mijn radiotherapie-behandelingen (bestralingen).	❍	❍	❍	❍	❍	❍	❍

Heeft u een stoma?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
138. Ik heb problemen met het verzorgen en schoon houden van de stoma.	❍	❍	❍	❍	❍	❍	❍

Heeft u een prothese?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
139. Ik heb problemen met mijn prothese.	❍	❍	❍	❍	❍	❍	❍

Gelieve onderstaand nog ieder kanker- of behandeling-gerelateerd probleem te vermelden dat nog niet aan bod kwam, maar wat u wel graag met hulpverleners wenst te bespreken.

a).....

b) .....

c) .....

CARES-Short Form

Cancer Rehabilitation Evaluation System

Oorspronkelijk instrument

Ontwikkeling en validatie door Schag CA & Heinrich RL:

Schag CA, Heinrich RL. *Cancer Rehabilitation Evaluation System (CARES) Manual*, ed. 1. Los Angeles: CARES Consultants; 1989.

Schag CA, Heinrich RL. *Development of a comprehensive quality of life measurement tool: CARES.*Oncology (Williston Park, NY). 1990 May;4(5):135-8;discussion 47. PubMed PMID: 2143399. Epub 1990/05/01. eng.

Vlaamse CARES

Vertaling en validatie door Schouten B et al.:

Schouten B, Van Hoof E, Vankrunkelsven P, Schrooten W, Bulens P, Buntinx F, Mebis J, Vandijck D, Cleemput I, Hellings J. *Assessing cancer patients' quality of life and supportive care needs: Translation-revalidation of the CARES in Flemish and exhaustive evaluation of concurrent validity*.BMC health services research. 2016;16(1):86. PubMed PMID: 26969509. Pubmed Central PMCID: PMC4788884. Epub 2016/03/13. eng.

Schouten B, Hellings J, Van Hoof E, Vankrunkelsven P, Bulens P, Buntinx F, Mebis J, Vandijck D, Schrooten W. *Validation of the flemish CARES, a quality of life and needs assessment tool for cancer care*.BMC cancer. 2016;16:696. PubMed PMID: 27576341. Pubmed Central PMCID: PMC5006609. Epub 2016/09/01. eng.

Schouten, Bojoura; Hellings, Johan; Vankrunkelsven, Patrick; Mebis, Jeroen; Bulens, Paul; Buntinx, Frank; Vandijck, Dominique & Van Hoof, Elke (2017) Qualitative research on the Belgian Cancer Rehabilitation Evaluation System (CARES): An evaluation of the content validity and feasibility. In: Journal for Evaluation in Clinical Practice, doi: 10.1111/jep.12681. [Epub ahead of print].

Vlaamse Verkorte CARES

Instructies

Hierna volgt een **overzicht met stellingen** die situaties en ervaringen beschrijven van personen die kanker hebben of hadden. Lees elke stelling en **DUIDT HET ANTWOORD AAN** dat het **BESTE OMSCHRIJFT IN HOEVERRE ELKE STELLING VOOR U VAN TOEPASSING IS** gedurende **afgelopen maand**, vandaag inbegrepen.
Gelieve **BIJ ELKE PROBLEEMSTELLING DIE VOOR U VAN TOEPASSING IS**, **AAN TE GEVEN OF** dit een probleem is waarbij **U HULP WENST OF NIET**.

De stellingen zijn onderverdeeld in blokken. Sommige onderdelen, ingeleid door een vraag, zijn niet voor u van toepassing. Gelieve deze over te slaan en over te gaan naar het volgende onderdeel.

VOORBEELD

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik heb problemen met wandelen.	❍	❍	❍	❍	❍	❍	❍
Ik vind dat eten slecht smaakt.	❍	❍	❍	❍	❍	❍	❍

VRAGENLIJST

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik heb problemen met bukken of tillen.	❍	❍	❍	❍	❍	❍	❍
Ik heb niet dezelfde energie als vroeger.	❍	❍	❍	❍	❍	❍	❍
Ik heb problemen met huishoudelijke taken.	❍	❍	❍	❍	❍	❍	❍
Ik heb problemen om me te wassen, mijn tanden te poetsen of mijn haar te kammen.	❍	❍	❍	❍	❍	❍	❍
Ik heb moeite om activiteiten te plannen door de kanker of door de behandelingen.	❍	❍	❍	❍	❍	❍	❍
Ik kom niet bij in gewicht.	❍	❍	❍	❍	❍	❍	❍
Ik kom te veel bij in gewicht.	❍	❍	❍	❍	❍	❍	❍
Ik vind eten niet aantrekkelijk	❍	❍	❍	❍	❍	❍	❍
Ik heb vaak diarree.	❍	❍	❍	❍	❍	❍	❍
Ik heb soms geen controle over mijn blaas.	❍	❍	❍	❍	❍	❍	❍
Door de kanker of de behandelingen heb ik het moeilijk om te werken.	❍	❍	❍	❍	❍	❍	❍
Ik heb vaak/regelmatig pijn.	❍	❍	❍	❍	❍	❍	❍
Ik vind dat mijn kleren me niet passen.	❍	❍	❍	❍	❍	❍	❍
Ik vind dat dokters niet uitleggen wat ze met me doen.	❍	❍	❍	❍	❍	❍	❍

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik heb moeite om aan dokters vragen te stellen.	❍	❍	❍	❍	❍	❍	❍
Ik heb problemen met de uitleg van dokters over de kanker of over de behandeling.	❍	❍	❍	❍	❍	❍	❍
Ik zou meer inspraak willen hebben in wat de dokters met me doen.	❍	❍	❍	❍	❍	❍	❍
Ik heb moeite met de veranderingen die mijn lichaam ondergaat.	❍	❍	❍	❍	❍	❍	❍
Ik voel me vaak angstig.	❍	❍	❍	❍	❍	❍	❍
Ik voel me vaak eenzaam.	❍	❍	❍	❍	❍	❍	❍
Ik heb moeite om te slapen.	❍	❍	❍	❍	❍	❍	❍
Ik heb moeite om me te concentreren.	❍	❍	❍	❍	❍	❍	❍
Ik heb moeite om mijn vrienden of familieleden te vragen om dingen voor mij te doen.	❍	❍	❍	❍	❍	❍	❍
Ik heb moeite om mijn vrienden of familieleden over de kanker te vertellen.	❍	❍	❍	❍	❍	❍	❍
Ik heb het gevoel dat mijn vrienden en familieleden me zeggen dat ik er goed uitzie als dat niet het geval is.	❍	❍	❍	❍	❍	❍	❍
Ik vind dat mijn vrienden of familieleden me niet vaak genoeg komen bezoeken.	❍	❍	❍	❍	❍	❍	❍
Ik heb het gevoel dat mijn vrienden of familieleden moeite hebben om met mij over mijn ziekte te praten.	❍	❍	❍	❍	❍	❍	❍
Ik maak me zorgen over de manier waarop mijn dierbaren (partner/kinderen/ouders) omgaan met het feit dat ik een kankerdiagnose kreeg.	❍	❍	❍	❍	❍	❍	❍
Ik word nerveus terwijl ik op de dokter wacht.	❍	❍	❍	❍	❍	❍	❍
Ik word nerveus bij een bloedafname.	❍	❍	❍	❍	❍	❍	❍
Ik maak me zorgen dat de kanker uitbreidt.	❍	❍	❍	❍	❍	❍	❍
Ik maak me zorgen dat ik niet voor mezelf kan zorgen.	❍	❍	❍	❍	❍	❍	❍
Ik voel me seksueel niet aantrekkelijk.	❍	❍	❍	❍	❍	❍	❍
Ik heb geen zin in seks.	❍	❍	❍	❍	❍	❍	❍
Ik houd me soms niet aan wat de dokter me zegt.	❍	❍	❍	❍	❍	❍	❍
Ik heb financiële problemen.	❍	❍	❍	❍	❍	❍	❍
Ik heb problemen met mijn verzekering.	❍	❍	❍	❍	❍	❍	❍
Ik heb problemen met vervoer van en naar doktersafspraken en/of andere plaatsen.	❍	❍	❍	❍	❍	❍	❍

Heeft u kinderen?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik heb moeite om mijn kinderen te helpen om met mijn ziekte om te gaan.	❍	❍	❍	❍	❍	❍	❍

Werkt u of was u tewerkgesteld gedurende de laatste maand?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik heb moeite om met mijn collega's over de kanker te praten.	❍	❍	❍	❍	❍	❍	❍
Ik heb moeite om (sociaal) verlof te vragen op het werk voor behandelingen.	❍	❍	❍	❍	❍	❍	❍
Ik ben bang te worden ontslagen.	❍	❍	❍	❍	❍	❍	❍

Was u de afgelopen maand op zoek naar werk?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik heb problemen om opnieuw werk te vinden na mijn kanker.	❍	❍	❍	❍	❍	❍	❍

Hebt u seksuele gemeenschap gehad sinds uw kankerdiagnose?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik vind dat we minder seks hebben dan vroeger.	❍	❍	❍	❍	❍	❍	❍

Bent u getrouwd of heeft u een vaste relatie?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Mijn partner en ik hebben moeite om samen over onze gevoelens te praten.	❍	❍	❍	❍	❍	❍	❍
Mijn partner en ik hebben moeite om samen te praten over een testament en financiële regelingen.	❍	❍	❍	❍	❍	❍	❍
Ik heb geen zin om mijn partner te omhelzen, te kussen of te knuffelen.	❍	❍	❍	❍	❍	❍	❍
Mijn partner en ik komen niet zo goed overeen als we gewend zijn.	❍	❍	❍	❍	❍	❍	❍
Mijn partner besteed teveel tijd aan mijn zorg.	❍	❍	❍	❍	❍	❍	❍
Ik heb moeite om mijn partner te vragen om voor mij te zorgen.	❍	❍	❍	❍	❍	❍	❍

Bent u vrijgezel? (niet in een vaste relatie)
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik heb moeite om contacten te leggen met leuke mannen/vrouwen.	❍	❍	❍	❍	❍	❍	❍
Ik heb moeite om een afspraakje te vertellen over de kanker of over de behandelingen.	❍	❍	❍	❍	❍	❍	❍

Heeft u chemotherapie-behandelingen gehad in de laatste maand?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik word nerveus als ik chemotherapie krijg.	❍	❍	❍	❍	❍	❍	❍
Ik word misselijk tijdens en/of voor chemotherapie.	❍	❍	❍	❍	❍	❍	❍
Ik voel me misselijk nadat ik chemotherapie krijg.	❍	❍	❍	❍	❍	❍	❍
Ik moet braken na chemotherapie.	❍	❍	❍	❍	❍	❍	❍
Ik heb andere nevenwerkingen na mijn chemotherapie.	❍	❍	❍	❍	❍	❍	❍

Heeft u radiotherapie-behandelingen (bestralingen) gehad in de laatste maand?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik word nerveus als ik radiotherapie-behandelingen (bestralingen) krijg.	❍	❍	❍	❍	❍	❍	❍
Ik voel me misselijk of ik moet braken na mijn radiotherapie-behandelingen (bestralingen).	❍	❍	❍	❍	❍	❍	❍

Heeft u een stoma?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik heb problemen met het verzorgen en schoon houden van de stoma.	❍	❍	❍	❍	❍	❍	❍

Heeft u een prothese?
❍ Ja
❍ Nee Zo niet, ga naar het volgende onderdeel

	In welke mate is dit voor u van toepassing?					Wilt u hulp?	
	Niet	Een beetje	Behoorlijk	Zeer	Zeer sterk	Ja	Nee
Ik heb problemen met mijn prothese.	❍	❍	❍	❍	❍	❍	❍

Gelieve onderstaand nog ieder kanker- of behandeling-gerelateerd probleem te vermelden dat nog niet aan bod kwam, maar wat u wel graag met hulpverleners wenst te bespreken.

a).....

b) .....

c) .....

List of References

1. Ferlay J, Soerjomataram I, Dikshit R, et al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. International journal of cancer. 2015 Mar 1;136(5):E359-86. doi: 10.1002/ijc.29210. PubMed PMID: 25220842; eng.
2. Belgian Cancer Registry. Available from: http://www.kankerregister.org/Cijfers_over_kanker
3. Registry BC. Cancer burden in Belgium 2004-2013. Brussels2015.
4. World Health Organisation. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York , 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States and entered into force on 7 April 1948. Official Records of the World Health Organization. Vol. no. 21948. p. p. 100.
5. Engel GL. The need for a new medical model: a challenge for biomedicine. Science. 1977 Apr 8;196(4286):129-36. PubMed PMID: 847460; eng.
6. Hofmann B. On the triad disease, illness and sickness. J Med Philos. 2002 Dec;27(6):651-73. doi: 10.1076/jmep.27.6.651.13793. PubMed PMID: 12607162.
7. Alonso Y. The biopsychosocial model in medical research: the evolution of the health concept over the last two decades. Patient education and counseling. 2004 May;53(2):239-44. doi: 10.1016/s0738-3991(03)00146-0. PubMed PMID: 15140464; eng.
8. Carlson LE, Waller A, Groff SL, et al. What goes up does not always come down: patterns of distress, physical and psychosocial morbidity in people with cancer over a one year period. Psycho-oncology. 2013 Jan;22(1):168-76. doi: 10.1002/pon.2068. PubMed PMID: 21971977; eng.
9. Feyer P, Kleeberg UR, Steingraber M, et al. Frequency of side effects in outpatient cancer care and their influence on patient satisfaction--a prospective survey using the PASQOC questionnaire. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2008 Jun;16(6):567-75. doi: 10.1007/s00520-008-0422-4. PubMed PMID: 18322707.
10. Heins MJ, Korevaar JC, Rijken PM, et al. For which health problems do cancer survivors visit their General Practitioner? European journal of cancer (Oxford, England : 1990). 2013 Jan;49(1):211-8. doi: 10.1016/j.ejca.2012.07.011. PubMed PMID: 22897842; eng.
11. Browne S, Dowie A, Mitchell L, et al. Patients' needs following colorectal cancer diagnosis: where does primary care fit in? The British journal of general practice : the journal of the Royal College of General Practitioners. 2011 Nov;61(592):e692-9. doi: 10.3399/bjgp11X606582. PubMed PMID: 22054330; PubMed Central PMCID: PMCPMC3207086. eng.
12. Howard-Anderson J, Ganz PA, Bower JE, et al. Quality of life, fertility concerns, and behavioral health outcomes in younger breast cancer survivors: a systematic review. Journal of the National Cancer Institute.

2012 Mar 07;104(5):386-405. doi: 10.1093/jnci/djr541. PubMed PMID: 22271773; eng.

13. Brix C, Schleussner C, Fuller J, et al. The need for psychosocial support and its determinants in a sample of patients undergoing radiooncological treatment of cancer. Journal of psychosomatic research. 2008 Dec;65(6):541-548. doi: DOI 10.1016/j.jpsychores.2008.05.010. PubMed PMID: WOS:000261622900005; English.
14. Deckx L, van den Akker M, Vergeer D, et al. The Value of Fatigue Severity to Rule Out Depression in Older Adult Patients With Cancer. Oncol Nurs Forum. 2015 Jul;42(4):E302-9. doi: 10.1188/15.onf.e302-e309. PubMed PMID: 26148326; eng.
15. Boyes AW, Girgis A, D'Este C, et al. Prevalence and correlates of cancer survivors' supportive care needs 6 months after diagnosis: a population-based cross-sectional study. BMC Cancer. 2012;12:150. doi: 10.1186/1471-2407-12-150. PubMed PMID: 22510387; PubMed Central PMCID: PMCPMC3430551. eng.
16. Knobf MT, Ferrucci LM, Cartmel B, et al. Needs assessment of cancer survivors in Connecticut. Journal of cancer survivorship : research and practice. 2012 Mar;6(1):1-10. doi: DOI 10.1007/s11764-011-0198-2. PubMed PMID: WOS:000302419400001; English.
17. Mikkelsen T, Sondergaard J, Jensen AB, et al. Cancer rehabilitation: Psychosocial rehabilitation needs after discharge from hospital? Scandinavian Journal of Primary Health Care. 2008;26(4):216-221. doi: Pii 902484499 Doi 10.1080/02813430802295610. PubMed PMID: WOS:000261190600005; English.
18. Parry C, Lomax JB, Morningstar EA, et al. Identification and correlates of unmet service needs in adult leukemia and lymphoma survivors after treatment. Journal of oncology practice. 2012 Sep;8(5):e135-41. doi: 10.1200/jop.2011.000464. PubMed PMID: 23277776; PubMed Central PMCID: PMCPMC3439239. eng.
19. Aldaz BE, Treharne GJ, Knight RG, et al. 'It gets into your head as well as your body': The experiences of patients with cancer during oncology treatment with curative intent. J Health Psychol. 2016 Oct 5. doi: 10.1177/1359105316671185. PubMed PMID: 27708126; Eng.
20. Deckx L, van Abbema DL, van den Akker M, et al. A cohort study on the evolution of psychosocial problems in older patients with breast or colorectal cancer: comparison with younger cancer patients and older primary care patients without cancer. BMC geriatrics. 2015 Jul 09;15:79. doi: 10.1186/s12877-015-0071-7. PubMed PMID: 26156892; PubMed Central PMCID: PMCPMC4496825. eng.
21. Stanton AL. What Happens Now? Psychosocial Care for Cancer Survivors After Medical Treatment Completion. Journal of Clinical Oncology. 2012 Apr 10;30(11):1215-1220. doi: Doi 10.1200/Jco.2011.39.7406. PubMed PMID: WOS:000302995700008; English.
22. Hulbert-Williams N, Neal R, Morrison V, et al. Anxiety, depression and quality of life after cancer diagnosis: what psychosocial variables best predict how patients adjust? Psycho-oncology. 2012 Aug;21(8):857-867. doi: Doi 10.1002/Pon.1980. PubMed PMID: WOS:000306896500008; English.
23. Mikkelsen T, Sondergaard J, Sokolowski I, et al. Cancer survivors' rehabilitation needs in a primary health care context. Family practice.

2009 Jun;26(3):221-30. doi: 10.1093/fampra/cmp004. PubMed PMID: 19264838.
24. Mitchell AJ, Vahabzadeh A, Magruder K. Screening for distress and depression in cancer settings: 10 lessons from 40 years of primary-care research. Psycho-oncology. 2011 Jun;20(6):572-584. doi: 10.1002/Pon.1943. PubMed PMID: WOS:000291113500002; English.
25. Detmar SB, Aaronson NK, Wever LDV, et al. How are you feeling? Who wants to know? Patients' and oncologists' preferences for discussing health-related quality-of-life issues. Journal of Clinical Oncology. 2000 Sep 15;18(18):3295-3301. PubMed PMID: WOS:000089433700013; English.
26. Ernstmann N, Neumann M, Ommen O, et al. Determinants and implications of cancer patients' psychosocial needs. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2009 Nov;17(11):1417-23. doi: 10.1007/s00520-009-0605-7. PubMed PMID: 19283411; eng.
27. Kirchheiner K, Czajka A, Ponocny-Seliger E, et al. Validation and practical implementation of a multidisciplinary cancer distress screening questionnaire. Strahlenther Onkol. 2013 May 25. doi: 10.1007/s00066-013-0348-8. PubMed PMID: 23703402; Eng.
28. Merckaert I, Libert Y, Messin S, et al. Cancer patients' desire for psychological support: prevalence and implications for screening patients' psychological needs. Psycho-oncology. 2010 Feb;19(2):141-9. doi: 10.1002/pon.1568. PubMed PMID: 19382112; eng.
29. Allison PJ, Locker D, Feine JS. Quality of life: a dynamic construct. Social science & medicine (1982). 1997 Jul;45(2):221-30. PubMed PMID: 9225410; eng.
30. Moons P, Budts W, De Geest S. Critique on the conceptualisation of quality of life: a review and evaluation of different conceptual approaches. International journal of nursing studies. 2006 Sep;43(7):891-901. doi: 10.1016/j.ijnurstu.2006.03.015. PubMed PMID: 16696978; eng.
31. Dijkers M. "What's in a name?" The indiscriminate use of the "Quality of life" label, and the need to bring about clarity in conceptualizations. International journal of nursing studies. 2007 Jan;44(1):153-5. doi: 10.1016/j.ijnurstu.2006.07.016. PubMed PMID: 16978628; eng.
32. Velikova G, Stark D, Selby P. Quality of life instruments in oncology. European journal of cancer (Oxford, England : 1990). 1999 Oct;35(11):1571-80. PubMed PMID: 10673964.
33. Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, D.C: National Academy Press; 2001.
34. Harteloh PP. The meaning of quality in health care: a conceptual analysis. Health care analysis : HCA : journal of health philosophy and policy. 2003 Sep;11(3):259-67. doi: 10.1023/B:HCAN.0000005497.53458.ef. PubMed PMID: 14708937; eng.
35. Bate P, Robert G. Experience-based design: from redesigning the system around the patient to co-designing services with the patient. Qual Saf Health Care. 2006 Oct;15(5):307-10. doi: 10.1136/qshc.2005.016527. PubMed PMID: 17074863; PubMed Central PMCID: PMCPMC2565809. eng.

36. Epstein RM, Street RL. The Values and Value of Patient-Centered Care. Annals of Family Medicine. 2011 01/23/received 01/27/accepted;9(2):100-103. doi: 10.1370/afm.1239. PubMed PMID: PMC3056855.
37. McInnes DK. Don't forget patients in patient-centered care. Health affairs (Project Hope). 2010 Nov;29(11):2127; author reply 2128. doi: 10.1377/hlthaff.2010.0990. PubMed PMID: 21041761; eng.
38. Medicine Io. Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs. Adler N, Page, AEK, editor. Washington, DC: The National Academies Press; 2008.
39. European Union. Council conclusions on reducing the burden of cancer. Luxembourg, 10 June 2008 [www.eu2008.si°en/News_and_Documents/Council_Conclusions/June/0609_EPSCO-cancer.pdf]
40. Centre NBC. Clinical practice guidelines for the psychosocial care of adults with cancer. Camperdown2003.
41. Network NCC. NCCN practice guidelines for the management of psychosocial distress. Oncology 1999 May;13(5A):113-47. PubMed PMID: 10370925; eng.
42. Network NCC. Distress management (v.1.2008): National Comprehensive Care Network, Inc.; 2007 [cited 2015 6 March]. Available from: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp
43. Accreditation C. Omentum program 2009 standards: cancer care and oncology services (ver 2). Ottawa, ON. 2008.
44. Holland J, Watson M, Dunn J. The IPOS new International Standard of Quality Cancer Care: integrating the psychosocial domain into routine care. Psycho-oncology. 2011 Jul;20(7):677-80. doi: 10.1002/pon.1978. PubMed PMID: 21710503; eng.
45. Breitbart W, Bultz BD, Dunn J, et al. 2012 President's Plenary International Psycho-Oncology Society: future directions in psycho-oncology. Psycho-oncology. 2013 Jul;22(7):1439-43. doi: 10.1002/pon.3332. PubMed PMID: 23832818; eng.
46. Carlson LE, Waller A, Mitchell AJ. Screening for Distress and Unmet Needs in Patients With Cancer: Review and Recommendations. Journal of Clinical Oncology. 2012 Apr 10;30(11):1160-1177. doi: 10.1200/Jco.2011.39.5509. PubMed PMID: WOS:000302995700003; English.
47. Holland JC, Bultz BD. The NCCN guideline for distress management: a case for making distress the sixth vital sign. J Natl Compr Canc Netw. 2007 Jan;5(1):3-7. PubMed PMID: 17323529; eng.
48. Bultz BD, Carlson LE. Emotional distress: the sixth vital sign--future directions in cancer care. Psycho-oncology. 2006 Feb;15(2):93-5. doi: 10.1002/pon.1022. PubMed PMID: 16444764; eng.
49. Bultz BD, Johansen C. Screening for distress, the 6th vital sign: where are we, and where are we going? Psycho-oncology. 2011 Jun;20(6):569-71. doi: 10.1002/pon.1986. PubMed PMID: 21626609; eng.
50. Aaronson NK, Sprangers MA. Measuring quality of life in every oncological patient. Ned Tijdschr Geneeskd. 2011;155(45):A3749. PubMed PMID: 22085564; dut.

51. Jacobsen PB, Wagner LI. A New Quality Standard: The Integration of Psychosocial Care Into Routine Cancer Care. Journal of Clinical Oncology. 2012 Apr 10;30(11):1154-1159. doi: Doi 10.1200/Jco.2011.39.5046. PubMed PMID: WOS:000302995700002; English.
52. Turner J. The changing landscape of cancer care – the impact of psychosocial clinical practice guidelines. Psycho-oncology. 2015;24(4):365-370. doi: 10.1002/pon.3803.
53. Watson M, Dunn J, Holland JC. Review of the history and development in the field of psychosocial oncology. Int Rev Psychiatry. 2014 Feb;26(1):128-35. doi: 10.3109/09540261.2013.849230. PubMed PMID: 24716506; eng.
54. Grassi L, Fujisawa D, Odyio P, et al. Disparities in psychosocial cancer care: a report from the International Federation of Psycho-oncology Societies. Psycho-oncology. 2016 Jul 25. doi: 10.1002/pon.4228. PubMed PMID: 27452183; Eng.
55. Grassi L, Watson M. Psychosocial care in cancer: an overview of psychosocial programmes and national cancer plans of countries within the International Federation of Psycho-Oncology Societies. Psycho-oncology. 2012 Oct;21(10):1027-1033. doi: Doi 10.1002/Pon.3154. PubMed PMID: WOS:000309455400002; English.
56. Gorgojo; L, Harris; M, Garcia-Lopez E, et al. FINAL PRELIMINARY REPORT: National Cancer Control Programmes: Analysis of Primary Data from Questionnaires. European Partnership for Action Against Cancer (EPAAC); 2012. p. 1-155.
57. Addressed by Laurette Onkelinx MoSAaPH. The Belgian National Cancer Plan: 3 days to debate, 30 visits on the field, 30 concrete actions Brussels2008. Available from: http://www.epaac.eu/from_heidi_wiki/Belgium_National_Cancer_Plan_2008-2010_English.pdf
58. Rommel W, Rigolle C. Het nationaal Kankerplan 2008-2010: de eindafrekening. Een kritische kijk of het kankerbeleid. Brussel: Vlaamse Liga tegen Kanker; 2010. p. p 58-66.
59. Van Hoof, E., Lenaerts, L., Remue, E. (2012). Evaluatie van het Kankerplan 2008-2010, Wetenschappelijk instituut Volksgezondheid, Kankercentrum, 171p (D/2012/2205/36).
60. France V, Laurence K, Cécile D, et al. Ten years of multidisciplinary teams meetings in oncology: current situation and perspectives. Brussel: Belgian Health Care Knowledge Centre (KCE); 2015.
61. Brandenbarg D, Roorda C, Stadlander M, et al. Patients' views on general practitioners' role during treatment and follow-up of colorectal cancer: a qualitative study. Family practice. 2016 Dec 05. doi: 10.1093/fampra/cmw124. PubMed PMID: 27920118; eng.
62. Engler J, Kone I, Holmberg C, et al. Oncologists' views on the importance of general practitioners for cancer patients: a qualitative interview study from Germany. Family practice. 2017 May 09. doi: 10.1093/fampra/cmx044. PubMed PMID: 28486693; eng.
63. Ngune I, Jiwa M, McManus A, et al. Do patients with long-term side effects of cancer treatment benefit from general practitioner support? A literature review. Int J Integr Care. 2015 Apr-Jun;15:e023. PubMed PMID: 26150761; PubMed Central PMCID: PMCPMC4491325. eng.

64. Kvamme OJ, Olesen F, Samuelson M. Improving the interface between primary and secondary care: a statement from the European Working Party on Quality in Family Practice (EQuiP). Quality in health care : QHC. 2001 Mar;10(1):33-9. PubMed PMID: 11239142; PubMed Central PMCID: PMCPMC1743417. eng.
65. Warrington L, Absolom K, Velikova G. Integrated care pathways for cancer survivors - a role for patient-reported outcome measures and health informatics. Acta oncologica (Stockholm, Sweden). 2015 Mar 9:1-9. doi: 10.3109/0284186X.2014.995778. PubMed PMID: 25751758.
66. Every NR, Hochman J, Becker R, et al. Critical Pathways [10.1161/01.CIR.101.4.461]. Circulation. 2000;101(4):461.
67. Whittle C, Hewison A. Integrated care pathways: pathways to change in health care? Journal of health organization and management. 2007;21(3):297-306. doi: 10.1108/14777260710751753. PubMed PMID: 17713189; eng.
68. Vanhaecht K, De Witte K, Panella M, et al. Do pathways lead to better organized care processes? Journal of evaluation in clinical practice. 2009 Oct;15(5):782-8. doi: 10.1111/j.1365-2753.2008.01068.x. PubMed PMID: 19811589.
69. Allen D, Gillen E, Rixson L. Systematic review of the effectiveness of integrated care pathways: what works, for whom, in which circumstances? International journal of evidence-based healthcare. 2009 Jun;7(2):61-74. doi: 10.1111/j.1744-1609.2009.00127.x. PubMed PMID: 21631848; eng.
70. Hogan C, Barry M, Burke M, et al. Healthcare professionals' experiences of the implementation of integrated care pathways. International journal of health care quality assurance. 2011;24(5):334-47. doi: 10.1108/09526861111139179. PubMed PMID: 21916088; eng.
71. Rankin NM, Butow PN, Thein T, et al. Everybody wants it done but nobody wants to do it: an exploration of the barrier and enablers of critical components towards creating a clinical pathway for anxiety and depression in cancer. BMC health services research. 2015 Jan 22;15:28. doi: 10.1186/s12913-015-0691-9. PubMed PMID: 25608947; PubMed Central PMCID: PMCPMC4307637. eng.
72. Ortmann O, Rosler W, Helbig U. Current developments in cancer care: including the patients' perspective-3rd European Roundtable Meeting (ERTM) June 17, 2016, Berlin, Germany. Journal of cancer research and clinical oncology. 2017 Apr;143(4):673-676. doi: 10.1007/s00432-016-2320-3. PubMed PMID: 27988842; eng.
73. Sikavi D, Weseley AJ. The relationship between psychosocial factors in the patient-oncologist relationship and quality of care: A study of breast cancer patients. Journal of psychosocial oncology. 2017 Jan-Feb;35(1):32-46. doi: 10.1080/07347332.2016.1247406. PubMed PMID: 27918875; eng.
74. Walker MS, Ristvedt SL, Haughey BH. Patient care in multidisciplinary cancer clinics: does attention to psychosocial needs predict patient satisfaction? Psycho-oncology. 2003 Apr-May;12(3):291-300. doi: 10.1002/pon.651. PubMed PMID: 12673812.
75. Lis CG, Rodeghier M, Gupta D. Distribution and determinants of patient satisfaction in oncology: A review of the literature. Patient Prefer

Adherence. 2009;3:287-304. PubMed PMID: 19936172; PubMed Central PMCID: PMCPMC2778427. eng.
76. van de Poll-Franse LV, Horevoorts N, van Eenbergen M, et al. The Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship registry: scope, rationale and design of an infrastructure for the study of physical and psychosocial outcomes in cancer survivorship cohorts. European journal of cancer (Oxford, England : 1990). 2011 Sep;47(14):2188-94. doi: 10.1016/j.ejca.2011.04.034. PubMed PMID: 21621408; eng.
77. te Velde A, Sprangers MA, Aaronson NK. Feasibility, psychometric performance, and stability across modes of administration of the CARES-SF. Ann Oncol. 1996 Apr;7(4):381-90. PubMed PMID: 8805930; eng.
78. Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine. 2000 Dec 15;25(24):3186-91. PubMed PMID: 11124735; eng.
79. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. Journal of clinical epidemiology. 2007 Jan;60(1):34-42. doi: 10.1016/j.jclinepi.2006.03.012. PubMed PMID: 17161752; eng.
80. Schag CA, Heinrich RL. Cancer Rehabilitation Evaluation System (CARES) Manual, ed. 1. Los Angeles: CARES Consultants; 1989.
81. Schag CA, Heinrich RL, Aadland RL, et al. Assessing problems of cancer patients: psychometric properties of the cancer inventory of problem situations. Health Psychol. 1990;9(1):83-102. PubMed PMID: 2323331; eng.
82. Ganz PA, Schag CC, Heinrich RL. The psychosocial impact of cancer on the elderly: a comparison with younger patients. J Am Geriatr Soc. 1985 Jun;33(6):429-35. PubMed PMID: 3998352; eng.
83. Ganz PA, Schag CA, Cheng HL. Assessing the quality of life--a study in newly-diagnosed breast cancer patients. Journal of clinical epidemiology. 1990;43(1):75-86. PubMed PMID: 2319284; eng.
84. Heinrich RL, Schag CC, Ganz PA. Living with cancer: the Cancer Inventory of Problem Situations. J Clin Psychol. 1984 Jul;40(4):972-80. PubMed PMID: 6480863; eng.
85. Schag CA, Heinrich RL. Development of a comprehensive quality of life measurement tool: CARES. Oncology (Williston Park). 1990 May;4(5):135-8;discussion 147. PubMed PMID: 2143399; eng.
86. Meyerowitz BE, Heinrich RL, & Schag CC. A competency- based approach to coping with cancer. In: Bradley L and Burish TG, editor. Coping with Chronic Disease: Research and Applications. New York: Academic Press; 1983.
87. Schag CC, Heinrich RL, Ganz PA. Karnofsky performance status revisited: reliability, validity, and guidelines. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 1984 Mar;2(3):187-93. PubMed PMID: 6699671; eng.
88. Mor V, Laliberte L, Morris JN, et al. The Karnofsky Performance Status Scale. An examination of its reliability and validity in a research setting. Cancer. 1984 May 1;53(9):2002-7. PubMed PMID: 6704925; eng.
89. Karnofsky DA, Burchenal JH. The clinical evaluation of chemotherapeutic agents in cancer. In: Macleod CM, ed. Evaluation ofchemotherapeutic agents. New York: Columbia University Press, 1949:191-205.

90. Spinhoven P, Ormel J, Sloekers PP, et al. A validation study of the Hospital Anxiety and Depression Scale (HADS) in different groups of Dutch subjects. Psychol Med. 1997 Mar;27(2):363-70. PubMed PMID: 9089829.
91. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand. 1983 Jun;67(6):361-70. PubMed PMID: 6880820.
92. Bjelland I, Dahl AA, Haug TT, et al. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. Journal of psychosomatic research. 2002 Feb;52(2):69-77. PubMed PMID: 11832252; eng.
93. van Sonderen E. The measurement of social support with the Social Support List-Interactions (SSL-I) and the Social Support List-Discrepancies (SSL –D). Dutch manual Groningen, the Netherlands: Noordelijk Centrum voor Gezondheidsvraagstukken; 1993.
94. Bridges KR, Sanderman R, van Sonderen E. An English language version of the social support list: preliminary reliability. Psychol Rep. 2002 Jun;90(3 Pt 1):1055-8. PubMed PMID: 12090497; eng.
95. van Sonderen E. Het meten van sociale steun met de Sociale Steun Lijst - Interacties (SSL-I) en Sociale Steun Lijst - Discrepanties (SSL-D): een handleiding. Tweede herziene druk. Groningen, The Netherlands: UMCG /Rijksuniversiteit Groningen, Research Institute SHARE; 2012.
96. Arrindell WA, Boelens, W., & Lambert, H. . On the psychometric properties of the Maudsley Marital Questionnaire (MMQ): Evaluation of self-ratings in distressed and 'normal' volunteer couples based on the Dutch version. Personality & Individual Differences. 1983;4(3):293–306.
97. Arrindell WA, Schaap C. The Maudsley Marital Questionnaire (MMQ): an extension of its construct validity. Br J Psychiatry. 1985 Sep;147:295-9. PubMed PMID: 4063595; eng.
98. Orathinkal J, Vansteenwegen A, Enright RD, et al. Further validation of the Dutch version of the Enright Forgiveness Inventory. Community Ment Health J. 2007 Apr;43(2):109-28. doi: 10.1007/s10597-006-9065-4. PubMed PMID: 17063390.
99. Joseph O, Alfons V, Rob S. Further validation of the Maudsley Marital Questionnaire (MMQ). Psychol Health Med. 2007 May;12(3):346-52. doi: 10.1080/13548500600855481. PubMed PMID: 17510905; eng.
100. Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. Journal of the National Cancer Institute. 1993 Mar 3;85(5):365-76. PubMed PMID: 8433390; eng.
101. Tuinman MA, Gazendam-Donofrio SM, Hoekstra-Weebers JE. Screening and referral for psychosocial distress in oncologic practice: use of the Distress Thermometer. Cancer. 2008 Aug 15;113(4):870-8. doi: 10.1002/cncr.23622. PubMed PMID: 18618581.
102. Holland JC, Andersen B, Breitbart WS, et al. Distress management. J Natl Compr Canc Netw. 2007 Jan;5(1):66-98. PubMed PMID: 17239328.
103. Bauwens S, Baillon C, Distelmans W, et al. The 'Distress Barometer': validation of method of combining the Distress Thermometer with a rated complaint scale. Psycho-oncology. 2009 May;18(5):534-42. doi: 10.1002/pon.1425. PubMed PMID: 18823077.

104. Pauwels EE, Charlier C, De Bourdeaudhuij I, et al. Care needs after primary breast cancer treatment. Survivors' associated sociodemographic and medical characteristics. Psycho-oncology. 2013 Jan;22(1):125-32. doi: 10.1002/pon.2069. PubMed PMID: 21956765.
105. Nunnally JC, Bernstein IH. Psychometric theory. 3rd ed. New York: McGraw-Hill; 1994.
106. Terwee CB, Dekker FW, Wiersinga WM, et al. On assessing responsiveness of health-related quality of life instruments: guidelines for instrument evaluation. Qual Life Res. 2003 Jun;12(4):349-62. PubMed PMID: 12797708.
107. Bartko JJ. The intraclass correlation coefficient as a measure of reliability. Psychol Rep. 1966 Aug;19(1):3-11. doi: 10.2466/pr0.1966.19.1.3. PubMed PMID: 5942109; eng.
108. Burns N, Grove SK. The practice of nursing research. 4th edn. US: WB. Saunders Philadelphia; 2001.
109. Kodner DL, Spreeuwenberg C. Integrated care: meaning, logic, applications, and implications--a discussion paper. Int J Integr Care. 2002;2:1568-4156. PubMed PMID: 16896389; PubMed Central PMCID: PMCPMC1480401. eng.
110. Breitbart W, Rosenfeld B, Pessin H, et al. Meaning-centered group psychotherapy: an effective intervention for improving psychological well-being in patients with advanced cancer. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2015 Mar 1;33(7):749-54. doi: 10.1200/jco.2014.57.2198. PubMed PMID: 25646186; PubMed Central PMCID: PMCPMC4334778. eng.
111. Meyer LA, Nick AM, Shi Q, et al. Perioperative trajectory of patient reported symptoms: a pilot study in gynecologic oncology patients. Gynecol Oncol. 2015 Mar;136(3):440-5. doi: 10.1016/j.ygyno.2015.01.547. PubMed PMID: 25647455; eng.
112. Institute of Medicine (IOM). 2008. Cancer care for the whole patient: Meeting psychosocial health needs. Nancy E. Adler and Ann E. K. Page eW, DC: The National Academies Press.
113. Carlson LE, Groff SL, Maciejewski O, et al. Screening for Distress in Lung and Breast Cancer Outpatients: A Randomized Controlled Trial. Journal of Clinical Oncology. 2010 Nov 20;28(33):4884-4891. doi: Doi 10.1200/Jco.2009.27.3698. PubMed PMID: WOS:000284353000016; English.
114. Bauwens S, Baillon C, Distelmans W, et al. Systematic screening for distress in oncology practice using the Distress Barometer: the impact on referrals to psychosocial care. Psycho-oncology. 2014 Jan 24;23(7):8004-844. doi: 10.1002/pon.3484. PubMed PMID: 24458691; Eng.
115. Sanson-Fisher R, Girgis A, Boyes A, et al. The unmet supportive care needs of patients with cancer. Supportive Care Review Group. Cancer. 2000 Jan 1;88(1):226-37. PubMed PMID: 10618627; eng.
116. Schag CC, Heinrich, R.L., & Ganz, P.A. . The Cancer Inventory of Problem Situations: An instrument for assessing cancer patients' rehabilitation needs. Journal of psychosocial oncology. 1983;1(11-24).
117. Deragotis LR. SCL-90-R. Manual-I. Baltimore: MD: John Hopkins University School of Medicine; 1977.

118. Spanier GB. Measuring dyadic adjustment. New scales for assessing the quality of marriage and similar dyads. J Marriage Fam. 1976;38(1):15-28.
119. Karnofsky DA, Burchenal, J.H. . The clinical evaluation of chemotherapeutic agents in cancer. C.M. Macleod (Ed.), Evaluation of Chemotherapeutic Agents. New York: Columbia University Press; 1949.
120. Gough IR, Furnival CM, Schilder L, et al. Assessment of the quality of life of patients with advanced cancer. Eur J Cancer Clin Oncol. 1983 Aug;19(8):1161-5. PubMed PMID: 6684561.
121. Ganz PA. Cancer Rehabilitation Evaluation System (CARES) and CARES-SF now publicly available. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2012 Nov 10;30(32):4046-7. doi: 10.1200/JCO.2012.44.9926. PubMed PMID: 23008314.
122. Gjersing L, Caplehorn JR, Clausen T. Cross-cultural adaptation of research instruments: language, setting, time and statistical considerations [journal article]. BMC Medical Research Methodology. 2010;10(1):1-10. doi: 10.1186/1471-2288-10-13.
123. Harkness JA S-GA. Questionnaires in translation. In: JA H, editor. ZUMA Nachrichten Spezial No. 3 Cross-Cultural Survey Equivalence. Mannheim: ZUMA; 1998.
124. Harkness JA, Pennell, B-E, Schoua-Glusberg, A. Survey Questionnaire Translation and Assessment. In: Presser S, Rothgeb, J.M., Couper, M.P., Lessler, J.T., Martin, E., Martin, J. Singer, E editor. Methods for Testing and Evaluating Survey Questionnaires. New York: Wiley; 2004.
125. Schouten B, Van Hoof E, Vankrunkelsven P, et al. Assessing cancer patients' quality of life and supportive care needs: Translation-revalidation of the CARES in Flemish and exhaustive evaluation of concurrent validity. BMC health services research. 2016;16(1):86. doi: 10.1186/s12913-016-1335-4. PubMed PMID: 26969509; PubMed Central PMCID: PMCPMC4788884. eng.
126. Sobin L.H., Wittekind Ch. . TNM Classification of Malignant Tumours, 6th Edition. Wiley; 2002.
127. Mitchell AJ, Meader N, Symonds P. Diagnostic validity of the Hospital Anxiety and Depression Scale (HADS) in cancer and palliative settings: a meta-analysis. J Affect Disord. 2010 Nov;126(3):335-48. doi: 10.1016/j.jad.2010.01.067. PubMed PMID: 20207007.
128. Schouten B, Hellings J, Vankrunkelsven P, et al. Screening Cancer Patients' Distress and Care Needs: Translation and Validation of the Cancer Rehabilitation Evaluation System (CARES) for the Flemish Population in Belgium [abstract]. Psychooncology. 2013;22:305-306.
129. BelgianCancerRegistry. Cancer Prevalence in Belgium 2010 Brussels: Belgian Cancer Registry; 2014.
130. Harrison JD, Young JM, Price MA, et al. What are the unmet supportive care needs of people with cancer? A systematic review. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2009 Aug;17(8):1117-28. doi: 10.1007/s00520-009-0615-5. PubMed PMID: 19319577.
131. UK National Institute of Clinical Excellence. Improving supportive and palliative care for adults with cancer. 2004.
132. Government A. Australian clinical practice guidelines for the psychosocial care of adults with cancer, 2003. 2003.

133. Mitchell AJ. Screening for cancer-related distress: when is implementation successful and when is it unsuccessful? Acta oncologica (Stockholm, Sweden). 2013 Feb;52(2):216-24. doi: 10.3109/0284186x.2012.745949. PubMed PMID: 23320770; eng.
134. Wen KY, Gustafson DH. Needs assessment for cancer patients and their families. Health Qual Life Outcomes. 2004 Feb 26;2:11. doi: 10.1186/1477-7525-2-11. PubMed PMID: 14987334; PubMed Central PMCID: PMCPMC394345. eng.
135. Richardson A, Medina J, Brown V, et al. Patients' needs assessment in cancer care: a review of assessment tools. Supportive Care in Cancer. 2007 Oct;15(10):1125-1144. doi: DOI 10.1007/s00520-006-0205-8. PubMed PMID: WOS:000249632900002; English.
136. Ganz PA, Coscarelli A, Fred C, et al. Breast cancer survivors: psychosocial concerns and quality of life. Breast cancer research and treatment. 1996;38(2):183-99. PubMed PMID: 8861837; eng.
137. Ganz PA, Desmond KA, Leedham B, et al. Quality of life in long-term, disease-free survivors of breast cancer: a follow-up study. Journal of the National Cancer Institute. 2002 Jan 2;94(1):39-49. PubMed PMID: 11773281; eng.
138. Ganz PA, Schag CA, Lee JJ, et al. The CARES: a generic measure of health-related quality of life for patients with cancer. Qual Life Res. 1992 Feb;1(1):19-29. PubMed PMID: 1301111; eng.
139. Schag CA, Ganz PA, Wing DS, et al. Quality of life in adult survivors of lung, colon and prostate cancer. Qual Life Res. 1994 Apr;3(2):127-41. PubMed PMID: 8044158; eng.
140. Khan F, Amatya B. Factors associated with long-term functional outcomes, psychological sequelae and quality of life in persons after primary brain tumour. J Neurooncol. 2013 Feb;111(3):355-66. doi: 10.1007/s11060-012-1024-z. PubMed PMID: 23292152; eng.
141. Parker PA, Alba F, Fellman B, et al. Illness uncertainty and quality of life of patients with small renal tumors undergoing watchful waiting: a 2-year prospective study. Eur Urol. 2013 Jun;63(6):1122-7. doi: 10.1016/j.eururo.2013.01.034. PubMed PMID: 23419322; PubMed Central PMCID: PMCPMC3866912. eng.
142. Zimmermann C, Swami N, Krzyzanowska M, et al. Early palliative care for patients with advanced cancer: a cluster-randomised controlled trial. Lancet. 2014 May 17;383(9930):1721-30. doi: 10.1016/s0140-6736(13)62416-2. PubMed PMID: 24559581; eng.
143. Borstelmann NA, Rosenberg SM, Ruddy KJ, et al. Partner support and anxiety in young women with breast cancer. Psycho-oncology. 2015 Mar 13. doi: 10.1002/pon.3780. PubMed PMID: 25765893; Eng.
144. Schouten B, Hellings J, Van Hoof E, et al. Validation of the flemish CARES, a quality of life and needs assessment tool for cancer care. BMC Cancer. 2016;16:696. doi: 10.1186/s12885-016-2728-9. PubMed PMID: 27576341; PubMed Central PMCID: PMCPMC5006609. eng.
145. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. Nurse Educ Today. 2004 Feb;24(2):105-12. doi: 10.1016/j.nedt.2003.10.001. PubMed PMID: 14769454; eng.

146. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006 2006/01/01;3(2):77-101. doi: 10.1191/1478088706qp063oa.
147. Kvale S. InterViews: An Introduction to Qualitative Research Interviewing. Thousand Oaks, CA: Sage; 1996.
148. Schag CA, Ganz PA, Heinrich RL. CAncer Rehabilitation Evaluation System--short form (CARES-SF). A cancer specific rehabilitation and quality of life instrument. Cancer. 1991 Sep 15;68(6):1406-13. PubMed PMID: 1873793; eng.
149. Corney RH. Sex differences in general practice attendance and help seeking for minor illness. Journal of psychosomatic research. 1990;34(5):525-34. PubMed PMID: 2231486; Eng.
150. Galdas PM, Cheater F, Marshall P. Men and health help-seeking behaviour: literature review. Journal of advanced nursing. 2005 Mar;49(6):616-23. doi: 10.1111/j.1365-2648.2004.03331.x. PubMed PMID: 15737222; Eng.
151. Waller A, Girgis, A., Johnson, C., Lecathelinais, C., Sibbritt, D., Forstner, D., Liauw, W., Currow, D.C. Improving Outcomes for People With Progressive Cancer: Interrupted Time Series Trial of a Needs Assessment Intervention. Journal of Pain and Symptom Management. 2012 March 2012;43(3):569-589.
152. Allen JD, Savadatti S, Levy AG. The transition from breast cancer 'patient' to 'survivor'. Psycho-oncology. 2009 Jan;18(1):71-78. doi: Doi 10.1002/Pon.1380. PubMed PMID: WOS:000262625700009; English.
153. Armes J, Crowe M, Colbourne L, et al. Patients' supportive care needs beyond the end of cancer treatment: a prospective, longitudinal survey. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2009 Dec 20;27(36):6172-9. doi: 10.1200/JCO.2009.22.5151. PubMed PMID: 19884548.
154. Choi KH, Park JH, Park JH, et al. Psychosocial needs of cancer patients and related factors: a multi-center, cross-sectional study in Korea. Psycho-oncology. 2012 May 4. doi: 10.1002/pon.3105. PubMed PMID: 22565501; Eng.
155. Ploos van Amstel FK, van den Berg SW, van Laarhoven HW, et al. Distress screening remains important during follow-up after primary breast cancer treatment. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2013 Aug;21(8):2107-15. doi: 10.1007/s00520-013-1764-0. PubMed PMID: 23455455; eng.
156. Hall A, Lynagh M, Bryant J, et al. Supportive care needs of hematological cancer survivors: A critical review of the literature. Crit Rev Oncol Hematol. 2013 Apr 10. doi: 10.1016/j.critrevonc.2013.03.008. PubMed PMID: 23582686; Eng.
157. Oskam IM, Verdonck-de Leeuw IM, Aaronson NK, et al. Prospective evaluation of health-related quality of life in long-term oral and oropharyngeal cancer survivors and the perceived need for supportive care. Oral Oncol. 2013 May;49(5):443-8. doi: 10.1016/j.oraloncology.2012.12.005. PubMed PMID: 23318122; eng.
158. Schouten B, Hellings J, Vankrunkelsven P, et al. Qualitative research on the Belgian Cancer Rehabilitation Evaluation System (CARES): An evaluation of the content validity and feasibility. Journal of evaluation in

clinical practice. 2017 Jan 23. doi: 10.1111/jep.12681. PubMed PMID: 28111884; eng.
159. Fann JR, Ell K, Sharpe M. Integrating Psychosocial Care Into Cancer Services. Journal of Clinical Oncology. 2012 Apr 10;30(11):1178-1186. doi: Doi 10.1200/Jco.2011.39.7398. PubMed PMID: WOS:000302995700004; English.
160. Dilworth S, Higgins I, Parker V, et al. Patient and health professional's perceived barriers to the delivery of psychosocial care to adults with cancer: a systematic review. Psycho-oncology. 2014 Feb 11. doi: 10.1002/pon.3474. PubMed PMID: 24519814; Eng.
161. Hess LM, Pohl G. Perspectives of quality care in cancer treatment: a review of the literature. Am Health Drug Benefits. 2013 Jul;6(6):321-9. PubMed PMID: 24991367; PubMed Central PMCID: PMCPMC4031722. eng.
162. World Health Organisation. Quality of care: A Process for making strategic choices in health systems. Geneva: WHO Press; 2006.
163. Maurer J, Schafer C, Maurer O, et al. Anxiety and depression in cancer patients during the course of radiotherapy treatment. Strahlenther Onkol. 2012 Oct;188(10):940-5. doi: 10.1007/s00066-012-0143-y. PubMed PMID: 22923039.
164. Carlson LE, Waller A, Groff SL, et al. Online screening for distress, the 6th vital sign, in newly diagnosed oncology outpatients: randomised controlled trial of computerised vs personalised triage. Br J Cancer. 2012 Aug 7;107(4):617-25. doi: 10.1038/bjc.2012.309. PubMed PMID: 22828610; PubMed Central PMCID: PMC3419958.
165. Meiklejohn JA, Mimery A, Martin JH, et al. The role of the GP in follow-up cancer care: a systematic literature review. Journal of cancer survivorship : research and practice. 2016 Dec;10(6):990-1011. doi: 10.1007/s11764-016-0545-4. PubMed PMID: 27138994; eng.
166. Spence RR, Heesch KC, Brown WJ. Exercise and cancer rehabilitation: a systematic review. Cancer treatment reviews. 2010 Apr;36(2):185-94. doi: 10.1016/j.ctrv.2009.11.003. PubMed PMID: 19962830; eng.
167. Mishra SI, Scherer RW, Snyder C, et al. Exercise interventions on health-related quality of life for people with cancer during active treatment. The Cochrane database of systematic reviews. 2012 Aug 15(8):Cd008465. doi: 10.1002/14651858.CD008465.pub2. PubMed PMID: 22895974; eng.
168. Korpan MI, Crevenna R, Fialka-Moser V. Lymphedema: a therapeutic approach in the treatment and rehabilitation of cancer patients. American journal of physical medicine & rehabilitation. 2011 May;90(5 Suppl 1):S69-75. doi: 10.1097/PHM.0b013e31820be160. PubMed PMID: 21765266; eng.
169. Paccagnella A, Morassutti I, Rosti G. Nutritional intervention for improving treatment tolerance in cancer patients. Current opinion in oncology. 2011 Jul;23(4):322-30. doi: 10.1097/CCO.0b013e3283479c66. PubMed PMID: 21552123; eng.
170. Lis CG, Gupta D, Lammersfeld CA, et al. Role of nutritional status in predicting quality of life outcomes in cancer--a systematic review of the epidemiological literature. Nutrition journal. 2012 Apr 24;11:27. doi: 10.1186/1475-2891-11-27. PubMed PMID: 22531478; PubMed Central PMCID: PMCPMC3408376. eng.

171. Humphris GM. The missing member of the head and neck multidisciplinary team: the psychologist. Why we need them. Current opinion in otolaryngology & head and neck surgery. 2008 Apr;16(2):108-12. doi: 10.1097/MOO.0b013e3282f470f9. PubMed PMID: 18327028; eng.
172. Zebrack B, Walsh K, Burg MA, et al. Oncology social worker competencies and implications for education and training. Social work in health care. 2008;47(4):355-75. doi: 10.1080/00981380802173954. PubMed PMID: 19042491; eng.
173. Borras JM, Albreht T, Audisio R, et al. Policy statement on multidisciplinary cancer care. European journal of cancer (Oxford, England : 1990). 2014 Feb;50(3):475-80. doi: 10.1016/j.ejca.2013.11.012. PubMed PMID: 24321260; Eng.
174. Nationaal Kankerplan België 2008 [cited 2016 22.12.2016]. Available from: http://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/32_initiatieven_n.pdf
175. Arora NK. Interacting with cancer patients: the significance of physicians' communication behavior. Social science & medicine (1982). 2003 Sep;57(5):791-806. PubMed PMID: 12850107; eng.
176. Taylor S, Harley C, Campbell LJ, et al. Discussion of emotional and social impact of cancer during outpatient oncology consultations. Psycho-oncology. 2011 Mar;20(3):242-51. doi: 10.1002/pon.1730. PubMed PMID: 20336633; eng.
177. Vermeer WM, Bakker RM, Kenter GG, et al. Cervical cancer survivors' and partners' experiences with sexual dysfunction and psychosexual support. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2016 Apr;24(4):1679-87. doi: 10.1007/s00520-015-2925-0. PubMed PMID: 26412245; PubMed Central PMCID: PMCPMC4766206. eng.
178. Stergiou-Kita M, Grigorovich A, Tseung V, et al. Qualitative meta-synthesis of survivors' work experiences and the development of strategies to facilitate return to work. Journal of cancer survivorship : research and practice. 2014 Dec;8(4):657-70. doi: 10.1007/s11764-014-0377-z. PubMed PMID: 24993807; eng.
179. Fagerlind H, Kettis A, Glimelius B, et al. Barriers Against Psychosocial Communication: Oncologists' Perceptions. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2013 Sep 16. doi: 10.1200/jco.2012.45.1609. PubMed PMID: 24043746; Eng.
180. Wei RL, Mattes MD, Yu J, et al. Attitudes of radiation oncologists toward palliative and supportive care in the United States: Report on national membership survey by the American Society for Radiation Oncology (ASTRO). Practical radiation oncology. 2017 Mar - Apr;7(2):113-119. doi: 10.1016/j.prro.2016.08.017. PubMed PMID: 28274395; eng.
181. Travado L, Reis JC, Watson M, et al. Psychosocial oncology care resources in Europe: a study under the European Partnership for Action Against Cancer (EPAAC). Psycho-oncology. 2015 Dec 21. doi: 10.1002/pon.4044. PubMed PMID: 26685870; Eng.
182. Ercolano E. Psychosocial Concerns in the Postoperative Oncology Patient. Seminars in oncology nursing. 2017 Feb;33(1):74-79. doi: 10.1016/j.soncn.2016.11.007. PubMed PMID: 28062332; eng.

183. Vannieuwenborg L, Buntinx F, De Lepeleire J. Presenting prevalence and management of psychosocial problems in primary care in Flanders. Archives of public health = Archives belges de sante publique. 2015;73(1):10. doi: 10.1186/s13690-015-0061-4. PubMed PMID: 25755877; PubMed Central PMCID: PMCPMC4353667. eng.
184. Podsakoff PM, MacKenzie SB, Lee JY, et al. Common method biases in behavioral research: a critical review of the literature and recommended remedies. The Journal of applied psychology. 2003 Oct;88(5):879-903. doi: 10.1037/0021-9010.88.5.879. PubMed PMID: 14516251; eng.
185. Wolff HA, Ihler F, Zeller N, et al. (Chemo)radiotherapy after laser microsurgery and selective neck dissection for pN2 head and neck cancer. Eur Arch Otorhinolaryngol. 2015 Apr 12. doi: 10.1007/s00405-015-3619-4. PubMed PMID: 25864181; Eng.
186. Carlson LE, Bultz BD. Cancer distress screening. Needs, models, and methods. Journal of psychosomatic research. 2003 Nov;55(5):403-9. PubMed PMID: 14581094.
187. Meijer A, Roseman M, Delisle VC, et al. Effects of screening for psychological distress on patient outcomes in cancer: A systematic review. Journal of psychosomatic research. 2013 Jul;75(1):1-17. doi: 10.1016/j.jpsychores.2013.01.012. PubMed PMID: 23751231; eng.
188. Heyn L, Finset A, Eide H, et al. Effects of an interactive tailored patient assessment on patient–clinician communication in cancer care. Psycho-oncology. 2013;22(1):89-96. doi: 10.1002/pon.2064.
189. Ristevski E, Regan M, Jones R, et al. Cancer patient and clinician acceptability and feasibility of a supportive care screening and referral process. Health Expect. 2015 Jun;18(3):406-18. doi: 10.1111/hex.12045. PubMed PMID: 23369083.
190. Whitney RL, Bell JF, Bold RJ, et al. Mental health needs and service use in a national sample of adult cancer survivors in the USA: has psychosocial care improved? Psycho-oncology. 2014 May 13;24(1):80-8. doi: 10.1002/pon.3569. PubMed PMID: 24818821; Eng.
191. Zabora JR, Macmurray L. The history of psychosocial screening among cancer patients. Journal of psychosocial oncology. 2012 Nov;30(6):625-35. doi: 10.1080/07347332.2012.721491. PubMed PMID: 23101547; eng.
192. Cox A, Jenkins V, Catt S, et al. Information needs and experiences: An audit of UK cancer patients. European Journal of Oncology Nursing. 2006 Sep;10(4):263-272. doi: DOI 10.1016/j.ejon.2005.10.007. PubMed PMID: WOS:000245664600002; English.
193. Zucca A, Sanson-Fisher R, Waller A, et al. Patient-centred care: making cancer treatment centres accountable. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2014 Jul;22(7):1989-97. doi: 10.1007/s00520-014-2221-4. PubMed PMID: 24696084.
194. Galway K, Black A, Cantwell M, et al. Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients. The Cochrane database of systematic reviews. 2012;11:CD007064. doi: 10.1002/14651858.CD007064.pub2. PubMed PMID: 23152241; eng.
195. Goedendorp MM, Gielissen MF, Verhagen CA, et al. Psychosocial interventions for reducing fatigue during cancer treatment in adults. The

Cochrane database of systematic reviews. 2009 (1):CD006953. doi: 10.1002/14651858.CD006953.pub2. PubMed PMID: 19160308; eng.
196. Parahoo K, McDonough S, McCaughan E, et al. Psychosocial interventions for men with prostate cancer. The Cochrane database of systematic reviews. 2013;12:CD008529. doi: 10.1002/14651858.CD008529.pub3. PubMed PMID: 24368598; eng.
197. Semple C, Parahoo K, Norman A, et al. Psychosocial interventions for patients with head and neck cancer. The Cochrane database of systematic reviews. 2013;7:CD009441. doi: 10.1002/14651858.CD009441.pub2. PubMed PMID: 23857592; eng.
198. Bidstrup PE, Johansen C, Mitchell AJ. Screening for cancer-related distress: Summary of evidence from tools to programmes. Acta Oncologica. 2011 Feb;50(2):194-204. doi: Doi 10.3109/0284186x.2010.533192. PubMed PMID: WOS:000286830500005; English.
199. Hack TF, Pickles T, Ruether JD, et al. Predictors of distress and quality of life in patients undergoing cancer therapy: impact of treatment type and decisional role. Psycho-oncology. 2010;19(6):606-616. doi: 10.1002/pon.1590. PubMed PMID: 105019675. Language: English. Entry Date: 20100917. Revision Date: 20150711. Publication Type: Journal Article.
200. McIllmurray MB, Thomas C, Francis B, et al. The psychosocial needs of cancer patients: findings from an observational study. Eur J Cancer Care (Engl). 2001 Dec;10(4):261-9. PubMed PMID: 11806677; eng.
201. Sidani S. Health Intervention Research: Understanding Research Design and Methods. London: Sage Publications Ltd; 2015.
202. Ranchor AV, Fleer J, Sanderman R, et al. Psychological interventions for cancer survivors and cancer patients in the palliative phase. Cochrane Database of Systematic Reviews. 2012 (1). doi: 10.1002/14651858.CD009511. PubMed PMID: CD009511.
203. Singer S, Danker H, Briest S, et al. Effect of a structured psycho-oncological screening and treatment model on mental health in cancer patients (STEPPED CARE): study protocol for a cluster randomized controlled trial. Trials. 2014 Dec 10;15(1):482. doi: 10.1186/1745-6215-15-482. PubMed PMID: 25491069; Eng.
204. Aaronson NK, Muller M, Cohen PD, et al. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. Journal of clinical epidemiology. 1998 Nov;51(11):1055-68. PubMed PMID: 9817123; eng.
205. Beck AT, Steer RA, Brown GK. BDI®-II Manual San Antonio, Texas, USA: The Psychological Corporation; 1996.
206. Hodgkinson K, Butow P, Hunt GE, et al. The development and evaluation of a measure to assess cancer survivors' unmet supportive care needs: the CaSUN (Cancer Survivors' Unmet Needs measure). Psycho-oncology. 2007;16(9):796-804. doi: 10.1002/pon.1137.
207. Bredart A, Bottomley A, Blazeby JM, et al. An international prospective study of the EORTC cancer in-patient satisfaction with care measure (EORTC IN-PATSAT32). European journal of cancer (Oxford, England : 1990). 2005 Sep;41(14):2120-31. doi: 10.1016/j.ejca.2005.04.041. PubMed PMID: 16182120.

208. Bredart A, Mignot V, Rousseau A, et al. Validation of the EORTC QLQ-SAT32 cancer inpatient satisfaction questionnaire by self- versus interview-assessment comparison. Patient education and counseling. 2004 Aug;54(2):207-12. doi: 10.1016/S0738-3991(03)00210-6. PubMed PMID: 15288916.
209. Kleeberg UR, Feyer P, Gunther W, et al. Patient satisfaction in outpatient cancer care: a prospective survey using The PASQOC questionnaire. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2008 Aug;16(8):947-54. doi: 10.1007/s00520-007-0362-4. PubMed PMID: 18204867.
210. Kleeberg UR, Tews JT, Ruprecht T, et al. Patient satisfaction and quality of life in cancer outpatients: results of the PASQOC study. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2005 May;13(5):303-10. doi: 10.1007/s00520-004-0727-x. PubMed PMID: 15729552.
211. Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. Available from www.cochrane-handbook.org: The Cochrane Collaboration; 2011.
212. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. PLoS Med. 2009 Jul 21;6(7):e1000100. doi: 10.1371/journal.pmed.1000100. PubMed PMID: 19621070; PubMed Central PMCID: PMC2707010.
213. Mohler R, Kopke S, Meyer G. Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2). Trials. 2015;16(1):204. doi: 10.1186/s13063-015-0709-y. PubMed PMID: 25935741; PubMed Central PMCID: PMCPMC4461976. eng.
214. Sackett MJ, Armitage JP, Sherwood EE, et al. Photoresponses of the purple nonsulfur bacteria Rhodospirillum centenum and Rhodobacter sphaeroides. J Bacteriol. 1997 Nov;179(21):6764-8. PubMed PMID: 9352928; PubMed Central PMCID: PMCPMC179607.
215. Kristman V, Manno M, Cote P. Loss to follow-up in cohort studies: how much is too much? Eur J Epidemiol. 2004;19(8):751-60. PubMed PMID: 15469032.
216. Sterne JAC, Higgins JPT, Reeves Bc on behalf of the development group for ROBINSI. ROBINS-I: a tool for assessing Risk Of Bias In Non-randomized Studies of Interventions, Version 7. Available from http://www.riskofbias.info [accessed 23/05/2016].2016.
217. Review Manager Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration; 2014.
218. Braeken AP, Kempen GI, Eekers DB, et al. Psychosocial screening effects on health-related outcomes in patients receiving radiotherapy. A cluster randomised controlled trial. Psycho-oncology. 2013 Dec;22(12):2736-46. doi: 10.1002/pon.3340. PubMed PMID: 23824561; Eng.
219. Bramsen I, van der Linden MH, Eskens FJ, et al. Evaluation of a face-to-face psychosocial screening intervention for cancer patients: acceptance and effects on quality of life. Patient education and counseling. 2008 Jan;70(1):61-8. doi: 10.1016/j.pec.2007.09.010. PubMed PMID: 17997260; eng.

220. de Leeuw J, Prins JB, Teerenstra S, et al. Nurse-led follow-up care for head and neck cancer patients: a quasi-experimental prospective trial. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2013 Feb;21(2):537-47. doi: 10.1007/s00520-012-1553-1. PubMed PMID: 22864472; eng.
221. Detmar SB, Muller MJ, Schornagel JH, et al. Health-related quality-of-life assessments and patient-physician communication: a randomized controlled trial. JAMA: Journal of the American Medical Association. 2002;288(23):3027-3034. PubMed PMID: 106806257. Language: English. Entry Date: 20030214. Revision Date: 20161112. Publication Type: journal article.
222. Geerse OP, Hoekstra-Weebers JE, Stokroos MH, et al. Structural distress screening and supportive care for patients with lung cancer on systemic therapy: A randomised controlled trial. European journal of cancer (Oxford, England : 1990). 2017 Feb;72:37-45. doi: 10.1016/j.ejca.2016.11.006. PubMed PMID: 28024265; eng.
223. Hilarius DL, Kloeg PH, Gundy CM, et al. Use of health-related quality-of-life assessments in daily clinical oncology nursing practice: a community hospital-based intervention study. Cancer. 2008 Aug 1;113(3):628-37. doi: 10.1002/cncr.23623. PubMed PMID: 18543317; eng.
224. Harrison JD, Young JM, Solomon MJ, et al. Randomized pilot evaluation of the supportive care intervention "CONNECT" for people following surgery for colorectal cancer. Dis Colon Rectum. 2011 May;54(5):622-31. doi: 10.1007/DCR.0b013e31820bc152. PubMed PMID: 21471765.
225. Livingston PM, White VM, Hayman J, et al. The psychological impact of a specialist referral and telephone intervention on male cancer patients: a randomised controlled trial. Psycho-oncology. 2010 Jun;19(6):617-25. doi: 10.1002/pon.1609. PubMed PMID: 19673008.
226. Schofield P, Ugalde A, Gough K, et al. A tailored, supportive care intervention using systematic assessment designed for people with inoperable lung cancer: a randomised controlled trial. Psycho-oncology. 2013;22(11):2445-2453. doi: 10.1002/pon.3306. PubMed PMID: 104106771. Language: English. Entry Date: 20140502. Revision Date: 20150710. Publication Type: Journal Article.
227. Thewes B, Butow P, Stuart-Harris R, et al. Does routine psychological screening of newly diagnosed rural cancer patients lead to better patient outcomes? Results of a pilot study. The Australian journal of rural health. 2009 Dec;17(6):298-304. doi: 10.1111/j.1440-1584.2009.01087.x. PubMed PMID: 19930195.
228. Young J, Harrison J, Solomon M, et al. Development and feasibility assessment of telephone-delivered supportive care to improve outcomes for patients with colorectal cancer: pilot study of the CONNECT intervention. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2010 Apr;18(4):461-70. doi: 10.1007/s00520-009-0689-0. PubMed PMID: 19626346; eng.
229. Young JM, Butow PN, Walsh J, et al. Multicenter randomized trial of centralized nurse-led telephone-based care coordination to improve outcomes after surgical resection for colorectal cancer: the CONNECT intervention. Journal of clinical oncology : official journal of the American

Society of Clinical Oncology. 2013 Oct 01;31(28):3585-91. doi: 10.1200/JCO.2012.48.1036. PubMed PMID: 24002519.
230. Giesler RB, Given B, Given CW, et al. Improving the quality of life of patients with prostate carcinoma: a randomized trial testing the efficacy of a nurse-driven intervention. Cancer. 2005 Aug 15;104(4):752-62. doi: 10.1002/cncr.21231. PubMed PMID: 15986401; eng.
231. Given C, Given B, Rahbar M, et al. Does a symptom management intervention affect depression among cancer patients: results from a clinical trial. Psycho-oncology. 2004;13(11):818-830. PubMed PMID: 106532991. Language: English. Entry Date: 20051028. Revision Date: 20150711. Publication Type: Journal Article.
232. Kutner JS, Foehner K, J.F S. Evaluation of the impact of a pre-visit questionnaire for addressing cancer patients' information needs. Journal of Cancer Education. 1999;14(4):248-253.
233. Rosenbloom SK, Victorson DE, Hahn EA, et al. Assessment is not enough: a randomized controlled trial of the effects of HRQL assessment on quality of life and satisfaction in oncology clinical practice. Psycho-oncology. 2007;16(12):1069-1079. PubMed PMID: 105835838. Language: English. Entry Date: 20080307. Revision Date: 20150711. Publication Type: Journal Article.
234. Williams PD, Graham KM, Storlie DL, et al. Therapy-related symptom checklist use during treatments at a cancer center. Cancer Nurs. 2013 May-Jun;36(3):245-54. doi: 10.1097/NCC.0b013e3182595406. PubMed PMID: 22744208; eng.
235. Hollingworth W, Metcalfe C, Mancero S, et al. Are needs assessments cost effective in reducing distress among patients with cancer? A randomized controlled trial using the distress thermometer and problem list. Journal of Clinical Oncology. 2013;31(29):3631-3638. doi: 10.1200/JCO.2012.48.3040. PubMed PMID: 104102785. Language: English. Entry Date: 20140404. Revision Date: 20150710. Publication Type: Journal Article.
236. Nimako K, Ayite B, Priest K, et al. A randomised assessment of the use of a quality of life questionnaire with or without intervention in patients attending a thoracic cancer clinic. Eur J Cancer Care (Engl). 2015 Nov 10. doi: 10.1111/ecc.12402. PubMed PMID: 26556778; eng.
237. Velikova G, Booth L, Smith AB, et al. Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. Journal of Clinical Oncology. 2004;22(4):714-724. PubMed PMID: 106579110. Language: English. Entry Date: 20050211. Revision Date: 20150711. Publication Type: Journal Article.
238. Maunsell E, Brisson J, Deschenes L, et al. Randomized trial of a psychologic distress screening program after breast cancer: effects on quality of life. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 1996 Oct;14(10):2747-55. PubMed PMID: 8874336.
239. Taenzer P, Bultz BD, Carlson LE, et al. Impact of computerized quality of life screening on physician behaviour and patient satisfaction in lung cancer outpatients. Psycho-oncology. 2000 May-Jun;9(3):203-13. PubMed PMID: 10871716.

240. Bergholdt SH, Hansen DG, Larsen PV, et al. A randomised controlled trial to improve the role of the general practitioner in cancer rehabilitation: effect on patients' satisfaction with their general practitioners. BMJ open. 2013;3(7). doi: 10.1136/bmjopen-2013-002726. PubMed PMID: 23824312; PubMed Central PMCID: PMCPMC3703581. eng.
241. Brenner MH, Curbow B, Legro MW. The proximal-distal continuum of multiple health outcome measures: the case of cataract surgery. Med Care. 1995 Apr;33(4 Suppl):AS236-44. PubMed PMID: 7723452.
242. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. Psychol Rev. 1977 Mar;84(2):191-215. PubMed PMID: 847061.
243. Leventhal H, Phillips LA, Burns E. The Common-Sense Model of Self-Regulation (CSM): a dynamic framework for understanding illness self-management. J Behav Med. 2016 Dec;39(6):935-946. doi: 10.1007/s10865-016-9782-2. PubMed PMID: 27515801; eng.
244. Lang M, Giese-Davis J, Patten S, et al. Does Age Matter? Comparing Post-Treatment Psychosocial Outcomes in Young Adult and Older Adult Cancer Survivors with their Cancer-Free Peers. Psycho-oncology. 2017 Jul 03. doi: 10.1002/pon.4490. PubMed PMID: 28672093; eng.
245. Morrison EJ, Novotny PJ, Sloan JA, et al. Emotional Problems, Quality of Life, and Symptom Burden in Patients With Lung Cancer. Clin Lung Cancer. 2017 Sep;18(5):497-503. doi: 10.1016/j.cllc.2017.02.008. PubMed PMID: 28412094; eng.
246. van Scheppingen C, Schroevers MJ, Smink A, et al. Does screening for distress efficiently uncover meetable unmet needs in cancer patients? Psycho-oncology. 2011 Jun;20(6):655-63. doi: 10.1002/pon.1939. PubMed PMID: 21381148.
247. Howell D, Mayo S, Currie S, et al. Psychosocial health care needs assessment of adult cancer patients: a consensus-based guideline. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2012 Dec;20(12):3343-54. doi: 10.1007/s00520-012-1468-x. PubMed PMID: 22581015; eng.
248. Luckett T, Butow PN, King MT. Improving patient outcomes through the routine use of patient-reported data in cancer clinics: future directions. Psycho-oncology. 2009;18(11):1129-1138. doi: 10.1002/pon.1545. PubMed PMID: 105236957. Language: English. Entry Date: 20100129. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical.
249. Bultz BD, Carlson LE. A commentary on 'effects of screening for psychological distress on patient outcomes in cancer: a systematic review'. Journal of psychosomatic research. 2013 Jul;75(1):18-9. doi: 10.1016/j.jpsychores.2013.04.002. PubMed PMID: 23751232; eng.
250. Price MA, Dhillon H. Review: insufficient evidence to recommend routine screening for psychological distress among people with cancer. Evidence-based mental health. 2013 Nov;16(4):108. doi: 10.1136/eb-2013-101498. PubMed PMID: 24057035; eng.
251. Boyes A, Newell S, Girgis A, et al. Does routine assessment and real-time feedback improve cancer patients' psychosocial well-being? Eur J Cancer Care (Engl). 2006 May;15(2):163-71. doi: 10.1111/j.1365-2354.2005.00633.x. PubMed PMID: 16643264; eng.
252. Grassi L, Rossi E, Caruso R, et al. Educational intervention in cancer outpatient clinics on routine screening for emotional distress: an

observational study. Psycho-oncology. 2011 Jun;20(6):669-74. doi: 10.1002/pon.1944. PubMed PMID: 21370316.
253. McLachlan S, Allenby A, Matthews J, et al. Randomized trial of coordinated psychosocial interventions based on patient self-assessments versus standard care to improve the psychosocial functioning of patients with cancer. Journal of Clinical Oncology. 2001;19(21):4117-4125. PubMed PMID: 106913293. Language: English. Entry Date: 20020405. Revision Date: 20150711. Publication Type: Journal Article.
254. Sarna L. Effectiveness of structured nursing assessment of symptom distress in advanced lung cancer. Oncology Nursing Forum. 1998;25(6):1041-1048. PubMed PMID: 107284578. Language: English. Entry Date: 19981001. Revision Date: 20150819. Publication Type: Journal Article.
255. Williamson PR, Altman DG, Blazeby JM, et al. Developing core outcome sets for clinical trials: issues to consider. Trials. 2012 Aug 06;13:132. doi: 10.1186/1745-6215-13-132. PubMed PMID: 22867278; PubMed Central PMCID: PMCPMC3472231. eng.
256. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ (Clinical research ed). 2014 Mar 07;348:g1687. doi: 10.1136/bmj.g1687. PubMed PMID: 24609605; eng.
257. Boyce MB, Browne JP, Greenhalgh J. The experiences of professionals with using information from patient-reported outcome measures to improve the quality of healthcare: a systematic review of qualitative research. BMJ quality & safety. 2014 Jun;23(6):508-18. doi: 10.1136/bmjqs-2013-002524. PubMed PMID: 24505110; eng.
258. Ozgen Z, Ozden S, Atasoy BM, et al. Long-term effects of neoadjuvant chemoradiotherapy followed by sphincter-preserving resection on anal sphincter function in relation to quality of life among locally advanced rectal cancer patients: a cross-sectional analysis. Radiation oncology (London, England). 2015 Aug 12;10:168. doi: 10.1186/s13014-015-0479-4. PubMed PMID: 26264590; PubMed Central PMCID: PMCPMC4554367. eng.
259. Marventano S, Forjaz M, Grosso G, et al. Health related quality of life in colorectal cancer patients: state of the art. BMC surgery. 2013;13 Suppl 2:S15. doi: 10.1186/1471-2482-13-s2-s15. PubMed PMID: 24267735; PubMed Central PMCID: PMCPMC3851259. eng.
260. Ganz PA, Hirji K, Sim MS, et al. Predicting psychosocial risk in patients with breast cancer. Med Care. 1993 May;31(5):419-31. PubMed PMID: 8501990; eng.
261. Ganz PA, Rowland JH, Desmond K, et al. Life after breast cancer: understanding women's health-related quality of life and sexual functioning. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 1998 Feb;16(2):501-14. PubMed PMID: 9469334; eng.
262. Gotay CC, Moinpour CM, Unger JM, et al. Impact of a peer-delivered telephone intervention for women experiencing a breast cancer recurrence. Journal of Clinical Oncology. 2007;25(15):2093-2099. PubMed PMID: 105953976. Language: English. Entry Date: 20080201. Revision Date: 20150711. Publication Type: Journal Article.

263. Libert Y, Merckaert I, Slachmuylder JL, et al. The ability of informal primary caregivers to accurately report cancer patients' difficulties. Psycho-oncology. 2013 Dec;22(12):2840-7. doi: 10.1002/pon.3362. PubMed PMID: 24038554; eng.
264. Rosenberg SM, Tamimi RM, Gelber S, et al. Treatment-related amenorrhea and sexual functioning in young breast cancer survivors. Cancer. 2014 Aug 1;120(15):2264-71. doi: 10.1002/cncr.28738. PubMed PMID: 24891236; PubMed Central PMCID: PMCPMC4116329. eng.
265. Saevarsdottir T, Fridriksdottir N, Gunnarsdottir S. Quality of life and symptoms of anxiety and depression of patients receiving cancer chemotherapy: longitudinal study. Cancer Nurs. 2010 Jan-Feb;33(1):E1-E10. doi: 10.1097/NCC.0b013e3181b4adb5. PubMed PMID: 20010331; eng.
266. Wieldraaijer T, Duineveld LA, van Asselt KM, et al. Follow-up of colon cancer patients; causes of distress and need for supportive care: Results from the ICARE Cohort Study. Eur J Surg Oncol. 2016 Aug 31. doi: 10.1016/j.ejso.2016.08.011. PubMed PMID: 27633339; Eng.
267. Admiraal JM, van Nuenen FM, Burgerhof JG, et al. Cancer patients' referral wish: effects of distress, problems, socio-demographic and illness-related variables and social support sufficiency. Psycho-oncology. 2016 Nov;25(11):1363-1370. doi: 10.1002/pon.4067. PubMed PMID: 26804486; eng.
268. Lambert SD, Kelly B, Boyes A, et al. Insights into preferences for psycho-oncology services among women with gynecologic cancer following distress screening. J Natl Compr Canc Netw. 2014 Jun;12(6):899-906. PubMed PMID: 24925200; eng.
269. Thalen-Lindstrom A, Glimelius B, Johansson B. Development of anxiety, depression and health-related quality of life in oncology patients without initial symptoms according to the Hospital Anxiety and Depression Scale - a comparative study. Acta oncologica (Stockholm, Sweden). 2017 Aug;56(8):1094-1102. doi: 10.1080/0284186x.2017.1305124. PubMed PMID: 28339305; eng.
270. Thorne S, Hislop TG, Kim-Sing C, et al. Changing communication needs and preferences across the cancer care trajectory: insights from the patient perspective. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2014 Apr;22(4):1009-15. doi: 10.1007/s00520-013-2056-4. PubMed PMID: 24287506; eng.
271. Pereira JL, Chasen MR, Molloy S, et al. Cancer Care Professionals' Attitudes Toward Systematic Standardized Symptom Assessment and the Edmonton Symptom Assessment System After Large-Scale Population-Based Implementation in Ontario, Canada. J Pain Symptom Manage. 2016 Apr;51(4):662-672.e8. doi: 10.1016/j.jpainsymman.2015.11.023. PubMed PMID: 26743641; eng.
272. Thayssen S, Hansen DG, Sondergaard J, et al. Completing a Questionnaire at Home Prior to Needs Assessment in General Practice: A Qualitative Study of Cancer Patients' Experience. Patient. 2015 Oct 30. doi: 10.1007/s40271-015-0144-x. PubMed PMID: 26518199; Eng.
273. Biddle L, Paramasivan S, Harris S, et al. Patients' and clinicians' experiences of holistic needs assessment using a cancer distress

thermometer and problem list: A qualitative study. European journal of oncology nursing : the official journal of European Oncology Nursing Society. 2016 Aug;23:59-65. doi: 10.1016/j.ejon.2016.04.004. PubMed PMID: 27456376; eng.

List of Abbreviations

ACG	assessment control group
ACG	attention control group
ADL	activities of daily living
BCR	Belgian Cancer Registry
BDI	Beck Depression Inventory
CARES	Cancer Rehabilitation Evaluation System
CARES-SF	Cancer Rehabilitation Evaluation System-Short Form
CaSUN	Cancer Survivors' Unmet Needs measure
CBAs	controlled before-after studies
CCCQ	Continuity and Coordination of Care Questionnaire
CEBAM	Belgian Center for Evidence-Based Medicine
CENTRAL	Cochrane Central Register of Controlled Trials
CES-D	Center for Epidemiological Studies Depression Scale
CG	control group
CIPS	Cancer Inventory of Problem Situations
CIs	confidence intervals
COOP	Dartmouth Primary Care Cooperative Information Functional Health Assessment
CT	chemotherapy
Dan-PEP	Danish Patients Evaluate General Practice
DAS	Dyadic Adjustment Scale
DIS/DSM	Diagnostic Interview Schedule according to Diagnostic and Statistical Manual criteria
DT	Distress Thermometer
ECOG	Eastern Cooperative Oncology Group
EORTC IN-PATSAT32	European Organisation for Research and Treatment of Cancer in-patient satisfaction with care measure
EORTC-QLQ-H&N35	European Organisation for Research and Treatment of Cancer - Quality of Life Questionnaire - Head-and-neck cancer 35 items
EORTC-QLQ-BR23	European Organisation for Research and Treatment of Cancer - Quality of Life Questionnaire - Breast cancer 23 items

EORTC-QLQ-C30	European Organisation for Research and Treatment of Cancer - Quality of Life Questionnaire - Core 30 items
EORTC-QLQ-CR38	European Organisation for Research and Treatment of Cancer - Quality of Life Questionnaire - Colorectal cancer 38 items
EORTC-QLQ-LC13	European Organisation for Research and Treatment of Cancer - Quality of Life Questionnaire - Lung Cancer 13 items
EPAAC	European Partnership for Action Against Cancer
EQ-5D	EuroQol 5D
EQ-5D-3L	EuroQol 5D-lungcancer
Equip	European Association for Quality in General Practice
EU	European Union
FACIT-II	Functional Assessment of Chronic Illness Therapy version 2
FACIT-sp	Functional Assessment of Chronic Illness Therapy Spiritual Well-Being
FACT-BCS	Functional Assessment of Cancer Therapy-Breast Cancer
FACT-C	Functional Assessment of Cancer Therapy-Colorectal Cancer
FACT-G	Functional Assessment of Cancer Therapy-General
FACT-HN	Functional Assessment of Cancer Therapy-Head-Neck Cancer
FACT-L	Functional Assessment of Cancer Therapy-Lung Cancer
FG	focus group(s)
FLIC	Functional Living Index-Cancer
GAD-7	Generalized Anxiety Disorder
GHQ-12	General Health Questionnaire 12 items version
GHQ-20	General Health Questionnaire 20 items-version
GP	general practitioner(s)
HADS	Hospital Anxiety and Depression Scale
HCP	Healthcare professional(s)
HCTs	historically-controlled studies
HRQOL	health-related quality of life
HRQOL-LASA	Health-Related Quality of Life Linear Analogue Self-assessment
ICC	intra-cluster correlation coefficient

ICQ	Illness Cognition Questionnaire
IES	Impact of Event Scale
IG	intervention group
IKNL	Integraal Kankercentrum Nederland
IOM	Institute Of Medicine
ITS	interrupted-time-series
KCE	Belgian Health Care Knowledge Centre
KMO	Kaiser-Meyer-Olkin
KPS	Karnofsky Performance status Scale
LES	Life Experiences Survey
LSM	Limburg Sterk Merk
LWMAT	Locke-Wallace Martial Adjustment Test
M	mean
MCQ	Medical Care Questionnaire
MD	mean difference
MHLC	Multidimensional Health Locus of Control questionnaire
MMQ-M	Maudsley Marital Questionnaire - Marital scale
MMQ-S	Maudsley Marital Questionnaire - Sexual scale
MOC	multidisciplinary oncological consultation
MPC	multiple choice
MRCG	medical records control group
MUIS	Mishel's Uncertainty in Illness Scale
N	number of participants
N/A	not available
N/E	not estimable
NA-ACP	Needs Assessment for Advanced Cancer Patients
NA-ALCP	Needs Assessment for Advanced Lung Cancer Patients
NAT:PD-C	Needs Assessment Tool: Progressive Diseased Cancer
NCCP	National Cancer Control Programmes
NIH	National Institutes of Health
NRCT	non-randomized controlled trial
NSCLC	non-small cell lung cancer
PAIS-SR	Psychosocial Adjustment to Illness-Self Report

PASQOC	Patient Satisfaction and Quality in Oncological Care
PCA	principal component analysis
PCQoL	Prostate Cancer Quality of Life questionnaire
PC-QOL	Prostate Cancer-Related Quality of Life Scales
PDIS	Patient-Doctor Interaction Scale
PEACE	Peace, equanimity and acceptance in the cancer experience scale
PHQ-9	Patient Health Questionnaire
PL	Problem List
POMS	Profile of Mood States
PRO	Patient-Reported Outcome
PROM	patient-reported outcome measure
PSI	Psychiatric Symptom Index
PSQ	Patient Satisfaction Questionnaire
PSQ-III	Patient Satisfaction Questionnaire 3rd update
PSYCH-6	Psychological Subscale of the Somatic and Psychological Health Report
QOC	Quality of Communication Scale
QOL	quality of life
QPP	Quality of Care from the Patients Perspective
RC	rehabilitation coordinator
RCT	randomized clinical trial
RePORTER	RePORT Expenditures and Results
RMS	repeated measures studies
ROBINS-I	Risk Of Bias In Non-randomized Studies - of Interventions
RT	radiotherapy
SCID	Structured Clinical Interview for DSM-IV
SCL-90	Symptom Checklist-90
SCLC	small cell lung cancer
SCNC	Supportive Care Needs Survey
SD	standard deviation
SF-36	Short Form Health Survey 36-items version
SI	screening intervention
SICG	Serious Illness Conversation Guide

SIPP	Screening Inventory of Psychosocial Problems
SMD	standardized mean difference
SPSS	Statistical Package for Social Sciences
SSL-D	Social Support List – Discrepancies
SSL-I	Social Support List – Interactions
TOI	Treatment Outcome Index
TPVCSQ	Trent patient Views of Cancer Services Questionnaire
TRSC	Therapy-Related Symptom Checklist
UCG	usual care control group
UICC	Union for International Cancer Control
UK	United Kingdom
VES-13	Vulnerable Elders Survey
WHO	World Health Organization
WONCA	World Organisation Project of National Colleges and Academics

List of Figures

List of Tables

Chapter 1. General introduction

Chapter 2. Preparations for the CARES validation study: A protocol

Chapter 3. Psychometric validation of the CARES

Summary

In the report 'Crossing the quality chasm: a new health system for the 21st century', the Institute Of Medicine (IOM) suggested that patient-centeredness one of the critical components in the pursuit of high-quality care. The IOM stated that 'care should be respectful of and responsive to patients' experiences, values, preferences and needs, and patients' input on these should guide all clinical decisions'. When confronted with cancer and related treatments, patients and their relatives can experience consequences of physical, psychological, social and practical nature. Due to earlier detection and successful therapeutic approaches more and more patients survive or live longer with cancer, and with the related long-term and late-effects. To adequately address the impact of cancer, cancer care should be comprehensive, integrating the medical and the psychosocial approach during active treatment, as well as in follow-up. The objective of this PhD-project was to contribute to the research on the psychosocial aspects and patient-centeredness in Belgian cancer care. This gave rise to several studies.

First, we conducted a quantitative study with 192 cancer patients to study the psychometric robustness of the Flemish Cancer Rehabilitation Evaluation System (CARES), a questionnaire for the assessment of cancer patients' quality of life (QOL) and care needs. From the psychometric analyses focused on the items, the subscales and comparisons with other tools, we could conclude that the Flemish CARES is a reliable and valid tool. In other words, it is consistent or stable in its measurement, and it measures what it is supposed to measure, namely QOL and care needs.

In the same period, four focus groups (FG) with 26 (ex-)patients were conducted to explore the relevance and completeness of the content, as well as the acceptability and feasibility of the instrument. The results of these FG supported the cross-cultural content validity and feasibility of the Flemish CARES version. Besides, these FG gave insights in patients' experiences with cancer care, and the match of the care offer with their care needs. Interpersonal and organizational aspects seem to play an important role in the establishment of the (mis)match between cancer care and cancer patients' care needs.

In a third study, we recruited a multidisciplinary group of healthcare professionals (HCP) working in the in-hospital and ambulatory care context. In an online survey, their perspective on the approach of psychosocial issues in cancer care was explored. The survey revealed that only half of the participants was satisfied with the support or care they provide when cancer patients suffer from psychosocial problems or care needs. In general psychosocial issues are not systematically addressed. The barriers that need to be addressed according to the HCP are mainly related to education, communication, healthcare policy and organization.

For the Cochrane Review conducted within this project, we searched for studies focusing on the effect of systematic screening and assessment of cancer patients' psychosocial well-being and care needs. Twenty four studies could be included. The evidence found did not support the overall effectiveness of the screening intervention, neither did it bring clarity on the intervention characteristics that could be determinative in the effectiveness of the intervention.

The last study conducted within this PhD-project was an exploratory pilot study. In two different gastroenterology departments, a systematic CARES-assessment was applied in the care process of 51 patients with a digestive cancer. At the start of treatment, three, six and twelve months later the CARES was used to assess their QOL and care needs, and a summary report was sent to the reference nurse for use in care and follow-up. Both patients and reference nurses had positive experiences with the systematic CARES-assessment in daily routine. The tool provided a broad insight on the well-being and care needs of patients, facilitated patient-HCP communication, and efficient referral.

The findings from this PhD-project are a plea for further efforts in clinical practice and research, focused on patient-centeredness and an integrated approach of patients' well-being. In these, there should be an emphasis on the importance of 'making connections': connections between cancer patients' needs and cancer care, connections between involved HCP, connections between care contexts and care phases.

Samenvatting

In het rapport 'Crossing the quality chasm: a new health system for the 21st century' stelde het Institute Of Medicine (IOM) dat patient-gerichtheid één van de belangrijke componenten is in het nastreven van hoog kwalitatieve zorg. Volgens het IOM zou gezondheidszorg respectvol moeten zijn voor en aansluiten bij de ervaringen, waarden, voorkeuren en noden van patiënten, en inzichten hierover zouden in beschouwing moeten worden genomen bij het maken van alle klinische beslissingen. Wanneer men geconfronteerd wordt met kanker en de bijbehorende behandelingen kunnen patiënten en hun familie gevolgen ervaren op fysiek, psychologisch, sociaal en praktisch vlak. Ten gevolge van vroegere detectie en succesvolle behandelingen zijn er steeds meer patiënten die de ziekte overleven, of langer leven met kanker en gerelateerde lange termijn- en laat optredende effecten. Om de impact die kanker kan hebben in iemands leven gericht aan te pakken zou de kankerzorg holistisch moeten zijn, waarbij de medische en de psychosociale benadering geïntegreerd worden ten tijde van de actieve behandeling en vervolgens ook in de verdere follow-up. De doelstelling van dit doctoraatsproject was een bijdrage te leveren aan het onderzoek met betrekking tot de psychosociale aspecten en patient-gerichtheid in de Belgische kankerzorg. Dit gaf aanleiding tot verschillende studies.

Eerst werd er een kwantitatieve studie met 192 patiënten uitgevoerd om de psychometrische robuustheid te bestuderen van de Vlaamse Cancer Rehabilitation Evaluation System (CARES), een vragenlijst voor het meten van kwaliteit van leven (QOL) en zorgnoden bij patiënten met kanker. Uit de psychometrische analyses toegespitst op de items, de subschalen en vergelijking met andere meetinstrumenten konden we afleiden dat de Vlaamse CARES een betrouwbaar en valide meetinstrument is. In andere woorden, het is consistent of stabiel in zijn metingen en het meet wat het zou moeten meten, namelijk QOL en zorgnoden.

In dezelfde periode werden er vier focusgroepen (FG) met 26 (ex-)kankerpatiënten georganiseerd om de inhoudelijke relevantie en volledigheid van het instrument, de aanvaardbaarheid van formuleringen, alsook de bruikbaarheid te bestuderen. De resultaten bevestigden de cross-culturele validiteit van de inhoud en de bruikbaarheid van de Vlaamse CARES versie.

Daarnaast gaven de FG ook aanleiding tot inzichten in de ervaringen van patiënten met betrekking tot de kankerzorg en de aansluiting van het zorgaanbod bij hun zorgbehoeften. Interpersoonlijke en organisatorische aspecten bleken een belangrijke rol te spelen in al dan niet aansluiten van het zorgaanbod bij de ervaren zorgnoden.

In een derde studie rekruteerden we een multidisciplinaire groep van zorgprofessionals uit de intramurale en extramurale zorgcontext. Aan de hand van een online bevraging werden hun ervaringen met de benadering van psychosociale aspecten in de kankerzorg verkend. Deze bevraging bracht aan het licht dat slechts de helft van de deelnemers een goed gevoel had bij de steun of zorg die zij aan kankerpatiënten verlenen wanneer deze kampen met psychosociale problemen of zorgnoden. Over het algemeen blijken psychosociale aspecten niet systematisch besproken te worden. Enkele knelpunten die volgens de zorgprofessionals moeten worden aangepakt om de psychosociale benadering beter te kunnen integreren zijn overwegend gerelateerd aan opleiding, communicatie, gezondheidszorg beleid en organisatie.

Voor de Cochrane Review die binnen dit project werd uitgevoerd, zochten we naar studies die gericht waren op het effect van systematische screening en bevraging van het psychosociaal welbevinden en de zorgnoden van patiënten met kanker. Vierentwintig studies konden worden geïncludeerd in de review. De verzamelde evidentie kon de algemene effectiviteit van het onderzochte type interventie niet bevestigen. Evenmin gaf het duidelijkheid over de interventie-karakteristieken die bepalend zouden kunnen zijn in de effectiviteit van de interventie.

De laatste studie die in dit doctoraatsproject werd uitgevoerd, was een verkennende pilootstudie. In twee gastro-enterologieafdelingen werd een systematische CARES-bevraging toegepast in het zorgproces van 51 patiënten met een diagnose digestieve oncologie. Bij het begin van de behandeling, drie, zes en twaalf maanden later, werd de CARES gebruikt om hun QOL en zorgbehoeften te bevragen en werd een samenvattend rapport naar de referentieverpleegkundige gestuurd om de bekomen inzichten te gebruiken in de verdere zorg en opvolging. Zowel patiënten als referentieverpleegkundigen hadden positieve ervaringen met het gebruik van de systematische CARES-bevraging in de dagelijkse praktijk. De vragenlijst zorgde voor een breed inzicht

in het welzijn en de zorgbehoeften van patiënten, het faciliteerde gerichte communicatie van de zorgprofessionals met patiënten en gaf input voor efficiënte verwijzing.

De bevindingen uit dit doctoraatsproject zijn een pleidooi voor verdere inspanningen in de klinische praktijk en het onderzoek, gefocust op patient-gerichtheid en een geïntegreerde benadering van het welzijn van patiënten. Hierbij moet er nadruk gelegd worden op het belang van 'het maken van connecties': connecties tussen de behoeften van kankerpatiënten en kankerzorg, connecties tussen betrokken zorgprofessionals, connecties tussen zorgcontexten en zorgfasen.

Curriculum Vitae

Bojoura Schouten was born on March 14th in Rotterdam (The Netherlands). In 2008 she obtained her master degree in Clinical Psychology at the KULeuven. She started her career in the HR sector at Manpower, and switched to the clinical field again when she started working in a secondary activity as a clinical psychologist in a private practice. From March 2010 Bojoura worked as a project coordinator and clinical psychologist at KOPP OP!, a project that provides support for children from parents with mental illnesses (COPMI). She was responsible for providing individual support to children, organized monthly group sessions with COPMI, gave presentations and organized workshops for students, teachers, and healthcare workers in the field of adults psychiatry. In combination with this, she worked at KPC Genk, were she was involved in psychiatric diagnosis in children. Later on she combined her work at KOPP OP! with activities for the sensitization project KOPP-Vlaanderen.
In January 2013 she started her PhD project at Hasselt University titled 'Psychosocial aspects in the care for patients with cancer'. In this projects she conducted a quantitative questionnaire validation study, focus groups, a cross-sectional survey, a Cochrane Systematic Review, and a pilot study. These research activities resulted in the current dissertation. Bojoura is also a member of the committee for medical ethics at Hasselt University.

Scientific Contributions

Publications

Published Articles

Schouten, Bojoura; Van Hoof, Elke; Vankrunkelsven, Patrick; Schrooten, Ward; Bulens, Paul; Buntinx, Frank; Mebis, Jeroen; Vandijck, Dominique; Cleemput, Irina & Hellings, Johan. *Assessing cancer patients' quality of life and supportive care needs: Translation-revalidation of the CARES in Flemish and exhaustive evaluation of concurrent validity.*
In: BMC HEALTH SERVICES RESEARCH, 2016;16(1): Art N°86, doi: 10.1186/s12913-016-1335-4.

Schouten, Bojoura; Hellings, Johan; Van Hoof, Elke; Vankrunkelsven, Patrick; Bulens, Paul; Buntinx, Frank; Mebis, Jeroen; Vandijck, Dominique & Schrooten, Ward. *Validation of the flemish CARES, a quality of life and needs assessment tool for cancer care.*
In: BMC CANCER, 2016;16: Art N° 696, doi: 10.1186/s12885-016-2728-9.

Schouten, Bojoura; Bekkering, Geertruida; Vankrunkelsven, Patrick; Mebis, Jeroen; Van Hoof, Elke; Hellings, Johan & Van Hecke, Ann. *Systematic screening and assessment of psychosocial well-being and care needs of people with cancer*.
In: Cochrane Database of Systematic Reviews, 2016;10: Art N° CD012387, doi: 10.1002/14651858.CD012387.

Schouten, Bojoura; Hellings, Johan; Vankrunkelsven, Patrick; Mebis, Jeroen; Bulens, Paul; Buntinx, Frank; Vandijck, Dominique & Van Hoof, Elke. *Qualitative research on the Belgian Cancer Rehabilitation Evaluation System (CARES): An evaluation of the content validity and feasibility.*
In: Journal for Evaluation in Clinical Practice2017 Jan 23. doi: 10.1111/jep.12681.

Schouten, Bojoura; Van Hoof, Elke; Schrooten, Ward; Mebis, Jeroen; Vankrunkelsven, Patrick; Hellings, Johan. *Een instrument om kwaliteit van leven en zorgnoden bij kankerpatiënten in beeld te brengen.*
In: Belgisch Tijdschrift voor Geneeskunde – geaccepteerd voor publicatie (02/05/2017).

Published Abstracts

Schouten, Bojoura; Hellings, Johan; Vankrunkelsven, Patrick & Vanhaecht, Kris (2013) Screening Cancer Patients' Distress and Care Needs: Translation and Validation of the Cancer Rehabilitation Evaluation System (CARES) for the Flemish Population in Belgium.
In: PSYCHO-ONCOLOGY, 22, p. 305-306.

Schouten, Bojoura; HELLINGS, Johan; Vankrunkelsven, Patrick & VAN HOOF, Elke (2014) Mr. and Mrs. Patient Speaking: Patients' Preferences on Psychosocial Screening and their Impression of the CARES.
In: PSYCHO-ONCOLOGY, 23 (S3), p. 329-329.

Schouten, Bojoura; HELLINGS, Johan; Vankrunkelsven, Patrick & VAN HOOF, Elke (2015) One Single Help Question versus Differentiated Needs Assessment and Their Potential Value for Quality Cancer Care.
In: PSYCHO-ONCOLOGY, 24 (S2), p. 327-328.

Schouten, Bojoura; HELLINGS, Johan; Vankrunkelsven, Patrick & VAN HOOF, Elke (2015) Efficient Differentiation: Detecting the Ones Clinically Distressed and Most in Need for Help with the Distress Thermometer.
In: PSYCHO-ONCOLOGY, 24 (S2), p. 255-255.

Schouten, Bojoura; VAN HOOF, Elke; Vankrunkelsven, Patrick & HELLINGS, Johan (2015) Translation and Validation of a Quality of Life and Needs Assessment Tool: The Cancer Rehabilitation Evaluation System and Its Short Form.
In: PSYCHO-ONCOLOGY, 24 (S2), p. 327-327.

Schouten, Bojoura; Vankrunkelsven, Patrick; Van Hoof, Elke & Hellings, Johan (2017) A survey in a multidisciplinary group of healthcare professionals: professionals' point of view on the psychosocial approach in cancer care.
In: PSYCHO-ONCOLOGY, 26, p. 10-11.

Schouten, Bojoura; Bekkering, Geertruida; Vankrunkelsven, Patrick; Mebis, Jeroen; Van Hoof, Elke; Hellings, Johan & Van Hecke, Ann (2017) A Cochrane review on systematic screening and assessment of cancer patients' psychosocial well-being and care needs.
In: PSYCHO-ONCOLOGY, 26, p. 41-41 (Art N° 452).

Schouten, Bojoura; Vankrunkelsven, Patrick; Van Hoof, Elke & Hellings, Johan (2017) The psychosocial approach in cancer care: a small step to realize its importance, one giant leap to implement in practice.
In: PSYCHO-ONCOLOGY, 26, p. 54-55 (Art N° 449).

Schouten, Bojoura; Decaestecker, Jochen; De Jonckheere, Dominiek & Hellings, Johan (2017) Systematic QOL and care needs assessment in a transmural clinical pathway for patients with gastrointestinal cancer.
In: PSYCHO-ONCOLOGY, 26, p. 138-139 (Art N° P-189).

Presentations

Oral presentations

Schouten, Bojoura; Bekkering, Geertruida; Vankrunkelsven, Patrick; Mebis, Jeroen; Van Hoof, Elke; Hellings, Johan & Van Hecke, Ann (2017) A Cochrane review on systematic screening and assessment of cancer patients' psychosocial well-being and care needs.
In: PSYCHO-ONCOLOGY, 26, p. 41-41 (Art N° 452). *19th World Congress of Psycho-Oncology*. 16-18 August 2017, Berlin, Germany.

Schouten, Bojoura; Vankrunkelsven, Patrick; Van Hoof, Elke & Hellings, Johan (2017) The psychosocial approach in cancer care: a small step to realize its importance, one giant leap to implement in practice. *19th World Congress of Psycho-Oncology*. 16-18 August 2017, Berlin, Germany.

Poster presentations

Schouten, Bojoura; Van Hoof, Elke; Vankrunkelsven, Patrick; Bulens, Paul; Mebis, Jeroen; Vandenborre, Katherine; Hellings, Johan. 'Screening cancer patients distress and care needs: translation and validation of the Cancer Rehabilitation Evaluation System (CARES) for the Flemish population in Belgium.' *15th World Congress of Psycho-Oncology*, 6-8 November 2013, Rotterdam, The Netherlands.

Schouten, Bojoura, Hellings, Johan; Vankrunkelsven, Patrick; Van Hoof, Elke. 'Mr. and Mrs. Patient Speaking: Patients' preferences on psychosocial screening and their impression of the CARES.' *16th World Congress of Psycho-Oncology*. 22-24 October 2014, Lisbon, Portugal.

Schouten, Bojoura, Hellings, Johan; Vankrunkelsven, Patrick; Van Hoof, Elke. 'Mr. and Mrs. Patient Speaking: Patients' preferences on psychosocial screening and their impression of the CARES.' *4th ARPH Conference*, 5-6 February 2015, Ghent, Belgium.

Schouten, Bojoura, Hellings, Johan; Vankrunkelsven, Patrick; Van Hoof, Elke. '(Mis)Match between cancer care and cancer patients concerns.' *4th ARPH Conference*, 5-6 February 2015, Ghent, Belgium.

Schouten, Bojoura; Van Hoof, Elke; Vankrunkelsven, Patrick; Hellings, Johan . 'Op de rooster gelegd: Validatie studie van de CARES, een QOL en zorgnoden assessment instrument.' 21e NVPO Congres, 20 maart 2015, Utrecht, Nederland.

Bojoura Schouten; Johan Hellings; Patrick Vankrunkelsven; and Elke Van Hoof. Efficient Differentiation: Detecting The Ones Clinically Distressed And Most In Need For Help With The Distress Thermometer. *17th World Congress of Psycho-Oncology*. 30 July-1 August 2015, Washington, United States.

Bojoura Schouten; Johan Hellings; Patrick Vankrunkelsven; and Elke Van Hoof. Translation And Validation Of A Quality Of Life And Needs Assessment Tool: The Cancer Rehabilitation Evaluation System And Its' Short Form. *17th World Congress of Psycho-Oncology*. 30 July-1 August 2015, Washington, United States.

Bojoura Schouten; Johan Hellings; Patrick Vankrunkelsven; and Elke Van Hoof. One single help-questions vs. differentiated needs assessment and their potential value for quality cancer care. *17th World Congress of Psycho-Oncology*. 30 July-1 August 2015, Washington, United States.

Bojoura Schouten; Ward Schrooten; Patrick Vankrunkelsven; Elke Van Hoof; en Johan Hellings. Meten is Weten: Validatie studie van de CARES, een meetinstrument voor QOL en assessment van zorgnoden. *3e Congres in de Psychosociale Oncologie*. 1 december 2015, Mechelen, België.

Schouten, Bojoura; Van Hoof, Elke; Vankrunkelsven, Patrick; Hellings, Johan . A survey in a multidisciplinary group of health care professionals: professionals' point of view on the psychosocial approach in cancer care. *British Psychosocial Oncology Society Annual Conference.* 16-17 March 2017, Oxford, United Kingdom.

Schouten, Bojoura; Decaestecker, Jochen; De Jonckheere, Dominiek & Hellings, Johan. Systematic QOL and care needs assessment in a transmural clinical pathway for patients with gastrointestinal cancer.*19th World Congress of Psycho-Oncology*. 16-18 August 2017, Berlin, Germany.

Symposium

Organization of the symposium 'Psychosociale aspecten in de zorg voor patiënten met kanker: Lessen uit praktijkgericht, wetenschappelijk onderzoek' where four healthcare professionals gave a testimony of their experiences with psychosocial aspects in the care of patients with cancer, and two researchers talked about their findings on this topic in research. In combination with the reception after the symposium, an information market was organized with scientific posters and information about supportive care initiatives for cancer patients offered in the hospital, by ambulatory care organizations, and by patient advocacy organizations.

Acknowledgements

Dankwoord

In januari 2013 ging ik vol enthousiasme aan de slag met mijn doctoraat. Als ik er nu op terug kijk, kan ik stellen dat de afgelopen jaren vruchtbaar waren. Letterlijk op privé vlak, want in 2013 en 2016 werden mijn man en ik trotse ouders van Yleander en Enola. Figuurlijk op professioneel vlak, omdat ik – hoewel het niet helemaal gelopen is zoals ik verwachtte- best tevreden ben met hetgeen ik uiteindelijk in mijn doctoraatsproject heb kunnen verwezenlijken.

Het ontstaan van mijn doctoraatsproject is te danken aan de financiële middelen die **Limburg Sterk Merk** en het **Oncologisch Studiecentrum Erika Thijs** ter beschikking stelden, waarvoor dank. Daarnaast wil ik ook een woordje van dank richten aan de mensen die mij in de afgelopen jaren omringt hebben, en daardoor rechtstreeks of onrechtstreeks hebben bijgedragen aan mijn doctoraat.

Ik wil graag mijn **promotor**, prof. dr. Johan Hellings, bedanken voor het vertrouwen en de steun die ik heb mogen ervaren in de afgelopen jaren. Ik heb veel vrijheid gekregen in het uitwerken van het project en ervaarde Johan als een coach die mij stimuleerde om voort te doen of mij terug floot zodra ik teveel hooi op mijn vork nam. Ook de komst van Yleander en Enola werden warm onthaald en allerminst gezien als belemmering voor de voortgang van het project. Ik denk dat niet elke promotor hier zo op zou reageren en ben hier heel dankbaar voor.
Mijn **copromotor** en de leden van de **doctoraatscommissie** werden regelmatig bestookt met mails van mij. Zij waren telkens bereid tot overleg m.b.t. de nodige onderzoeksaspecten, de voortgang van het project en gaven tips en feedback vanuit hun expertise. Dank hiervoor aan prof. dr. Patrick Vankrunkelsven, prof. dr. Frank Buntinx, dr. Paul Bulens en prof. dr. Jeroen Mebis.
Dank aan de **voorzitter** , prof. dr. Ivo Lambrichts, en de **externe leden** van de **doctoraatsjury**, prof. dr. Marjan van den Akker en prof. dr. Walter Sermeus, voor hun kritische reflecties en constructieve feedback op mijn doctoraatsproefschrift.

Ik ben een harde werker, maar ben me zeker bewust van de begrensdheid van mijn kennis en kunde. Gelukkig vond ik voor de verschillende onderzoekslijnen telkens weer personen waarmee ik kon **samenwerken op het vlak van contacten met het werkveld, ontwerp van de studie, datacollectie en –analyse**. Hiervoor wil ik de volgende personen graag hartelijk danken: prof. dr. Ward Schrooten, prof. dr. Ann Van Hecke, dr. Bert Avau, dr. Trudy Bekkering, dr. Jochen Bergs, dr. Sandrine Censabella, prof. dr. Elke Van Hoof en Paul Vanlimbergen. Ook wil ik prof. dr. Dominique Vandijck en prof. dr. Irina Cleemput danken voor hun kritische reflecties op een aantal artikels die ik schreef.

Onderzoek verrichten naar een onderwerp als dat van mijn doctoraat is onmogelijk zonder deelnemers. Ik ben alle **patiënten** die hun tijd en energie investeerden in deelname aan de CARES-studies dan ook enorm dankbaar hiervoor. Ik hoop dat de inzichten en aanbevelingen die resulteren uit dit project hen en hun lotgenoten dan ook ten goede zullen komen in de nabije toekomst. Eveneens dank ik alle **ziekenhuizen, diensten en zorgprofessionals** die mij toelieten om via hun organisatie deelnemers voor de verschillende onderzoekslijnen te rekruteren: Jessa Ziekenhuis, Ziekenhuis Oost-Limburg, AZ Vesalius, Mariaziekenhuis Noord-Limburg, St- Franciscusziekenhuis, St-Trudo Ziekenhuis, Geneeskundige Kring Houthalen-Helchteren, Huisartsenkring Bree & Omgeving, Huisartsenkring Groot-Riemst, Huisartsenkring Tongeren, Huisartsenkring Alden Biesen, Huisartsenkring Kanton Borgloon, Huisartsenkring Lanaken, Huisartsenkring Prometheus, Huisartsenkring Wendelen, Huisartsenkring Dilsen-Stokkem, Huisartsenkring KINEMA, Huisartsenkring Maasmechelen, Herkenrode Huisartsenkring, Lommelse Huisartsenkring, Huisartsenkring Beringen, Noord Limburgse Huisartsenkring, Solidariteit voor het Gezin, Thuisverpleegkundigen van De Voorzorg, Thuisverpleging A tot Z, Thuisverpleging Lemmens, KinéKring Genk-As-Opglabbeek-Zutendaal, KinéKring Groot-Bilzen-Diepenbeek, KinéKring Groot Sint –Truiden, KinéKring Maas en Kempen, KinéKring Zelfstandige Kinesisten Lanaken, Tongerse Kiné Kring, West-Limburgse Kinesitherapeutenkring, Vlaams ergotherapeutenverbond vzw, Zorgba(a)rs van De Voorzorg, Groep Demolder-Orthos-Elewaut, Spronken, LMN Maas en Kempen, LMN Apollo, LMN Herkenrode, LMN Maasland Zuid, LMN

Noord-Limburg, LMN St-Truiden, Borgloon en Omgeving, LMN West-Limburg & Klaverblad, LMN Zuid-Oost Limburg, CM Limburg, mutualiteit De Voorzorg Limburg, Liberale Mutualiteit, Limburgs Steunpunt OCMW's, CGG LITP, DAGG, VVKP, Familiehulp, Landelijke thuiszorg/ONS, Solidariteit voor het Gezin en het Koninklijk Limburgs Apothekers Verbond.
Een aantal **vaste contactpersonen** waarmee ik samenwerkte **voor de rekrutering van patiënten** wil ik speciaal bedanken voor de tijd en moeite die zij investeerden: dr. Eric Joossens, prof. dr. Mebis, Ruth Hilkens, Marc Aerts, dr. Daan Walgraeve, Stefan Claes, Katrien Spaas, dr. Paul Bulens, Jan Vastmans, Odette, dr. Patrick Willemen, Evy Bamps, dr. Eric Put, dr. Katherine Vandenborre, Lauren Ghaye, Nancy Leemans, dr. Peter Van Lint, Anke Schelfhout, Dominiek de Jonckheere, en dr. Jochen Decaestecker.
Voor de **piloottest van de survey voor zorgprofessionals** contacteerde ik een aantal al dan niet reeds betrokken zorgprofessionals: dr. Eric Joosens, prof. dr. Jeroen Mebis, Sandra Bortels, Ruth Hilkens, Nathalie Cardinaels, dr. Liesbeth Thielen, Marleen Steyfkens, Evelyne Bex, Wim Smolders en prof. dr. Frank Buntinx. Dank voor jullie bereidheid om deel te nemen aan deze piloottesting.

In mei 2017 organiseerde ik het **avondsymposium 'Psychosociale aspecten in de zorg voor patiënten met kanker: Lessen uit praktijkgericht, wetenschappelijk onderzoek'**. Mevr. Rita Heeb, dr. Mia Janssen, Nathalie Cardinaels en dr. Jos Truyen waren bereid om vanuit hun perspectief ervaringen in de dagdagelijkse praktijk te belichten. Prof. dr. Frank Buntinx nam samen met mij de reflecties vanuit het onderzoek voor zijn rekening. Na afloop van het symposium vond de receptie plaats in de context van een infomarkt. Bij de verschillende standjes gaven medewerkers van Huis Erika Thijs, BRUG , WenK, Kom Op Tegen Kanker, O2+ van het Jessaziekenhuis, vzw RozeRood, de KLIMOP studie en Solidariteit voor het Gezin meer uitleg over hun zorg- of onderzoeksinitiatief. Ik wil allen danken voor hun waardevolle bijdrage aan dit symposium.

Doorheen de jaren kon ik voor vragen met betrekking tot **administratieve kwesties, financiële aspecten en procedures** altijd terecht bij **een aantal rotsen in de branding**. Dankjulliewel Marleen Missotten, Kathleen Ungricht,

Ilse Henkens, Veronique Pousset, Rani Berben, Jean Fastré, Hilde Habex, Jessica Boes, Laura Mercier, Hélène Piccard en Stefanie Kerkhofs.
Anderen die ik nog graag wil bedanken voor **hulp en ondersteuning** zijn Dave Bosmans en Mayté Gomez Sanchez van de **lay-out dienst**, Jacques Steennot en zijn collega's van de **helpdesk** waar ik een 'frequente klant' was i.v.m. pc-problemen, en een aantal personen die mij geholpen hebben bij het **nalezen en verbeteren van het Engels taalgebruik** in mijn artikels voor internationale tijdschriften: dr. Elizabeth Fradgley, Aisha Andrewin, prof. dr. Eric Caers, Eva Cordery en Noémie Aubert Bonn.

Kristel Marquet, Liene Bervoets, Evelyne Louis, Laura Visconti, Noémie Aubert Bonn, Hannelore Storms, Sarah Creemers, Jochen Bergs, Melissa Desmet, Annemie Vlayen, Karolien Vanhove, Severina Windmolders, Ann Stevens en Annelies Thijssen, mijn **mede PhD-studenten, kantoor- en ganggenoten**, dank ik voor het uitwisselen van tips en de gezellige babbels tussendoor.
Kristel, Liene, Evelyne en Laura, nadat jullie verdedigden en/of de UHasselt inwisselden voor een andere werkplek werd het wel heel eenzaam op het werk. Gelukkig zijn we er wel in geslaagd om daarna op herhaalde momenten een hapje samen te gaan eten en wat bij te kletsen. Een traditie die we zeker verder in ere moeten houden!
Noémie, je bent een 'woman of the world'. Ik ben blij dat we samen een kantoor hebben kunnen delen en ben benieuwd naar het verdere traject dat je in je doctoraat, maar ook in je leven zult afleggen. Belgium, England, Italy, Canada,… and who knows where else you will be in the future! ☺ We'll stay in touch!

Specifiek wil ik **Marleen Missotten** en **prof. dr. Ivo Lambrichts** ook nog bedanken om mij te benaderen met de vraag of ik als commissielid deel wou nemen aan de **Commissie Medische Ethiek** van de Universiteit Hasselt. Ik heb met mijn eigen onderzoeksonderwerp altijd wat geïsoleerd gezeten binnen ons unief en sprak met weinig mensen tot in detail over de onderzoekslijnen. Het maandelijks doornemen van de CME dossiers en formuleren van mijn feedback hierop verbreedde mijn horizon. De interactie met de onderzoekers en andere commissieleden gaf me het gevoel een waardevolle bijdrage te kunnen leveren.

Hoewel ik een werkpaardje ben, is het niet al werken dat de klok slaat. Naast het werk heb ik ook een goed gevuld privéleven, waarin ik door vele lieve mensen wordt omringd. De momenten en belevenissen die ik doorheen de jaren met hen heb beleefd hebben bijgedragen tot de persoon die ik ben en tot hetgeen ik (ook in functie van het doctoraat) toe in staat ben. Graag wil ik dan ook mijn **man**, onze **Mini-Metten's**, mijn **ouders**, **grootouders**, **(schoon)familie**, en **vrienden** bedanken voor alles dat zij voor mij betekenen en doen.