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PhD Thesis

Annelise Mortensen

Needs assessment and symptom management in patients surgically treated for head and neck cancer

An investigation of needs for rehabilitation, patient involvement and quality of life

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Title: Needs assessment and symptom management in patients surgically treated for head and neck cancer

Author: Annelise Mortensen

Name of Department: Department of Otolaryngology, Head and Neck Surgery and Audiology, Copenhagen University Hospital, Rigshospitalet, Denmark

Principal supervisor
Mary Jarden, MScN, PhD, Professor
Department of Hematology and Oncology, Center for Cancer and Organ Diseases, Copenhagen University Hospital, Rigshospitalet, Denmark
Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Denmark

Co-supervisor
Irene Wessel, MD, PhD, Associate professor
Department of Otolaryngology, Head and Neck Surgery and Audiology, Copenhagen University Hospital, Rigshospitalet, Denmark
Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Denmark

Simon N. Rogers, MD, FRCS, FDRCS, Professor
Head and Neck Centre, Aintree University Hospitals NHS Trust, Liverpool, Great Britain
Faculty of Health and Social Care, Edge Hill University, Liverpool, Great Britain

Submitted on 29 September 2020

Assessment committee
(Chairperson) **Thordis Thomsen**, RN, PhD, Professor
Department of Anaesthesiology, Herlev and Gentofte Hospital, Copenhagen University Hospital, Denmark
Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Denmark

Christian Godballe, MD, Professor
Department of Otolaryngology - Head & Neck Surgery and Audiology, Odense University Hospital
Department of Clinical Research, University of Southern Denmark
Head of Graduate School, Faculty of Health Sciences, University of Southern Denmark

Mary Wells, PhD MSc BSc (Hons) RGN, Professor
Imperial College Healthcare NHS Trust
Imperial College London, London, Great Britain

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List of papers

The thesis is based on three scientific papers which can be found in the appendices

Paper 1

Early and late physical and psychosocial effects of primary surgery in patients with oral and oropharyngeal cancers: a systematic review. Mortensen, A; Jarden M. Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology 2016;121:583-594

Paper 2

The nurse-patient interaction during rehabilitation needs assessment of surgically treated head and neck cancer patients – a qualitative study. Mortensen, A; Thorne, S; Wessel, I; Rogers, SN; Jarden, M.
Published in European Journal of Oncology Nursing. Available online 8 June 2021

Paper 3

Needs assessment in patients surgically treated for head and neck cancer – a randomized controlled trial. Mortensen, A; Wessel, I; Rogers, SN; Tolver, A; Jarden, M.
Submitted to Supportive Care in Cancer

Abbreviations

CSM	The Common-Sense Model of Self-Regulation
CG	Control group
Dept. ORL, H&N	Department of Otolaryngology, Head and Neck Surgery and Audiology, Copenhagen University Hospital, Rigshospitalet
DAHANCA	The Danish Head and Neck Cancer Group
EORTC	The European Organisation for Research and Treatment of Cancer
EORTC QLQ	European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire
GHS	Global health status
HADS	Hospital Anxiety and Depression Scale
HNC	Head and neck cancer
HPV	Human papilloma virus
H&N35	EORTC module Head and Neck 35
IG	Intervention group
MDASI–HN	MD Anderson Symptom Inventory–Head and Neck
OPC	Oropharyngeal cancer
OPD	Out-patient-department
PCI	Patient Concerns Inventory
PRO	Patient Reported Outcomes
QoL	Quality of Life
RCT	Randomised Controlled Trial
RT	Radiotherapy
REDCap	Research Electronic Data Capture
SD	Standard deviation
TORS	Transoral Robotic Surgery
UW-QoL	University of Washington Quality of Life Questionnaire

Definition of terms

Rehabilitation. Defined by WHO, as the measures that help individuals with a disability or a disabling health condition achieve and maintain optimum functioning in interaction with their environments [1]

Health needs**.** Defined by WHO, as objectively determined deficiencies in health that require health care, from promotion to palliation.

Perceived health needs: the need for health services as experienced by the individual and which he/she is prepared to acknowledge; perceived need may or may not coincide with professionally defined or scientifically confirmed need. [2]

Professionally defined health needs: the need for health services as recognized by health professionals from the point of view of the benefit obtainable from advice, preventive measures, management or specific therapy; Professionally defined need may or may not coincide with perceived or scientifically confirmed need.

Scientifically confirmed health needs: the need confirmed by objective measures of biological, anthropometric or psychological factors, expert opinion or the passage of time; it is generally considered to correspond to those conditions that can be classified in accordance with the International Classification of Diseases.

Symptom. Defined in Webster's Third New International Dictionary, as ''the subjective evidence of disease or physical disturbance observed by a patient.'' Charles Cleeland [3] further states that implicit in this definition is the negative nature of symptoms and, that symptoms are observations of the person directly experiencing the evidence of disease or physical disturbance.

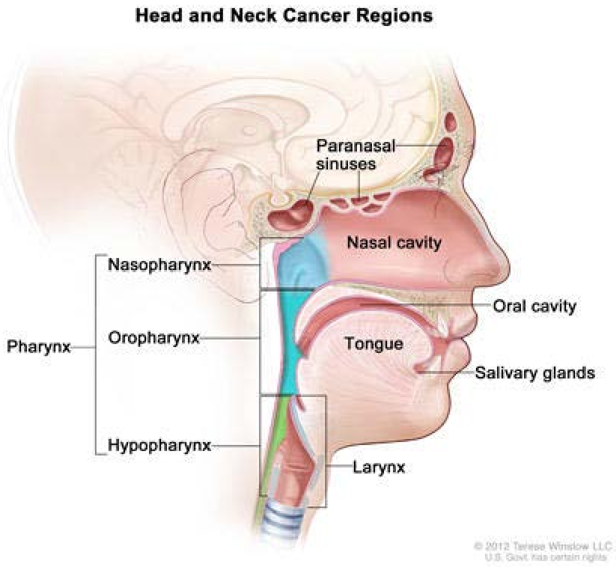
Symptom management

The National Cancer Institute (NIH) of USA defines symptom management in cancer patients as Care given to improve the quality of life of patients who have a serious or life-threatening disease. The goal of symptom management is to prevent or treat as early as possible the symptoms of a disease, side effects caused by treatment of a disease, and psychological, social and spiritual problems related to a disease or its treatment. [4]

Introduction

The global incidence of HNC is approximately 834.860 per year and deaths 430.000. [5] In Denmark the incidence is 1300 annually, with 175 deaths. [6] The treatment for HNC, which includes different modalities either alone or in combination, is radiation; chemotherapy and surgery. [7] Surgical patients face a number of short – and long-term effects due to their treatment, as it may involve resection of anatomical features in the head and neck, [7] affecting not only physical functioning, but also emotional and existential conditions. [8] Symptoms may manifest in all these areas, as problems with swallowing, breathing, chewing, speaking, facial or other disfigurement, emotional distress, social challenges and existential concerns. [9–15] Cancer survivors quality of life is affected physically, mentally, socially, existentially by the many symptoms they experience. [16] It is therefore important to assess symptoms early in the treatment trajectory and onwards, to accommodate late sequala and impact on quality of life long-term, by helping patients to manage symptoms or refer to rehabilitation. [17] The assessment of needs toward rehabilitation or symptom management, should be performed in cooperation with the patient. [16]

This PhD study comprises three sub-studies. Study I is a review of the early and late effects of surgical treatment in patients with oral and oropharyngeal cancers, one of the most affected subgroups of patients with head and neck cancers and how these patients experience multiple symptoms, highlighting the need for assessment and management of symptoms towards improvement of quality of life. Study II explores how needs of patients with head and neck cancers are assessed in nursing rehabilitation consultations; how patients and nurses experience the interaction during these assessment consultation, and patients' experiences of the information provided. Study III investigates whether a needs and concerns assessment instrument applied to a nursing rehabilitation consultation with patients surgically treated for head and neck cancer could improve their quality of life short-term compared to a group of patients receiving standard care.



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Background

Epidemiology, aetiology and treatment in head and neck cancer

The global incidence of HNC is approximately 834.860 per year and deaths 430.000. [5] Internationally the oral cancer incidence has increased, while the incidence for larynx has decreased between 2007 – 2017. [18] The incidence in Denmark is 1300 annually, [6] with a five-year survival rate between 29% to 62% for females and 26% to 65% for males depending on the tumour site. [19] Internationally the ratio of cancers in men and women differs according to the site of the HNC, but is most predominant in men with a ratio between 2:1 to 15:1. [20]

Head and neck cancer is a heterogenous group of cancers, involving tumours in the oral cavity, naso-, oro-, and hypopharynx, larynx, [21] as well as thyroid and salivary glands [22] (tumours in nasal cavity, thyroid and salivary glands, will not be mentioned in this introduction as patients with these cancers were not included in the study), whereas the different subgroups and sites stated above may be described separately in the thesis depending on the diverse treatments applied for each subgroup or site or patients included in the sub-studies.

Internationally more than 85 % of malignancies affecting head and neck are squamous cell carcinomas [7,20] with the most common site being oral cavity. [7] In Denmark the most common site is oropharynx cancers, representing 34% of head and neck cancers. [6] Risk factors for HNC are primarily linked to lifestyle factors, such as excessive use of tobacco and alcohol, [23] with an increase in risk at tobacco use alone, depending upon the amount and duration of tobacco use. [24] Alcohol consumption also increases the risk on its own but the use of tobacco and alcohol together has a synergistic effect increasing the total risk of cancer. [24,25]

Human papilloma virus (HPV)- positive oral and oropharyngeal cancer is linked to sexual behaviour. [23] There has been a distinct rise in the incidence of HPV positive cancers internationally, [7,22,23] as well as in Denmark, [26] while there has been some decrease in HNC cancers induced by lifestyle factors within recent years, [22,23] primarily in North America and Europe. [20] A study in a population of Eastern Denmark has confirmed this trend for Denmark too. [27] Thus the etiology of HNC is changing from mainly being induced by carcinogenic agents, to also being virally induced. [23]

The changing trends has had an effect on the demographics of HNC patients.[23] Patients diagnosed with HNC coming from a background of excessive use of tobacco and alcohol, often also come from a socially deprived background with low education, unemployment, and limited social network. [28,29] Some do not refrain from smoking and drinking after treatment, [30] increasing the risk of recurrences, [28] new primary cancers and comorbidities [25] and thus have a poorer prognosis for recovery and survival. [22,25,28] Patients with HPV-positive HNC, typically have no or very low consumption of tobacco and alcohol, are younger and better educated, [23] having a higher socio-economic status [31] and a better prognosis. [22,26] Patients with HPV-positive HNC are not included in this thesis, primarily for pragmatic reasons, as there was a limitation to including HPV-positive patients in Study III. At the time of inclusion, a similar study including exclusively HPV-positive patients with HNC and using a similar outcome measure was taking place in the department. Patients with comorbidities and a poor performance rate, which many patients with HNC have, also have a poorer prognosis, [8,32] as comorbidity affects the outcome of treatment. [32] Comorbidity is often related to excessive use of tobacco and alcohol. [32] Up to 60% of patients with HNC may have comorbidities[32], which further increases with rising age[32]. A Danish study showed that 36% of patients had comorbidities, [33] where six conditions in particular affected the overall survival: congestive heart failure, cerebrovascular disease, chronic pulmonary disease, peptic ulcer disease, liver disease, and diabetes. [33]

Treatment for HNC is typically surgery, radiotherapy and chemotherapy. Single modality or a combination may be used. The choice of treatment depends on many factors including tumour site and stage, [8] as well as presence of comorbidity. [32,34] Some patients present very late with symptoms of HNC [35] and therefore need more aggressive treatment. [8,22]

Multimodal treatment

As HNC is a heterogenic group of cancers [22] with tumours and stages depending on each anatomical site, treatment will also differ according to these [22,31]. In the following usual multimodality treatment will be mentioned according to these anatomical sites and staging.

For early stage cancers the treatment is usually single modality with either surgery or radiotherapy (RT) [22,31] and for locally advanced cancers multimodal with either surgery followed by RT alone or RT and chemotherapy (CT) combined.[22,31] Early stages of HNC's among which oropharyngeal cancers are treated with surgery, often using Transoral Robotic Surgery (TORS), laser microsurgery or RT. Studies have shown that more than 60% of oropharyngeal cancers are HPV-positive. [36] Previously the standard treatment for oropharyngeal cancers has been primarily RT, possibly combined with CT, [22,31] but as HPV-positive cancers primarily affects younger, non-smoking patients with a better long-term survival than HPV negative patients [22,31,36] a less invasive treatment without long-term effects are gaining foothold. [36–38]

Locally advanced HNC's are commonly treated with RT adjuvant to primary surgery possibly including neck dissection [37] or as chemoradiation. [22,31] Intensity-modulated RT makes it possible to administer RT sparing the salivary glands, diminishing the risk of xerostomia afterwards. [31]
Advanced HNC's commonly located to hypopharynx or larynx may be treated with chemoradiotherapy, [22] whereas recurrent larynx cancers are treated with surgery often involving free-flap surgery. [22,37]
When treating HNC's with chemoradiotherapy, induction CT may be used first, [31] although the positive effects still need to be further investigated.[22,31]

New and more targeted therapies are being used or investigated including stereotactic [36] -, particle beam, [39] or proton particle beam RT; [40] antibody treatment targeting epidermal growth factor, [41,42] which may be used in combination with RT or CT; [41]and immunotherapy. [39,42]
The impact of surgical treatment depends on whether the surgical treatment is prior to, combined with or is taking place after RT and/or CT. Surgery with adjuvant RT/CT causes worse QoL than surgery alone, [43–45] and causes more problems with swallowing, senses, dry mouth and sticky saliva. [44,46] Salvage surgery or neck dissection after recurrent HNC previously treated with RT and/or CT may be accompanied by increased morbidity [47,48] and complications due to tissue damage, such as wound dehiscence, wound infections, flap dehiscence, fistula and chyle leak and furthermore risk of swallowing and breathing problems with could lead to permanent tracheotomy and PEG. [49–52]

Surgical treatment in head and neck cancer

The setting of this study is a large head and neck surgery department in the Capital Region of Denmark. The setting will be described in more detail later. In the following the international approach to surgical treatment in general will be described, followed by a slightly more detailed description of the Danish approach.
Early stage tumours including those in the oral cavity or oropharyngeal cancers may be surgically treated, and may be using Transoral Robotic Surgery (TORS), with or without adjuvant radiotherapy (RT), [7,8,31,53] and advanced stage tumours are treated in a combination of surgery and RT. [7,31] Reconstructive surgery with microvascular free flaps will often be used [8] in particular with laryngectomies. [7]
In Denmark treatment for HNC follows the guidelines of The Danish Head and Neck Cancer Group (DAHANCA). [54] Early stage oral cancers are primarily surgically treated, [55] with or without adjuvant RT, while advanced stage oral cancers are treated with primary surgery and RT. [55] Advanced stage cancers in larynx are treated surgically and if necessary, involving reconstructive surgery with microvascular free flaps; [56]

rhino-pharynx cancers may include a maxillary swing technique [57] and TORS is now being used for oropharyngeal cancers. [58]

In this study 80% of included patient in Study III were primarily surgically treated.

Danish head and neck cancer patient trajectory and follow-up care

The Danish head and neck cancer treatment follows a fast track cancer pathway initiated and monitored by the Danish health authorities. In 2007 a new structural reform for municipalities was introduced in Denmark. 271 municipalities were amalgamated into 98. [59] Previously the municipalities were gathered in 13 counties, in charge of tasks which required a larger catchment. At the reform the counties were replaced by five regions. Prior to the Structural Reform, hospitals were governed by the counties, but since the reform smaller hospitals have been amalgamated into large hospital units within the regions.

Previously much of the preventive care and rehabilitation was placed in the counties. With the new structure and the close down of counties, the distribution of responsibilities and tasks between primary and secondary sector in health care was changed. The new municipalities became responsible for prevention, care and rehabilitation, which do not take place during admission; home care nursing and treatment of substance abuse. [60]

Further in 2009 the Danish Health Authority finished the implementation of the National Integrated Cancer Pathways, [61] which is a fast track trajectory. The purpose was to reduce unnecessary delays and increase the number of cancer survivors by means of obtaining faster diagnostic and treatment. A cancer pathway is a standard pathway for diagnostics, treatment and follow-up of patients with cancer. It describes who is responsible for each step on the pathway and the timeframes for these. The pathway describes criteria for entrance into the pathway, the diagnostics, treatment and follow-up, including rehabilitation and palliation. [62,63] The timeframes are monitored by the Danish Health Data Authority to ensure patients follow the fast track trajectory. The implementation of the fast track trajectory showed a reduction in waiting times for diagnostic and treatment for patients with HNC. [64] Patients appreciate the fast trajectory, while they at the same time find it to be a period of time, which is experienced as chaotic and overwhelming. [65] The Integrated Cancer Pathway for HNC was revised in 2020 [63] and guides the specific pathway for HNC. An important element in the pathway is patient involvement (PI) throughout. This is seen at the multidisciplinary team (MDT) conferences at the Department of Otolaryngology, Head and Neck Surgery and Audiology, Copenhagen University Hospital, Rigshospitalet (Dept. ORL, H&N), where individual patients participate in the MDT-conference and decisions on the best treatment for the patient is often made by the team in cooperation with the patient him/herself at the conference. A report from a qualitative study by the Danish Cancer Society in 2018 on the PI at MDT-conferences at Dept. ORL, H&N, showed that the surgeons find the involvement of patients as time consuming, yet efficient, resulting in better treatment of the patients. [66] Patient involvement is seen as well in the follow-up programme. Patients are provided with an individual plan for follow-up at the end of active treatment, which follows the guidelines of the Danish Health Authority regarding rehabilitation generally [67] and specifically for HNC. [63] The guidelines also require all patients have their need for rehabilitation assessed at certain time-points during the treatment trajectory as well as at the end of treatment. The individual patients' resources, health, self-care ability and motivation are assessed. Further, by involving the patient in this assessment, it should uncover the patient's physical, psychological, social and existential needs. It is recommended that a needs assessment tool be used for this purpose [67] and the assessment to take place at a consultation with a health care professional. In cooperation with the patients decisions are then made for referral to rehabilitation in the municipality. [63,67]

Symptomatology and health related quality of life in head and neck cancer

As the majority of patients in this study were primarily surgically treated, the following section will focus on the impact of surgical treatment on symptoms and Health-Related Quality of Life (HRQoL) in patients with HNC.

The impact of the surgical treatment may influence functional abilities affecting the patients' psychological and physical wellbeing and social functioning. [8,9,31] The most common complications and sequelae include pain and difficulties with nutrition, breathing, voice, swallowing, disfigurement, social life and psychological distress. [10–12,14,15,68] The patient may need an artificial voice [12] and may suffer from facial disfigurement due to reconstructive surgery. [69]

Patients can encounter multiple symptoms occurring concurrently and experience a high symptom burden. [17] Furthermore, the symptom burden may lead to poorer physical functioning, social dysfunction and psychological distress. [70,71] Some patients may withdraw from social life, due to disfigurement, problems with speech and eating in public [14,72] or just interacting with partners, family and friends. [72] Social isolation may lead to poorer physical recovery from the effects of the illness and treatment. [73] Some patients with HNC have a limited social network and/or no partner [74] and lower affiliation to the work force, [34] than patients with other cancers, which may intensify the challenges of managing burdensome symptoms. Other factors of influence include lower educational level or low income. [75] Finally, there is a high prevalence of emotional or psychological distress in patients with head and neck cancer, leading to poorer HRQoL. [14,72,76] The intensity of symptoms and the overall impact of the symptom burden physically, emotionally, socially and existentially may lead to a poorer HRQoL, [77,78] due to physical and functional symptoms. [43,79] HRQoL and QoL in general may be affected during treatment, [80] in particular surgical treatment, [43,81] and can exist for years after treatment. [82] Social life [43] and in some even social isolation [83] is affecting HRQoL, as well as psychologically issues impacted by the disease, treatment and symptoms. [77,84–87] Patients with HNC are among those most affected psychologically among cancer patients. [86] Finally, spiritual/existential needs and issues also affects QoL. [88,89]

QoL and HRQoL are defined differently but are often used interchangeably in the literature. The WHO definition of QoL is: ‘An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns’. [90] According to Baiju, [91] several models and concepts have been developed to define HRQoL, of which Wilson and Cleary 1995, [92] is the most commonly used. [91] Wilson and Cleary [92] incorporates five domains in their definition which are biological/physiological; symptoms status, functional status, general health and quality of life. [92]

Needs assessment in head and neck cancer

Patients with HNC have a high symptom burden and require rehabilitation. For this purpose, their needs should be assessed. Thus, the following section will focus on the assessment of these needs.

Although there is growing interest in and knowledge about the needs of patients with HNC, there is still a high percentage of patients who have unmet needs, [93] with some studies showing up to 60 – 65%. [94] Patients have physical, [94] but even more psychosocial needs [85,95] in particular fears of cancer recurrence. [50] Patients have many and varied needs after treatment, which should be identified and managed. [17,96]

It is suggested that Holistic Needs Assessment covers the areas of physical, emotional and social challenges experienced by patient with HNC. [97,98] Patients require help to assess and manage symptoms, functional disabilities and daily activities. [97] Further the Holistic Needs Assessment should be tailored to support particular concerns. [99]

The Holistic Needs Assessment and identification of rehabilitation needs in HNC cancer are traditionally carried out by different health care professionals, such as doctors, nurses, psychologist or oncology social workers using a variety of approaches, [100] techniques [101] or instruments such as different kinds of Quality of Life Questionnaires including European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 and the EORTC QLQ-H&N35, MD Anderson Dysphagia Index and other general as well as cancer specific questionnaires, [102] M. D. Anderson symptom inventory, Head and Neck module (MDASI–HN), [71] University of Washington Quality of Life questionnaire (UW-QoL) [103] or the Patient Concerns Inventory (PCI), which is a patient concerns prompt list. [104] The EORTC QLQ-C30 and H&N35 uncovers a range of physical, functional and emotional needs in cancer generally and specifically related to HNC. The M.D. Anderson Dysphagia Index aids in uncovering symptoms and needs related to dysphagia and MDASI–HN uncovers symptoms in cancer in general as well as specifically related to HNC. UW-QoL likewise uncovers needs in patients with HNC but has a format which makes it easy to use for patients.

Nurses use various approaches and instruments when assessing needs in patient with HNC such as Hospital Anxiety and Depression Scale (HADS), [105] Distress Thermometer, [106] PCI, [98] systematic questioning [98,105] and patient conversations. [107,108] Applying HADS [105] and Distress Thermometer [106] detects psychological distress, while systematic questioning reveals physical, emotional and social needs. [105] Patient conversation and systematic questioning in combination uncovers symptoms and needs. [108] A guideline as well as a study has recommended using the PCI in Holistic Needs Assessment, since it supports the health care professional in interacting with the patient towards uncovering physical, emotional and social needs. [98,109]

Using Holistic Needs Assessment instruments combined with an individually adapted plan, [110] should lead to referral for rehabilitation in order to diminish the negative effects and impairment due to treatment, both during the treatment and long-term. [16,17] The rehabilitation effort should be specifically tailored to patients with HNC since they have very complex needs due to the anatomy of the head and neck. [16]

Patient involvement

The needs assessment towards rehabilitation should preferably involve the patient as far as possible. This is not only a patient friendly approach, but also recommended by the Danish Health Authority, as mentioned above. Further, patient involvement is becoming increasingly important in many aspects of healthcare.

The concept of patient involvement is often used interchangeably or incorporating concepts such as patient participation, [111–115] shared decision making [115–117] or patient centred care. [111,115,118] Further, Patient involvement draws on other concepts such as empowerment [111,113] and self-management. [115,117,119] Patient involvement may further be discussed at three different levels macro; meso – and micro, where macro level is patient involvement at the governance or heath system level. Patient involvement on meso-level may be in relation to patient organisations and at the micro level in relation to individual care and the patient’s interactions with others. [115,120]

In the following the concepts will briefly be described, moving from a governance level, to meso-level, across different attempts to define the concepts, finishing at the micro-level, looking at how patient involvement is conceived and practiced in daily clinical and nursing practice.

Patient involvement on a governance level in Europe is based on a political decision to involve patients in health care, while at the same time reducing costs of running these facilities. [116] Dent et al [116] have tried to model a framework for defining patient involvement, using three approaches called ‘choice, ‘voice’ and ‘co-production’ [116]. Vrangbaek [117] uses the same framework relating it to a Danish context. [117] where ‘choice’ means patients possibility to select which health care providers they wish to avail themselves of. [117] ‘Voice’ means patients should have access to information on their own health, such as ehealth records [117] and finally ‘co-production’ where the main part of the concept is involving patients in producing public services together with public organizations. However, Vrangbaek points out there is a need to use co-production at a much more individual level, in which case co-production involves elements such as decision-making and management. [117] In this view patient involvement is then mostly seen regarding symptom management and monitoring of chronic diseases. [117]

At the meso-level patient organisations are involved in influencing patient involvement in health care, by defining patient involvement at the individual patient level. The European Patient's Forum state that individual participation is the patients participation in decisions related to their condition (shared decision-making, patient preferences, self-management) [113]) The Danish Patients, an umbrella organization for 83 patient organizations, have established The Danish Knowledge Center for User Involvement, [121] where they define user involvement at the individual level as giving the user a possibility to influence their own hospital/health care trajectory based on individual needs, preferences and knowledge. [121]

Clinical concepts

A number of studies have tried to analyse and describe the concept of patient involvement, patient participation and other concepts or dimensions linked to this. In the following some of these will be addressed.

Halabi, et al [111] proposed in their scoping review on the concept of 'patient participation' a description of the different dimensions making up this concept of which patient involvement is one. They found no less than 28 dimensions, six influencing factors and four expected outcomes describing this concept. They concluded that the unifying factor of the many concepts is to include the patient in the healthcare system. [111]

Snyder, et al [115] performed a narrative review on the concept of patient involvement. They defined patient involvement in different forms, such as in shared decision-making related to treatment; actively inviting patient to participate in their own care (self-care, medication and self-monitoring).

Sahlsten, et al [112]completed a concept analysis of patient participation in relation to nursing. Their conclusion was that patient participation in nursing practice takes place when a relationship has been established between nurse and patient; the nurse has given up a certain amount of control; when information and knowledge is shared between nurse and patient and there is some form of involvement in either intellectual and/or physical activities.

Finally, two clinical studies on patient involvement or patient participation in nursing relating to cancer patients are presented.

Lin et al [119] conducted a qualitative study on cancer patients, doctors and nurses perception on patient participation in symptom management. They stated that patient participation in symptom management is much more than participating in decision-making on treatment. Doctors and nurses need to facilitate the participation of patients for them to get involved.

Thaysen, et al [118] carried out a qualitative study investigating the perspectives of patients, relatives and health professionals on patient involvement in complex surgical cancer care. They applied the macro/governance level of co-production as mentioned previously, in order to see if this can be applied to the acute surgical cancer patients as opposed to the more common application of co-production in relation to chronic diseases. This was a Danish study, so patients followed the fast track cancer pathway, which applies to all patients with cancer and is mentioned earlier in this introduction. The fast track nature of the pathway is meant to give patients 'voice' but showed to pose problems at the organisational as well as individual level concerning patient involvement. It was suggested that patients and relatives are offered patient-centred care, by supporting them in asking questions and securing necessary information about their treatment pathway.

As mentioned above patient involvement requires a willingness on behalf of doctors and nurses to involve the patient. However, not all patients are able or willing to be involved in their own treatment and care. [115] A Danish report [122] on involvement of vulnerable cancer patients in decisions on their own treatment, showed that some patients did not want to be involved at all and others only to a certain degree. In the report vulnerable patients were defined as someone with limited network, no or low education and no affiliation to the work market. For patients a prerequisite for involvement was feeling secure and confident in the interaction with the health care professional.

The Common-Sense Model of Self-Regulation

As already mentioned, patients with HNC have a high symptomburden and receive diagnoses and treatments, which affect their lives short – and long-term. Patients may handle these challenges differently, but the Common-Sense Model of Self-Regulation (CSM), which will be mentioned below, is one model for explaining how patients manage their illness.

The CSM has been used as a theoretical framework partly in Study II and mainly in Study III, as the two studies showed how the issue of fear of cancer recurrence and need of nurses to address this issue was prevalent.

The Common-Sense Model of Self-Regulation was developed primarily by Howard Leventhal, a health psychologist and thus CSM operates within the discipline of health psychology. CSM has been developed as a model over several decades of research and has been described as a theoretical framework since the 1980's. [123] Research in CSM is ongoing in many areas of illnesses since CSM as a framework is frequently used in research that seeks to explain patient's reactions to the perceived threats from onset of illness. [124]

In the following CSM will be described in more detail, followed by a few studies that have applied CSM to patients with HNC.

CSM explains how patients become aware of health threats, their reaction to and understanding of these, [125] how they believe they should act to the threat and make plans to address or cope with it. It addresses reactions to both acute and chronic illness [126] and addresses issues of self-management of illness. [127] The self-regulation or self-management of illness is central to CSM and is often described as a process in stages by which a stimuli (which could be a symptom) activates the representations or beliefs of a health threat at the cognitive as well as emotional level. [123] The individual then develops or activate coping responses or action plans at the cognitive and emotional levels and finally appraises the success of these coping responses or action plans concurrently. If needed adjustments are made to the action plans. [125] This process acts as a self-regulation system in the individual. [128]

CSM operates with concepts like prototypes and representations/beliefs. [124] A prototype is a memory structure which aids the individual in acting upon a certain illness based on former experience, like a common cold. [124] An illness representation/belief is when a new episode of illness like the common cold presents itself with symptoms. [124] Illness representations can be both abstract (semantic) or concrete (perceptual/experiential). [123,124] These prototypes and representations operate within five domains or areas: 1. Identity, 2. Timeline, 3. Consequences, 4. Cause, 5. Control. [123,124] *Identity*: the name of an illness or the symptoms commonly attached to it; *timeline*: when the illness begins, how long it lasts and when it fades off; *consequences*: the expected or experienced physical, cognitive and social disturbances; *causes*: reasons why the individual has caught the disease; *control*: who is in charge of the treatment – the individual or an health care professional?. [123,124] The same five areas also apply to treatment representations, whether they have been prescribed by an health care professional or chosen by the individual. [124] *Identity*: the name of the treatment and how it is felt by the individual; *timeline*: the time it takes for a treatment to have effect, whether it causes side-effects or does not seem to have effect at all, influences adherence to a treatment; which is also related to *consequences* and finally *control* can influence the choice of treatment. [124]

Threats to health are processed not only as physical or functional (somatic) symptoms, but also as emotional (psychological) experiences. [123,124] Threat works within and without. Outwardly as a danger to health leading to planning for how to cope physically and inwardly as fear, again leading to coping emotionally. How plans and which plans are made, depends on how the individual views the threat – as danger or fear. [123,124] Leventhal [123] uses the example of Fear of Cancer Recurrence (FOR), which is very common in HNC patients, [129–131] to illustrate this. The patients experiencing somatic symptoms of cancer, while being emotionally worried about the cancer coming back experience Fear Of Cancer Recurrence. [123] The absence of either symptoms or worry, does not lead to Fear Of Cancer Recurrence. [123]

CSM does not operate only in the physical, functional and emotional domains, but also in a social context. [123] The individual experiencing a threat will consult family, friends or other social contacts about the threat. During treatment support is sought from people socially, like family, friends or the wider social community. The social context has an effect on the actions taken to manage a threat but does not alter it entirely. [123]

Few studies have been performed using CSM as a framework in patient with cancer in general or HNC. Some of these will be mentioned in more detail below.

A study in illness perceptions as predictors of psychological distress by Zhang et al, [132] showed consistent with CSM that patients who experienced more symptoms and considered their illness to be more serious, also had greater worries about their illness and higher emotional impact. However, illness representations were not the highest predictor of psychological distress. This was symptom burden. [132]
A study by Llewellyn et al, [133] investigated whether baseline representations/beliefs were associated with coping over time and further whether illness and treatment representations/beliefs were predictive with outcomes. In the study they used an expanded model of CSM including QoL. The expanded model had been used previously to address adherence to medication as a treatment representation/belief, so the researchers maintained that the treatment representation/belief could just as well be an experience of outcome like QoL. The study showed there was a relationship between pre-treatment illness and treatment representations/beliefs and coping over time, especially in relation to Global Health Status (GHS)/QoL and depression, indicating that low acceptance corresponded with high QoL and low levels of depression. This does not agree with CSM but was explained by these patients being in denial of their cancer possibly due to experiencing few signs of their cancer.
Generally cancer survivors neither experience acute nor chronic illness, since they are beyond the acute phase of the illness, but still at risk of cancer recurrence. [126] Therefore it is suggested that CSM may be applied to research in CSM. [126]
Four studies focused on Fear of Cancer Recurrence in relation to HNC will be presented below.
In 1997 Lee-Jones et al [128] hypothesized that a formulation of Fear Of Cancer Recurrence could be understood by using CSM. They suggest an individual's experience of Fear of Cancer Recurrence will vary according to the individual's perception of illness representations/beliefs. Their formulation of Fear of Cancer Recurrence suggests that internal and external stimuli activates cognitive and emotional responses related to Fear of Cancer Recurrence. Many different inward and outward factors influence this experience, including threats; information seeking; cognitive responses (risk of recurrence) and emotional responses (worry), as well as acting on consequences by body checking; seeking advice; limit plans for the future or emotionally with increased anxiety or tendency to panic attacks. They conclude that Fear of Cancer Recurrence consists of cognitions, beliefs and emotions and suggests further research on interventions that gives patients an opportunity to discuss their Fear of Cancer Recurrence.
Humphries et al [134] conducted a qualitative study as preparation for an intervention aimed at reducing Fear of Cancer Recurrence. Patients were interviewed about their perceptions of illness representations. They related their illness experiences to the past or by discussing with family and friends or finding information through the media. The concern for Fear of Cancer Recurrence was an important issue to patients. The study further showed that giving patients an opportunity to address their fears alleviated them.

Another study by Llewellyn et al [135] also explored the risk of Fear of Cancer Recurrence in patients with HNC. They looked at possible factors for predicting Fear of Cancer Recurrence in HNC survivors. CSM could explain a possible relationship between anxiety and Fear of Cancer Recurrence, related to how the individual perceives signs of a probable recurrence. The perceptions may not be medically correct, nevertheless the illness belief affects the coping strategy the patient chooses. [135] One third of the patients had high Fear of Cancer Recurrence at the time of diagnosis, while 12% still had Fear of Cancer Recurrence over time, that is after treatment. The cognitive and emotional representations/beliefs and coping strategies were related to Fear of Cancer Recurrence to some extent.

Finally, a recent study on cancer survivorship and Fear of Cancer Recurrence seeing how CSM research has looked into the way survivors cope with this risk of recurrence. [126] Durazo et al [126] present an elaboration of CSM in the context of cancer recurrence and how it affects the individual cognitively, emotionally and their behaviours, in particular related to coping; recurrence risk and worry. [126] When looking at the risk of recurrence the five areas of representations can be used again. *Identity*: symptoms of recurrence; or causal (the possible causal factors for development of cancer); *timeline:* duration of the illness and lifespan; *consequences*: physical, emotional and social effects; *control*: can the cancer be cured by treatment or behavioural/lifestyle changes. [126] The individual who is more attentive to symptoms of recurrence; that the cancer may come back soon, and consequences of a cancer recurrence will be more prone to worry. [126]

The Common-Sense Model of Self-Regulation provides a framework Fear of Cancer Recurrence understanding how patients react to the threats of an illness; make cognitive, emotional and behavioural changes or adaptation to the illness. Although CSM was developed to explain threats through acute or chronic illness, it has also been shown to be useful in cancer patients beyond the acute phase and into survivorship, in particular related to Fear of Cancer Recurrence.

Hypothesis and aims

Overall

The study's hypothesis was that a disease-specific patient-reported needs assessment tool integrated in the clinical management of HNC would improve the short-term health related quality of life and control the short-term symptom burden in surgically treated patients with HNC.

The purpose of the study was to investigate whether a systematic patient reported needs and concerns assessment integrated prior to and during rehabilitation consultations with nurses, was feasible and safe, and would improve patient involvement in needs assessments during the consultation. Further, whether patient involvement in needs assessment would result in increased referral to multi-disciplinary follow-up and ultimately reduce the symptom burden, improve physical, mental and social wellbeing and global HRQoL.

Aims

Study I

To conduct a literature review to explore the early and late physical and psychosocial effects of patients primarily surgically treated for oral and oropharyngeal cancers and to investigate the factors that influence these effects

Study II

To explore nurse-patient interactions during rehabilitation consultations that assess the needs of patients with HNC in order to understand how nurses and patients experience the rehabilitation consultation, the extent to which patients experience being involved in the needs assessment and how patients experience the information delivered

Study III

To investigate whether a systematic patient reported needs and concerns assessment integrated prior to and during consultations with health care professionals would improve patient HRQoL, when compared to standard care, reduce the symptom burden and increase the number of referrals to multi-disciplinary follow-up. Further, to investigate feasibility and safety of the intervention.

Study I may inform about the early and late effects of surgical treatment in oral and oropharyngeal cancers and possible needs for rehabilitation. These two subgroups of HNC, especially oropharyngeal cancers, constitute those known to have the most symptoms and sequela after surgical treatment.

Study II may inform about nurses' and patients experiences of a rehabilitation consultation and in particular patient's experiences of involvement in the consultation and needs assessment process, as well as the information being delivered. This may give insight into the benefits, as well as challenges, of conducting nursing rehabilitation consultations for nurses and patients as well as inform about the standard care of the department.

Study III will, incorporating the information derived from the previous studies, investigate whether using a needs assessment instrument integrated in a nursing rehabilitation consultation, will improve patient involvement in the needs assessment, uncover more needs for rehabilitation and thus ultimately lead to an increase of referrals for management of their symptomburden.

Design

The PhD study is based on the three studies listed in the table below and referred to in the text by their Roman numerals. The papers included are presented in the Appendices. The first part of the thesis presents the methods, materials, main results and methodological considerations for each study. The last part of the thesis discusses the studies and the overall strengths and limitations.
Finally, a conclusion on the results of the included studies is drawn and implications for clinical practice and research are outlined.

Studies included	**Design**	**Methods**	**Literature search/ Participants**	**Phenomenon of interest/ Outcome**
Study I (Paper 1) Systematic literature review	Systematic literature review	Systematic literature search in PubMed, Cinahl and PsycInfo	20 papers included in review	Early and late physical and psychosocial effects of primary surgery
Study II (Paper 2) Qualitative study	Ethnographically inspired study with non-participant observations, semi-structured individual interviews, focus-group interview	Interpretive Description approach with analysis using systematic text condensation	N=15 non-participant observations N=15 individual semi-structured interviews N=1 focus group interview	Patients and nurses' experiences of interactions during rehabilitation consultations
Study III (Paper 3) Randomized controlled trial	2-arm randomized controlled trial	Randomized controlled trial with a control group and an intervention group	N=48 control group N=44 intervention group	Primary outcome: Health-related QoL Secondary outcomes: symptom burden
Post-intervention Qualitative study (Thesis pg. 53)	Semi-structured individual interviews	Thematic analysis	N=9	Patients experiences of involvement in nursing rehabilitation consultations using UW-QoL and PCI

Setting

The study was carried out at the Department of Otolaryngology, Head and Neck Surgery and Audiology, Copenhagen University Hospital, Rigshospitalet, which is a tertiary, tax-funded, public health care facility with an uptake area of 2.6 million people. The department performs approximately 276 operations on patients with head and neck cancer annually. [6]

As all recruited patients in the study had their needs assessed for rehabilitation, these followed the guidelines of the Danish Health Authority [67] as outlined in the introduction to this thesis.

Patient involvement in research

Patient involvement in research, seen as a particular form of involvement apart from the patient involvement mentioned above, has become increasingly incorporated in the research process, [136,137] as patient advocates and health care providers have pointed to the need of not doing research about but with patients. [136] [138] Patient involvement in research may take place during any part of the research process, from conception of a research project until writing and publication of results. [137,139] A review by Pii et al [137] on patient involvement in cancer research, showed that patients were involved primarily at the early stages of research and further reflected the challenge of involving patients from all demographic backgrounds and not only those of socioeconomic advantaged groups in research.

In this study patients were only involved in the linguistic and cultural validation in Danish of the two instruments used in the intervention group: the patient reported outcome (PRO) questionnaire UW-QoL [103,140] and the PCI [99,141] a 56-item prompt list of concerns to be used in clinical management to aid patients in raising issues that might otherwise be missed. [141]

Patients were involved in the validation through several stages of testing the Danish translation.

First stage was a testing on 12 patients or survivors of HNC which took place at the following places:

- Two networks for patients with Head and Neck Cancer (Netværket for hals - og mundhulekræft and Dansk Landsforening for Hals – og Mundhuleopererede – the local chapter)
- The patient education day at the Out-Patient-Department (OPD) of Dept. ORL, H&N
- The in – and out-patient departments of Dept. ORL, H&N.

A second testing of a few items, were tested on five patients at the OPD of Dept. ORL, H&N

See Appendix 5 ‘Report on translation of University of Washington Quality of Life Questionnaire and Patient Concerns Inventory’.

Ethics

The study was carried out in accordance with the Helsinki Declaration. Approval from the Danish Data Protection Agency (2012-58-0004-05781) was obtained before commencement of the study. Approval from the Regional Ethics Committee is not required in Denmark in studies where biological material is not collected. The Regional Ethics Committee was approached and deemed an approval unnecessary.

(16036032). The study was registered at ClinicalTrials.com (NCT03443258). Written informed consent was obtained from all participants in the study. For observations patients in the in - and outpatient units were informed through posters displayed in the units and verbal consent was obtained from patients individually prior to observations. Staff received oral and written information beforehand at staff meetings and in individual e-mails. For the focus-group interview nurses gave written informed consent.

Study I. Systematic literature review (Paper 1)

In order to get a better insight into the symptoms and challenges faced by surgically treated HNC patients as they move along the treatment trajectory from the time before surgery into survivorship years after treatment, a systematic literature search was performed on patients with oral and oropharyngeal cancers. Oral cancers include cancers of the oral cavity, which is lips, buccal mucosa, floor of mouth, palate, gingiva and tongue. Oropharyngeal cancers are found at the base of tongue, tonsillar region, soft palate, uvula, and the posterior and lateral pharyngeal walls. Further, oropharyngeal cancer as a subgroup of HNC, is known to affect patients with particularly many or troublesome symptoms. [142,143] The term oropharyngeal cancer (OPC) will be used in the following as an inclusive term.

Materials

A PICOS [144] was developed as follows: Population: Patients with OPC; Interventions: primarily surgically treated; Comparator: explore the early and late psychosocial effects of treatment; Outcomes: investigate the factors that influence the effects; Study designs: quantitative and qualitative studies.
A systematic literature search was conducted in PubMed, Cinahl, and PsycInfo for published articles, by using the Boolean search operators and the search string: (Mouth Neoplasms[mh] OR "Mouth Cancer"[ti] OR "Oral Cancer"[ti]) AND (Rehabilitation[mh] OR Rehabilitation[sh] OR Rehabilitat*[ti]) AND ("Mouth Surgery"[tiab] OR Oral Surgery[mh] OR "Oral Surgery"[tiab] OR Surgery[sh]) AND (anxiety[tw] OR "body image"[tw] OR depress*[tw] OR distress*[tw] OR dysphag*[tw] OR eating[tw] OR nurs*[tw] OR pain[tw] OR psychosocial[tw] OR speech[tw] OR swallow*[tw]) AND (English[lang] OR Danish[lang] OR Dutch[lang] OR Norwegian[lang] OR Swedish[lang])
Inclusion criteria were:

1. Quantitative and qualitative articles in English published between January 2004 and January 2014
2. Patients with oropharyngeal cancers (non-HPV-induced squamous cell carcinomas)
3. Patients that were intended for surgical treatment or patients with surgery as the primary treatment modality
4. Treatment trajectory including time of diagnosis
5. Studies that investigated physical and psychosocial well-being of patients

Exclusion criteria were:

1. Patients with diagnoses other than non-HPV induced squamous cell carcinoma of the oral cavity or oropharynx
2. Patients treated only oncologically (RT or CT)
3. Articles describing surgical procedures

Data analysis

The methodologic and statistical quality of the included studies were assessed independently by AM and MJ using a 7-item criteria checklist adapted from previously published, standardized quality checklists. [145–147] Articles were assigned 1 point for each criterion that was met, for a total possible score of 7; thus, a higher total score refers to better methodologic score.

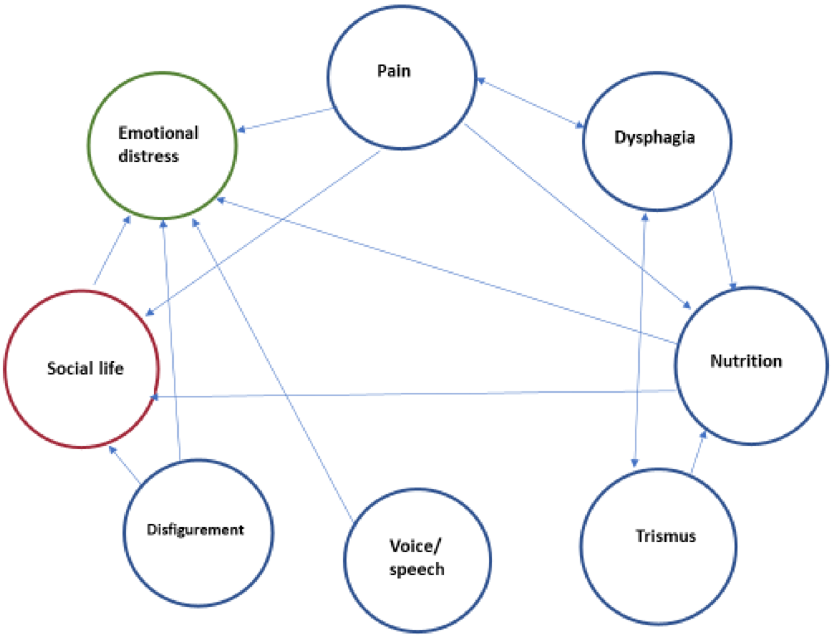
1. Sample characteristics: Well-characterized patient population with defined inclusion and exclusion criteria
2. Sample size: The sample is adequate to assess the outcomes or is appropriately justified
3. Data collection: The process of data collection is described (e.g., interviews, questionnaire)
4. Response rates: Participation and response rates are described and are above 75%
5. Outcome measurement: Standardized measurement of psychological, physical, or social functioning
6. Comparison group: Results are compared between two groups or more (i.e., patient populations)
7. Statistical analysis: The statistical analyses are adequately described, including levels of significance and/or confidence intervals, when appropriate; a general determination of the extent to which all analyses that should have been done were carried out

Results

In total, 438 articles were accessed and screened by title and abstract, of which 387 were excluded. Fifty-one studies were read in full of which 31 were excluded for not meeting the inclusion criteria, resulting in 20 articles being included (See fig. 1 PRISMA diagram of Paper 1). The study designs of the included articles were quantitative and qualitative.

Patients present with early and late physical effects, having a high symptom burden, due to many factors of influence. Further there exist an interrelatedness between the symptoms, where one or more symptoms influence each other or reinforces the effect of symptoms, such as the magnitude of physical symptoms having an effect on social life and emotional distress. See Figure 1. Interrelatedness.

Figure 1. Interrelatedness



Methodological considerations

This review used a systematic approach including a rationale for the review, a clear objective using the PICOS approach, with a systematic literature search, which is possible to reproduce, and a display of the process of selecting studies for inclusion; with an assessment of the included studies; a systematic presentation of these with a description of the included studies and their outcomes and finally a synthesis of the studies. [148]

However, some aspects of the approach could be considered. The included studies used primarily PRO's as the main outcome, except for one study and structured or semi-structured interviews. Mixing quantitative and qualitative studies can be a problem if a purely statistical synthesis is the aim. Thus, PRISMA reporting criteria were not used. Although it was not the intention of this study to use a mixed-methods systematic review, this type of approach could have been an option as it reflects the approach used in this review, since it combined the results from 16 quantitative and four qualitative studies. The Joanna Briggs Institute, [149] recommends the use of Mixed-Methods Systematic Review when combining quantitative and qualitative studies in the same review. This may be useful, as in this review, when wishing to explore effects and factors of influence in a patient group, based on patient experiences. This may bring more depth and understanding to the review question posed. [149] Using a Mixed-Methods Systematic Review approach requires a 'quantitizing' of qualitative data, [149] which also took place in this review, where qualitative studies were assigned a numerical number on the criteria checklist.

It is recommended that the quality of included studies be assessed by evaluating the risk of bias (medical or clinical). [148] However, this study did not include any comparative studies or studies with medical/clinical testing, reducing this risk. Instead a quality assessment criteria checklist was applied. This checklist was a 7-item criteria checklist adapted from similar studies, as this checklist has previously been used to quality appraise quantitative and qualitative studies in the same review. [145–147]

The synthesis of included studies could be considered, as they were very heterogenous. The aim was to include solely surgically treated patients, however the retrieved studies also included patients who had surgery as a primary modality, followed by RT or CT. This limits the possibility of generalising the treatment effects on the outcomes. Although it is known that patients with oropharyngeal cancers often have more symptoms than patients with oral cavity cancers, the two cancer groups have been grouped together in nearly all the included studies, which makes it difficult to differentiate. The original aim was to include only oral cancers, but this flaw was pointed out by the journal reviewers, and the title altered accordingly. The inclusion of oropharyngeal cancers thus, do not appear in the search string, although included in all, but one study in the review. Further, the search string did not specify the inclusion of qualitative studies, which may have limited the number of included qualitative studies. The exclusion of HPV induced oropharyngeal cancers, could pose a limitation. However, the literature search period was from 2004 to 2014, where in particular the early studies may not have differentiated between HPV-positive and HPV-negative oropharyngeal cancers. On the other hand, the possibly different effects of primary surgical treatment on HPV positive oropharyngeal cancers, as well as the influence of the demographics of this patient group may have been missed. Finally, the studies used 36 different types of measurements or tools which made it difficult to compare data.

Study II. Qualitative study (Paper 2)

Study I showed that patients treated for oral and oropharyngeal cancers have a high symptom burden and sequela and are in need for rehabilitation to alleviate those. Further, the two subgroups of HNC, especially oropharyngeal cancers, constitute those known to have the most symptoms and sequela after surgical treatment. Needs for rehabilitation should be assessed. In Dept. ORL, H&N these needs are assessed in a nursing rehabilitation consultation.

To gain insight and attain better understanding of the interactions taking place between nurse and patient in the rehabilitation consultations at Dept. ORL, H&N, an exploratory study was conducted.

Method

The study used interpretive description as described by Sally Thorne. [150] Interpretive description is an applied inductive methodological approach that draws on elements from ethnography, grounded theory and phenomenology, without being restricted by their theoretical frames. [151] Interpretive description is focused on answering questions of health care disciplines in such a way that practice will be informed and potentially changed. As we wished to explore the nurse-patient interactions in rehabilitation consultations and nurses and patients experiences of this, interpretive description was chosen as an approach in order to gain clinically applicable insight and knowledge from these experiences. The method will be described in more detail below.

Ethnographic approach

As interpretive description draws on elements from among others ethnography, this study used an ethnographic approach.

Ethnography today – as opposed to historically – is used in many different ways, and thus a specific definition of ethnography is difficult. [152] According to Hammersley and Atkinson, [152] an ethnographic study usually involves studying people in their everyday conditions, most often using participant observations or informal conversations. Data collection does not follow a structured plan, but usually starts out rather unstructured and is then built upon observations made or interviews carried out. Thus, ethnography does not use structured observation schedules and interviews will often be semi-structured to a degree where questions are not formulated – at least to begin with – but only a collection of issues to be discussed. [152] The analysis of data usually leads to generating theories and comes in a verbal form. Further, analysis is performed continually and concurrently with data collection and not only after data collection [152] without following any specific method of analysis.

An important issue in ethnography is the situating in the field of the researcher. This may be in a participant on non-participant manner, which again implies the degree of immersion in the culture or context to be studied. The researcher needs to be aware of how and how much he/she immerses in the context. There is a warning against immersing to the degree that one 'goes native', which means one behaves like or is considered an insider to the context. Therefore, doing research in your own culture or context is not recommended. [152] However, Green and Thorogood, mentions the possibility of doing research within the health field, in one's own setting. [153] This has the advantage that the researcher has a good understanding of the setting to be studied, but also poses the challenge of getting or maintaining an analytic distance to the study. [153]

Philosophical assumptions behind Interpretive Description studies

According to Thorne [150] the studies:

- Are conducted in a context as naturalistic as possible, at the same time being respectful of the participants
- Seeks applied practice insight, by attending to the value of subjective and experiential knowledge
- Benefit from those interests that are common to humans, while at the same time focusing on the individual's variances

- Reflects issues that are not bound by time and context, while at the same time being attentive to the time and context within which human expression are presented
- Human experience has socially ‘constructed’ elements that cannot be meaningfully separated from its nature
- Recognize, that in human experience ‘reality’ involves multiple constructed realities that may well at times be contradictory
- Acknowledge that the researcher and the ‘object’ of research influence each other in the production of research outcomes

These assumptions, of which many are inspired by Lincoln and Guba, [154] are the epistemological standpoint of interpretive description. Interpretive description may be carried out in many different ways but should be founded on these assumptions to be an interpretive description study, distinguishable from other qualitative studies.

Interpretive Description

As interpretive description is drawing on other types of qualitative research methodologies, it ‘borrows’ from these without being limited by their theoretical frames. This means that interpretive description may be carried out in many different ways, yet has some distinct features. [150] From the onset of the interpretive description study, the research question should be inspired by questions derived from the disciplinary area and/or needs of the disciplinary audience. It may include many different data sources of which individual and focus group interviews and participant observations are more common. [150] As in ethnography concurrent data collection and analysis takes place at least to some degree. Interpretive description uses an inductive approach to analysis, without applying any specific steps to analysis, although one may use specific analytic methodologies. Usually it will involve some elements of Constant Comparative Analysis. [155] The analysis should result in a coherent narrative, in contrast to a collection of themes and subthemes. Finally, it is important to consider implications for practice. [150]

Participants

15 patients for individual interviews; 15 patients and 4 nurses in observations and 3 nurses for one focus-group interview. The included patients had been diagnosed and treated surgically for HNC and were able to speak and understand Danish. Excluded patients had been treated surgically for thyroid or parotid cancers, Further, patients with poor or no voice quality or difficulty in articulating for individual interviews were excluded. Patients were recruited in the period between June 1, 2017 – August 31, 2018.

Data collection

The data collection consisted of observations of nursing rehabilitation consultations; individual interviews and one focus-group interview with nurses from the rehabilitation team. The data collection began with 10 observations, followed by five additional observations at a later point. Patients for observations were approached and recruited at the in-patient ward or in the OPD, shortly before the consultation was going to take place. Purposive sampling was used to obtain a broad range of experiences representative of HNC, including diagnoses, gender, age and consultation time-point. [156] Nurses had been informed and consented to participate beforehand. Observations took place at the three different time-point's mentioned earlier in the background section of this theses, with five observations at each time-point. It was expected that the observations would inform AM as the researcher about the interactions taking place during the consultation. AM also observed the preceding consultations with the surgeon, as issues for further discussion in the nurse consultation would be addressed at this time and it was important for AM to obtain this background information. Non-participant observations were chosen, as a participant approach would make it difficult to maintain a necessary distance to the interactions taking place. Contrary to most other qualitative research, including ethnography, interpretive description takes place in the clinical setting and very often in the researchers own setting or context. AM carried out the observations without wearing a uniform and positioned herself in the room, in such a way that she was away from the interaction between nurse and patient and at the same time was able to not only hear, but also see what was taking place. The content of the communication, verbal as well as non-verbal was observed. Field notes from observations was written by hand as short notes and transferred to textual data shortly after the observations. Approximately 12 hours of observations were conducted, with each observation lasting 30 to 60 minutes. After the first 10 observations had taken place, 15 individual patient interviews were carried out. Patients were recruited at the inpatient ward for interviews at all three time-points, before discharge, in order to apply with the regulations of the Danish Data Protection Agency. Purposive sampling was used as for observations to obtain a broad sample of patient experiences, including HNC diagnoses, gender and age. [156] The purpose of the individual interviews was to explore the patient's experiences of the nursing consultations. Observations and interviews give different information about a situation or setting, as what people do and say may not always correspond fully. [152,153] According to interpretive description (and ethnography), data collection and analysis is carried out concurrently. Thus, the semi-structured interview guide used for the interviews was based on background literature [157–160] as well as information gained from the first 10 observations (see Appendix 6 'Interview guides' and Appendix 7 'Preliminary analysis of observations'). The interviews took place just after the rehabilitation consultation with five each at the three time-point's mentioned earlier. Patients in the observations and for interviews were not the same. The interviews lasted between 15–25 minutes. After the first four individual interviews a focus group interview with three out of four nurses in the rehabilitation team took place. The nurses had been approached and recruited at their office at the inpatient ward. Ideally the numbers in the group should be slightly larger, but the team only consisted of four nurses. Focus groups were chosen, as this gives the participants an opportunity to discuss their experiential knowledge about a phenomenon, [150] in this case their shared experience of conducting nursing rehabilitation consultation with HNC patients. When focus group interview participants interact with each other they share and perhaps come to understand each other's perspectives, [150] as they discuss and share experiences based on a common context. [161] As the purpose of an focus group interview is to explore the shared experiences of the group, the approach should be quite different to an individual interview. [161] The interview guide was again based on background literature, [157,158,162,163] and information gained from the first observations and individual interviews. Further, the interview guide was made to enhance and facilitate group discussions and interaction, [150] see Appendix 6: Interview guides. To facilitate discussion a number of prompt cards, [164] were developed and used in addition to the interview guide. The prompt cards were derived from the PCI and described four needs areas: physical, mental, social and existential. Each of the focus group interview participants were provided with a set of prompt cards (see Appendix 6 'Interview guides'). AM functioned as the facilitator who guided the discussion points and use of prompt cards, but otherwise interfered as little as possible, [150,165] A colleague, a clinical nurse specialist, assisted as moderator and had been given oral and written instructions on her role beforehand. [161] The focus group interview lasted one hour.

Data analysis and interpretation

Individual and focus group interviews were transcribed by AM into textual data in Word. Notes from observations were converted into textual data in Word as well. In total the transcribed data constituted 191 pages. Doing the transcription in person gives a good impression of the data. Data was analysed across the three data sources and was inspired by interpretive description [150] and Systematic Text Condensation by Malterud. [166] Although interpretive description does not make use of any specific data analysis method, one may borrow analytic approaches and techniques, though preferably an interpretive approach.[150] Systematic Text Condensation and interpretive description have several approaches in common, as Systematic Text Condensation and interpretive description encourages analysis concurrently with data collection, as well as both being inductive, iterative and interpretive. [150,156] Further, Systematic Text Condensation is a pragmatic approach to thematic analysis across data and may be used in individual as well as focus group interviews and also observations. [166]

Systematic Text Condensation takes place through four stages: 1) total impression – from chaos to themes; 2) identifying and sorting meaning units – from themes to codes; 3) condensation – from code to meaning; 4) synthesizing – from condensation to descriptions and concepts.

According to Step 1, all the transcribed text was read and reread several times. Having transcribed all the text gave a further impression and overall overview of all the data. Then as a second part of Step 1, several preliminary themes were developed from the read text. In Step 2, meaning units are identified in the transcribed text. Meaning units are fragments of text, that relates to the research question. A code was then attached to each meaning unit. A code labels the meaning units and helps group meaning units together in code groups. The coding was done using Nvivo 11. [167] From the code groups new condensates were developed in Step 3. Condensates are meaning units in a code group, made into one new text. The text condensates the units and creates a new artificial quote grouping together all the expression from the meaning units. Finally, in Step 4, the condensates are developed into descriptions and concepts, ending out in a number of themes. Throughout the analysis AM and MJ discussed the contents of each step in the analysis. Discussing the analysis with others creates a wider analytic space. [166] Although Systematic Text Condensation is based on Giorgi's psychological phenomenological analysis, it is not so much a theoretically based method as a procedure. [166] Systematic Text Condensation was in this study used as a procedure to aid the analysis of a very large amount of data, but it is also important to remember this is an interpretive description study. As such many different approaches and methods for analysis may be used as mentioned earlier, while one should be cautious about ending out with a number of themes and categories. In Interpretive Description the coherent narrative reflecting the original research question constitute the findings, (see Appendix 8 'Audit trail analysis')

Findings

The analysis revealed that conducting nursing rehabilitation conversations where patients with HNC are actively involved is a complex and challenging process. The three interrelated themes that constitutes the findings reflect this complexity. They were, The challenges of building rapport; Barriers to adequately identifying rehabilitation needs; and Factors inhibiting communication of advice and recommendations.

The challenges of building rapport: The nurses felt unsure on how to start the consultation, build rapport with the patient and cause the patient to feel confident with the interaction. The nurses tried to involve the patients in the consultation, but it ended up becoming a barrier to building rapport. Their attempt at involvement was by inviting patients to ask question, but they did not do so. Patients said they wished to but did not know what to ask.

Barriers to adequately identifying rehabilitation needs: One of the nurses' goals, was involving the patient, but they may have hindered this by their own preparation for the consultation. They prepared a list of needs to be addressed from their professional point of view and thus took charge of identifying the needs of the patient. They tried to confirm the needs on their list by asking patients probing questions, but some patients were put off by this approach. Nurses primarily uncovered physical and functional needs, while psychological and existential needs were not uncovered nearly as often and were more difficult for nurses to discuss with patients.

Factors inhibiting communication of advice and recommendation: Mainly at discharge many patients received a lot of information about different aspects of their follow-up care, like health and safety measures when discharged; contact information; referrals; symptom- and self-management. A majority of patients found the amount of written information to be in excess. They were unable to process the amount of verbal information and incapable of making use of the written information.

Methodological considerations

As this study used Interpretive Description, the methodological considerations will be based on this. Interpretive Description typically apply the following criteria to the evaluation of a study: Epistemological Integrity; Representative Credibility; Analytic Logic and Interpretive Authority. In the following each criterion will be reviewed in relation to this study.

Epistemological Integrity is the line of reason throughout the study. Does the method, the rules of the method, the research question, the interpretation of data and the strategies for this follow this line. The epistemological standpoint of interpretive description is based on the philosophical assumptions mentioned earlier in this chapter. It is believed that this study followed this line of reason, making up an interpretive description study, [151] as the source or basis of the research question was derived from the context of nursing rehabilitation consultations at AM's department. [150] The research question related to nurses and patients experiences and therefore interpretive description was chosen as a method in order to get clinically applicable knowledge about these. [150] The study used triangulation of data collection to obtain broad perspectives of experiences and data and analysis was conducted partly concurrently in order that the different perspectives from different types of data collection could inform each other. [150] Finally, data was analysed using Systematic Text Condensation and findings formulated in a wider narrative, with suggestion for nursing implications.

Representative credibility concerns the way the data sources were sampled and whether triangulation of these sources took place. In the following not only the data collection and sampling of each data source will be mentioned, but also the main considerations for using these sources. The study followed a timeline, where data collections started out with 10 observations. The purpose of the observations was to gain understanding of the interactions taking place between nurse and patient during the consultations. According to ethnographic method there was no structured observation schedule, [152] but focused on the interactions taking place between the nurse and patient, which topics were discussed, who initiated the discussion, and the verbal and nonverbal reactions to these topics. Short field notes were taken during observations and transferred to Word later the same day. Observations made one day informed further observations or specific issues to explore during following observations. After each observation, short ad hoc interviews with patients and nurses took place to expand on actions or discussion taking place during the observation. AM wore private clothing in order to signal a researcher and not nursing role during observations; placed herself away from the interaction, yet close enough to see and hear the interactions taking place. The observations took place in AM's own department and caution was taken at the time of data collection on this background (see data collection paragraph of this study II). It is further important to be aware of how one observes these consultations depending on previous experience as a nurse. To which degree does one take aspects of the consultation for granted and therefore do not enquire or become curious about what is going on. [150] As mentioned in the above data collection paragraph, AM had no experience of this particular type of nursing consultations which were a fairly new form of consultation in the clinic at the time of data collection and thus was quite curious about and open-minded to the actions taking place during the consultations. The 15 observations were purposively sampled in order to represent a broad base of the population of patients with HNC participating in these consultations, as to gender, age and diagnosis and the patients were identified by a project nurse, before being approached by AM for recruitment. The observations were followed by individual semi-structured interviews. Semi-structured interviews are more structured than in-depth or ethnographic interviews, which may be based on very few opening questions, from which the interview develops. [152,153] The semi-structured interview sets the agenda of the interview, but with the view of probing answers given by the interviewee. [153] The questions should be open-ended, to obtain as much information as possible, [153] but may at times be more closed, in order to obtain specific information. [153] The interview guide for this study, was based on background literature and informed by the observations (see appendix 7 'Preliminary analysis of observations'). [150,152] Further, the guide contained open-ended opening questions, with more closed questions for exploration of certain issues. Further, it is important that questions are expressed in a way which is understandable to the interviewee. [153] For this reason, the interview guide was tested on a few working-class men and afterwards altered. The interview guide then existed in two versions and which version was used depended on the background of and interaction with the interviewee. Again, the matter of context was very important. In order to signal a researcher and not nursing role in the interview, AM again wore private clothing and introduced herself as a researcher. Thorne [150] notices that the qualitative health care interview may be constrained by the busyness of the health care system. [150] This too posed a problem in this study, as the duration of the interviews were quite short. This was mainly due to patients wanting to leave the department before too long. By the time the interviews at time-point 2 and 3 took place, patients had been through a doctor's consultation, followed by the nursing consultation and possible follow up to both or waiting time before and between consultations. Some were beginning to get tired at this time-point and others were eager to catch patient transport back home, since many patients come from afar. The sampling followed the same method as for observations, but recruitment was a challenge, as patients were identified by a project nurse and following this AM invited the identified patients to participate in the interviews. As a researcher is not allowed to contact a patient directly according to regulations by the Danish Data Protection Agency, all patients had to be recruited before discharge – also for time-point 2 and time-point 3. Some patients declined participation at time-point 3, when the day of interview occurred two months after recruitment. After approximately two months of interviewing, the focus group interview took place. The purpose of an focus group interview is different from individual interviews, as the group members engage with each other as individuals, but around a common phenomenon. [150] In this case the nurses' experiences of conducting nursing consultations and interaction with patients was the common phenomenon. The aim was to get the group to interact with each other. [150] AM functioned as the facilitator, as recommended [150,165] and tried not to influence the interaction, but facilitated the discussion among the group members and ensured the topic was adhered to. [161] The group was informed of the purpose of the discussions from the beginning [161] and guided through the discussion by being introduced to and using prompt cards (see data collection paragraph). Finally, a moderator took part in the focus group interview. This role could have been handled by the facilitator, but having a moderator supported AM in the facilitating role and enabled her to focus on the discussion and interaction of the group. The moderator watched the time, took field notes of the interaction and ensured a debriefing of the group at the end of the focus group interview. [161] Recruitment and sampling posed a problem as an focus group interview with only three participants was a bit small in number, since around 6 – 12 is considered the number which is recommended, [161] to gain enough participation and discussion from all participants. Although the group was small, the nurses knew each other fairly well. When participants in an focus group interview are coming from the same background, they can expand on each other's perspectives. [161] Thus, this focus group interview also gave the nurses an opportunity to reflect together on many issues of their daily practice as rehabilitation nurses not previously discussed by the them. Finally, a strength of the study was the use of triangulation with data from three different sources. [150] The very large amount of data was a challenge, but on the other hand it gave a good possibility to shed light on the nurse-patient interaction in the rehabilitation consultations, as both nurses and patients views were explored as well as the actual interactions were observed.

Analytic logic describes how this is applied through the study and incorporate the use of an audit trail. [151] An audit trail describes how data is collected, analysed and interpreted. [168] As an audit trail on all data of this study would be too voluminous, an audit trail of the analysis of two subthemes and their merger into a final theme has been provided, to give insight into the process (Appendix 8), as well as the audit trail of the preliminary analysis of the first ten observations (Appendix 7). One challenge to data analysis had to do with the duration of the individual interviews of which some were quite short. This does not give the broad or in-depth perspective of the patients experience as preferable.

In this study Systematic Text Condensation was applied for analysis and as mentioned earlier in the methods section of this chapter, Systematic Text Condensation provides a pragmatic approach for an inductive, iterative and interpretive analysis across data. [156] To increase reliability in the process the analysis should preferably take place in cooperation with others. [153] In this study the coding, emergent and final themes were discussed with MJ.

Interpretive authority shows that the interpretations made are trustworthy, [151] meaning they are authentic and truthful and is about the degree of trust one may have in the findings of the study. [168] This may be achieved through a reflexive account of how the study was conducted.[150]

Several aspects of how the study was conducted is mentioned above, such as the rigour applied from conception of the study to the final results. Aspects mentioned already, as well as others will be mentioned in the following.

The research question was in accordance with Interpretive Description and sampling aimed at being representative for patients with HNC participating in a nursing rehabilitation consultation. The method applied triangulation of the data sources, including observations of the nurse-patient interactions during the rehabilitation consultations; individual interviews incorporating the patient perspective and a focus group interview incorporating the nurse perspective on the nurse-patient interaction. Individual interviews were conducted primarily by AM, as well as the focus group interview. All interviews were transcribed by AM, which gave a good insight into the data during the process. The analysis used an acknowledged method including an inductive, iterative and interpretive approach. All data was analysed across the three data sources and the actual coding as well as the thematizing was performed by two researchers, who discussed the steps of the analytic process, as it went along.

Reflexivity

When doing qualitative research, it is unavoidable to influence the data, whether they be interviews or field notes. [156] Davies [169] points out the importance of attempting to control this influence by being reflective of one's own effect on data and thus aim at ensuring objectivity. Malterud [156], further writes that this practically means to be aware of one's own role in the research setting; consider how one may influence on data and the significance of this when it comes to interpretation and conclusions.

One important way of aiming for objectivity is being aware of one's own preconceptions and the interpretation of data. Gadamer [170], argues that we are all situated in historical and individual conditions which influence our conception of the world around us. It is thus very important to be aware of one's preconceptions before entering the field or setting or before interpreting the data, as the preconceptions may influence these.

A point of discussion in qualitative research is whether it is recommendable to do research in familiar settings. In ethnography this is traditionally avoided (see methods section). Malterud [156] writes that doing research in own settings contains the risk of 'field blindness' meaning that one is unable to see beyond the familiar. On the other hand, she mentions the advantage of researching in a field, where one has an understanding for many phenomena, not as easily grasped for someone outside the same setting. Thorne [150] also mentions the benefits of doing research in one's own setting, but cautions about taking care when situating oneself in the setting. It is important not to get clinically involved in the situation observed.

As I (AM) carried out the research in my own department, where I had been employed as a clinical nurse specialist for more than 10 years, this was very important. My job as a clinical nurse specialist consisted for a major part in initiating, conducting and implementing research – and development activities, but without direct patient contact. In this capacity I had been responsible for implementing the rehabilitation consultations, without participating in actual consultations or other patient contact. During all observations and interviews I wore private clothing, to signal my researcher role. However, as hospital regulations require that all staff, whether wearing a uniform or private clothing, should always wear a name-badge (coloured according to profession), this may very well have reminded the patients that I was a nurse. I was further very aware of my own preconceptions in regard to how rehabilitation consultations were conducted. At the time I had no actual experience in conducting rehabilitation consultations as already mentioned, but previous experience with patients with HNC and a vast – mainly theoretical - background knowledge on rehabilitation of patients with HNC and needs assessments.

Study III. Randomized controlled trial (Paper 3)

Study I showed that patients treated for oral and oropharyngeal cancers have a high symptom burden and sequela and are in need for rehabilitation to alleviate those. Study II explored the interactions between nurse and patients in a nursing rehabilitation consultation assessing the needs of patients with HNC for rehabilitation. The study showed that nurses are using a systematic questioning approach when assessing needs; are challenged when assessing emotional and existential needs; and further takes charge of the interaction taking place during the consultation.

In order to investigate whether the application of an HNC specific needs assessment tool covering physical, emotional, social and existential aspects would improve HRQoL when compared to standard care, reduce the symptom burden and increase the number of referrals to multi-disciplinary follow-up, a randomised controlled study was conducted, as a randomised controlled study can show if an intervention has an effect on an outcome. [171]

Methods

The study was a randomised controlled study with a control group (CG) receiving standard care and an intervention group (IG) receiving interventional care. CG received the standard care postoperatively consisting of three rehabilitation needs assessment consultations. The consultations were delivered by a staff nurse on the rehabilitation team and did not make use of a needs assessment tool. Consultations took place prior to discharge (time-point 1), 7–10 days after discharge (time-point 2), and approximately two months post-surgery (time-point 3). Consultations at time-point 1 took place in the bed ward while consultations at time-point 2 and 3, took place in the OPD immediately after an appointment with the surgeon. The standard care is described in more detail in the background under the sections 'Danish Head and Neck Cancer follow-up care' and 'Study Context'. IG received interventional care consisting of three nursing rehabilitation consultations which took place at the same three time-point's and places as for CG. The nursing rehabilitation consultation followed a certain sequence aimed at enhancing Patient Involvement and made use of an needs assessment HRQoL PRO and concerns tool. The intervention will be described in more detail below.

Intervention

Nursing rehabilitation consultation

The rehabilitation consultation followed the guidelines of the Danish Health Authority, [67] which requires all patients to have their needs assessed for rehabilitation post-treatment relating to physical, functional, emotional, social and existential needs. [67] The assessment should be based on the individual patient's needs and be made in cooperation with the patient. [67] In order to ensure this, a certain sequence for the consultation was followed, inspired by Smith's Patient Centered Interviewing. [172] This meant that the nurse consultation was carried out in 7 steps:

1. Welcome the patient and set the stage for the consultation
2. Inform the patient of the purpose of the consultation and the time frame
3. Introduce the patient to UW-QoL and PCI and guide in the use of these
4. Starting with the symptoms and concerns the patient has highlighted in the UW-QoL and PCI, the consultation will be based on these. If the patient has highlighted a large number of issues, negotiate the list to find out which issues are most important to discuss
5. Follow up on the patient's symptoms, concerns and emotional reactions or problems from a professional point of view
6. Accompany and support the patient during the appointment with the surgeon and in cooperation with the patient and the surgeon and ensure that problems and issues arising from the nurse consultation needing medical attention, as well as issues the patient wish to discuss with the surgeon, are focused on
7. Continue the consultation after the appointment with the surgeon; discuss needs and topics the patient wishes to talk about and give advice. Depending on the severity of needs and the patient's preferences, it is decided in collaboration with the patient, if a referral to multi-disciplinary team members is needed. Written information and advice based on the discussion in the consultation are offered to the patient. The patient decides which information they wish to take with them (See Figure 1 Flow for nursing consultations of Paper 3)

Needs assessment using University of Washington Quality of Life and Patient Concerns Inventory

At the Dept. ORL, H&N it has previously been attempted to make use of the recommended needs assessment tool provided by the Capital Region of Denmark. This tool is however generic, and some patients and staff thus found it difficult to use.

The intervention applied the UW-QoL and PCI as needs assessment tools. They are both HNC specific tools and accessed on an iPad. (See Appendix 9 'Examples of items on UW-QoL and PCI')

UW-QoLv4 consist of 14 domains; a QoL rating and an Importance Rating. [103,140] It is brief, easy to fill in for most patients, HNC specific and does not require input from health care professional's. [140] The UW-QoL gives an output which also helps the health care professional to discover any symptoms or unmet needs, which could otherwise be missed. [173] The PCI is a 56-item symptoms and concerns prompt list. [99,141] It is filled in by the patient independently of the health care professional and allows the patient to choose which items they wish to discuss with the doctor, nurse or other health care professional at a consultation. [99] Apart from the items of concern or for discussion, patients can also choose between professionals they wish to talk to or be referred to. In the English version of the PCI this consists of 18 professionals and in the Danish version 21 professionals or persons.

Preparation

Before commencement of the study and the intervention, further preparations took place. The UW-QoL and PCI were validated in Danish and an evidence-based management manual for addressing issues in the nursing consultation was developed. Finally, a patient information leaflet was written with information for patients on how to access help and information. These will be described in more detail below.

Research nurses, who conducted nursing consultations were instructed in how the consultations should be carried out, as well as the functions of the UW-QoL and PCI on iPad and the contents of the management manual and patient information leaflet.

Linguistic validation of UW-QoL and PCI

The UW-QoL and PCI were both validated in Danish. The validation process followed the guidelines of the EORTC for cross-cultural adaptation of QoL questionnaires, [174] with two forward translators and two backwards translators. An expert panel consisting of doctors and nurses from Dept. ORL, H&N assisted in assuring a correct translation of HNC specific items as well as suggestions for relevant professionals, which are not the same in Denmark as in the United Kingdom. Finally, the translation was tested and refined in two steps with patients with HNC. For an in-depth report on the translation procedure please see Appendix 5 'Report on translation of University of Washington Quality of Life Questionnaire and Patient Concerns Inventory'. Finally, the Danish versions were transferred to an IT-solution for access via iPad. The solution was approved by the Centre for IT, Medical Technology and Telephony Services of Capital Region of Denmark who required that the actual programming was done by a private company, in this case l-r software a/s.

Management manual

In order to enhance and qualify the discussions with patients based on the results of UW-QoL and PCI an evidence-based management manual was developed. The manual covered in total 58 areas addressing each of the possible results of UW-QoL and choices to be made on PCI and was divided into physical (33), psychological (16), social (7) and existential/spiritual (2) areas. The evidence was based on the existing literature, including guidelines, as well as regional and local guidelines and regulations pertaining to referrals for multi-professional follow-up. The manual provided guidance on discussing issues of need with the patient, assessing the severity of needs, and when patient might benefit from a referral to multi-disciplinary follow-up, see Appendix 10: Management manual.

Patient information leaflet

One of the findings in Study II showed that patients were overwhelmed by the amount of information they received both orally and written. In order to lower the amount of information and at the same time assure that the necessary information was passed on to the patient, an information leaflet was developed, containing the most important information. The leaflet included information on how to access support from psychologist or counsellor with special knowledge on cancer; dentist (if teeth have been removed due to treatment); smoking cessation and alcohol reduction/cessation, priest; imam or other religious support and the Danish Cancer Society. These items were chosen as they contained information on accessing support outside the hospital, where a referral is not possible, due to the set-up of the Danish healthcare system. (See Appendix 11 ‘Patient information leaflet’.

Participants

Of 244 eligible patients 92 were included. 44 were allocated for IG and 48 for CG. Those included had been diagnosed and treated surgically for HNC within the last few days and were able to speak, understand and read Danish. Patients were excluded if they had been surgically treated for thyroid or parotid cancers or were expected to be referred to adjuvant chemoradiotherapy as they would then leave the department for further treatment elsewhere. Patients with cognitive impairment or unstable psychiatric illness were also excluded.

Data collection

Patient were recruited into the study during the period between June 1, 2018 and August 31, 2019.
All data was collected and/or stored using REDCap, which is a web-based application for managing databases. [175]

Randomisation

Patients were randomized after having provided baseline information, including replying to baseline questionnaires. Following this they were randomized using REDCap which has a randomization module.

[175] They were randomly assigned 1:1 to either CG or IG, and stratified according to being newly diagnosed and recurrences, as well as ASA classification [176] since ASA classification is performed by the anaesthesiologist preoperative and gives an indication of the patients comorbidity. Finally, block randomization was applied. The assignments were not blinded to either investigator or patients, but the statistician was blinded to treatment allocation. The REDCap module was created by the statistician and the actual randomization activated by AM or one of the research nurses, who obtained the baseline information from the patient.

Variables

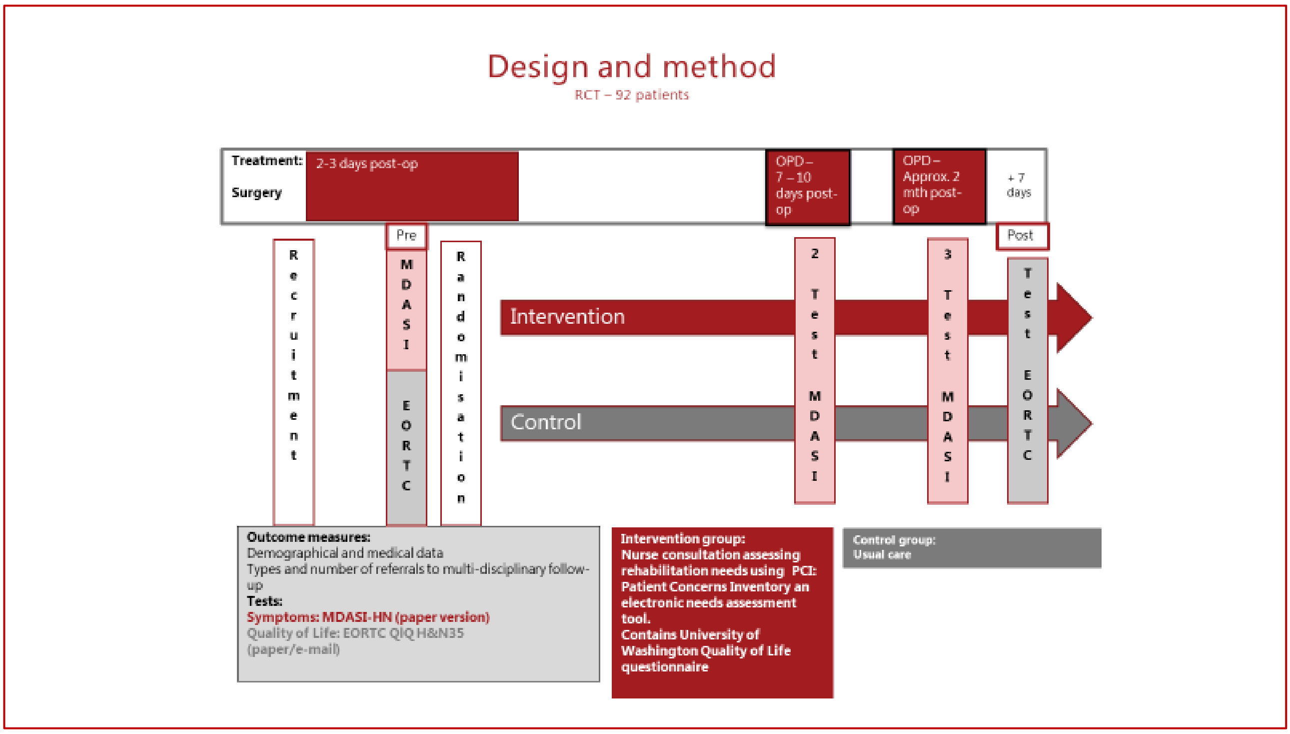
In order to assess the HRQoL, we used EORTC QLQ, for the primary outcome measuring GHS and QoL. The GHS/QoL scale consists of two items rating the overall health and overall quality of life. In order to measure HNC cancer specific symptoms we used EORTC QLQ–H&N35. [177] The core questionnaire EORTC QLQ has 30 items and includes five functional scales (Physical, Role, Emotional, Cognitive and Social) and nine symptom scales (Fatigue, Nausea and vomiting, Pain, Dyspnoea, Insomnia, Appetite loss, Constipation, Diarrhoea and Financial difficulties). H&N35 is a 35-item questionnaire to be used with EORTC QLQ. H&N35 includes 18 symptom scales (Pain, Swallowing, Senses, Speech, Social eating, Social contact, Less sexuality, Teeth, Opening mouth, Dry mouth, Sticky saliva, Coughing, Felt ill, Pain killers, Nutritional supplements, Feeding tube, Weight loss, Weight gain). Each item is rated on a four-point scale, except for the last five items on H&N35, which are binary. The scales range from 0–100, where a high score on functional scales indicates high functioning and a high score on symptom scales indicates a high symptom burden. When measuring changes over time, it is suggested that changes of 5–10 means little change; 10–20 moderate change; and more than 20 very much change, with changes above 10 being clinically relevant. [178] EORTC QLQ–H&N35 was completed at two time-points: baseline (before randomization) and seven days after the two-month post-treatment appointment. Completion at baseline was done on paper and at the post-treatment appointment, either electronically through email and link generated by REDCap or a letter by regular mail. Patients rated their scores based on the past seven days, (see Appendix 12 'Questionnaires').

In order to further assess symptom prevalence and severity, the MDASI–HN questionnaire was used as a secondary outcome. MDASI-HN, [179] is a multi-symptom PRO measure for clinical and research use. The MDASI–HN module consist of a 28-item questionnaire measuring symptoms and their severity in patients with HNC with 13 Core symptoms (Pain, Fatigue, Nausea, Disturbed sleep, Being distressed, Shortness of breath, Difficulty remembering, Lack of appetite, Drowsy (sleepy), Dry mouth, Sadness, Sadness, Numbness/tingling) 9 Head and Neck symptom (Problems with mucus in the mouth/throat, Difficulty swallowing/chewing, Coughing/ choking, Difficulty with voice/speech, Skin pain/burning/rash, Constipation, Problems with tasting food, mouth/throat sores, Problems with teeth or gums) and 6 Interference symptoms (Activity, Mood, Work, Relations with others, Walking, Enjoyment of life). The

MDASI-HN uses a numerical rating scale from 0–10, wherein 0 means a symptom is not present and 10 means as bad as imaginable. Scores between 1–4 are considered mild; 5–6 moderate, and 7–10 severe. [180] When measuring changes over time, a minimum important difference (MID) is 0.98–1.21. [179] MDASI–HN was completed at three TP: baseline (before randomization), 7 – 10 days post-operative and at the two-month post-treatment appointment. Patients rated their scores based on the past 24 hours. MDASI-HN was completed on paper, (see Appendix 12 ‘Questionnaires’).

The completed questionnaires EORTC QLQ-H&N35 and MDASI-HN on paper were entered into REDCap by a student assistant. AM had beforehand instructed the student assistant on the needed meticulousness in the task.

Other secondary outcomes were the types and number of multi-disciplinary referrals which were registered at three time-point: before discharge, 7–10 days and two months post-treatment. Demographic and medical data and comorbidity using the Charlson Comorbidity Index [181] were registered at baseline. For IG, the UW-QoL scores are scaled from 0 – 100, where 0 is the worst possible score and 100 the best possible. The outcomes and items chosen on the PCI and UW-QoL were registered before discharge, 7 – 10 days and two months post-treatment. See Figure 2. Test times.



Data analysis and interpretation

Statistical analysis

Sample size justification was based on results from studies with similar groups of patients reporting a standard deviation (SD) of size 20 on within-group changes of QoL on EORTC QLQ. [182] A between-group difference of 15 for changes from baseline to post-intervention was considered clinically relevant. Based on a two-sample t-test, we found that 29 patients in each group were required to obtain a power of 0.80. To account for an expected dropout of 20%, it was decided to include at least 72 patients. Descriptive statistics was used to describe the demographics and baseline characteristics of the two groups. For numerical variables, mean and range are reported, and for categorical variables, numbers and percentages. For EORTC QLQ-H&N35 and MDASI–HN mean, SD, and the number of data available at each assessment time are presented for both groups. A linear mixed model was used with treatment, assessment time, and their interaction as fixed effects, and subject as random effect for estimation of within-group changes and for between-group comparison of changes. The Wald test was used to test the hypothesis that within-group changes or between-group differences equal zero. For binary outcomes from H&N35, estimated prevalence and standard error for each combination of assessment time and treatment group are reported. McNemar's test was used to test for within-group changes over time of paired binary outcomes. P-values <0.05 were reported as statistically significant, but they must be interpreted with care. Due to many secondary outcomes, the risk of reporting false positive results is high; hence, this should be regarded as an exploratory analysis. The types and number of referrals were reported for each group at each assessment time. For IG, UW-QoL scores are reported as means, SD, and percentage reporting best scores. In addition, the numbers and percentages of patients indicating a significant problem along with a 95 % confidence interval are reported, and median and inter-quartile ranges (IQR) for the composite scores of Physical Function and Social Function are presented. For the PCI, the percentage of items chosen were calculated at each assessment time and reported. All statistical analyses were carried out using R. [183]

Results

Of the 244 eligible patients, 92 were included. 64 patients were excluded for not meeting inclusion criteria, 32 were unreachable for inclusion and 56 declined to participate. Patients were randomly allocated to CG (n=48), 13 of whom withdrew or were excluded, and IG (n=44), 14 of whom withdrew or were excluded. In total 15 patients were excluded. Seven from CG and eight from IG, who were referred to oncologic treatment according to Danish guidelines, [56,57] leaving 12 patients (six in each group) who dropped out during the study. A drop-out analysis has been performed according to the following baseline demographic and medical characteristics: gender; age; living alone or cohabiting; educational level and comorbidity level. Only for the following two characteristic the patients who dropped out showed a difference compared to the patients who remained in the study: they were slightly older with the mean age among drop-out 71,6 years, compared to mean age 64,6 years among included patients. Further, more patients among those who dropped out were cohabiting, than among included patient. The primary outcome GHS/QoL measured by EORTC QLQ, showed no statistically significant difference between within-group change. However, both groups showed statistically significant improvements over time. There was a drop in response rate to EORTC QlQ and H&N35, post-time of 6 (17 %) for CG and 3 (10 %) for IG.

For secondary outcomes, the symptom burden, was measured on MDASI-HN. There were no significant differences between groups in symptom prevalence and severity, but significant improvements over time were observed in many areas in both groups. The response rate to MDASI–HN dropped by 2 (6%) in CG and 2 (7%) for IG at post-treatment assessment. When looking at MDASI-HN measured at time-point 2 (not included in Paper 3) both groups were doing the worst at baseline and improving at time-point 2 and further at time-point 3 in the following areas: pain, fatigue/tiredness, drowsy (sleepy), disturbed sleep, difficulty with swallowing/chewing, activity and work. There were only minor differences between the groups.

See Figure 3: MDASI-HN Core symptoms; Head and Neck symptoms and Interference symptoms.

There was a notable difference between groups regarding referrals in the emotional area, where more IG patients were advised to contact a psychologist than in CG.

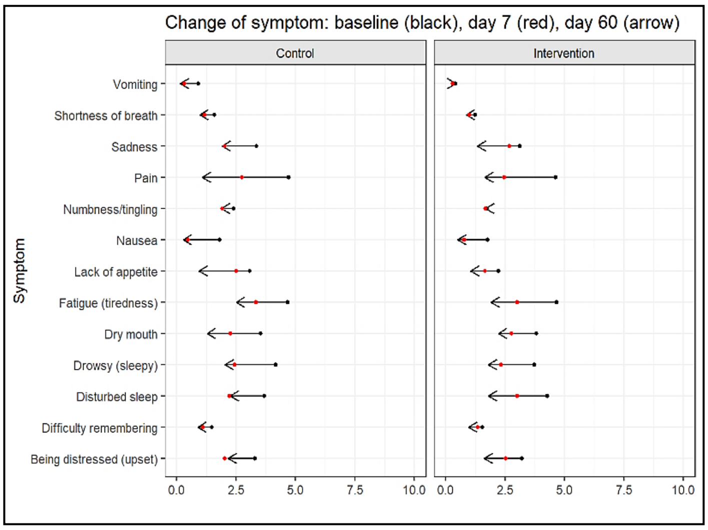
UW-QoL and PCI was used at time-point 1 by 43, time-point 2 by 36, and time-point 3 by 26. No patients declined to use UW-QoL and PCI at any time-point, but data for four patients were lost to follow-up due to IT-problems at time-point 3.

The most frequently chosen subjects on the PCI were in the functional, emotional and existential areas. UW-QoL results (not presented in Paper 3) showed that scores improved for all domains over time, except for Fear of Cancer Recurrence, which has a minor drop at time-point 2. Considering the percentage reporting best scores there were also improvements over time, however for the domains Recreation, Speech, Shoulder, Taste, Saliva and Fear of Cancer Recurrence the percentage dropped between 4 - 22 during the time-period of time-point 1 and time-point 2. The proportion reporting significant problems at time-point 1 were highest in the domains Pain, Swallowing, Chewing and Anxiety. At time-point 2 they were Pain, Swallowing, Chewing, Speech and Anxiety. The overall median scores for Psychical Functioning were 65 (IQR 53.3 - 83.3) and for Social Functioning 70 (IQR 55 - 82.9) at time-point 1; for time-point 2, Physical Functioning median 72.9 (IQR 57.1 - 83.8) and Social Functioning median 75.4 (IQR 69.0 - 83.3) and for time-point 3, Physical Functioning median 90.4 (IQR 74.6 - 95.6) and Social Functioning median 86.7 (IQR 79.8 - 91.5).

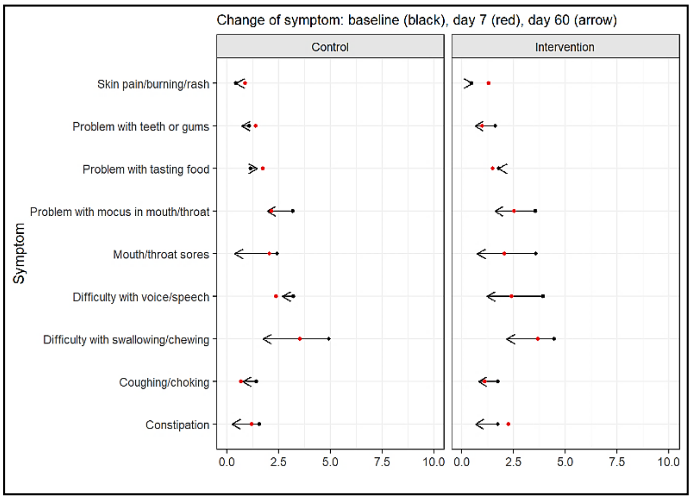
See Table 1. University of Washington Quality of Life questionnaire scores, Table 2. University of Washington Quality of Life questionnaire – Significant problem
and Figure 4. UW-QoL Physical and Social Function.

Figure 3. MDASI-HN Core symptoms; Head and Neck symptoms and Interference symptoms

Core symptoms



Head and Neck Symptoms



Interference symptoms

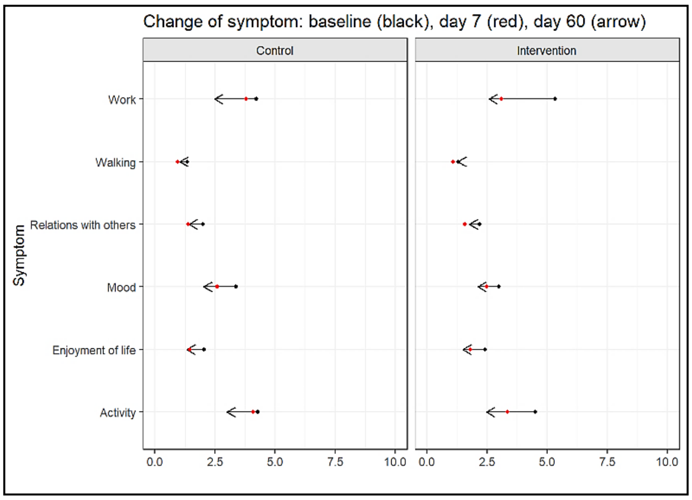


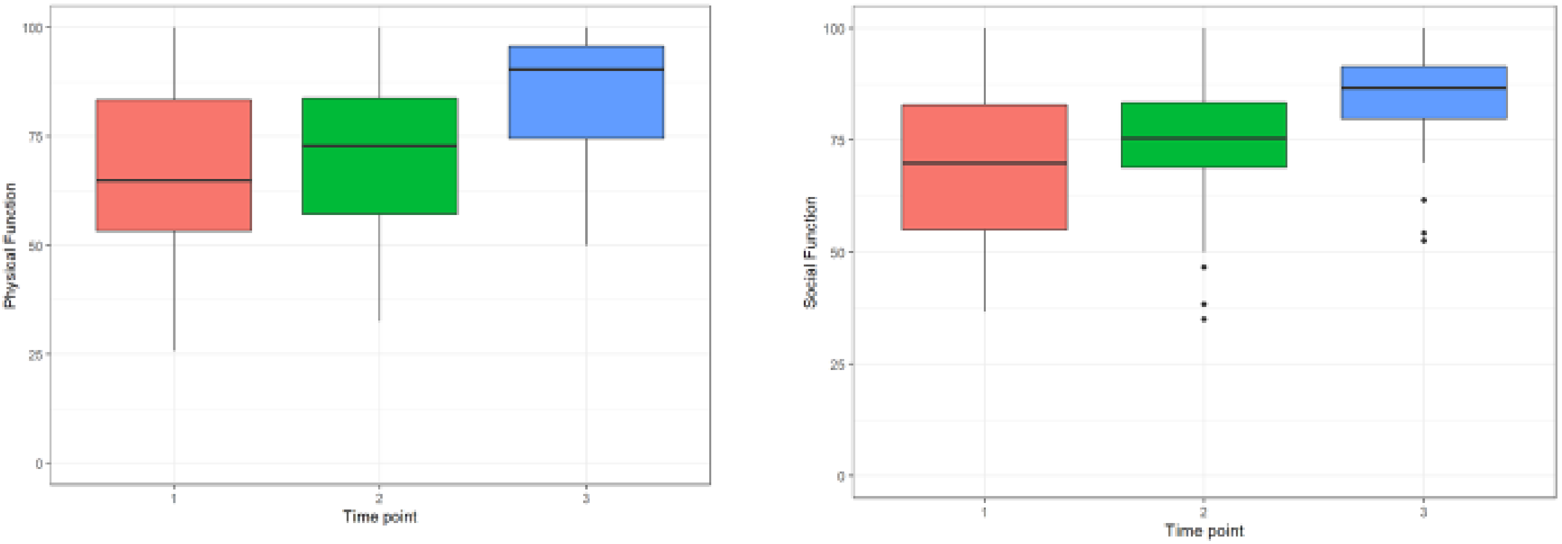
Table 1. University of Washington Quality of Life questionnaire scores

	n	Before discharge (TP1)		n	7 - 10 days post-operative (TP2)		n	2 months post-operative (TP3)	
Score		Mean (SD)	% best score		Mean (SD)	% best score		Mean (SD)	% best score
Pain	43	56.4 (24.5)	19	36	63.2 (30.2)	31	26	86.5 (19.0)	58
Appearance	43	79.7 (14.7)	28	36	81.2 (13.9)	31	26	85.6 (21.4)	54
Activity	43	59.9 (32.8)	28	36	67.4 (22.2)	22	26	77.9 (32.8)	42
Recreation	43	62.8 (32.4)	30	36	70.1 (22.2)	19	26	82.7 (25.3)	62
Swallowing	43	57.2 (34.7)	33	36	75.0 (29.1)	44	26	88.1 (22.5)	69
Chewing	43	54.7 (40.6)	37	36	62.5 (32.5)	36	26	92.3 (18.4)	85
Speech	43	74.2 (31.8	44	36	68.6 (32.8)	36	26	83.1 (21.3)	54
Shoulder	43	94.9 (17.2)	88	36	91.9 (21.5)	83	26	94.2 (12.1)	81
Taste	43	73.3 (36.8)	56	36	74.2 (30.8)	44	26	80.0 (31.5)	62
Saliva	43	62.2 (44.8)	51	36	63.9 (42.4)	50	26	78.8 (33.7)	58
Mood	43	69.2 (24.3)	23	36	74.3 (24.3)	31	26	81.7 (20.7)	46
Anxiety	43	70.2 (27.2)	30	36	70.6 (30.6)	36	26	81.2 (18.2)	42
Intimacy	43	91.6 (19.6)	81	36	95.8 (10.5)	86	26	95.0 (15.6)	88
Fear of cancer recurrence	43	73.3 (21.4)	26	36	70.1 (23.8)	22	26	74.0 (19.3)	23

Table 2. University of Washington Quality of Life questionnaire – Significant problem

	N	Before discharge (TP1)			N	7 – 10 days post-operative (TP2)			N	2 months post-operative (TP3)		
Score		N with significant problem	% Reporting significant problem	95% CI		N with significant problem	% Reporting significant problem	95% CI		N with significant problem	% Reporting significant problem	95% CI
Pain	43	21	48.8	34.6 -63.2	36	10	27.8	15.8-44	26	1	3.8	0.7 – 18.9
Appearance	43	0	0.0	0.0 – 8.2	36	0	0.0	0.0 – 9.6	26	0	0.0	0.0 – 12.9
Activity	43	2	2,3	0.4 – 12.1	36	3	8	2.9 – 21.8	26	1	4	0.7 – 18.9
Recreation	43	2	4.7	1.3 – 15.5	36	0	0.0	0.0 – 9.6	26	0	0.0	0.0 – 12.9
Swallowing	43	22	51.2	36.8-65.4	36	6	16.7	7.9-31.9	26	1	3.8	0.7 – 18.9
Chewing	43	12	27.9	16.7-42.7	36	4	11.1	4.4 -25.3	26	0	0.0	0.0 – 12.9
Speech	43	6	14	6.6-27.3	36	8	22.2	11.7 -38.1	26	2	7.7	2.1 – 24.1
Shoulder	43	0	0.0	0.0 – 8.2	36	0	0.0	0.0 – 9.6	26	0	0.0	0.0 – 12.9
Taste	43	0	0.0	0.0 – 8.2	36	2	5.6	1.5-18.1	26	0	0.0	0.0 – 12.9
Saliva	43	4	9.3	3.7 – 21.6	36	2	5.6	1.5 – 18.1	26	3	11.5	4.0 – 29.0
Mood	43	2	4.7	1.3 – 15.7	36	3	8.3	2.9-21.8	26	2	7.7	2.1 – 24.1
Anxiety	43	8	18.6	9.7 – 32.6	36	7	19.4	9.8 – 35.0	26	1	3.8	0.7 – 18.9
Intimacy	43	0	0.0	0.0 -8.2	36	0	0.0	0.0-9.6	26	0	0.0	0.0 – 12.9
Fear of cancer recurrence	43	4	9.3	3.7 – 21.6	36	1	2.8	0.5 – 14.2	26	1	3.8	0.7 – 18.9

Figure 4. UW-QoL box-plot representation composite scores



Post-intervention interviews

In order to explore patient perspectives on nurse-patient interactions and patient involvement during nursing rehabilitation consultations using UW-QoL and PCI, semi-structured interviews were conducted with patients who participated in the intervention. An interview guide was developed based on background literature. [157,158,160,162,184] The interviews were conducted by four nurses all with some experience in carrying out semi-structured interviews.

Patient participation

Nine patients who had participated in interventional nursing consultations at all three time-point's.

Data collection

Patients were recruited from January to October 2019. Interviews took place just after the final nursing consultation at time-point 3. The interviewers wore private clothing in order to signal a researcher and not nursing role during interviews.

Data analysis and interpretation

The interviews were transcribed by a secretary into textual data in Word. Data was analysed across data using thematic analysis. [185] AM and MJ carried out the analysis following six levels, where the first level is reading and re-reading all transcripts to get familiar with the contents. Second, initial codes were generated based on the data, followed thirdly by a search for themes, where codes were gathered into potential themes. At the fourth level the potential themes were then reviewed in order to assure that they were in accordance with the data set, before the themes were defined and named at the fifth level and finally at level six, the report on the findings took place. The results from the interviews are presented in synopsis form without illustrative quotations from individual interviews.

Results

Three women and six men participated in the interviews. The average age was 63 (range: 38 – 75) and the duration of the interviews were between 10 – 31 minutes.

Three themes were identified, in relation to the patient's experience and evaluation of the intervention; Trustful communication; Patients are in charge and Support in identifying needs and topics. The patients found the communication taking place during the interview as being trustful since they felt secure in the interaction with the nurse, because they felt comfortable about discussing and asking about issues on their mind. Further the contents and topics of the communication were experienced as relevant to their situation, and useful to their specific circumstances. The topics of discussion for the different conversations during consultations could be very diverse and yet directed to the individual patient. When the nurse, initiated conversations on topics not addressed by the patient, they were welcomed. They perceived the nurse as helpful, supporting and guiding on practical issues as well as emotional needs. Patients felt they were in charge of the communication and interaction taking place during the consultation, since they had chosen the topics for discussion. Some patients put this in contrast to previous experiences where they had not felt involved or felt they had been instructed by the health care professional on for instance lifestyle behavioural changes. Patients felt involved regarding decisions on how to manage their rehabilitation and followed the professional guidance given by either the nurse or other health care professional, while some patients likewise welcomed the guidance, but wanted to feel free to decide not to follow the guidance and advice given. On a whole, patients found they were supported in identifying needs and topics on the UW-QoL and PCI. In particular the PCI was helpful in identifying subjects for discussion, as it guided toward important topics which might not otherwise have been chosen for conversation.

Methodological considerations

Overall, this study had a robust design which was carried out with rigour aimed at reducing bias. The eligibility criteria for participants was made clear, as this is important in order to judge the applicability of the outcomes to clinical practice. [186] The eligible patients for this study were surgically treated patients with HNC. Ideally patients of all HNC treatment groups should have been included, as the needs assessment instrument is considered equally useful for patients treated with RT or CT. [141] However, due to the way the Danish cancer treatment is organized, surgical and oncologic treatment takes place in different departments and further the needs assessment times have to be different due to the diverse trajectories of surgically and oncologically treated patients. However, there was a risk of selection bias, [187] not in the selection itself, but because the number of patients who declined were 56 (23%). Although patients were asked about their reason for declining, most patients were reluctant to give much information apart from 'not feeling up to participating'. Further, decliners were not asked to sign a written consent, permitting access to their medical records, providing information on basal demographic and medical characteristics. Thus, we do not know much about the group of patients that declined, except that the literature on patients with cancer and in particular HNC shows, it is those with a higher symptom burden and worse QoL and function that are more prone to decline and further, they have shorter education, a poorer lifestyle and more often live alone. [188,189] This corresponds well with the population recruited into our study, having a higher education and cohabiting, compared to what is known on patients with HNC. [190] The primary outcome instruments were EORTC QLQ and H&N35, both well validated and reliable instruments, [177,191] as well as MDASI-HN used as a secondary outcome, [180] which should improve the assessment of QoL. [186] The sample size was determined based on similar but limited number of studies on head and neck cancer patients and effect size on recommendations from EORTC and further based on previous research in the Dept. ORL, H&N. Patients were randomized using REDCap. The statistician created the REDCap module, which was then managed by AM or a project nurse. They were in this way not able to interfere with the allocation or randomization process. [186] The nature of the study and design made it impossible to blind patients to the intervention and knowledge of which group a patient participated in, which could influence the outcome. [171] In this case, their reply to questionnaires. [171] The main investigator, AM, was neither blinded to allocations, in particularly as she did most of the interventional consultations herself. This may constitute a risk of bias. Having an independent and blinded researcher would have been optimal. The risk of bias was reduced as variations in the approach of the rehabilitation consultation was based on a particular flow and AM and the research nurses based their advice and recommendations on the management manual. Also, AM was blinded to the content of the consultations in CG, as well as being blinded to the outcome (the replies to questionnaires) in both groups, [171] since they were handled by a student assistant. The transfer of data (outcomes) from paper to REDCap, contained a risk in itself, since there is always a risk of losing or contaminating data while transferring. AM made random tests at regular intervals to check on this. [171]

The aim of a randomised trial is to compare groups of participants that only differ as far as the intervention is concerned. [186] When comparing patients in the two groups of this study, they appear to be comparable for all demographical characteristics except for tumour sites where CG had more patients with tumours in larynx and pharynx compared to IG. The difference is however low and may not have too much significance.

Using PRO's as measurements instruments gives the patient a voice on what matters to them [192] and informs the researcher on many aspects of importance to treatment and how it affects the patient. [192] Further, HRQoL is most often measured using PRO's. [193] This, however, has its challenges, which needs to be recognised and managed as much as possible. It is important to ensure a high rate of completion of PRO questionnaires [194] which we tried to ensure by allowing patients to fill in these on paper while waiting in the OPD. Likewise, it is important to avoid missing data. [195] We unfortunately did have some missing data, especially when patients had to reply to EORTC QLQ and H&N35 seven days after the two-month appointment. We tried to prevent missing data, by contacting non-responders on the ninth day either by phone and/or mail. Yet, some patients did not respond in spite of several reminders. This of course is unfortunate as both internal and external validity suffer when questionnaire completion is low. [196]

The study did not show any difference in effect in GHS/QoL on the EORTC-QLQ and H&N35. The dropout and exclusion rate increased over time, as well as the amount of missing data, especially towards the end of the study. The drop-out analysis which was performed on the 12 patients who dropped out of the study, showed no differences between groups apart from drop-out's being slightly older than those remaining in the study. Lastly, the final test time-point was at approximately nine weeks, and patients may have needed more time to act on and benefit from the consultations and advice given, [105,108] particularly in terms of their emotional and existential needs, to have an effect on HRQoL. The last test time-point was only seven days after the last consultation. Patients in need of emotional, psychological, existential support from either psychologist or clergy, would need to access this support themselves. This would possibly require more time – maybe months – to have an effect on their QoL. Further, one could speculate whether patients had been very good to self-regulate as described in the CSM model. This could then lead to similar improvements in both groups.

Finally, patients may rate their QoL as acceptable while experiencing negative effects of their treatment, which is known to be related to an adaptation to their impairments over time, that is a response shift, [16,43] however, the patients in this study would likely not have had enough time to adapt to their impairments, for this to have an effect on the QoL.

Of the patients who participated in the post-intervention interviews five reported they found UW-QoL a little difficult to use, as the graduation of the options for response within each topic could be difficult to choose between. The UW-QoL is a well validated instrument, [197,198] however the validation in another language than the original or source language, may require a psychometric validation in the new language. [199] The translation of the UW-QoL into Danish followed the guidelines of EORTC quality of life group translation procedure, [174] however Beaton et al [199], recommends in their guideline on cross-cultural adaptation of questionnaires, not only a translation procedure very similar to EORTC, but also a psychometric validation, which should be carried out after the translation in a larger group of patients. The Danish translation for this study, was discussed and further tested on different groups of patients, to ensure the validity of the Danish version of UW-QoL, however, a more in-depth psychometric validation on a larger group of patients might have been beneficial to counter the risk of difficulties with replying to the questionnaire. A psychometric validation could consist of cognitive debriefing where patients are interviewed after replying to a questionnaire on their ability to understand the questions and willingness to reply to them. [200]

Post-intervention interviews

The post-intervention interview appraisals shows that the design is considered appropriate for the aim of exploring patient perspectives on the nursing rehabilitation consultations. [153] As in Study II, semi-structured interviews were used as this sets the agenda of the interview, with probing and open-ended questions. [153] The interview guide was based on background literature. The interviews were carried out by four different nurses, all with experience in interviewing. Four interviewers for nine interviews may be a bit much, but was necessary for practical reasons, as AM could not carry out the interviews, since she was the main nurse carrying out the interventional consultations. The duration of some of the interviews were quite short. This was mainly due to patients wanting to leave the department after a possible long waiting time between nursing and doctor's consultations, which also in these interviews as in Study II revealed the challenges of conducting interviews in a busy health care system. [150] Sampling posed a challenge as only nine out of 26 patients who had participated in a nursing rehabilitation consultation using UW-QoL and PCI participated in an interview. All 26 patients were invited to participate in an interview, but a few declined. Other interviews had to be disregarded for lack of an interviewer, for practical reasons. The study used a systematic approach to data collection, analysis and interpretation. The analysis was carried out using an acknowledged method described by Braun and Clarke. [185] As in Study II, an audit trail could describe how data was collected, analysed and interpreted. [168] The post-intervention interviews are thus deemed to have been conducted in a transparent way. [153] The results are considered valuable as they contribute with important knowledge on the patients experience and benefits of participating in a nursing rehabilitation consultation using a needs assessment tool as the UW-QoL and PCI. [153]

Discussion

The overall focus of this thesis is needs assessment and symptom management of patients surgically treated for head and neck cancer in relation to needs for rehabilitation, patient involvement and quality of life. In study I a systematic literature review was conducted in order to obtain an overview of the existing literature in relation to early and late effects of primarily surgical treatment of patient with oral or oropharyngeal cancers. In study II the nurse-patient interactions in rehabilitation consultations was explored in a qualitative ethnographically inspired study and in study III a needs assessment and patient concerns instrument was applied in an intervention with nursing rehabilitation consultations. The study was designed as a two-arm randomised controlled trial, comparing the intervention to standard care. The primary outcome was Global Health Status and Quality of Life. The patients in study II and III were followed over a period of approximately 9 weeks at three time-points from baseline, 7 – 10 days and two months postoperatively.

In the following the assessments of patient’s needs as they take place in a nursing consultation, with the aim of reducing the detrimental effects of symptoms and improve HRQoL by referring patient’s to rehabilitation will be discussed. In the discussion symptoms are defined as the patient’s subjective experience of disease [3] and needs as the patient’s perceived need of health care. [2] Rehabilitation is the measure that help the patient to achieve and maintain the best functioning. [1] See Definition of terms at the beginning of this thesis.

Symptoms and needs assessment

It is acknowledged that patients with cancer have physical/functional, emotional/psychological, social and existential/spiritual needs. [201] This is even more true for patients with HNC, [93] as the surgical treatment affects some of the most vital as well as visual parts of the human anatomy. [16,202,203] The abilities to chew, swallow and speak; cognitive impairment; disfigurement; distress due to functional disabilities and cancer diagnosis; worry about the future; need of or sometimes lack of social support; fear of cancer recurrence are just some of the most common physical, emotional, social and existential symptoms and needs. [16,17,204] These symptoms and needs should be uncovered and managed possibly through rehabilitation. [16] As showed in Study I patients with oral and oropharyngeal cancers as a needy subgroup of HNC have multiple and complex symptoms. Symptoms that need to be managed to prevent early and late sequalae following disease and treatment. The study showed, as also other studies, [16,93] that symptoms do not occur or present as single entities, but sometimes multiple symptoms present at the same time, where one symptom may compound another, or multiple symptoms have a synergistic effect on each other. These symptoms and needs should be assessed, [16,205] and patients referred to rehabilitation and/or follow-up. However, needs may be very complex, [16,204] as also the uncovering of them may be, as shown in Study II, where nurses assessing these needs found the rehabilitation consultation challenging especially when it came to assessing emotional and existential needs of the patients. The nurses in Study II used an interview style of questioning, when trying to assess patient's needs which did not prove beneficial in uncovering the emotional and existential needs. Studies have shown the valuable effect of using different types of needs assessment tools. [16,205] In Study III a needs assessment tool was used to aid in the assessment of needs, which was able to uncover many physical/functional needs but showed to be particularly beneficial in uncovering emotional and existential needs. The use of the UW-QoL and PCI as tools will be discussed in more detail below, as well as the context of a nursing rehabilitation consultation in which this tool was applied.

The UW-QoL was developed as a PRO QoL questionnaire [206] and has been used as such in a number of research studies measuring QoL in patients with HNC. [198] However, it has also been used routinely for many years in consultations with HNC oncologists or surgeons, usually in combination with PCI to aid the assessment and discussion with patients about their symptoms and concerns. [207] Using QoL questionnaires to assess patient's individual symptoms is a growing tendency. [94] The PCI was developed particularly to support patients in identifying the concerns they wish to discuss in the consultation. [141] UW-QoL and PCI have both been linguistically validated in several languages other than English [208,209] and has in preparation for Study III also been linguistically validated in Danish. It is thus the first time UW-QoL and PCI have been used in a Danish linguistic and cultural context. Patients in the post-interviews said they found the PCI useful in supporting them in identifying subjects for discussion, which they might not otherwise have chosen. In a similar study in patients surgically treated for oral cavity cancer, [210] the patient's QoL after surgery were measured using UW-QoL at two months post-operative, [210] which compares to time-point 3 in Study III. The scores in Study III were slightly better in most domains, except for Pain, Mood and Anxiety where scores were similar and for Saliva scores were worse in Study III compared to Viana 2017. [210] The domain Fear of Cancer Recurrence was not measured in the study. Compared to this single study in surgically treated patients the results from Study III are similar, with generally good scores in all domains at two months postoperative. In a report from a single British head and neck cancer unit, where the PCI has been used routinely in follow-up clinics for the past many years, the concerns raised by patients have been summarised for a seven-year period. [99] 49 % of the patients had been surgically treated and 37% primarily surgically treated with adjuvant RT. The most common concerns mentioned by patients in this report were dry mouth (34%), fear of recurrence (33%), sore mouth (26%), dental health (25%), chewing (22%) and fatigue/tiredness (21%). Another study collected and compared the use of the PCI in 19 HNC departments world-wide. [211] In this study 77% of patients had received surgery alone or combined with RT/CT. Patients using the PCI were 12 to 60 months from diagnosis, of which one quarter were within 12 months. The most common concerns raised across all times and countries, were fear of cancer returning (39%) and dry mouth (37%). Other frequently chosen items were chewing/eating, swallowing, speech/voice/being understood, dental health/teeth, fatigue/tiredness, salivation, pain in the head and neck, cancer treatment and mouth opening.

Patients in Study III of this thesis do not differ much from either the British or the international studies in the concerns they have raised through the use of the PCI. Fear of cancer returning, is the most frequently chosen item in all studies, indicating this is a dominating concern in many patients with HNC. Fear of cancer recurrence (FOR) will be addressed in more detail in one of the following paragraphs of this thesis. Other frequently chosen concerns raised in this PhD study were chewing/eating, swallowing, dental health/teeth and cancer treatment. All of which again is similar to the above studies. Thus, the Danish population in this study do not seem to differ substantially from those of other countries in the concerns they raise.

Frame for symptom and needs assessment

The UW-QoL and PCI were used as needs assessment instruments to assess needs for rehabilitation in the context of a nursing consultation in this PhD study. Using a needs assessment instrument is a helpful tool for the patient and health care professional/nurse to guide the discussion about needs and concerns. However, it cannot stand alone. The tool must be used within a certain frame to promote Patient Involvement, two-way communication and aid in managing the complexity of symptoms and needs the patient battles with. The nursing consultations in Study III therefore followed a certain sequence as illustrated in Figure 1 Flow for nursing consultations, of Paper 3. Johnston et al [212] wrote about the use of Holistic Needs Assessment tools: ”*The key ways in which an assessment will impact on patient experiences and outcomes relate to the extent to which assessors can effectively detect concerns, distress and/or unmet need, discuss and deal with these within the consultation, then when appropriate direct individuals to local sources of support*”.

In the following the different aspects of a needs assessment beyond the tool itself, will be discussed. A very basic prerequisite for an Holistic Needs Assessment that will have an impact on the individual patient's life, is to which extent the patient is involved in the process. Patients and health care professionals express this need for Patient Involvement. The patient wants to cooperate with the health care professionals, [93] as also the health care professionals seek cooperation and Patient Involvement to achieve the best outcome. [94,207] Study II showed the necessity for inviting patients to be involved in the process of their own assessment. Study II further revealed that patients were not prepared for or fully understood the purpose of the consultation and the nurses tended to take control of the interaction, directing the interview and assessing needs by asking probing questions, a not too uncommon way of conducting consultations, [213] but one that does not involve the patient very much. Patients need to be informed from the outset about the purpose of the interview. [172,214,215] Further, they should be able to raise their concerns at the beginning of the consultation, [172,215] which has been shown to help patients to share these more actively. [172,215] For this reason also, the needs assessment consultations in Study III started out with discussing the results of the UW-QoL and PCI at the beginning of the consultation. Once the patient's needs and concerns have been addressed and discussed, the resulting professional advice and possible referrals, must be further discussed and a mutual agreement reached with the patient on these. [172,213] Patients expressed in the post-interviews, they experienced being able to take charge of the conversation, as the needs and concerns they had identified, were the ones to be addressed first. At the same time, they welcomed the nurses' initiative when addressing needs for discussion they had not chosen themselves. An important part of the frame for needs assessment beyond and yet interconnected with Patient Involvement is patient centred communication, [216] since the assessment requires good communicative skills on behalf of the health care professional involved in the assessment. Studies have shown that patients require a type of communication that will meet their informational needs, at the appropriate time and delivered in an understandable way. [217,218] Further, good communication requires health care professional's to listen to patient's expressions, [217] not only verbally, but also non-verbally [172,219] including expression of cues. [160] In Study II the nurses found it a challenge when patient's in the nurses' observations used distancing behaviours, presumably to avoid talking about emotional needs. Yet, they found it difficult to address. Studies have shown that nurses often find it difficult to act on or explore cues from patients, [160] which otherwise could have led to a better identification of patients' needs. [160] Emotional needs were not explored in any depth in Study II. In this context it is interesting to notice that among the most common needs patient's chose in Study III were emotional and existential needs, indicating that patients do wish to talk about emotional/existential needs if given the opportunity. As mentioned earlier the nurses in Study II used probing questions to assess patients' needs and also invited patients to ask questions. However, many did not do so. Patients explained they did not ask, because they did not know what to ask. A study has shown that patients from lower socioeconomic background, such as some patient with HNC come from [190] in particular do not wish to ask questions in a consultation, as they find it inappropriate. [220] While other studies have shown that using an Holistic Needs Assessment tool improves communication between patients and health care professionals. [221,222] Again, using an Holistic Needs Assessment tool as in Study III, may give patients permission to raise their questions and concerns, as HNC specific issues are prespecified and open up the discussion about their needs, which correspond with a study by Ozakinci, et al, [130] which showed that using the PCI in a doctor's consultation facilitated the discussion about psychological issues.

The frame for the Holistic Needs Assessment in Study III was in the context of a nursing consultation. A number of studies have been published within the last years concerning nursing consultations with patients with HNC, most of which included needs assessments, [101,105,108,223–225] which is also a tendency seen in cancer in general. [212] Two studies in particular, Hansson [108] and vd Meulen [105], have looked at nursing consultations and their effect on HRQoL in an RCT measured by EORTC-QlQ and HN35. Both studies compare a nursing consultation intervention to a control group of usual care consisting of doctor's consultations. Hansson's study measures GHS/QoL at baseline and 4, 10, 18 and 52 weeks after start of treatment. Further, Hansson focuses on using a patient centred approach involving the patients and their own resources in the rehabilitation process. This approach has many similarities to Study III, with patient involvement in assessing needs and decisions regarding managing symptoms and rehabilitation, although Hansson employ what seems to be a patient conversation approach to the consultation without the use of an Holistic Needs Assessment instrument. Further, Hansson's study focuses on patients treated with RT and/or CT and patients thus have a different treatment trajectory, and symptom burden peak compared to Study III. Hansson's study shows a difference in GHS/QoL between IG and CG, where IG were better than CG. Of interest is to see that the difference in QoL between IG and CG in Hansson's study only differs numerically significant at 18 and 52 weeks, which also corresponds with vd Meulen's study where a numerically significant difference in GHS/QoL only shows at 18 months. See 'Appendix 13 'Comparison of studies' for a schematic comparison of Hansson, 2017 and Study III.

We believe this study has shown that using a needs assessment tool within a nursing consultation, which has a certain frame to it, securing the individual patient's needs, concerns, symptoms and necessity for rehabilitation is attended to is a feasible model. However, more research is needed to develop the best model for a nursing rehabilitation consultation with a view to patient centred cancer care. [213]

Symptom management and rehabilitation

The purpose of uncovering the symptoms and needs of a patient, is to alleviate the detrimental effects of the treatment to the patient, both short – and long-term, [226] as shown in Study I. Rehabilitation interventions can diminish the impairment brought on by the treatment and improve functionality and HRQoL. [16] Patients further need help to manage unpleasant symptoms [17] and guidance as well as recommendations regarding referral to appropriate rehabilitation and follow-up. [213] Due to the anatomy of the head and neck area, patients with HNC have very complex rehabilitation needs. [16] Therefore patients may need rehabilitation and support in a large range of areas, provided by many different professionals from the multi-disciplinary team, spanning functional, psychological, social and existential rehabilitation and support. [16]

Patients in Study III had the most problems in certain functional, emotional and existential areas, for which they needed referrals and advice. These will be addressed in more detail below.

As mentioned earlier nurses in Study II found it challenging to uncover and address emotional and existential needs, while patients in Study III using the needs assessment tool, in particular chose emotional and existential needs. The most frequently chosen item on the PCI was Fear of the cancer coming back and on UW-QoL it was among the five most significant problems. This item is closely linked to the more professional term Fear of Cancer Recurrence (FOR). FOR is very common in patients with HNC and has been described in many studies. [16,129–131,227]

In the following FOR will be discussed related to CSM. Fear of Recurrence is a major concern or among the five most frequent concerns identified by patients with cancer. [228] Although there is no official definition of FOR, Lebel et al [229] has proposed one based on a Delphi survey among researcher, 'Fear, worry, or concern about a cancer returning or progressing'. FOR may be expressed in many ways ranging from normal reactions to those that are clinically noteworthy requiring professional intervention or support. [128]

Lee-Jones [128] suggested a way of adapting CSM to FOR in cancer patients, which will be used as a basis for the following discussion in relation to patients in Study III using UW-QoL and PCI. These are all quantitative measures, so it is not possible to know why patients have chosen as they did. For this a qualitative study interviewing patient about their thoughts, feelings and choices would be necessary. However, the literature has shown that the patient's fear may have to do with how they interpret the threat of cancer and how these fears are triggered by internal or external stimuli or cues, such as the regular medical follow-up consultations post-treatment for patients with HNC, [130] or the physical symptoms they may still experience, [130] increasing the fear the more symptoms they have [228] or triggered externally by TV shows on cancer. [130] Patients may further interpret these threats based on their knowledge or experience with cancer, like having a family history of cancer and especially if a close friend or family have died from this [130] or their personal characteristics, that is, which coping strategies may be employed. A common way described is to use distraction from thinking about FOR. [130] Finally, patients may react to the threat of cancer recurrence through behavioural changes, like increasing their body checking for signs of cancer. These patients may not, as one could expect, find a medical check-up reassuring. [130] Patients may also react emotionally, with increased levels of distress, anxiety or intrusive thoughts. [130,228]

The patients participating in the intervention group of Study III, used UW-QoL and PCI as assessment tools. In the PCI the item Fear of the cancer coming back, was among the top-five chosen items at all time-points, indicating this was a concern, patients wished to discuss. When patients scored which items had been most significant to them for the past seven days on UW-QoL, Fear of cancer recurrence was not among the top-five most significant items. However, it is important to notice how Fear of cancer recurrence is rated on UW-QoL. Items are scaled according to five possible responses ranging from best possible 'I have no fear of recurrence' to worst possible 'I am fearful all the time that my cancer might return, and I struggle with this'. Since only about 25% scored high on best possible score for Fear of cancer recurrence, the rest scored lower. The possibility of graduating the severity or intrusiveness of thoughts on UW-QoL, indicates that some patients struggle to a smaller or larger degree with FOR. Yet, the result on PCI indicates a wish to discuss this fear, even if it may not be very emotionally burdensome.

Patients in Study III had the most needs in certain functional, emotional and existential areas, for which they needed referrals and recommendations. According to the Danish Health Authority [67] and the Danish Ministry of Finance, [60] rehabilitation should take place in the municipalities. However, patients cannot be referred to any type of rehabilitation. Certain types of support have to be accessed by the patient him/herself, for which they will need advice on how to access, as it may be difficult for the patient to know which type of support is available. [213]

Patients in this study had many functional needs and required referrals for members of the multi-disciplinary team, in particular speech-pathologist and swallowing therapist or recommendations on how to access counsellor, psychologist or smoking cessation programme. Other studies have shown the need for the same rehabilitation measures or follow-up in patients with HNC. [16,222,230] Studies have also found an increase in uncovered needs in the emotional domain, requiring referrals, after introduction of the PCI [222] as in Study III. Patients in Denmark have to access emotional or psychological support themselves; which studies have shown may be difficult for some cancer patients to initiate and fulfil. [213,231] Therefore, patients in this study received a specific patient information leaflet about how to access support (Appendix 11 'Patient information leaflet (Guide when in need of help)'), but we do not know to which extent they made use of it or accessed the support they wanted or needed. A further challenge was the number of patients recommended to contact a smoking cessation program. Patients with HNC who are smokers are known to have difficulties with quitting [232] and only about 50 % of smokers in a study, [230] were interested in participating in a smoking cessation program. [230] Maybe because patients with HNC who are smokers prefer individual support rather than programmes. [230,232] As mentioned earlier referrals and recommendations were based on the discussions in the nursing consultations and reached in agreement with the patient. Discussions that also contained immediate advice and support related to the areas where patients had to access further support in the municipality themselves. However, the possible challenges in doing so, stress the need for further support to manage emotional needs or smoking cessation within the nursing consultation.

Altogether, the three studies emphasise that surgically treated patients with HNC have multiple physical, functional, emotional, social and existential symptoms and needs. Symptoms are complex and interrelated. Needs should be uncovered in cooperation with the patient and symptoms should be managed and patients referred to multi-disciplinary rehabilitation, follow-up and support. All with the aim of preventing or alleviating the negative impact of illness and treatment and ultimately improving the HRQoL.

Overall methodological strengths and limitations

The overall strength of this thesis is the incorporation of different methodological approaches, to investigate the symptoms and needs of patients with HNC towards rehabilitation and how these needs may be managed in a nursing rehabilitation consultation. The literature review of Study I gave insight into the existing literature on the effects of surgical treatment on short – and long-term symptom burdens of patient with oral and oropharyngeal cancers (a subgroup of HNC). Study II revealed the nurses challenges in assessing the patient's needs, in particular emotional/existential needs, using a triangulation of qualitative methods, and Study III tested the effect of using a PRO and electronic-based concerns prompt list in needs assessment during nursing consultations on QoL in a randomised controlled study, carried out with rigour. Thus, a strength of the thesis, is that the three studies contributes to a better understanding of how the symptoms and needs of patients with HNC may be assessed and managed through multi-disciplinary follow-up and rehabilitation.

The thesis has some limitations though. The patients studied in this thesis are surgically treated for HNC, however, the articles in the review of Study I, included several studies of only primarily surgically treated patients with oral or oropharyngeal cancers. In Study II a limitation is the extent to which nurses in the rehabilitation consultations may have had interactions with the patients other than during the consultations, which could influence these interactions and in Study III, the exclusion of HPV in all studies of the thesis is a final limitation, as the two patient groups constituting HPV-positive and HPV-negative HNC are very different as to etiology, epidemiology and demography. Without being able to distinguish between the two groups, this may have affected some of the conclusions in the studies.

Conclusions

Surgically treated patients with HNC have multiple physical, functional, emotional, social and existential symptoms and needs. Symptoms should be managed, and patients referred to multi-disciplinary rehabilitation, follow-up and support. Symptoms and needs should be uncovered in cooperation with the patient. Although the study showed that employing a needs assessment tool in nursing rehabilitation consultations, did not improve HRQoL or reduce the symptom burden, the intervention suggests that patients may benefit from having their needs assessed in a nursing rehabilitation consultation using a needs assessment instrument, such as the UW-QoL and PCI, as it facilitates Patient Involvement. This approach allows patients to speak out on and discuss matters of concern, especially regarding emotional and existential needs and particularly fear of cancer recurrence. The overall aim of the need's assessment is to prevent or alleviate the negative impact of illness and treatment and ultimately improve the HRQoL. This PhD showed that a nursing rehabilitation consultation is feasible, and patients find themselves involved in the need's assessment.

Future perspectives

The use of nursing rehabilitation consultations is relatively new in Denmark however nurse assessments of cancer patient's needs are at the increase, yet not always using a needs assessment tool applicable to the patient's cancer subgroup. In a future health care system with sparse resources and increase in the number of cancer patients; an expectation from governments and patient organisations for increased Patient Involvement and influence on health care, nursing rehabilitation consultations may become an avenue for the professional assessment of symptoms and needs involving patients.

The use of information technology in health care has already increased vastly with amongst others e-health records, accessible by patients. There is further an increase in ePROs measured by patients at home via the internet as a means of informing health care staff of their symptoms. This has been tested and now in use in patients with chronic diseases in many hospitals in Denmark [233] Internationally, there is growing experience in relation to patients with HNC and the use of health apps and ePRO's. [234,235] An application of the UW-QoL and PCI completed by the patient at home and accessed during the hospital appointment for discussion with the health care professional or nurse, could be a future avenue, enhancing the usefulness of the instrument, as patients may use the tool in the calm surroundings of their home.

The health care system in Denmark carries within it some barriers on the patient's pathway to access support for emotional or existential needs. Patients may contact a counsellor with special knowledge on cancer, through the Cancer Society. However, the Cancer Society can only offer a few consultations with alternating counsellors. Otherwise patients can only access a psychologist via their GP, who will refer to a psychologist, whom they will have to pay for consultations. As it is known that patients with HNC have a high incidence of depressions or anxiety [236] and that depressed persons find it difficult to take initiative, [237] it would be useful if other avenues of accessing support in or outside the hospital through direct referral could be found.

Implications for clinical practice

This thesis has shown it should be recognised that patients treated surgically for HNC are vulnerable, due to their cancer diagnosis, the experiences of the effects of their physical symptoms and uncertainty about the future. The necessity of assessment of symptoms and needs are recognised but as Study II showed it is important that patients are made aware of the purpose of the consultation and are given the opportunity to articulate their concerns by invitation into the assessment and discussion of their symptoms and needs. As Study III showed the discussion of concerns should preferably be based on an HNC specific Holistic Needs Assessment instrument, which helps the patient to focus on specific concerns, they might not otherwise have been attentive to. A formal approach to a nursing rehabilitation consultation with a certain sequence to it as outlined in Study III, could be beneficial, as this ensures Patient Involvement from the onset of the consultation. This involvement should include decisions on the subjects for discussion, patient-professional discussion on referrals and recommendations and the amount of oral and written information the patient wishes and find able to take along.

Study III revealed that patients wish to discuss their fear of cancer recurrence, but nurses find it difficult to talk to patients about emotional and existential concerns, as shown in Study II. Nurses could therefore benefit from training in having conversations on emotional and existential needs with cancer patients.

Implications for future research

Several aspects from this thesis might be investigated further in future research. As the RCT did not show effects on GHS/QoL, a study with a larger study sample and a longer follow-up period between 6 - 12 or up to 24 months could possibly reveal a longer-term effect. Studies could include participants that involve non-surgically treated patients with HNC; and locations could be extended beyond the hospital setting and into the municipality, as rehabilitation and follow-up primarily takes place there. Future research could explore different outcome measures, as patient empowerment; self-efficacy, patient activation; or patient self-management. Qualitative studies could explore patient experiences to all of the above. 23% of eligible patients in this study declined. Future studies could aim to obtain written consent from decliners and compare basal demographic and medical characteristics between decliners and participants to investigate if any and which characteristics differ between the two groups. This could possibly also inform about different approaches for recruitment of decliners in future studies in patients with HNC.

Further, future studies could test models for nursing rehabilitation consultations in order to develop the best model with focus on patient centred care. Such research would in particular be fitted for Patient Involvement in the research process. Finally, research into psychosocial interventions in nursing consultations could be employed, addressing different aspects of psychosocial need, such as anxiety or fear of cancer recurrence.

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English summary

Surgically treated patients with head and neck cancer may experience short – and long-term effects of their treatment as it may involve resection of anatomical features in the head and neck, affecting not only physical functioning, but also emotional and existential conditions. Symptoms may manifest in all these areas, as problems with swallowing, breathing, chewing, speaking, facial or bodily disfigurement, emotional distress, social challenges and existential concerns. Head and neck cancer survivor's quality of life is affected by the many symptoms they experience. It is therefore important to assess symptoms early in the treatment trajectory and onwards, to accommodate sequala and impact on quality of life, by supporting patients in managing symptoms or refer to rehabilitation. Little is known of the best way to assess needs for symptom management and rehabilitation in patients with HNC and how to involve the patient in the assessment.

The purpose of this PhD study was to investigate whether a systematic patient reported needs assessment integrated in rehabilitation consultations with nurses, would improve patient involvement in needs assessments and whether this would result in increased referral to multi-disciplinary follow-up, reduce the symptom burden and improve physical, emotional and social wellbeing and health-related quality of life.

The study comprised three studies, of which the first showed that patients with head and neck cancer experience multiple symptoms post-operatively and that these symptoms do not present as single entities, but sometimes multiple symptoms present at the same time, where one symptom may compound another, or multiple symptoms have a synergistic effect on each other. The second study looked at how the needs and symptoms of patients with head and neck cancers are assessed in a nursing rehabilitation consultations, revealing the complexity of needs and the challenges of assessing these in cooperation with the patient and finally study three investigated whether a needs assessment instrument applied to a nursing rehabilitation consultation could improve their quality of life short-term compared to a group of patients receiving standard care. The study showed no difference in improvement in quality of life, however the intervention revealed that patients had a high prevalence of emotional and existential needs. Post-intervention interviews with patients participating in the intervention revealed that patients found themselves to be involved in the assessment, as they were supported in expressing their needs, symptoms and concerns during the nursing rehabilitation consultation.

This PhD study brings attention to the necessity of assessment of symptoms and needs and suggests that patients should be given opportunity to articulate concerns by invitation into the discussion about these symptoms and needs. This discussion should include decisions on the subjects for discussion, patient-professional cooperation on referrals and recommendations for symptom management.

Resumé på dansk (Summary in Danish)

Kirurgisk behandlede patienter med hoved-halskræft kan opleve kort – og langtidsfølger af deres behandling, da den kan medføre resektion af anatomiske funktioner i hoved og hals regionen, der påvirker ikke alene den fysiske funktion, men også emotionelle og eksistentielle tilstande. Symptomer kan manifestere sig på alle disse områder, som problemer med at synke, trække vejret, tygge, tale, dysfiguration af ansigt eller krop, emotionelt ubehag, sociale udfordringer og eksistentielle bekymringer. Hoved-halskræft overleveres livskvalitet bliver påvirket af de mange symptomer de oplever. Det er derfor vigtigt at vurdere symptomer tidligt i behandlingsforløbet og videre frem, for at imødegå sekvæle og påvirkning af livskvaliteten, ved at støtte patienten i at håndtere symptomer eller henvise til rehabilitering. Der er begrænset viden om den bedste måde at vurdere behov for symptomhåndtering eller rehabilitering hos patienter med hoved-halskræft, samt hvordan man involverer patienten i vurderingen.
Formålet med dette ph.d.-studie var at undersøge om en systematisk patient rapporteret behovsvurdering i rehabiliteringskonsultationer med sygeplejersker kan forbedre patientinvolvering i behovsvurderingen og om dette vil resultere i øget henvisning til multi-disciplinær opfølgning, reducere symptombyrden og forbedre det fysiske, emotionelle og sociale velbefindende og globale sundhedsrelaterede livskvalitet.

Studiet omfattede tre studier, hvoraf det første studie viste at patienter med hoved-halskræft oplever multiple symptomer postoperativt og at disse symptomer ikke viser sig som enkeltstående enheder, men nogle gange viser sig som multiple symptomer på en gang, hvor ét symptom kan forstærke et andet, eller multiple symptomer har en synergistisk effekt på hinanden. Det andet studie udforskede hvordan behov og symptomer hos patienter med hoved-halskræft bliver vurderet i en sygepleje rehabiliteringskonsultation, hvor studiet viste behovenes kompleksitet og udfordringen med at vurdere disse i samarbejde med patienten og endelig undersøgte studie tre om et behovsvurderingsredskab anvendt i en sygepleje rehabiliteringskonsultation kunne forbedre livskvaliteten på kort sigt sammenlignet med en gruppe det modtog standard pleje. Studiet viste ingen forskel på forbedring af livskvaliteten, men interventionen viste at patienterne havde en høj forekomst af emotionelle og eksistentielle behov. Postinterventions interviews med patienter der deltog i interventionen, viste at patienterne oplevede at være involverede i vurderingen, eftersom de blev støttet i at udtrykke deres behov, symptomer og bekymringer i løbet af sygepleje rehabiliteringskonsultationen.
Dette ph.d.-studie gør opmærksom på nødvendigheden af vurdering af symptomer og behov og foreslår at patienter får mulighed for at udtrykke deres bekymringer ved at invitere dem ind i samtalen om disse symptomer og behov. Denne samtale bør inkludere beslutninger relateret til de emner der tales om, i et samarbejde mellem patient og fagprofessionel, om henvisninger til rehabilitering og anbefalinger til symptomhåndtering.

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Appendices

Appendix 1: Paper 1

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Early and late physical and psychosocial effects of primary surgery in patients with oral and oropharyngeal cancers: a systematic review

Annelise Mortensen, RN, MHA,[a] and Mary Jarden, MScN, PhD[b]

The purpose of this systematic review is to explore early and late physical and psychosocial effects of primary surgery for oral and oropharyngeal cancers and to investigate the factors that influence these effects. PubMed, Cinahl, and PsycInfo were searched for studies concerning patients diagnosed with oral and oropharyngeal cancers and treated with primary surgery and which followed the treatment trajectory from time of diagnosis to 10 years after surgery; these studies reported the quantitative assessments and qualitative experiences of the patient's physical and psychosocial well-being. Of the 438 articles accessed, 20 qualified for inclusion, of which 16 and 4 were quantitative and qualitative articles, respectively, and mainly quality-of-life assessments. Time of measurement ranged from time of diagnosis to 9 years after the surgical procedure. The total number of patients included in this review was 3386; of these, 1996 were treated by surgery alone and 1390 with combined surgery and adjuvant radiation therapy and/or chemotherapy. The studies showed that because of the nature of their disease, patients are negatively affected by the different types of surgical treatment for oral and oropharyngeal cancers, with both early and late interrelated effects, and by the side effects of adjuvant therapy. (Oral Surg Oral Med Oral Pathol Oral Radiol 2016;121:583-594)

The global incidence of oral and oropharyngeal cancer (OPC) is on the rise in many countries.[1,2] As a result of advancements in treatment in some Western countries, many patients live with early and late effects of the disease and its treatment.[3,4] OPCs, grouped together, are the sixth most common cancer worldwide; however, there is geographic disparity in the incidence of oral cancers, with the highest incidence being reported in South Asia and Taiwan, Eastern Europe, South America, and Melanesia.[2,5-7] The global overall 5-year survival is approximately 50% to 60%,[5] with wide geographic variations resulting from differences in access to treatment.[1]

Cancer of the oral cavity involves tumors in the lips, buccal mucosa, tongue, floor of mouth, palate, and gingiva, and oropharyngeal tumors occur in the base of tongue, tonsillar region, soft palate, uvula, and the posterior and lateral pharyngeal walls.[8,9] The term OPC will be used in this article as an inclusive term. More than 90% of malignancies that affect the mouth and maxillofacial area are squamous cell carcinomas.[1] Risk factors for OPC are primarily linked to lifestyle factors, such as excessive use of tobacco, alcohol, poor nutrition, and the use of betel quids, and human papillomavirus (HPV)–positive OPC is linked to sexual behavior.[1]

Treatment for OPC is typically surgery and/or adjuvant radiotherapy (RT) and/or chemotherapy (CT). Treatment at an early stage is most effective; however, up to 50% of patients with OPC are diagnosed at a very late stage.[10] At this point, tumors can be large, requiring more aggressive surgical procedures, which result in tissue defect where reconstructive surgery is necessary.

OPC and its treatment can compromise patients' psychological and physical well-being and social functioning.[8] An increasing number of studies report challenges associated with the quality of life (QOL) and experiences of patients with OPC. However, the evidence for rehabilitation interventions in patients who are primarily surgically treated for OPC is limited.[11,12]

Currently, no evidence-based rehabilitation guidelines are available for the management of OPC patients who have undergone surgical treatment. To inform future rehabilitation guidelines, it is therefore imperative to gain a greater understanding of patients' psychological, physical, and social sequelae after surgery for OPC. The aim of this review is to explore the early and late physical and psychosocial effects in patients

Statement of Clinical Relevance

Patients with oral cancer continue to experience physical and functional impairment and psychosocial limitations many years after surgical treatment. Various factors influence these effects, leading to a heavy symptom burden that consists of interrelated and compounding symptoms.

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[a]Department of Otorhinolaryngology and Audiology, Head and Neck Surgery, Copenhagen University Hospital, Copenhagen, Denmark.
[b]University Hospitals Center for Health Research, Copenhagen University Hospital and University of Copenhagen, Denmark.

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treated primarily with surgery for OPC and to investigate the factors that influence these effects.

MATERIALS AND METHODS

Published articles were identified through a systematic literature search in PubMed, Cinahl, and PsycInfo, by using the Boolean search operators and the search string: (Mouth Neoplasms OR “Mouth Cancer” OR “Oral Cancer”) AND Rehabilitation OR Rehabilitation OR Rehabilitat* AND (“Mouth Surgery” OR Oral Surgery OR “Oral Surgery” OR Surgery) AND (anxiety OR “body image” OR depress* OR distress* OR dysphag* OR eating OR nurs* OR pain OR psychosocial OR speech OR swallow*).

Inclusion criteria were as follows:

1. English-language quantitative and qualitative articles published between January 2004 and January 2014
2. Patients with OPC (non−HPV-induced squamous cell carcinomas)
3. Patients intended for surgical treatment or if surgery was the primary treatment modality at one or more time points along the treatment trajectory, including time of diagnosis
4. Studies that investigated physical and psychosocial well-being of patients

Exclusion criteria were as follows:

1. Patients with diagnoses other than non−HPV-induced squamous cell carcinoma of the oral cavity or oropharynx
2. Patients treated only oncologically (RT or CT)
3. Articles describing surgical procedures

The methodologic and statistical quality of the included studies were assessed independently by two authors (A.M., M.J.) using a 7-item criteria checklist.[13] Articles were assigned 1 point for each criterion that was met, for a total possible score of 7; thus, a higher total score refers to better methodologic score.

1. *Sample characteristics:* Well-characterized patient population with defined inclusion and exclusion criteria
2. *Sample size:* The sample is adequate to assess the outcomes or is appropriately justified
3. *Data collection:* The process of data collection is described (e.g., interviews, questionnaire)
4. *Response rates:* Participation and response rates are described and are above 75%
5. *Outcome measurement:* Standardized measurement of psychological, physical, or social functioning
6. *Comparison group:* Results are compared between two groups or more (i.e., patient populations)
7. *Statistical analysis:* The statistical analyses are adequately described, including levels of significance and/or confidence intervals, when appropriate; a general determination of the extent to which all analyses that should have been done were carried out

RESULTS

In total, 438 articles were accessed and screened by title and abstract. Fifty-one studies were read in full and 31 articles that did not meet the inclusion criteria were excluded, resulting in 20 articles being included (Figure 1). The time of measurement ranged from time of diagnosis to 9 years after the surgical procedure; and 16 and 4 quantitative and qualitative articles, respectively, were included. Study designs of the quantitative articles were longitudinal (n = 13), cross-sectional (n = 3), prospective (n = 8), and retrospective (n = 5). All qualitative studies used semistructured interviews (n = 4), which were carried out at 1 time-point, either before hospital discharge or 1 or 4 years after treatment. The total number of patients included in this review was 3386: those treated by surgery alone (n = 1996), and those treated with combined surgery and adjuvant RT and/or CT (n = 1390). Three articles included patients who had undergone surgery alone; 2 articles included preoperative (intended for surgery) patients; 7 articles included patients who had unimodal or bimodal treatment (surgery/RT); and 8 articles included patients who had unimodal, bimodal, or trimodal treatment (surgery and/or RT/CT).

Studies in this review did not include comparative groups, and samples were generally small, ranging from 20[14] to 90.[15] A few studies had larger samples ranging from 231[11] to 1652.[16] Eleven of 20 studies were critically appraised as having high-quality scores according to the criteria. Four studies were qualitative and thus attained a lower rating; however, the appraisal tool was not specific for qualitative studies, which might have resulted in the studies receiving a lower assessment score.

Key study details, including authors, study design, outcome measurements, and results, are presented in Table I.

The key areas of the physical and psychosocial early and late effects of the surgical treatment for OPC and the factors that influence these effects are summarized in the following section.

Early and late physical effects

Pain. Pain was found to be a continuing problem and was most severe at the time of diagnosis and/or shortly after the operation and then decreased over time.[17-19] The largest reduction in pain was found to occur

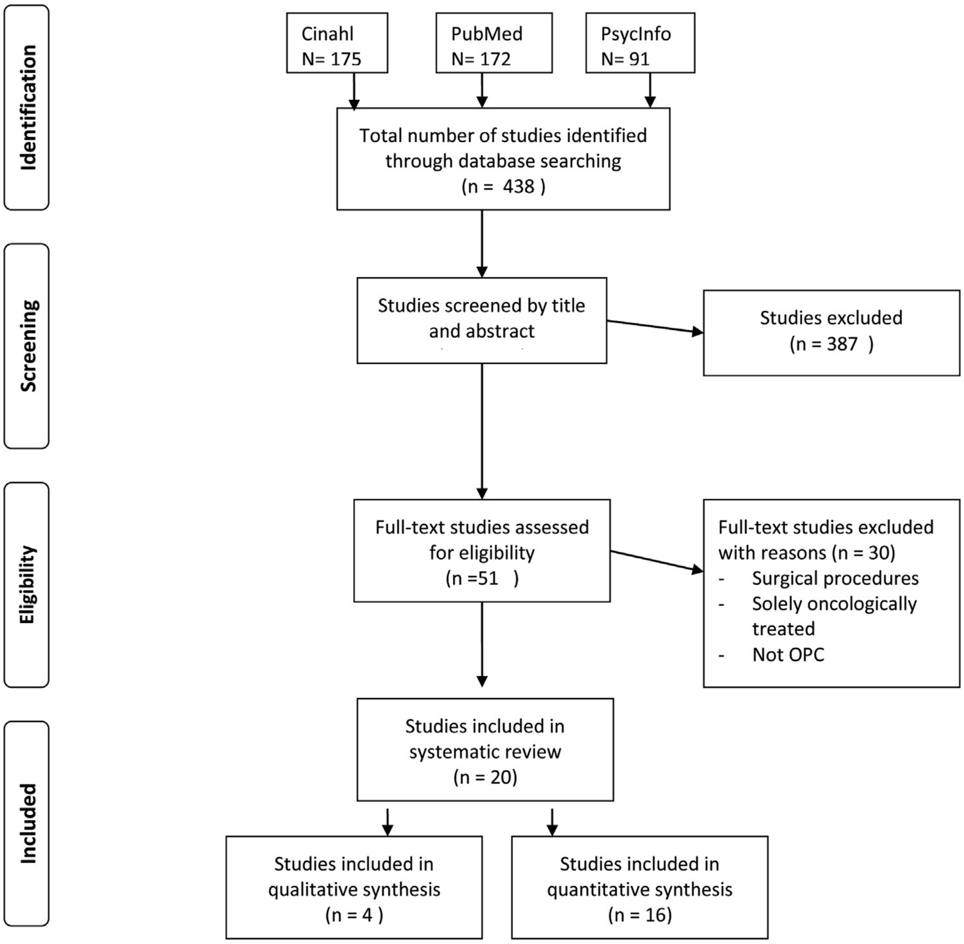

Fig. 1. Flow diagram. (From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097.)

between time of surgery (or termination of adjuvant RT) and 3 months postoperatively.[11,18,19] At 1 year after surgery, pain was shown to decrease further,[4,11]; however, some patients experienced pain years after completion of treatment.[20]

Nutrition and ability to eat. Approximately one fifth of patients were found to have critical weight loss at the time of diagnosis as a result of eating and swallowing difficulties.[21] Immediately after surgery, patients were found to have significant eating problems,[22] and this continued in some patients for months and years after treatment. It is reported that patients experienced the worst problems at 6 months postoperatively and found that eating difficulties affected QOL more than any other aspects at this time. A number of patients were not able to eat normally even after 9 years.[20] Eating was experienced as a challenge and source of frustration, as many could only consume liquid or soft food. Smith et al.[23] showed that even 5 years postoperatively, 50% of patients were still on a diet limited to soft food. Eating in public or together with others was reported as being difficult for many. Social eating deteriorated during the first couple of years but was found to normalize thereafter. The inability to eat with others was related to higher levels of depression and anxiety.[16,24,25]

Dysphagia. Even at the time of diagnosis, chewing ability was found to be a problem,[17] and some patients experienced critical weight loss as a result of dysphagia[26] and chewing difficulties.[21] These problems often improved after the operation, although many still had difficulty swallowing[27] and were discharged from the hospital with nasogastric tubes. Swallowing difficulties were found to persist for months[16] and affected QOL for up to 2 years after the operation.[4,11,26] At this time, some patients were still edentulous or unable to wear dentures for anatomic reasons.[26] Dysphagia was shown to be related to higher levels of depression and anxiety.[24] However, at 9 years after diagnosis, most patients were found to be no longer experiencing dysphagia.[20]

Trismus. Restricted mouth opening was shown to have a significant effect on QOL postoperatively.[16,27]

Table I. Patients treated with primary surgery for oral and oropharyngeal cancer

First author Year	*Sample*	*Study design*	*Time*	*Measurement tools*	*Results* *a. Statistical significance* *b. Clinical effects (physical, psychosocial)* *c. Factors of influence*	*Methodologic and Statistical quality*
Quantitative studies						
Biazevic, MGH (2008)[17]	N = 47 Lip Oral cavity Oropharynx Treatment: Surgery	Longitudinal Prospective HRQOL-Questionnaire	- Pre-op - At discharge	UW-QOL	a. HRQOL ↓ 31% immediately after surgery - Anxiety ↑ (65.5 %) b. Chewing, taste, swallowing, speech, pain c. Anxiety and pain	5
Van den Brink J (2006)[15]	N = 90 27 free flap reconstruction 42 neck dissection 21 laryngectomy Treatment: Surgery	Longitudinal Prospective QOL-Questionnaire	- At discharge - 6 wks post-op - 3 mo post-op	3 self-developed QOL questionnaires with 22 subscales	a. Feelings of control and physical self-efficacy ↓ b. Psychosocial problems: Uncertainty, negative feelings, loss of control, threatened self-esteem c. Physical problems: Speech, swallowing Being single, lower levels of education	6
Smith GI (2006)[23]	N = 63 Oral cavity Treatment: Surgery 30 Adj. RT	Longitudinal Retrospective HRQOL Questionnaire	Median 5.2 yr Post-op	FACT-G FACT-HN UW-QOL PSS-HN	a. — b. Dentition, speech, eating, disfigurement c. Adj. RT gives poorer outcome on speech, eating, disfigurement	4
Jenewein J (2008)[24]	N = 62 (31 males and 31 female partners) Oral cavity Treatment: Surgery 11 Adj. RT and/or CT	Longitudinal Retrospective QOL Questionnaire	Median 3.7 yr Post-diagnosis	WHOQOL-BREF HADS DAS EORTC QOL-H&N35	a. QOL ↓ due to higher degrees of anxiety/ depression. b. QOL ↓ due to physical complaints c. Pain, swallowing, social eating, distress/depression Influence of relationship on QOL: Living in stable relationship QOL ↑. Living in unstable relationship QOL ↓	5
Yang Z et al. (2010)[11]	N = 289 Tongue cancer Treatment: Surgery 93 Adj. RT 24 Adj. CT	Longitudinal Retrospective QOL Questionnaire	- Pre-op - 3 mo post-op - 6 mo post-op - 12 mo post-op	UW-QOL, version 4	a. 12 mo post-op: Appearance, activity, speech, swallowing, shoulder function, taste ↓ ($P < .05$); pain, anxiety, mood ↑ ($P < .05$) b. Appearance, activity, speech, swallowing, shoulder function, taste, pain, anxiety, mood c. RT, clinical stage, economic status, age	6
Shepherd K (2004)[18]	N = 38 Oral cavity Oropharynx Treatment:	Longitudinal Prospective QOL Questionnaire	- At diagnosis - 2 wk post-op. - 1 mo post-op - 3 mo post-op/post-RT	EORTC QLQ-C30 EORTC H&N35 HADS	a. at 2 wk: Role functioning ↓ 23%, b. Fatigue, pain, insomnia, swallowing, speech, social eating, social contact, trismus, anxiety, depression c. —	4

(*continued on next page*)

Table I. Continued

First author Year	*Sample*	*Study design*	*Time*	*Measurement tools*	*Results* *a. Statistical significance* *b. Clinical effects (physical, psychosocial)* *c. Factors of influence*	*Methodologic and Statistical quality*
	Surgery and/or Adj. RT					
Rogers SN (2008)[4]	N = 561 Oral cavity Oropharynx Treatment: Surgery 223 Adj. RT	Longitudinal Retrospective QOL Questionnaire	Median: 28 mo	UW-QOL	a. — b. Appearance, chewing, saliva, speech, swallowing, social interaction c. Tumor size, type of surgery, adj. RT	7
Oskam IM (2013)[20]	N = 26 Oral cavity Oropharynx Treatment: Surgery 24 Adj. RT	Longitudinal Prospective HRQOL-Questionnaire	- pre-op - 6 mo post-op - 12 mo post-op - mean 9.2 yr post-diagnosis	EORTC QLQ-C30 EORTC QLQ-H&N35 Self-developed 61 item study specific Questionnaire	a. Diff. in HLQOL over time: Emotional and social functioning, swallowing, speech, taste, dry mouth ($P < .01$) b. Supportive care needs: Speech, eating, psychosocial, social support c. —	4
Handschel J (2013)[16]	N = 1652 Oral Treatment: Surgery 502 Adj. RT 78 Adj. CT 131 Adj. RT/CT	Longitudinal Retrospective QOL Questionnaire	>6 mo post-treatment	FKV KKG IPC D-S STAI Depressive state on 5-level scale Anxiety state according to Laux	a. QOL values: Immediately after therapy mean 35.61; > 6 mo after therapy mean 21.21 b. Anxiety, eating, swallowing, appearance, trismus c. Having a psychological interview	4
Kamstra JI (2011)[26]	N = 89 Oral cavity Oropharynx Treatment: Surgery 56 Adj. RT	Cross-sectional Structured interview Questionnaire	Median 1.7 yr post-treatment	MFIQ structured interview	a. MFIQ-score higher in RT than in non-RT pts ($P = .001$) b. Lack of saliva (RT pt) (52%), Restricted mouth opening (48%), Restricted tongue mobility (46%) c. Restricted mouth opening, tongue mobility, lip mobility, reduced tongue sensation, inability to wear dental prosthesis, surgery of mandible	6
Chen, S-C (2011)[19]	N = 72 Oral cavity Treatment: Surgery Adj. RT Adj. CT	Longitudinal Prospective Questionnaires	- 1 mo post–op - 1 mo post RT	USCF-OCPQ SSS HADS KPS	a. — b. Pain c. Influence on pain: Age, eating difficulty, speech difficulty, depression	5

(*continued on next page*)

Table I. Continued

First author Year	*Sample*	*Study design*	*Time*	*Measurement tools*	*Results* *a. Statistical significance* *b. Clinical effects (physical, psychosocial)* *c. Factors of influence*	*Methodologic and Statistical quality*
Fingeret MC (2010)[30]	N = 75 Oral cavity Treatment: Surgery	Cross-sectional Structured interview Questionnaires	Pre-op	BIS ASI-R BSS FNAES HNS BSI-18	a. 77% current and/or future appearance-related concerns 36 % reported moderate levels of distress associated with thoughts about appearance b. — c. Influence on body-image concern: Smoking, unemployment, depression	6
Humphris, GM (2004)[31]	N = 87 Oral cavity Oropharynx Treatment: Surgery 47 Adj. RT 3 Adj. CT	Longitudinal Prospective Questionnaire	- 3 mo post-op - 7 mo post-op - 11 mo post-op - 15 mo post-op	WOCS HADS	a. Higher level of anxiety among smokers than nonsmokers ($P < .001$ Higher level of depression among smokers than nonsmokers ($P < .05$) b. — c. Influence on level of distress: Cigarette consumption pre- and post-op	7
Jager-Wittenaar H (2007)[21]	N = 407 279 larynx 131 oropharynx/oral cavity Treatment: Intended for surgery and/or radiotherapy	Longitudinal Prospective Screening Exploratory study	At diagnosis	UMCG H&N CST	a. 34% have dysphagia before treatment b. Tumor location c. Loss of appetite, loss of taste, dysphagia	5
Rieger J (2006)[14]	N = 20 Oropharynx (speech samples of) (40 listeners) Treatment: Surgery and Adj. RT	Cross-sectional Exploratory Study	- Pre-op - 6 mo post-op	Recorded speech samples using sentences from CAIDS. Social Perception Scale with 8 adjectives	a. Positive social perception of speakers ↓ postsurgery b. Degree of tumor resection, tumor location c. Time since surgery, gender, degree of tumor resection	6
Yamauchi T (2012)[32]	N = 75 Oral cancer Treatment: Surgery 17 RT	Longitudinal Prospective Exploratory	Pre-op until discharge	1. Time until start of training to eat ± 11 days 2. Time until eating meal orally ± 11 days 3. Feeding route (oral/tube)	a. Pts >11 days pre-op cancer stage ↑ ($P = .007$) b. — c. Pre-op cancer stage; neck dissection, tracheotomy	5

(*continued on next page*)

Table I. Continued

First author Year	*Sample*	*Study design*	*Time*	*Measurement tools*	*Results* *a. Statistical significance* *b. Clinical effects (physical, psychosocial)* *c. Factors of influence*	*Methodologic and Statistical quality*
Qualitative studies						
O'Brien K (2012)[28]	N = 16 14 Oral cavity 2 Nasal cavity/ Nasopharynx Treatment: Surgery 8 Adj. RT and 2 Adj. CT	Exploratory study	>1 yr post- treatment	Semistructured interview	a. Personal identity; re-establishment of social network; intimate relationships b. Need to support pt's adaptive and coping strategies re: intimacy/social life c. Loss of independence, loss of self-esteem, disfigurement, speech, gender, fatigue	3
Chen S-C (2012)[27]	N = 13 Oral cancer Treatment: Surgery	Exploratory study	Predischarge	Semistructured interview	a. Impact of threatening symptoms; concerns about survival; restrictions of interpersonal relationships; self-restructuring; constructing a support network b. Dysphagia, pain, trismus, speech, disfigurement c. Need to support pt's coping strategies	2
Hu, T-W 2009[22]	N = 6 Oral cancer Treatment: Surgery 2 Adj. RT	Exploratory study	Post-treatment	Semistructured interview	a. To understand cancer diagnosis; the challenges of the treatment; adjustment to changes b. Difficulty eating, trismus, speech, diminished self-esteem, Need to support pt's adaptive and coping strategies re: new appearance and living with cancer c. Degree of social support	2
Röing M et al. (2009)[29]	N = 5 Oral cancer Tongue Treatment: Surgery 3 Adj. RT 2 solely RT	Exploratory study	Median 4 yr post-treatment	Semistructured interviews	a. To exist as one self; To exist in the view of other; To exist together with others b. Speech, difficulty eating, disfigurement, dry mouth, social activities, diminished self c. —	3

Pre-op, Preoperative; *post-op,* postoperative; *wk*, weeks; *mo*, months; *yr*, years; *adj.*, adjuvant; *RT*, radiotherapy; *CT*, chemotherapy; *HRQOL*, health-related quality of life; *QOL*, quality of life; *pt.*, patient. *ABS* (Affect Balance Scale); *SI-R* (Appearance Schemas Inventory − Revised); *ATKLH* (Atkinson Life Happiness Rating); BIS (Body Image Scale); *BSNI* (The Berkman Social Network Inventory); *BSI-18* (Brief Symptom Inventory); *BSS* (Body Satisfaction Scale); *CAIDS* (Computerized Assessment Intelligibility of Dysarthric Speech); *CES-D* (Center for Epidemiologic Studies−Depression Scale); *DAS* (Dyadic Adjustment Scale); *D-S* (Depressivitäts-Skala = questionnaire measuring depressiveness); *EORTC QLQ-C30* (The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, C-30); EORTC QOL-H&N35 (The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, with additional module for Head and Neck Cancer patients); *FACT-G* (Functional Assessment of Cancer Therapy-General); *FACT-HN* (Head and Neck); *FKV* (Freiburger Fragebogen zur Krankheitsverarbeitung = questionnaire for illness processing); *FNAES* (Fear of Negative Appearance Scale); *HADS* (Hospital Anxiety and Depression Scale); *HNS* (Head and Neck Survey - Appearance Subscale); *IES* (Impact of Event Scale); *IIRS* (Intrusiveness Ratings Scale); *IPC* (German questionnaire measuring control strategies); KKG (Fragebogen zur Erhebung von Kontrollüberzeugungen zu Krankheit und Gesundheit = questionnaire for measuring control beliefs regarding disease and health); *KPS* (Karnofsky's Performance Status Index); *MOS-SSS-C* (Medical Outcomes Study − Social Support Survey); *PSS-HN* (Performance Status Scale for Head and Neck Cancer); *SICPA* (Stanford Inventory of Cancer Patient Adjustment); SMAST-13 (Short Michigan Alcoholism Screening Test); *SSS* (Symptom Severity Scale); STAI (State-Trait Anxiety Inventory); *UMCG H&N CST* (UMCG Head and Neck Clinical Screening Tool); *USCF-OCPQ* (University of California San Francisco Oral Cancer Pain Questionnaire); UW-QOL (University of Washington Quality of Life Questionnaire); *WHOQOL-BREF* (World Health Organization Quality of Life − abbreviated version); *WOCS* (Worry of Cancer Scale).
Statistical significance $P = .05$; ↑ = increase, ↓ = reduced.

Even 2.5 years after treatment, half of the surgically treated patients found trismus to be among the third most burdensome symptom.[26] Trismus was found to negatively affect the ability to eat and communicate and hindered intimacy with partners.[28]

Voice and speech. Even before surgery, the ability to speak was found to be one of the most affected areas, only to worsen after surgery.[17,18] The deterioration was found to continue 3 months after surgery[18] and only improved slightly at 6 months. Patients found that speech difficulties affected their QOL more than any other complication.[16] QOL remained reduced 1 year after the operation[11]; however, at 5 years postoperatively, the understandability of speech was found to improve significantly but remained impaired over the long term.[20] The inability to speak in an understandable way, to be heard in public, or to interact with family at home had a great impact on the patients' relationships and social life.[27,28] Employability was also found to be negatively affected.[22] Patients reported that voice and speech problems led to feelings of being diminished as an individual,[29] low self-esteem, and poor psychosocial functioning.[22]

Disfigurement. Preoperatively, 77% of patients were found to be concerned about their appearance, including fear of scarring after surgery, loss of teeth, or loss of hair as a result of adjuvant radiotherapy.[30] Immediately after surgery, patients were affected by their altered appearance and withdrew socially,[27] and this continued for years.[11,28,29] Facial disfigurement influenced personal identity and feelings of self-confidence,[22,29] and it also became a barrier to intimacy with partners or interactions with the opposite sex.[28] Smith et al. showed that 5 years postoperatively, 90% of patients who had undergone free-flap surgery felt that their forearm was disfigured and yet felt comfortable wearing short-sleeved shirts.[23]

Early and late psychosocial effects

Social life. The physical impact of the treatment affected patients' social life even before discharge.[27] As a result of difficulties with speaking or eating in public, social contact continued to be affected for years[18,28] and was significantly affected over the long term.[20,29] Patients expressed a need for support from family and friends and help to construct a supportive social network at the time of diagnosis[27] and which persisted even at 9 years after treatment.[20]

Emotional distress. Before surgery, patients were found to experience anxiety,[17] which reduced considerably postoperatively.[17] Even before discharge, patients were concerned about their cancer returning.[27] One month postoperatively, emotional distress was still high,[19] but the emotional state slowly improved during the first 3 months, although not returning to baseline.[15,18] At 1 year, mood and anxiety scores were still high,[11] and this continued until 5 years after diagnosis.[24] At 5 years, a number of patients were still worried about recurrence, but not to the extent that it interfered with QOL.[23] Finally, at 9 years after diagnosis, emotional functioning returned to normal.[20] Over the years, patients suffered from the physical impact of surgery, which had a negative influence on their psychological and social experiences.[18] Patients were found to struggle with feelings of powerlessness, feelings of being diminished, loss of independence, and low self-esteem and self-confidence,[22,28,29] and they struggled to reconstruct their self-image.[27]

	Pre-op	Discharge	1mo	3 mo	6 mo	12 mo	18 mo	5 yrs	9 yrs
Pain	↑	↑		↘		↘		↓	
Nutrition/ inability to eat	↑	↑			↑			↘	↓
Dysphagia	↑	↓					↘		↓
Trismus							↑		
Voice/speech	↑	↑		↑	↘	↘		↓	
Disfigurement	↑	↑						↓	
Social life		↑						↑	↑
Emotional distress	↑		↑	↘				↘	↓

Fig. 2. Time frame of physical and psychosocial effects and symptoms. ↑ = symptom burden is high; ↘ = symptom burden decreasing; ↓ = symptom burden low. Discharge, Discharge to 2 weeks postop; 1 mo, 1 mo to 6 wk postop; 18 mo, 15 to 28 mo; 5 yr, 3.5 to 5 yr.

Lifestyle. At diagnosis, the number of patients who consumed alcohol was found to range from 36% to 100%,[17,19,22] those who chewed betel nut from 93% to 100%,[19,22] and those who smoked from 31% to 100%.[17,19,22,30] Immediately after surgery, it was shown that rates dropped to 0% for alcohol consumption,[19] to 4% for betel nut,[19] and to 6% for smoking.[19] At 3 months, 28% smoked,[31] at 6 months 28% to 80% still smoked,[16,31] and the rate was reduced at 15 months to 28%.[31] Nine years postoperatively, it was shown that 31% were heavy alcohol users, and 23% smoked.[20]

Time factors. Patients experienced the burden of symptoms the most during the first 3 months after surgery,[15,17-19,21,27,30,32] with symptoms being troublesome even before surgery and in some cases worsening after surgery and then improving during the time up to 3 months. The burden of symptoms decreased further during the following years until 5 years after treatment, when many of the symptoms were no longer burdensome.[4,23,24,29] However some patients experienced symptoms even 9 years after treatment[20] (Figure 2).

Factors of influence. A range of interrelated factors were found to influence the early and late physical and psychosocial effects of the surgical treatment for OPC. Factors that had the greatest influence included tumor size, location, stage of cancer, type of surgery (reconstructive), and adjuvant RT, which affected the level of pain,[4,11,19] nutrition,[19,22,23,32] dysphagia,[4,11,19,21,32] trismus,[26] speech[4,14,16,23] disfigurement,[4] and level of emotional distress.[4] Pain was found to influence the ability to eat and speak,[17,19] and loss of taste, aversion to food, and loss of appetite affected the ability to eat.[21] Men were found to be more affected by pain compared with women,[17] and pain had a negative impact on speech articulation. Compared with men, women were found to be judged more harshly when their speech was not understandable.[14] Age was found to influence pain levels, as older people rated pain higher than younger patients did[19]; however; older patients were found to manage speech difficulties better.[14]

Apart from surgery, factors of influence related to disfigurement were worry about future appearance, being a smoker, being unemployed or depressed,[30] and being in a difficult economic situation.[11] One study showed that impairment causing disfigurement affected the overall experience of QOL more negatively compared with other factors.[16] The physical impact of the treatment negatively influenced social life,[18,22,27,28] whereas support from family and friends had a positive influence.[28] The physical impacts of the illness and the treatment were associated with higher levels of pain, anxiety, and depression.[19,24] Patients who had a low socioeconomic status, had lower education, were single,[15] or lived in unbalanced relationships[24] were more negatively affected. There is some disagreement as to the influence of age. Biazevics et al.[17] showed that older patients were more anxious compared with younger patients, whereas Yang et al.[11] found that older people managed their anxiety better. Some patients were found to be influenced positively by their religious beliefs, as these patients managed their emotions better.[22,27] Finally, lifestyle had an impact; as Humphris et al. showed, smokers had higher levels of distress and anxiety.[31]

DISCUSSION

This review explores the early and late physical and psychosocial effects in patients treated primarily surgically for OPC and the factors that influence these effects. We found that patients with OPC experience physical and functional impairment and psychosocial limitations many years after surgical treatment. The level of impairment and limitation varies, as it depends on the location of the tumor, the type of surgical procedure, and the side effects of adjuvant therapy.

Not surprisingly, the severities of symptoms are worse shortly after discharge but are considerably alleviated by 3 months. However, many patients struggle with one or more symptoms for years after treatment. Patients suffer initially from pain, dysphagia, nutritional deficits, disfigurement, and the psychosocial effects of the physical symptoms, but problems with dysphagia and nutrition, as well as psychosocial problems, persist over the long term.

Patients with head and neck cancers are known to be affected severely by the nature of their illness and the treatment[33] and by a heavy symptom burden. This is true for OPC as well and results from multiple symptoms occurring concurrently. One symptom may compound the impact of another symptom, or the symptoms may be interrelated. This affects QOL more negatively because of the synergistic effect of multiple symptoms.[34] Cleeland described the impact of multiple symptoms on the patient, the severity of the symptoms, and the patient's perception of the impact of the symptoms, a combination that has been referred to as the "symptom burden."[35] Patients with OPC do not suffer from single symptoms, such as pain or disfigurement, occurring separately, but rather a number of symptoms that occur simultaneously and compound the effects of each other; for example, trismus leads to restricted mouth opening, which can affect the functions of speech and eating and, ultimately, the patient's psychosocial life. This symptom burden may eventually have an impact on patient outcome, as found in patients with lung cancer, who experience a reduction in physical and social functioning associated with multiple concurrent symptoms.[36]

The findings in this review show the interrelatedness among symptom burden, poorer physical functioning, social dysfunction, and psychological distress. Patients tend to withdraw from social life because of disfigurement and problems with speech, eating in public, or simply interacting with partners, family, and friends. Increased social isolation may be a risk factor for poorer physical recovery from the effects of both the illness and the treatment.[37] Some patients with OPC have a limited social network or no life partner,[38] which may intensify the challenges of managing burdensome symptoms. Patients with head and neck cancers are among those most affected with regard to their ability to work. Some of the reasons for discontinuing work are low functioning in eating and speech, concerns about appearance, pain or discomfort, and fatigue.[39] Other factors of influence are lower educational level, low income, or living alone.[40]

Patients with OPC suffer in the long term from emotional distress, compounded by physical dysfunction and social isolation. Head and neck cancer has been found to be more emotionally traumatic compared with any other type of cancer,[41] and there is a high prevalence of emotional or psychological distress in patients with head and neck cancer, leading to poorer QOL.[42,43] Bornbaum has shown that there is an inverse relationship between distress and measures of QOL.[44]

Daily life can become quite burdensome if a patient is discharged from the hospital with a range of symptoms affecting physical and psychosocial functionality. Because of lack of rehabilitation interventions, patients are left to manage burdensome symptoms, to a large degree, on their own or are only aided by family and friends.[45] Furthermore, patients are required to make major adaptations to their daily life to manage their situation.[46]

Lifestyle patterns play an important part in the etiology of OPC and in the incidence of recurrence. Smoking, drinking alcohol, and, in Asian countries, chewing betel nut, are known to be the cause of up to 90% of head and neck cancers and OPC.[1,47] Moreover, smoking has a negative impact on postoperative wound healing,[48] and the risk of developing secondary cancers persists[49] when patients with head and neck cancer continue to smoke after diagnosis; their death rate also increases significantly.[50] Thus, there is a need for informing patients about lifestyle changes and supporting them, in particular with smoking and alcohol cessation.

It is acknowledged that the treatment of OPC, because of the nature of the disease and the invasiveness of its treatment, has profound effects on patients' lives. Life cannot be the same as it was before the treatment, but prevention of sequelae could give patients a better QOL in the long term. Therefore, there is a need to find the means to prevent or alleviate the symptoms and the early and late negative effects of the illness and its treatment. Cancer centers are being established worldwide and offer hospital-based or community-based rehabilitation interventions to patients surgically treated for OPC, although these interventions are not based on evidence-based guidelines as yet.[51]

A limitation of this review is that the studies included in it did not have comparative groups. Although all of the patients in the included studies underwent surgery as the primary treatment modality, patients received different types of surgery, with or without bimodal or trimodal treatments. This poses a limitation when generalizing the treatment effects, especially in terms of pain and nutritional difficulties. However, 15 out of 20 articles evaluated the effects based on bimodal or trimodal treatments.

No fewer than 36 different types of measurement tools had been applied in the included studies, which poses some difficulty in comparing and pooling data. However, most of the tools are ackowledged and well-validated QOL questionnaires. Some studies included patient groups other than patients with OPC, although the groups were clearly separable. All but 1 study used either patient-reported outcomes (questionnaires) or structured or semistructured interviews and thus reflected the patient experience of life after treatment for OPC. This review excludes HPV-induced cancers, which have lifestyle patterns, such as sexual behaviour, as a risk factor. However, as the literature search period is from 2004 to 2014, the early articles may have included HPV-induced cancers.

CONCLUSIONS

This systematic review found that patients surgically treated for OPC are affected by their disease and its treatment, both early and late, and that many different factors influence these effects, leading to a heavy symptom burden consisting of interrelated and compounding symptoms. Thus, patients are in need of support for rehabilitation to alleviate and prevent the burdensome symptoms and sequelae.

Further studies are required to establish interventions that support the complex physical, psychological, and social needs of patients with OPC who were primarily surgically treated. Tailored rehabilitation programs, based on systematic reviews, need to be developed to achieve the optimal outcomes, such as patient training for managing dysphagia, nutritional deficits, or trismus. Furthermore, programs need to be developed on how caregivers can best assist and support patients in managing their own postoperative care and in participating actively in daily life. Finally, there is a need for studies on patient education about the most appropriate type of physical rehabilitation or psychosocial support, that is, individual support; smaller or larger group interventions; conversations; and class teaching. Future research should inform the development of evidence-based clinical guidelines for the rehabilitation of patients treated primarily with surgery for OPC.

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Reprint requests:

Annelise Mortensen, RN, MHA
Department of Otorhinolaryngology and Audiology
Head and Neck Surgery
Dept. 2071
Rigshospitalet
Blegdamsvej 9
DK 2100 Copenhagen Ø
Denmark
annelise.mortensen.01@regionh.dk

Appendix 2: Paper 2

The nurse-patient interaction during rehabilitation consultations in patients surgically treated for head and neck cancer– a qualitative study

Annelise Mortensen, RN, Master Anthropology of Health, PhD student [a]
Sally Thorne, RN, PhD, FAAN, FCAHS, professor [b]
Irene Wessel, MD, PhD, associate professor [a]
Simon N. Rogers, MD, FRCS, FDRCS, professor [c]
Mary Jarden, MNSc, PhD, professor [d]

[a] Department of Otorhinolaryngology, Head and Neck Surgery and Audiology, Copenhagen University Hospital, Rigshospitalet, Blegdamsvej 9, 2100 Copenhagen Ø, Denmark
[b] School of Nursing, University of British Columbia, Canada
[c] Faculty of Health, Social Care and Medicine, Edge Hill University, Ormskirk, and Liverpool Head and Neck Centre, Liverpool University Hospital Aintree, Liverpool, Great Britain
[d] Department of Clinical Medicine, Faculty of Health and Medical Sciences, Copenhagen University and Department of Hematology and Oncology, Center for Cancer and Organ Diseases, Copenhagen University Hospital, Rigshospitalet, Blegdamsvej 9, 2100 Copenhagen Ø Denmark

Corresponding author: Annelise Mortensen, annelise.mortensen.01@regionh.dk
Department of Otorhinolaryngology, Head and Neck Surgery and Audiology, Copenhagen University Hospital, Rigshospitalet, Blegdamsvej 9, 2100 Copenhagen Ø, Denmark. Tel: +45-35458896

Email addresses:

Sally Thorne: sally.thorne@nursing.ubc.ca

Irene Wessel: Irene.Wessel.01@regionh.dk

Simon Rogers: simonn.rogers@aintree.nhs.uk

Mary Jarden: mary.jarden@regionh.dk

1. Introduction

Patients treated surgically for head and neck cancer (HNC) may experience detrimental early and late effects of the treatment and have been shown to benefit from postoperative rehabilitation to ameliorate these effects (Fitzmaurice, 2018; Hutcheson and Lewin, 2013; Mortensen and Jarden, 2016). Treatment of HNC is typically surgery and/or chemoradiotherapy, as a single modality or in combination (Crozier and Sumer, 2010) and depending on the specific location of the tumour, the treatment will cause a number of complications, symptoms, concerns and challenges (Wells et al., 2015). Symptoms are often experienced in combination, leading to a complex symptom burden (Mortensen and Jarden, 2016). To prevent and counteract effects, it is recognised that the postoperative needs of patients should be identified and assessed, and symptoms alleviated through specialised rehabilitation aimed at addressing symptoms to help reduce detrimental post-surgical deficits (Hutcheson and Lewin, 2013; Passchier et al., 2016; Rodriguez et al., 2018). Accurate assessment of patient needs, using physical, instrumental and verbal assessments, including self-management strategies of rehabilitation and in alleviation of symptoms, is a fundamental prerequisite for establishing an optimal comprehensive supportive care and rehabilitation programme (Gold, 2012; Hutcheson and Lewin, 2013). However, although the literature reports useful descriptions of various approaches and instruments, including Hospital Anxiety and Depression Scale (HADS) (Van Der Meulen et al., 2014); Patient Concerns Inventory (PCI) (Dempsey et al., 2016); systematic questioning (Dempsey et al., 2016; Van Der Meulen et al., 2014) and patient conversation, there is limited evidence and consensus on the best approach for needs assessment of patients with HNC carried out by nurse professionals (de Leeuw et al., 2014; Hansson et al., 2017). Thus, nurse professionals may face a challenge in recognising and responding to indirect cues from the patient, often resulting in needs not being identified (de Leeuw et al, 2014). A guideline (Dempsey et al., 2016) and the findings of a recent study (Semple et al., 2018) both recommend the use of PCI in holistic needs assessment (HNA), as it allows the patient and nurse to interact in such a way that uncover physical, emotional and social needs.

It is well recognised that needs assessment and self-management should be patient-led or patient-centred (Ahmed et al., 2014; Hansson et al., 2017). To ensure patient-centred care, it has been found that a two-way sharing of information is essential, as well as respect for patient values and preferences (Tobiano et al., 2016; Willem et al., 2016). Evans' (2016) concept analysis found that nurse-patient interactions, verbal and nonverbal, were at the core of nursing care. Evans went on to suggest that nurses must understand how best to use their professional and interpersonal skills to guide interactions that facilitate health and involvement in patients.

Despite the need, there is limited evidence of how nurse-patient interactions during needs assessment of surgically treated patients with HNC facilitate patient involvement in uncovering and managing the needs of the patient.

2. Purpose

The purpose of the study is to explore nurse-patient interactions during rehabilitation consultations that assess the needs of patients with HNC in order to understand how nurses and patients experience the rehabilitation consultation, the extent to which patients experience being involved in the needs assessment and how patients experience the information delivered.

3. Materials and methods

3.1 Study design and methodology

The study used interpretive description (ID), an applied methodological approach that draws on elements from ethnography, grounded theory and phenomenology, without being restricted by the theoretical frames of these methods (Thorne, 2016). ID aims to create ways of understanding clinical phenomena that yield implications for improving nursing practice (Thorne, 2016). Thus an ethnographic approach was applied (Hammersley and Atkinson, 2019), using data from three different data sources, in order to explore the interactions taking place in rehabilitation consultations from different perspectives: 1) non-participant observations of nurse-patient interactions during rehabilitation consultations, to gain understanding of the interactions taking place between nurse and patient; 2) individual semi-structured patient interviews, to explore patients perspectives and 3) a focus group interview (FGI) with nurses, to explore their perspective. The observations and individual patient interviews took place at three different time points during the patient trajectory and involved different patients each time.

3.2 Participants and recruitment procedures

Data collection was conducted from July 2017 to August 2018 at the Department of Otorhinolaryngology, Head and Neck Surgery and Audiology, Copenhagen University Hospital, Rigshospitalet, Denmark (Dept. ORL, H&N). The hospital is tertiary treating 2.6 million inhabitants and performs almost 50% of Danish head and neck patient’s surgery. Denmark has a tax funded health care system where all treatments and rehabilitation is for free. Patients are usually discharged one to three days post-operatively, except for laryngectomees who are discharged seven to 10 days postoperatively.

Patients included had been diagnosed and treated surgically for HNC and able to speak and understand Danish. Patients excluded were those surgically treated for thyroid or parotid cancers, referral to adjuvant chemoradiotherapy. Patients with poor or no voice quality or difficulty in articulating were excluded for individual interviews. Posters displayed in the inpatient and outpatient units announced the observations and informed about the purpose of the study. Patients were approached individually for verbal consent immediately prior to the observations. Staff received oral and written information beforehand at staff meetings and in individual e-mails. Patients were recruited for individual interviews and observations through purposive sampling to attain a broad range of experiences representative of HNC, including diagnoses, gender, age and time point (Malterud, 2017). Hospitalised patients were approached post-operatively for individual interviews, received written information about the purpose of the study and a signed informed consent was obtained. The nurses who participated in the FGI were approached individually for written informed consent. We determined our sample size guided by Malterud's (2017) criteria for information power. All participants were informed about confidentiality, anonymity and voluntariness. The study was carried out in accordance with the Helsinki Declaration and approved by the Danish Data Protection Agency (2012-58-0004-05781). Approval from the Regional Ethics Committee is not required in Denmark in studies where biological material is not collected.

3.3 Study context

The Danish Health Authority's (2018) recommend in the 'Guidelines for Rehabilitation and Palliation in Cancer', that all cancer patients in Denmark must have their physical, emotional, social and existential needs assessed for rehabilitation post-treatment (Danish Health Authority, 2018). In cooperation with the patient, it is then decided how these needs can be met through rehabilitation in the primary sector (Danish Health Authority, 2018). The Danish healthcare system is divided into regional sectors that run the hospitals and specialised rehabilitation in-hospital and the primary sector, consisting of municipalities responsible for delivering rehabilitation and support for life style changes such as smoking and alcohol cessation ("Ministry of Finance," 2020).

A four-person team of nurses at Dept. of ORL, H&N conducts rehabilitation consultations assessing patient needs at three different time points post-surgery: 1. before discharge; 2. 7–10 days after surgery in the out-patient-department (OPD); and 3. two months after surgery in the OPD. Rehabilitation consultations are based on recommendations from the above-mentioned guidelines and using patient conversations with patients to detect their needs. Based on the needs assessment, the nurses offer support and guidance on symptom management, with emphasis on self-management, and provide advice and referrals such as to psychology, counselling or multi-disciplinary municipal follow-up.

3.4 Data collection

Data were collected through observations, individual interviews and an FGI. Fig. 1 provides an overview of the data collection time points. Data was primarily collected by the principal investigator (AM), supported by a clinical nurse specialist. AM had been employed as a clinical nurse specialist in Dept. ORL, H&N for more than 10 years. Her function consisted of initiating, conducting and implementing development activities, but without direct patient contact. In this capacity AM had been responsible for implementing the rehabilitation consultations, without participating in actual consultations or other patient contact. AM's preconception was thus influenced by her knowledge of HNC and patients affected by this, the nursing staff as well as the department itself (Malterud, 2017).

Observations (n=15) of nurse-patient interactions during rehabilitation consultations were carried out at the three time points and comprised five observations at each. Approximately 12 hours of observations were conducted over four months and each observation lasted 30 to 60 minutes, with no more than one observation conducted daily. Guided by ideas from background literature, the observations focused on the interactions taking place between the nurse and patient, with special attention focused on the topics addressed and by whom, in addition to verbal and nonverbal reactions to what was discussed. Thus, the content and style of nurse-patient verbal and nonverbal interactions were observed, as well as any other actions that could potentially influence their consultation.

Subsequently, short ad hoc interviews with patients and nurses took place to elaborate on the observations, by asking clarifying questions such as 'Can you tell me why you asked that question of the patient (nurse)' or 'Can you tell me a little more about how the cancer diagnosis affected on you'**.** The preliminary analysis of the first ten observations informed the final five observations. Observations and ad hoc interviews were recorded as handwritten field notes and digitally transcribed the same day. Dressed in ordinary clothing to signify her non-participant status, AM carried out all observations sitting discretely in the corner to ensure a good view without interfering in the patient-nurse interaction.

Individual patient interviews (n=15) were carried out at the same three time points in the patient trajectory as the observations. Interviews took place immediately after the nurse-patient consultation to obtain the patient's immediate impression of the interaction. In accordance with ID, data analysis took place both concurrently with and subsequent to data collection. The interviews were based on a semi-structured interview guide developed from the literature on nurse-patient interaction, patient involvement and communication, and the needs of surgically treated patients with HNC, as well as being informed by the first 10 observations. The interview guide focused on what patients experienced and the impression they had of their interaction with the nurse, their own involvement in the consultation and the content and issues that were discussed. Interviews took place in a private hospital room, were recorded digitally and conducted by AM or a clinical nurse specialist and lasted between 15–25 minutes. Relatives could be present during the interviews but were informed that their comments would not be used in the study. Table 1 presents participant demographics.

To provide additional perspective on this phenomenon from the nurses' perspective, an FGI was carried out with three out of four nurses who comprise the department's rehabilitation team. The three nurses had previous experience in either oncological and/or surgical cancer nursing and had been part of the rehabilitation team for six, seven and 18 months respectively. The FGI took place in a conference room during the nurses' work hours.

An FGI guide was developed with prompt cards and discussion points inspired by data from the observations and individual interviews (Halkier, 2016). The prompt cards described four needs areas: physical, mental, social and existential and were derived from the PCI (Rogers et al., 2009), which is a list that prompts patients to provide an individualised account of their concerns and needs. The discussion points were based on the observations and focused on the nurses' opinions, experiences and ability to discuss issues and needs with the patients. AM, as the primary interviewer, conducted the FGI supported by a clinical nurse specialist who served as the moderator and had been given written and oral instructions on her role in advance. The interview was recorded digitally and lasted one hour.

3.5 Analysis

The main author (AM) transcribed the interviews. Field notes from observations were converted into textual data. All data were transferred to NVivo 11 for management ("NVivo qualitative data analysis software," 2015).

The data analysis was inspired by systematic text condensation (STC) (Malterud, 2012) and ID (Thorne, 2016), the former based on Giorgi's psychological phenomenological analysis.

STC is carried out in four steps: 1) gaining a total impression – from chaos to themes; 2) identifying and sorting meaning units – from themes to codes; 3) condensation process– from code to meaning; 4) synthesizing – from condensation to descriptions and concepts. In the following each step is explained and examples from one theme is presented.

According to Step 1, all transcribed text was read and reread several times. Then as a second part of Step 1, several preliminary themes were developed from the read text, example *'Information'*.

In Step 2, meaning units are identified in the transcribed text. Meaning units are fragments of text, that relates to the research question. A code was then attached to each meaning unit. A code labels the meaning units and helps to group meaning units together in code groups, example *'Information; Many pieces of information'*. From the code groups new condensates were developed in Step 3. Condensates are meaning units in a code group, made into one new text. The text condensates the units and creates a new artificial quotation grouping together all the expression from the meaning units, example *'Patients experience receiving much information'*.

Finally, in Step 4, the condensates are developed into descriptions and concepts, resulting in a number of themes, example '*Factors inhibiting communication of advice and recommendation.*

Throughout the analysis AM and the last author (MJ) discussed the contents of each step. All authors read the material and reflected and commented on the findings.

4. Results

Across data from observations, interviews, and FGI four interrelated themes were revealed within the dataset exposing the complexity of conducting rehabilitation consultations and actively involving patients with HNC: expectations for nurse-patient interaction differ; the challenges of building rapport; barriers to adequately identifying rehabilitation needs; and factors inhibiting communication of advice and recommendations. The themes are presented separately but are interrelated and thus influence each other.

4.1 Expectations for nurse-patient interaction differ

Although patients are found to be generally quite satisfied with the interaction, nurses and patients began with discrepant expectations. Nurses prepared carefully for the consultations by reading the patient's hospital record and by undertaking a preliminary assessment of the patient's expected needs, while the patients did not prepare for their consultations and also did not have any expectations. This discrepancy in expectations was surprising to the nurses at times, as they mentioned themselves, however they had not fully informed the patients about the purpose of the consultations.

> *"I didn't really have any expectations about anything at all" (Patient 4)*
>
> *"Sometimes, I experience, just asking about wife and kids puts the patient off, but then I sort of explain [to the patient] that this [the consultation] is part of their disease and treatment trajectory" (FGI, nurses)*

Patients are generally happy about the conversations during the consultations and find nurses to be emphatic.

> *"I have no complaints about the consultation – not at all. It worked well for me, but then again I did not really have any expectations either" (Patient 3)*
>
> *"Well, they [the nurses] are the human face in a course of treatment like this – and it is – well – you need that everything is not all about medical [terms] and results and this and that, but you also get some advice on how to handle the situation in your everyday life, if you are not sure how to do that" (Patient 9)*

4.2 The challenges of building rapport

After preparing, the nurses began the consultation by inquiring about the patient's health and wellbeing and listening to their responses; or by introducing themselves before expanding on the information that was given earlier during the doctor's consultation. Some nurses asked patients questions to gather information for the needs assessment.

The nurses felt uncertain about how to start the consultation, build rapport (i.e. make the patient feel safe and comfortable, listened to, valued and respected) and engender confidence in the patient. At the same time, they were aware that they had not informed patients about the specific purpose of the consultation or the reason why certain information was requested of them.

> *"I haven't done so much about that … given a reason for my questioning and I think I will try to improve that and explain why I am asking these questions." (FGI, nurse)*

Although the nurses encouraged the patient to ask questions, some patients were unable to ask any because they were unprepared and unsure about what to ask. The nurses' attempts to involve patients in the consultation ended up becoming a barrier to building rapport. Many patients did not respond to the invitation to ask question. Patients said that they would like to ask questions but did not know what to ask. When asked if they felt involved in the conversation with the nurse, they confirmed they did so, most often by stating that their questions were answered. Thus, in many instances, there was a difference between what the researchers observed and the patient's own experience.

> *" I don't really have any questions about anything" (Patient 6)*

Additional aspects that seemed to hinder building rapport was the impact of the cancer diagnosis and the way patients perceived and coped with it. Despite their experience of the diagnosis as a shock, many associating it with death and dying, during all three time points, how the diagnosis affected the patients rarely came up as a topic of conversation. Instead, patients found various ways to cope with and communicate about their diagnosis and treatment. Taking a highly pragmatic approach, patients said that they did not worry about or discuss their diagnosis with others and instead focussed on managing life one day at a time. Others admitted they were quite scared and could not face their situation, frequently leading to joking during the consultations. One patient explained that humour helped them cope with the illness.

> *"Well, I take my illness and turn it into something funny. Because there's nothing else I can do. I have to look at this disease with a sense of humor. Otherwise I won't get through it – I make fun of what is going on all the time." (Patient 11)*
>
> *"During the entire consultation, the patient laughs all the time. She explains herself – unsolicited - that she makes fun of her situation to be able to cope with it."*
> *(Observation 7, tp 2)*
>
> *"… to get behind that facade and if you ask some questions, then you sense it is wiped off with some – a little humor ….or the patients who say I manage one day at the time – that may also be a way of saying – I have been told a little and I am satisfied with that, but actually I (the nurse) have not said to the patient – 'then you may need to talk to me tomorrow or how do you handle that one day where it is too difficult?' (FGI, nurses)*

The nurses recognised that some patients felt the need to use avoidance techniques during consultations. However, they found that these techniques made it difficult to start up or continue conversations when the goal was to create an open atmosphere, build rapport and encourage the patient to talk about their emotional or existential needs.

4.3 Barriers to adequately identifying rehabilitation needs

Although patient involvement was one of the nurses' goals, one aspect that may have hindered this purpose was the preparation the nurses put into creating a list of expected needs and informational topics to be addressed that are important from a professional point of view. The nurses set the agenda and took sole responsibility for identifying the needs of the patient prior to the consultation; patients were neither asked to prepare for the consultation nor identify their needs beforehand. As a result, the nurses approached the consultations as a means to validate their list by asking patients probing questions about their physical and functional needs or social situation. In most cases this was helpful not only in assessing the accuracy of the list but also in identifying other needs. The nurses reported that some patients were put off by this approach, while others felt that even though the nurse set the agenda, they did not mind because they also believed that the nurse could help guide them.

> *"This border you cross – sometimes I experience that just asking a patient whether he has a wife or children – some find we violate their privacy that way.*
>
> *But, then of course, we do have some points, a list of things we wish to go through … and then we do control, at least to some extent, what is going to take place." (FGI, nurses)*
>
> *"It [the consultation] is very much on your terms, isn't it? So, you [nurses] set the agenda, but I'm fine with that." (Patient 3)*

The types of needs that the nurses primarily identified in this manner included the patients' physical and functional needs in terms of, e.g. speech, swallowing, chewing, nourishment and pain.

The patients' psychological and existential needs were not discussed or identified nearly as often and were more difficult for nurses to identify, and even more difficult for them to discuss with the patient, even though the nurses found that these needs were just as important. The nurses were especially concerned about starting sensitive conversations about emotional or existential concerns that might be difficult to carry out, thus causing the patient more harm than good.

> *"Am I equipped to initiate this talk? Am I doing it correctly? And am I opening up something I'm not able to finish in a good way? – And then there's physical issues – they're just so hands on, and we know all the answers …" (FGI, nurse)*

Though concerned about discussing emotional or existential needs, the nurses would sometimes give the patient an opportunity to talk more generally about this by asking about their mood or how they are doing.

Patients felt that their needs fluctuated over time. Especially emotional and existential needs only surfaced later, for example by the third consultation, which took place two months after their operation. Several patients shared how they began to react emotionally to their diagnosis and treatment trajectory at this time.

> *"… then you reflect – this was a very ugly ordeal, when you actually begin to think about it" (Patient 13)*

During the initial months of the postoperative trajectory, the patients focused primarily on their physical needs and symptoms. As these needs and symptoms improved or were resolved, they began to reflect on the symptoms they experienced during the hectic period from diagnosis to surgery to recovery. Two months post-surgery at the third consultation, patients were ready to talk about their emotions and reflect on their situation. Patients described how they looked back and considered their trajectory an atrocious, frightening experience.

> *"Less than three weeks – that's a very intense course of treatment! Where you get the whole kit and caboodle – everything – really – you don't get a chance at all to connect with your emotions at any time – and that means it comes back as a post-traumatic stress disorder [PTSD] boomerang – a few months pass – exactly – a month or two, right? And then the reactions come – it's a type of PTSD that comes rushing in." (Patient 12)*

However, not much assessment of or inquiries about the patients' emotional needs occurred at the third consultation, and patients did not address this issue themselves. This may be due to the nurses' hesitation to address these needs or their lack of awareness of emotional needs surfacing at this time point. Finally, the nurses found it difficult to identify and discuss sexual concerns with the patients. In fact, these concerns and needs were not mentioned at all, neither during the observations nor the individual interviews.

4.4 Factors inhibiting communication of advice and recommendations

When needs had been assessed, the nurses spent a good part of the consultation providing information about various aspects of the patient's follow-up care, such as health and safety precautions when discharged; contact information; referrals; symptom control and self-management. Patients received much information, particularly on nutrition, because many of them were discharged with either tube feedings or a liquid/soft diet. A considerable amount of written information and verbal instructions were given on how to manage food intake, including the importance of eating a high calorie/high protein diet and not losing weight, in addition to other written information on a wide range of issues. The greatest amount of information was provided at the first consultation just prior to discharge, which often took place 2–3 days after surgery.

At time point 1, we observed that typically, this involved the nurse handing the patient a large envelope filled with food recipes and other written information, provided with little explanation. Most patients found the amount of written information excessive, especially right before discharge. They found themselves incapable of processing the amount of verbal information and unable to apply the written information. Patients had diverse ways of managing the quantity of information received, some passing on the responsibility to family members and others putting it aside for later use. Several patients explained that they planned to read it at some point.

> *"Then I'm having this conversation with the nurse, then there were these cookbooks and then there was this and then there was that and I just felt – I had already shut down mentally because you're all mixed up and then I had all these papers – well, well – and then I gave all the papers to him [boyfriend], and then we went home and he [boyfriend] read through all the papers and he took control of them. That was too much. But then, what should they do [the nurses]? Because … should they mail it to you later ...?" (Patient 12)*

A few patients, however, expressed being pleased about the amount of information.

> *"You can't have too much information – and there's nothing like coming home and then saying to yourself – I should have asked about this or that …" (Patient 2)*

As required by the Danish Health Authority, a main focus during consultations, in addition to nutrition, is related to lifestyle factors, such as smoking, alcohol and exercise. The nurses talked to patients primarily about smoking cessation and, to a lesser extent, alcohol consumption. Patients were informed of the detrimental effects of continuing to smoke, including risk of recurrence. There was a striking difference between observations and the nurses' accounts of this focus, and how seldom patients recounted these conversations in the interviews. The nurses thought it was difficult to discuss smoking cessation with patients and found themselves approaching the issue in a way they felt uncomfortable with.

> *"As far as smoking is concerned, I sometimes feel I end up beating around the bush because it gives the patient a lot of quality of life, and it's a matter of habits and chemistry in the brain, I would say – and in that situation, I sense that if I push them too much, because it's a matter of quality of life, habits – addiction …" (FGI, Nurse)*

When patients smoked less or stopped altogether, nurses were highly encouraging. But little actual practical information on how to self-manage their own cessation was provided. The only tool nurses applied was referral to a smoking cessation programme, which very few patients agreed to do.

In summary, the findings revealed that communication in rehabilitation consultations assessing needs was a complex interaction between nurse and patient, with both entering the consultations with different expectations. This was a barrier for the nurses, who attempted to build rapport with the patient, and used a questioning interview style, to enhance their interaction and communication. As a result**,** patients were involved in the consultation to a varying degree; their needs were not always fully identified or managed, and the subsequent advice and recommendations were therefore sometimes difficult to communicate.

5. Discussion

These findings revealed that the interaction and assessment of needs was complex, as depicted in the interrelated themes of differing expectations, challenges to building rapport with the patient, barriers to adequately assessing rehabilitation needs of patients, and factors inhibiting communication of advice and recommendations to the patient.

In the context of the rehabilitation consultation, our study suggests that nurse-patient interaction during assessment of patient needs is a complex communication process requiring both the nurses' interpersonal and professional skills, but also cooperation with the patient. The nurses in this study found it especially important, but also challenging, to initiate the interaction and establish a relationship with the patient from the outset, as a prerequisite for the ensuing assessment of needs.

To establish this relationship, the nurses needed to build rapport to make the patient feel safe and comfortable, listened to, valued and respected (Prescott et al., 2018). However, the nurse and patient entered the interaction from different starting points, as only the nurse knew the full purpose of the consultation beforehand. Lack of transparency regarding the purpose of the consultation led not only to a disparity in what each group knew about the consultation but also resulted in nurses and patients having much different expectations toward the consultation. The nurses had expectations concerning the content, relationship and interaction, whereas the patients had none, nor had they reflected on their needs beforehand, or how they might benefit from the consultation. Knowing the purpose of and having clear expectations about an interaction, as well as toward building a relationship between patient and nurse during consultations, have important bearings on the outcome of the consultation (Evans, 2016; Wiechula et al., 2016). In a context where discrepancies exist concerning purpose and expectations, establishing a trusting relationship appears to be imperative, but also challenging, for the patient to feel at ease while interacting during consultations. Nurse-patient interaction, building rapport and establishing a trusting relationship are interrelated issues (Dang et al., 2017; Evans, 2016; Prescott et al., 2018; Wiechula et al., 2016), that encourage patient participation and involvement (Aldaz et al., 2017; Prescott et al., 2018) and support their ability to express their needs (Aldaz et al., 2017). Thus, there may be considerable room for advancement in planning interviews to a greater effect.

After initiating the interaction, nurses in this study proceeded to assess patient needs. To detect these needs, the nurses conversed with patients without using a method comprising any set way of conducting the consultation. When the nurses assessed patient needs, it resulted, to some degree, in one-way communication, where the nurses used an interview style of questioning and the patient's role became one of answering these questions. Nurses observed that the large number of questions surprised some patients. Our observations supported this in that patients often did not participate in the needs assessment beyond answering questions, and although nurses encouraged patients to ask questions, many refrained from doing so. The patients explained that they did not know what to ask and that they had not prepared for the consultation.

Involving patients in a consultation through the exchange of information is important for including them in collaborating on needs assessment. Protheroe (2013) showed that patients do not feel at ease asking questions, either because they find doing so inappropriate, or they do not feel invited to participate in a consultation with healthcare professionals. Patients need to know explicitly that their questions are welcomed (Dang et al., 2017; Judson et al., 2013), and this message needs to be reiterated several times during consultations (Dang et al., 2017) and not only at the end, as observed in the present study.

Some patients may not ask highly specific questions or be especially explicit during the conversation if unsure about whether the topic is permitted, perhaps causing them to communicating less precisely, making it difficult for health care professionals to pick up subtle verbal or non-verbal cues (de Leeuw et al., 2014; Del Piccolo et al., 2005). Several studies have found it is difficult for nurses to pick up emotional cues when communicating with patients with cancer (de Leeuw et al., 2014; Uitterhoeve et al., 2009).

Another avenue for involving patients in the consultation towards exchange of information and collaboration on needs assessment, has been shown to be the use of Patient Reported Outcomes Measures (PROM) or HNA (McEwen et al., 2018; Young et al., 2015). Thus the application of a needs assessment instrument (Johnston et al., 2019; Kotronoulas et al., 2017), could aid the patients in expressing their own needs (Johnston et al., 2019).

Our study found that assessing emotional needs was generally challenging for the nurses, which research has shown is not uncommon among healthcare professionals (Dean and Street, 2014). In our study, nurses found it difficult to address emotional needs and thus asked probing questions, such as “How are things going?” and “How is your mood?” Studies have shown, however, that general non-specific questions may not be the most effective method (Leppin et al., 2018; Uitterhoeve et al., 2009). It is important to not only pick up cues but also to employ an inquiring, conversational approach to assist in further exploring the specific emotional needs of the patient (Dean and Street, 2014). Establishing rapport and a trusting relationship at the onset of an interaction have been shown to facilitate uncovering emotional needs and picking up on related cues (Aldaz et al., 2017; Dang et al., 2017; Dean and Street, 2014).
The nurses in this study express a need for training in conducting rehabilitation consultations, thus nurses might benefit from participating in training towards acquiring the necessary skills for this, as has been found in studies regarding implementation of HNA (Johnston et al., 2019; Thewes et al., 2009; Young et al., 2015)

We found that once patient needs are assessed and identified during a consultation, the nurse provides information and advice according to the patient's individual needs. Receiving an overload of information was a challenge for most patients, especially 1–3 days postoperatively and just prior to discharge, a point at which many patients struggle with multiple physical symptoms and emotions. Patients found that the amount of information, including written information, was excessive. Patients felt that they were unable to process the quantity of information and either handed it over to a relative to read or left it for later. Both the amount and timing of information provided during the cancer trajectory play an important role in the patient's ability to take in the information (Aldaz et al., 2017; Mazor et al., 2013; Thorne et al., 2014). Further, the interpersonal skills of nurses and patient preferences influence the exchange of information (Mazor et al., 2013). Thus, the delivery of information is influenced by the ability of nurses to build a relationship with the patient and to secure patient involvement in communicating advice (Dang et al., 2017), for instance by involving the patient in deciding which information they wish to receive at different time points during their trajectory.

5.1 Implications for practice

Our data showed that conducting nurse-patient consultations in assessing the rehabilitation needs of patients with HNC is a complex and interrelated process that requires various steps when assessing and identifying rehabilitation needs and giving patients the necessary support. It is important that the goals and purposes of the consultation are clear to both the nurse and the patient in order to assess rehabilitation needs and to provide information and guidance on managing these needs, all in collaboration with the patient. Nurses need to invite patients into the interaction by building rapport and a trusting relationship as a foundation for the subsequent needs assessment and communication of advice and information. Failing to establish this foundation may cause challenges in subsequent interaction.

Although patients in this study express to be satisfied with the interactions with nurses, this does not necessarily imply that their needs have been met. Rather we must look more deeply into how effectively they have engaged with articulating their concerns and questions, and how effectively tailored to their distinctive circumstances is the information that is ultimately provided. Patients are vulnerable, contending with a serious illness and unpleasant symptoms from their treatment, which requires sensitivity by the nurses when communicating with them. We propose using a systematic consultation practice involving specific steps to ensure an effective sequence in rehabilitation consultations that includes an explanation about its purpose (Dwamena and Fortin, 2012) at the onset of the consultation. One possible way of meeting the challenge involved in ensuring that all needs are uncovered, particularly emotional needs, as well as cancer specific needs could be to apply a HNC specific needs assessment instrument that would allow the patient to become involved and permitted to articulate their own needs (Johnston et al., 2019). Such an instrument could be a HNA instrument (Johnston et al., 2019) or a PROM (Kotronoulas et al., 2014). This would form a basis to assist in an individualised approach and dialogue with each patient, to meet his or her specific needs. Finally, patients might benefit from nurses recommending which information is most needed at the time of discharge and, based on this, in agreement with the patient, provide further information at subsequent consultations.

5.2 Methodological considerations

Collecting data from three different sources across the patient treatment trajectory provided a multi-facetted impression of the interchange between the patients and nurses during the rehabilitation consultations. However, we do not know the extent to which other interactions, aside from the consultations, may have influenced the nurse-patient relationship, and how patients experienced the interaction. Further, the recruitment for individual interviews, did not achieve as broad a sample as aimed for, since only women participated at time point three. Finally, relatives were present during 1/3 of individual interviews and some observations. We do not know to which extent their presence may have influenced the contents of interviews or interactions during observations.

6. Conclusion

Although patients reported being satisfied with the consultations, there was conflicting evidence as to the depth and relevance of the rehabilitation needs identified as a result of the consultations. Nurse-patient interaction in the rehabilitation consultation is complex and involves many different interrelated aspects that require the nurse to have the necessary interpersonal and professional skills to support the patient to enhance their involvement in the encounter. Future research should explore whether patients could benefit by nurses participating in training on conducting consultations that involve patients in assessing their own needs – physically, psychologically, socially and existentially. Furthermore, the type and flow of a systematic nurse-patient consultation approach requires further study, as does the benefit of consultations following a certain order. Another avenue of future exploration is whether involving patients in completing a needs assessment instrument can facilitate patient involvement, thereby enhancing the uncovering of important needs. Finally, it would be advantageous to determine whether a stepwise transfer of information at different time points, based on patient needs, interests and acceptance, can minimise information overload.

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Fig 1: Data collection time points

2017 **2018**

June	July	Aug - Dec	Jan	Feb	March	April	May	June	July	Aug
					FGI **n= 1**					

FGI = Focus Group Interview

Table 1 Participant demographics

Interview time points	**Patient number**	**Age (years)**	**Gender**	**Diagnosis**	**Next-of-kin present during interview**	**Interview duration** (minutes)
1	1	71	M	OCC	No	30
	2	77	M	OCC	No	15
	3	44	M	OCC	Yes	15
	4	68	F	OCC	No	15
	5	61	M	OCC	No	15
2	6	54	M	OCC	No	15
	7	79	F	OCC	Yes	20
	8	78	M	OCC – and sinus maxillaris cancer	Yes	15
	9	60	M	OCC	Yes	20
	10	63	M	OCC	No	15
3	11	74	F	Oro-pharynx cancer	No	15
	12	65	F	OCC	No	20
	13	67	F	OCC	Yes	15
	14	86	F	OCC	No	15
	15	59	F	OCC	No	15

Age - Average: 67 years Range: 44 – 86 OCC= Oral Cavity Cancer

Time point 1; xxx, time point 2; xxx, time point 3; xxx

Appendix 3: Paper 3

Appendix 4: Report on translation of University of Washington Quality of Life Questionnaire and Patient Concerns Inventory

This report describes the procedure involved in the linguistic and cultural translation of University of Washington Quality of Life Questionnaire (UW-QoL) and Patient Concerns Inventory (PCI).

Background

The University of Washington Quality of Life questionnaire is a brief and self-administered questionnaire, which is multifactorial, allowing sufficient detail to identify subtle change, is specific to head and neck cancer, and it allows no input from the health provider, thus reflecting the Quality of Life (QOL) as indicated by the patient [1]. Since the first development of version 1 by Hassan and Weymuller in 1993 [2], UW-QoL has undergone several revisions and is now available in version 4.

UW-QoL contains 14 items, each having between 3 – 5 statements, by which the patient can state their current status pertaining to the item. Further the patient can state which items have been most important to them and finally a rating of the overall QoL.

The Patient Concerns Inventory (PCI-H&N) is a 55-item checklist specifically designed for use in routine follow-up clinics for patients with head and neck cancer. The first version of the PCI, was developed in 2007, in Liverpool, Great Britain [3]

The PCI-H&N is not a traditional Patient Reported Outcome, measuring Health-Related Quality of Life (HR-QoL) outcomes, as the concept of a PCI is broader than that of HR-QoL, since it allows patients to formulate an individualized record of their concerns, needs and priorities that can be used as a framework to help patient's express their needs; guide out-patient consultations and promote multidisciplinary care [4].

This report will describe the procedure for both UW-QoL and PCI in their electronic versions, as they will be used in conjunction and the procedure was similar for both. The translation followed the guidelines of European Organisation for Research and Treatment of Cancer [5]

The translation process took place from June – December 2017 and was carried out at Dept. of Otorhinolaryngology, Head and Neck Surgery and Audiology (Dept. ORL, H&N), Copenhagen University Hospital, Rigshospitalet.

1. **Forward translation** (June – September 2017)
   The forward translation was performed by two translators, who had Danish as their native language and a good command of English.
   The reconciliation of the two translations was performed by a Danish translator with good command of English and a Danish/American. A few words and expressions caused difficulties:
   UW-QoL:
   Recreation; the statement 'I can't do anything enjoyable'; *Swallowing*; I cannot swallow certain <u>solid foods.</u>
   PCI:
   The title itself, Patient Concerns Inventory and the word 'Coping' do not translate easily into Danish.
   An expert-panel consisting of a doctor, clinical nurse specialist, nurse - leader of the department's rehabilitation team, nurse – team member in the department's rehabilitation team, were asked about their advice.

The following decisions were made on the issues:

UW-QoL:

Recreation: 'I can't do anything enjoyable', was translated into 'Jeg kan ikke lave noget hyggeligt' and *Swallowing*: 'I cannot swallow certain solid foods', was translated into 'Der er noget mad/fast føde jeg ikke kan synke'.

PCI:

'Patient Concerns Inventory'. It was decided to ask the patients about their opinion, at the pilot-testing. *Coping*: possible translation was discussed at length and it was decided to use the sentence 'At kunne håndtere situationen'.

2. **Backward translation** (September – November 2017)
   The backward translation was performed by two translators, of whom one had Danish as her native language, but a very good command of English and a professional translator who is Danish/American. Further the translation of 'People I would like to talk to' on the PCI, could not be translated directly. 'People I would like to talk to' refers to a list of health care professionals (HCP) and other people, whom the patient might wish to talk to. The HCP's and other people who can be contacted in Denmark and Great Britain are not the same. Again, the expert panel was approached for their advice and a Danish list of people to contact was made. See appendix 2.

3. **Pilot-testing and re – test** (Nov. 22 – Dec. 18 and Dec. 19 – 28, 2017)
   The Danish versions of UW-QoL and PCI were tested on 12 patients or survivors of Head and Neck cancer at the following places: two networks for patients with Head and Neck Cancer (Netværket for hals - og mundhulekræft and Dansk Landsforening for Hals – og Mundhuleopererede – the local chapter); at the patient education day and at the in – and out-patient departments of Dept. ORL, H&N. A few items needed re-testing and were tested on 5 patients at the OPD of Dept. ORL, H&N

The results of the patient pilot-test and re-test are the following:

UW-QoL:

Recreation: 'I can't do anything enjoyable', was first translated into: 'Jeg kan ikke lave noget hyggeligt'. This did not pass the pilot-test. Instead the following options were suggested by the patients: 'Jeg kan ikke lave noget rart'/'Jeg kan ikke lave noget der gør mig godt'/'Jeg kan ikke lave noget jeg har lyst til'/'Jeg kan ikke lave noget fornøjeligt'. The last option was chosen in the re-test.

Swallowing: 'I cannot swallow, it 'goes down the wrong way' and chokes me', was first translated into: 'Jeg kan ikke synke, fordi jeg "får det i den gale hals" og det kvæler mig' This did not pass the pilot-test. Instead the following options were suggested by the patients:

'Jeg kan ikke synke, fordi jeg "får det i den gale hals" og det giver mig stort ubehag'/'Jeg kan ikke synke, fordi jeg "får det i den gale hals" og det giver mig kvælningsfornemmelse' The last option was chosen in the re-test

Saliva: Several patients noticed that the saliva item moved from consistency of saliva and into amount of saliva. This issue was discussed with Simon Rogers one of the present copyright owners of UW-QoL . It was decided, that for the purposes of the present study 'My saliva is of normal consistency' was changed into 'My saliva is normal' which in Danish became 'Mit spyt er normalt'.

PCI:

Fatigue was translated into: ‘Fatigue/træthed’. Some patients were happy about the expression ’fatigue’, while others did not understand the meaning of the word and wanted it removed. Some patients argued that fatigue and træthed (tiredness) is not the same. At the re-test it was decided to keep the combination of the two.

PEG tube was translated into ’PEG-sonde’. Neither the word ’PEG’ nor the word ’sonde’, was understood by all patients. After re-test the word ‘Ernæringssonde’ was chosen.

Vomiting/sickness were translated into: ‘Opkastning/forkvalmet’. The word ‘forkvalmet’, was not accepted in pilot-test. In re-test ‘opkastning/kvalme’ was chosen.

Patients were asked which *title* they found most suitable for the Patient Concerns Inventory. They were given the following options, with the possibility of making other suggestions: ‘Patient Bekymrings Liste’; Behovsliste; Liste over patient interesser’; Skema for patientbekymring. The majority preferred the word: ‘Behovliste’

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Appendix 5: Interview guides

Interview guide – semi-structured interviews

- Experience of rehabilitation consultation
  - How did you experience the consultation with the nurse a little while ago?
  - Which subjects did you talk about?
  - How and how much were your expectations for the consultation with the nurse accommodated?

- Experience of own involvement/inclusion in the consultation
  - Did you experience being involved/included in the consultation?
  - In your opinion did you get an opportunity to talk/ask about those issues you wished to talk about or know more about?
  - How did you experience your own influence on the decisions that were made regarding your rehabilitation? For instance, referral to swallowing therapist or speech pathologist?
  - Did the nurse listen to the subjects you wished to tell her about? How did you experience that?

- Subjects talked/ informed about
  - How did you like the subjects that were discussed?
  - Was there something else you would rather have talk about/asked about?
  - Did you talk about your social or emotional concerns?
  - How and how much did you experience the nurse respected your values?
  - Did you express your needs and concerns? And did you the experience that the nurse listened to you?

- Subjects informed about
  - How about the information you received? Was it enough? Too much? Too little?
  - Was the information passed on in a way that was understandable to you? Or was it confusing?
  - Was the information appropriate for your present situation?

- Locality
  - What is your opinion on the locality/room where the consultation took place?

Interview guide focus group

- Experience of rehabilitation consultations
  - How do you generally experience the consultation with the patient?
  - Do you experience having alternating ’roles’ in relation to the patient? I.e. teacher; resource person; counsellor; health care expert?

- Subjects discussed
  - Which areas of need do you most often touch on (physical/functional; psychological/emotional; social; existentially/spiritual)?

- Challenges in communication
  - Are there certain subjects/areas of need that are easier to address and others? And why?
  - What makes it difficult to talk about certain subjects?

- Experience of involving/including the patient in the consultation
  - Who do you believe has the most influence on which subjects are being discussed? The patient or you? Why?

- Subjects which are informed about
  - What is most important to inform about in your opinion? Why?
  - Has the contents, the way of delivery and the amount of information an importance? How and why?
  - Is there a difference in the way information may or is given depending on the social background of the patient?

  The influence of the surrounding on the consultation

  - How do you experience the different localities and rooms, where you conduct consultations?
  - Do you think the locality has any influence on the consultation?
  - How do you get affected by the surroundings when having a consultation (busy atmosphere; difficulties finding a (appropriate) room to have the consultation)?

Prompt cards (focus group interview – practices)

The group is asked to discuss different issues related to four areas of need of Head and Neck Cancer patients: 1. Physical, 2. Psychological/emotional, 3. Social, 4. Spiritual/existential

The issues will be displayed on four cards – one issue on each card

Discussions:

1. Please arrange the cards according to importance. Are there issues you find it more important to address than others? Why?
2. Please arrange the cards according to patient preference. Are there issues you find the patients prefer to discuss above other? Do you have an impression of why?
3. Please arrange the cards according to your ability to discuss. Are there issues you find it easier to discuss with the patients than others? Why?

Physical and functional

Activity, Energy level, Fatigue,

Shoulder problems

Weight, Appetite, Chewing/eating,

Swallowing, Mouth opening; Oral

hygiene; Dental problems

Dry mouth, Saliva,

Speech/voice

Pain

Respiration, Cough,

Bowel movements (diarrhoea or

constipation)

Regurgitation

Sleep

Social

(Social support and social well-being)

Carers, Support for family,

Children or other dependants

Recreation

Speech/voice/being understood

Finances/ social benefits

Lifestyle factors (Smoking/alcohol)

Psychological

Appearance, memory

Depression, Mood

Personality and temperament

Self-esteem, Anxiety

Intimacy, Sexuality

Coping

Spiritual/existential

Spiritual/religious aspects

Fear of cancer recurrence

Meaning in life

Appendix 6: Preliminary analysis of first ten observations

Observation no:		Code
1.	The nurse hands the patient a large envelope with food recipes	Many informations – written and oral
3.	The nurse hands the patient a large envelope with food recipes. He looks surprised.	
4.	The nurse hands the patient a large envelope with food recipes, with the information that this is for when she (the patient) is able to eat again	
7.	Patient refuses to accept the envelope with recipes handed to her by the nurse.	
8.	Patient refuses towards the end of the consultation to receive any more oral information from the nurse	
9.	The patient is given a lot of oral information in-between other activities in the consultation room	
1.	Nurse questions patient on many relevant mainly physical issues re rehabilitation and recommends actions	Nurse takes charge
4.	Nurse questions patient on many relevant mainly physical issues re rehabilitation and smoking/alcohol use and recommends actions	
5.	The nurse has a small yellow stick-on with her, where all the questions/subjects for discussion with patient are jotted down	
1.	The consultation takes place in the patient's room in the in-patient ward. A cleaning lady enters the room during the consultation but is asked to leave by the nurse.	Room where consultation takes place and influence on consultation
6.	Most of the consultation takes place together with a doctor in an examination room at the OPD. The nurse follows up briefly on the consultation, as she and the patient walk down the hall towards the reception	
7.	Examination room in in-patient ward. The room is also used for storage.	
8.	The consultation takes place in the doctor's consultation room. The nurse tries to have her consultation, when the doctor is busy on the computer or consulting with other doctors by 'phone.	

9.	The consultation takes place in the doctor's consultation room. The nurse tries to have her consultation, intertwined with the doctor's consultation.	

Summary:
Nurse-patient interactions are nurse-led, with a focus on information and handling physical issues and problems. Questions are welcomed, but not always answered fully.
The setting of formal rehabilitation interviews is not conducive to patient involvement, i.e. cluttered rooms; during/alongside surgeon examination; rushed atmosphere.

Appendix 7: Systematic Text Condensation – audit trail – showing one theme

Stage 1. Total impression – from chaos to themes:

Preliminary themes are starting points for organizing data. They are not categories or results.
Preliminary themes: Interview; Cancer; information; physical/functional
Stage 2. Identifying and sorting meaning units – from themes to codes
A meaning unit is a text fragment from the transcriptions, containing some information about the research question
I= Interview O= Observation FGI=Focus Group Interview

Meaning units	Code	Subcode
I: You get an awful lot of information. You really do.	Information	Many informations
I: You are told a lot of things, aren't you and then it's a matter of remembering it all		
I: leaflets about this and leaflets about that!		
I: but when I was discharged, I thought I was going mad, really. First of all, you are handed all these cookbooks. They mean well ..		
O: The nurses starts giving information's again and the patient protests. She had heard it many times before. She does not want to hear anymore		
FGI: I think there is a lot of focus on instrumental and physical matters		Physical/ functional
I: We talked about my weight and such – because I have been told I should not lose weight, which I haven't		
O: The nurse asks about nourishment. The consultation finishes. The nurse asks the patient to step up on the scale in the consultation room		
O: The nurse advices the patient to get out – to move		
I: Well, well, things are moving forward. I have signed up for a smoking cessation program		
O: The nurse reminds the patient about the municipal cancer rehabilitation clinic, which they have talked about earlier. The nurse reminds the patient about the possibility of getting support for final smoking cessation or end to e-cigarettes. The patient replies she has thought about it but lives far from the clinic and find the distance too far by bus.		
FGI: … but smoking .. I feel that sometimes we 'beat around the bush', because the patient has a lot of quality of life. Sometimes you feel the patient can't be bothered to listen any longer- they have been handed the leaflet thrice – now they need to decide for themselves		
I: I don't drink liquor anymore – I have done a lot, but I am not allowed to do that either anymore		
O: The patient replies to the nurses' question, that she still uses e-cigarettes. The nurse informs about the drawbacks from using these		
O: The nurse talks to the patient about his alcohol consumption. The patient thinks he drinks around 20 units a week. Is encouraged to cut down. The nurses then initiate a conversation on smoking.		

Step 3. Condensation – from code to meaning

A condensate is a condensation of all meaning units within a code – making a new artificial quote

Condensation	Subcode	Source
Patients experience getting very many informations, verbal as well as written. Some experience getting too many information's. They are unable to handle the amount and leave it to family members to read and relate to the written information. Patients are handed big envelopes with leaflets and booklets. Patients experience especially this as being too much. At the same time as the amount of written information feels to be large, there is also an acknowledgement, that it might be possible to read at a later time and then it is after all good to have taken along. A few patients back off completely and refuse to accept leaflets or too much verbal information. Other patients are happy about the amount of information, because they do not believe they can get too much information. They would regret coming home and realize they had forgotten to ask about something. Maybe the answer is to be found in the written information handed out. Patients find it helpful when verbal information is summed up. Several nurses use little yellow stick-on's to write down the most important verbal information. Time factor: Most of the verbal and written information is handed out at discharge, where patients find it difficult to remember and handle. Patients use words like: I was going crazy; Difficult to contain; difficult to relate to.	Many informations	3 Interviews TP 1 3 interviews TP 2 3 interviews TP 3 4 observations TP 1 2 observations TP 2
There is much focus on physical matters and advice on nourishment, alcohol, smoking and exercise. Patients are encouraged to manage proper nourishment intake and not lose weight; not to drink too much alcohol and stop smoking, as well as being encouraged to get some exercise. Some patients appreciate the advice and follow it, others find it difficult or do not wish to follow the advice. The nurses find it difficult to talk about smoking cessation as they sense patient sometimes get tired about these talks.	Physical/ functional	1 Interviews TP 1 3 interviews TP 3 1 observations TP 1 2 observations TP 2 2 observations TP 3 2 focus group quotes

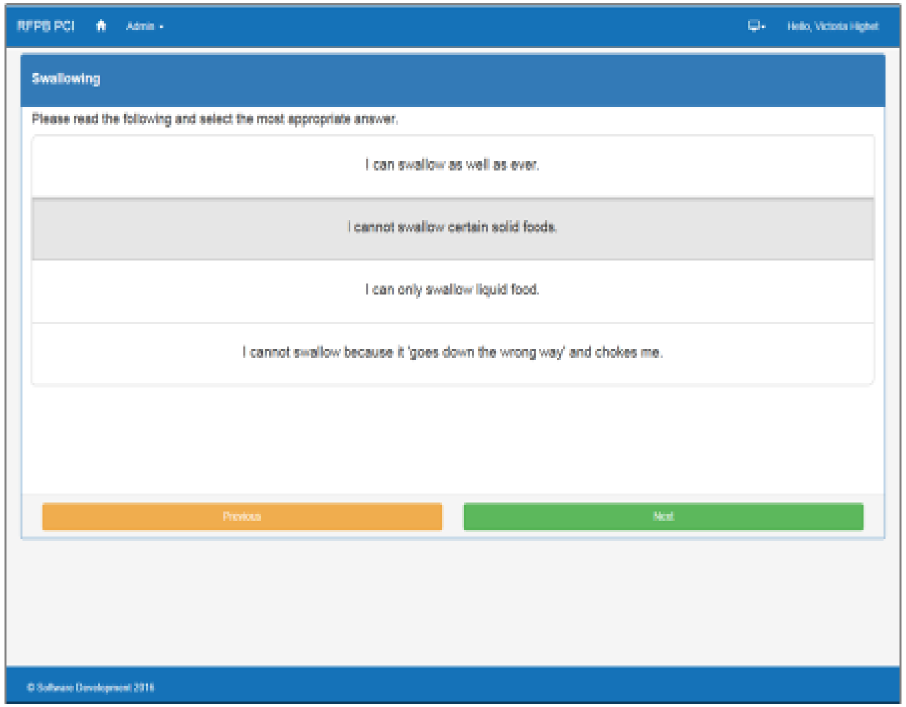
Step 4: Synthesizing – from condensation to descriptions and concepts.

Two sub-themes are condensed into one final theme: *Factors inhibiting communication of advice and recommendation*

Information overload is a barrier to effective communication	Discrepancies in communication about self-management and lifestyle factors
Large amount of oral and especially written information – most before discharge. 'Piles' of written information. Based on nurse's judgment. Nurses inform that referrals to municipality not always easy – many grey areas Information on self-management – especially nutrition. Patient management of information	KRAM – factors (KRAM= nutrition; smoking; alcohol; exercise) Nurses have much focus on need for proper nutrition, incl. oral and written information and ideas for self-management Smoking cessation. Much information from nurses and other HCPs on smoking cessation, but no ideas for self-management – only offer for referral or pamphlet. Nurses find the conversation hard and encroaching on the patients Patients refer very little to smoking cessation in their interviews.

Appendix 8: Examples of items on UW-QoL and PCI

University of Washington Quality of Life Questionnaire contains 14 domains accessible and displayed on and iPad, where each domain appears on a separate page. See example for the domain Swallowing.



Swallowing

Please read the following and select the most appropriate answer.

I can swallow as well as ever.

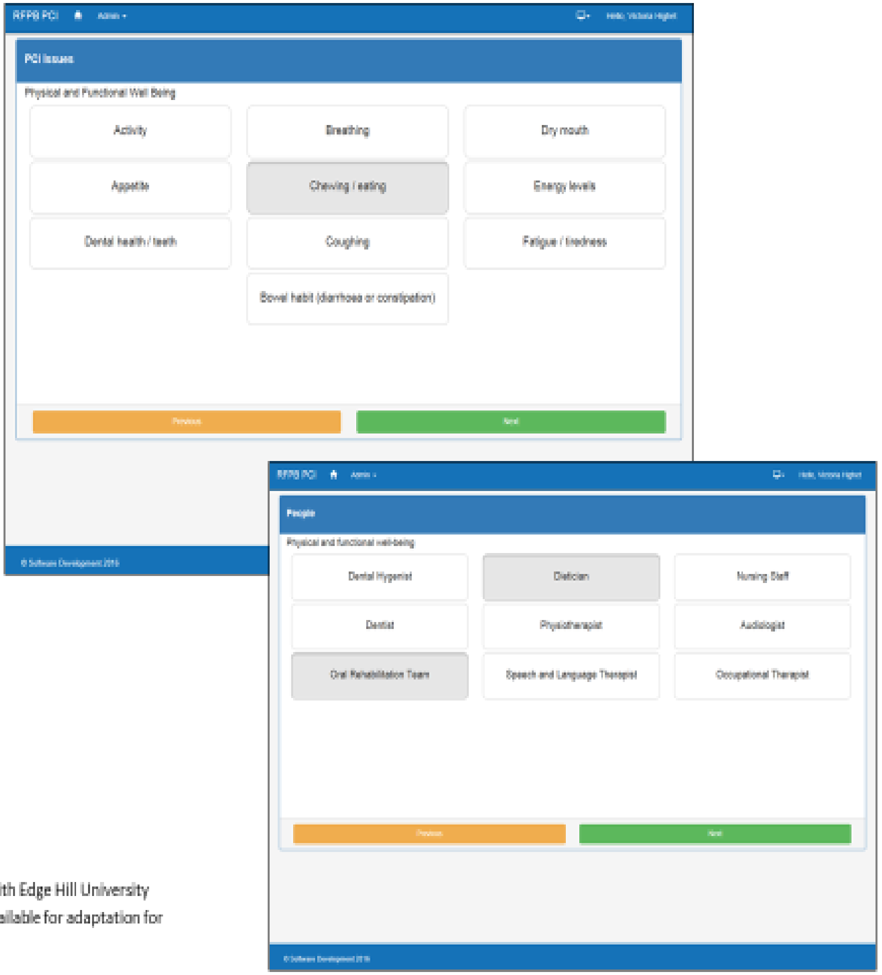
I cannot swallow certain solid foods.

I can only swallow liquid food.

I cannot swallow because it 'goes down the wrong way' and chokes me.

Rogers SN, Gwane S, Lowe D, Humphris G, Yueh B, Weymuller EA .The addition of mood and anxiety domains to the University of Washington Quality of Life Scale. Head Neck 2002; 24: 521-529.

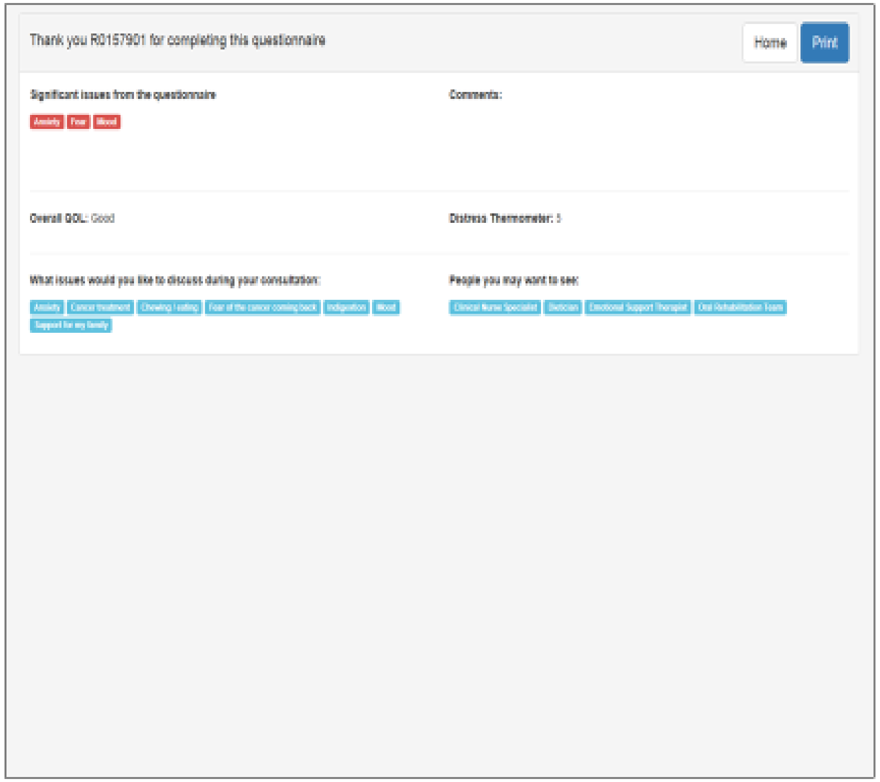
The PCI is a 56-item solution, related to functional, emotional, social and existential areas, accessible and displayed on and iPad, where items are grouped under the above headings.



Patients may further choose persons they wish to talk to

©The © Patient Concerns Inventory (PCI) was developed in collaboration with Edge Hill University (EHU) and Aintree University Hospital NHS Foundation Trust (AUH) and is available for adaptation for use in research and patient care.

When all domains on UW-QoL and concerns on PCI have been replied to, a result page will inform of items for attention and discussion
See example of result page



Thank you R0157901 for completing this questionnaire

Significant issues from the questionnaire

Anxiety Fear Mood

Comments:

Overall QOL: Good

Distress Thermometer: 5

What issues would you like to discuss during your consultation:

Anxiety Cancer treatment Chewing / eating Fear of the cancer coming back Indigestion Mood Support for my family

People you may want to see:

Clinical Nurse Specialist Dietician Emotional Support Therapist Oral Rehabilitation Team

Appendix 9: Management Manual

Physical

Pain; Sore mouth

Literature

Surgical interventions affect respiration; cardiac activity; muscular metabolism; blood modifications; psychological and emotional condition. Pain in patients with HNC of up to 70 %. Predictive factors: dry mouth; caries; eating/speech difficulties; anxiety and depression (Bianchini, 2014)

Pain in patients with HNC falls into three categories: nociceptive; neuropathic and muscular. DN4 scale may be used to diagnose neuropathic pain (Binzcak, 2014)

The department has pain treatment plans

Pain evaluation pocket cards

Activity; Energy levels; Fatigue, Recreation

Literature

Preferences regarding exercises: the majority of patients prefer to exercise alone and without supervision (Hunter, 2013; Sammut, 2013; Nieuwenhuizen, 2018). The preferred type is walks/exercise outdoors with low intensity (Hunter, 2013; Sammut, 2013; Nieuwenhuizen, 2018)

Patients with higher QoL prefer to train alone, while those with lower QoL prefer to train together with others (Hunter, 2012)

Exercise can improve QoL, including functional well-being (Sammut, 2013; Nieuwenhuizen, 2018; Cohen, 2016*)

Patients prefer advice on exercise and physical activity is passed on individually and face-to-face (Hunter, 2013)

Many patients with HNC give up any kind of exercise after diagnosis (Sammut, 2013)

Neck-dissection has a negative impact on recreational activities and return to work. Physiotherapy for shoulder problems has a positive effect (Gallagher, 2015)

Fatigue: At fatigue physical underlying reasons should be ruled out (anaemia; cardiac – and thyroid dysfunction). Patients may be referred for other support (if mood is affected; sleep or pain). Should be encourages to do exercises (Cohen, 2016*)

Factors promoting fatigue: Younger age, PEG-tube, depression, high symptom burden, sleep disturbances (Rogers, 2008)

Encourage to take walks. Get fresh air.
Refer to general physical rehabilitation if needed

Nutrition, Swallowing; Chewing; Taste; Saliva; Appetite; Regurgitation; Weight; PEG-tube; Nausea

Literature
Nutrition:
All patients should be screened at the time of diagnosis and with regular intervals after that (Talwar, 2016*)

Swallowing; Chewing; Taste; Saliva: Patients choice of nutrition is not only based on nutritional value, but also on factors such as how easy/difficult it is to eat; if it improves or worsens other symptoms (Alvarez-Camacho, 2016). If there are difficulties in finding food which can be swallowed/chewed then the patient should be referred to a dietician (Cohen, 2016*)

Swallowing/chewing: Pre-habilitative exercise may diminish the postoperative complications (dysphagia/trismus) (Cousins, 2013)

Swallowing: There is some evidence which indicate that thickened liquids may reduce the prevalence of aspiration (Barbon, 2015)
Swallowing: Important to be attentive to ’silent’ aspiration. More than 50 % of patients with chronic aspiration does so without coughing (Cohen, 2016*) Ability to swallow should be evaluated at all stages of the disease (Clarke, 2016*). Attention should be given to laryngectomees who may have difficulties with swallowing (Clarke, 2016*)

Local guideline: check the evaluation of the swallowing therapist regarding need for further treatment and referral or exercises on their own

Follow the guidance on diet prescribed by the operating surgeon. At long-term or ongoing problems, the patients may be referred to the oral rehabilitation team.

Digestion; Bowel habit (diarrhoea or constipation)

Literature
Constipation: up to 40 % of patients treated with opioids get constipation (Prichard, 2016). Should be treated with either laxatives or change of analgesics (Prichard, 2016)
Morphine lead to a larger risk of constipation (Prichard, 2016)
Diarrhoea: enteral feeding may cause diarrhoea. It may be recommended to change to nutrition with a higher content of fibre. If this has no effect, check how high the content of fibre is. It should not be too high. Refer to dietician (Brito-Ashurst, 2016)

Speech

Literature
Evaluation of speech should take place at all stages of the illness (Clarke, 2016*)

Local guideline:
Need for referral to speech pathologist depends on occupation; the patient's own experience of their voice/quality of speech (over time). Always necessary in patients with laryngectomees.

Shoulder

Literature
Laryngectomees who have also had Neck-dissection may have good effect of shoulder training with active and passive exercises (Sammut, 2013)
Shoulder pain and dysfunction is seen in up to 70 % of patients who have had a Neck-dissection (Cohen, 2016*)
Patients with shoulder pain and dysfunction should be referred to physiotherapists with special knowledge on this problem (Cohen, 2016*)
Shoulder pain is the most common complaint after Neck-dissection (Goldstein, 2012). Lowered strength and movement may be seen (Goldstein, 2012). Most common affect in daily life including lifting and carrying things or lean/lie on the 'bad' shoulder (Goldstein, 2012)

Possible need for referral for physiotherapy is a medical evaluation

Respiration; Saliva; Coughing

Literature

’Silent’ aspiration has been found in up to 76 % of patients. Clinical symptoms are affected speech (slurred/slimy), difficulties in controlling secretion (drools), unable to cough on demand and lack of reflexes in the throat. Patients are at greater risk of developing pneumonia, which does not respond to antibiotic treatment (Garon, 2009)

Mouth: Dry Mouth; Oral Hygiene; Mouth Opening

Literature

Oral hygiene: Patients should be encouraged to maintain a god oral hygiene and visit a dentist regularly to prevent (Cohen, 2016*)
Dry Mouth: Is often seen as a sequela after radiation therapy but may also occur after surgery with removal of salivary glands (Cohen, 2016*) Patients should be encouraged to use non-alcohol-based mouthwash (Cohen, 2016*). Can be treated with saliva substitutes. To drink frequent small mouthfuls of water has shown to have some effect. Saliva stimulating treatment may consist of Pilocarpine (Malallah, 2018; Strojan, 2017)
Seen as a sequela to radiation therapy, but other factors such as age, smoking, alcohol-based mouth wash, chemotherapy and some medical treatment may also play a role (Strojan, 2017)

Trismus: Physiotherapy has limited effect. Combination of physiotherapy and expansion works best (Cohen, 2016*)
Starting training early in the treatment course and carry it through, seems to have influence on the result (Kamstra, 2017)
Trismus is seen more often in women than in men and is more seldom in patient with a large alcohol consumption. Adjuvant treatment diminished the prognosis in surgically treated patients. A number of patients with trismus also have pain (Lee, 2012)

Local guideline:
If it is found there is a possible need for use of Therabite the patient should be referred to the Oral rehabilitation Team

Hearing

Literature

Problems are primarily seen in patients who have received ototoxic treatment (cisplatin), but may also occur following surgery (Cohen, 2016*; Theunissen, 2013; Schmitt, 2017)

Sleep

Literature

Sleep quality may be affected by free flap surgery, involving the base of tongue. This may affect respiration and following this sleep (Cohen, 2016*)

Patients sleep quality is generally poorer than the healthy population. It is worst at baseline and improves after one year. Factors of influence on sleep quality is: pain, dry mouth, tracheotomy, depression, age (younger patients have poorer sleep than older), women have poorer sleep than men (Shuman, 2010; Rogers, 2008)

Smell

No relevant/accessible literature. Neither for ability to smell or odour

At unpleasant smell from wounds a carbon bandage may be used – see hospital guideline Carbon Bandages

At odour Vibradox may be prescribed

Swelling

Literature

Lymphoedema: *There is a local/regional guideline*

Lymphoedema is a late effect following radiation therapy, but may also be seen after emergency surgical procedures (Cohen, 2016*)

See local guideline on how to refer patients for treatment of lymphedema and Smarttext ’Ordering Lymphoedema treatment’

Cancer Treatment

Talk to doctor/surgeon

Wound healing

No relevant/accessible literature

Psychological

Appearance

Literature

Body Image: Affects social interaction and intimacy (Cohen, 2016*; Howren, 2013). May be referred to counselling or psychologist (Cohen, 2016*)
May be separated into ’disfigurement’ and ’dysfunction’. Factors of influence: surgical procedures which causes a changed appearance – this may also cause changes in facial expressions or mimics. Younger patients and women find it more difficult; increased consumption of alcohol; ability to cope; support from partner, family, network (Rhoten, 2013). Causes a ’diminished self’, an experience of stigmatisation (Fingeret, 2015; Smith, 2017)
Lymphoedema may also affect appearance and due to that be emotionally burdensome. Men may not be affected to the same degree as women (McGarvey, 2014)

May be advised on contacting a psychologist
Referred to psychologist via GP or Cancer Society

Mood; Anxiety; Depression; Anger; Personality and temperament

Literature

Depression (D): The prevalence of D in some HNC patients is from 11-52 % (Smith, 2017; Howren, 2013). May lead to insufficient social support; dissatisfaction with treatment, care and information; increased abuse (narcotics, alcohol and tobacco) (Smith, 2017)
Patients should have an opportunity to express their emotional needs (Humpries, 2016*)
Depression screenings questions:
Have you within the last two weeks been bothered by:

1. Little interest or joy in doing things?
2. Felt down cast, depressed or had a feeling of hopelessness?

If the answer is – ’more than half og the time’ – there is 83 % probability of a diagnosis of depression (Smith’s Patient Centered Interviewing, Fortin, 2012)

May be advised on contacting a psychologist
Refer to psychologist via GP or Cancer Society

Fear of Cancer Recurrence (FOR)

Literature

FOR is a prominent concern in HNC patients and more prominent than in other cancer patients (Howren, 2013; Savard, 2013)
44 – 60 % of HNC patients have FOR (Van Liew, 2013; Ghazali, 2013; Savard, 2013). FOR has a negative influence on quality of life (Van Liew, 2013)
Family of HNC patients may be more worried of FOR than patients themselves (Hodges, 2009; Humpries, 2016*)
There seems to be a link between the specific fear of the individual that may lead to general distress or distress may influence on specific fear (Hodges, 2009). Personality trait influences the experience of FOR (age, fear) (Ghazali, 2013). Some experience FOR all the times, others sometimes (Ghazali, 2013). Some literature point to a connection between clinical prognosis and FOR (Ghazali, 2013) and some do not (Savard, 2013).
Matters which triggers fear: Symptoms which are interpreted as possible recurrence; death of family member /friend caused by cancer; difficulties with coping with FOR (Ozakinci, 2017).
Patients need to be invited to talk about their FOR (Ozakinci, 2017)

Management of FOR in clinical practice: Normalise fear (others experience the same); reassurance; suggest referral to psychologist or counsellor (Ozakinci, 2017)
Give the patient an opportunity to talk about the fear

Refer to psychologist via GP or Cancer Society

Advice about counsellors with special knowledge on cancer at the Cancer Society or about contacting the Cancer Line on 80 30 10 30

Regret about treatment

Literature

Survival is important to the patient, when the choice is between that and side effects or late effects of the treatment. Some patients do not accept severe side effects for longer survival. A subgroup of larynx cancer patients, prefer shorter survival rather than a laryngectomy (Blanchard, 2016)

Self-esteem

Literature

Is affected by appearance, lack of social interaction (Cohen, 2016*). May be referred to counselling or psychologist (Cohen, 2016*)
Distancing as a coping strategy may lead to higher self-esteem in some HNC patients (Devins, 2015)

Intimacy

Literature

1/3 of patients in a study had problems with sexual interest and joy and 1/4 had e problems with intimacy (Low, 2009). Younger persons had greater problems with intimacy. Older people do not wish to reply to questions about intimacy and sexuality (Low, 2009). Bad mood and depression are associated with intimacy problems (Low, 2009; O'Brien, 2012)

Barriers to intimacy may be associated to changes in personal identity as a result of the treatment (O'Brien, 2012). It may be difficult to re-establish social contacts and intimacy is affected by this (O'Brien, 2012). Communication is an important factor in reestablishment of intimacy (O'Brien, 2012). There is a great need for maintaining physical contact – kissing, hugs (O'Brien, 2012; Stenhammer, 2017) For women it is important to be able to talk about feelings; for men to have physical contact (O'Brien, 2012)

Factors promoting intimacy: Stable relationship (partners). Factors inhibiting intimacy: Underestimation of abilities; other people's disengagement (Stenhammer, 2017). There is a need for health care professional to be willing to talk about intimacy (Stenhammer, 2017)

Give the patient an opportunity to talk about the problem

Sexuality

Literature

Sexuality is affected by psychological reactions to the treatment and increased prevalence of depression (Smith, 2017)

1/3 of patients in a study had problems with sexual interest and joy and 1/4 had problems with intimacy (Low, 2009)

Between 24 – 100 % of HNC patients experience negative effect of treatment on sexuality. 50 % report the effect as being extremely negative. Review does not report any influencing factors, such as gender or age (Rhoten, 2016)

Clinical areas affecting sex life: PEG; smoking tobacco and drinking alcohol; codeine and other medicine; trismus; difficulties with oral hygiene. Early sexual dysfunction may be exacerbated by treatment for HNC. All these are issues which can be discussed with the patient, before a possible referral to sexologist (Hoole, 2015)

Refer to the website of the Cancer Society; there is guidance and a leaflet. One is welcome to contact the Cancer Society in your own municipality

Or call the Cancer Line at 80 30 10 30

In rare occasions it may be possible to refer to the Sexological Department at the hospital. See local guidelines.

Coping

Literature

Social support, educational level, optimism and active coping strategies has a beneficial effect (Howren, 2013; Morris, 2016)
Avoidance strategies (cognitive and behavioural) leads to lower quality of life in laryngectomees (Eadie, 2012)
Positive coping strategies in laryngectomees includes distancing, focusing on the positive, seeking social support (Eadie, 2012)
Patients using denial; are behaviourally disengaged; abuse alcohol and use self-blame, are at greater risk of developing PTSD after treatment. Using humour may further contribute to this (Richardson, 2016). 19 % have signs of PTSD 6 months after treatment (Richardson, 2016)

Suggestions for support: talking to a psychologist on better coping strategies, like problem solving, relaxation, goal setting, communication and development of a supportive network (Richardson, 2016)

Refer to psychologist via GP or Cancer Society

Memory, Cognitive functioning

Literature

Cognitive dysfunction before treatment is seen in patients with heavy use of alcohol; previous smoking, depending on the number of pack years. In this study 55 % used alcohol and another 55 % had contact to psychiatry of which 39 % had anxiety. Patients with low education and learning disabilities had poorer cognitive functioning. This group of patients find it more difficult to follow recommendations, keep appointments and plan hospital visits. May also have problems with memory (Williams, 2017; Zer, 2018).
Patients treated with radiation and/or chemotherapy, have increasing cognitive problems up to two years after treatment (Zer, 2018)

Fear of adverse even

No relevant/accessible literature

Social
Social support **Literature** Social support contributes to increased HRQoL (Smith, 2017) Patients with low income, short education and those living alone, are often also diagnosed at a late stage. These patients have a greater need for support during rehabilitation (Olsen, 2014) **SR-bistand http://sr-bistand.dk/ - has amongst others social workers and lawyers attached.** **May help as supporter at meetings with social authorities (Danish bisidder)** **See leaflet about Navigator possibility for cancer patients**
Carers; Dependants and/or children; Support for family **Literature** Carers should also receive support (Cohen, 2016*; Hanly, 2016). Carers have a higher risk for PTSD during the first six months after treatment (Howren, 2013). Express needs for psychologic support (Howren, 2013, Hanly, 2016). 37 % have experienced heightened levels of distress in the period after the patient's discharge (Ross, 2010) Carers take on themselves tasks like cleaning, shopping, etc., but beyond that give emotional support, stay in contact with hospital and health care, carries out cancer-specific care. Carers spend between 1 – 20 hours a week on supportive tasks. Spouses are the ones to give the most support. Carers feel uncomfortable when performing medical tasks (Balfe, 2016). Carers have a need for information (Hanly, 2016) Patients experience being a burden to their carers (ca. 30 %).
Financial /benefits No relevant/accessible literature applicable for Danish society **SR-bistand http://sr-bistand.dk/ - has amongst others social workers and lawyers attached.** **May help as supporter at meetings with social authorities (Danish bisidder)**

Lifestyle issues (smoking/alcohol)

Literature

Smoking

Up to 48 % of oral and pharynx cancer death may be ascribed to smoking (Cohen, 2016*).
The risk of recurrence of HNC declines already 1 – 4 years after smoking cessation (Marron, 2010).
Many patients stop smoking before or during treatment, but between 14 – 60 % start smoking again (Cohen, 2016*; Howren, 2013; Møller, 2015).
Danish patients who smoke during treatment or start smoking afterwards are younger (<60 years); have had early smoking debut; poor Performance Status; low income and living alone (Møller, 2015).
Depression may be an underlying and contributing reason for starting to smoke again. It is important to be attentive to this (Cohen, 2016*; Howren, 2013). Support for beginning and continuing smoking cessation should take place throughout the treatment trajectory and follow-up (Cohen, 2016*)
Patients with FOR smoke more than other patient with HNC (Van Liew, 2013).
Patients with HNC who smoke have a higher symptom burden, less social and psychological resources, than no – or ever smokers. A larger part is also unemployed. This group of smokers should therefore receive more support for smoking cessation preoperatively (Sterba, 2016)

When smoking cessation has been achieved: confirm/encourage. Warn about risk of relapse after two months.
When no smoking cessation is achieved: possibly use *Fagerstrøms score* *and guide according to this (see attachment at end of manual)*

Refer/advice about the Smoking cessation hotline or local smoking cessation possibilities

Alcohol

The risk of getting HNC after quitting alcohol only declines after 20 years. This only accounts for patients who have been drinking more than 1 unit/day (Marron, 2010). Alcoholics have increased risk of comorbidity, larger surgical procedures, poor wound healing, and a need for prolonged hospital stay and support at home after discharge. The risk of complications increases further with alcohol withdrawal symptoms (Genther, 2012). Alcoholics should receive preoperative optimization (Genther, 2012).

Refer to alcohol cessation hotline or local alcohol units

Existential/spiritual

Spiritual/religious aspects

Literature
If the ability to communicate is affected this may lead to feelings of isolation. This lack of ability may affect the feeling of humanity and lead to searching for (and sometimes finding) meaning in life (Fletcher, 2012).
Religious faith may be a coping resource for some patients. For others, it may have negative consequences. It depends on the religious belief of the patient at the onset of illness. If the belief is strong, coping will be strengthened; if religious belief is weak, it has the opposite effect (Allmon, 2013). Support in discussion religious or existential needs may strengthened quality of life (Kruizinga, 2015).
Patient may be more conscious about the fear of death at three timepoints during their treatment trajectory: 1. social awareness (cancer signals death); 2. personalized awareness (*I* could die from this cancer); 3. The lived experience (it det *feels* as if I am dying from this cancer) (Lee, 2012)
Having cancer is experienced a moving from a known life world into unknown territory (Hvidt, 2015)

Provide opportunity to discuss
Refer to hospital chaplains Christian Busch 5-1613, Lotte Blicher Mørk 5-1612,
Henning Nabe-Nielsen 5-1614, Maria Baastrup Jørgensen 5-6846.
The chaplains can provide contact to other denominations

Imam Naveed Baig 5 -42 06

Literature references marked with * come from guidelines.

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Appendix 10: Patient information leaflet

Kræftens Bekæmpelse

(Danish Cancer Society)
It is recommended to contact the Danish Cancer Society, where you may find much general information on cancer; specific information on head and neck cancer; help to get in contact with counsellors in your local area and guidance on contact to patient societies, and much more support. You may begin by looking at the website www.cancer.dk or call tel: 3525 7500.
If you live in Copenhagen you are welcome to contact Centre for Cancer and Health, at Nørre Alle 45 (just across the hospital).

Guide

when in need of help

With this leaflet we wish to inform you of your possibilities of getting support in relation to your cancer illness at a psychologist, dentist, municipality, lifestyle changes, the Danish Cancer Society, other charitable societies or clergy.

Psychologist

If you wish to talk to a psychologist, you can either contact the Danish Cancer Society (see information on the back of this leaflet) or you can contact your own GP. The Danish Cancer Society can offer a few interviews with a psychologist but not a course of counselling. The interviews are for free.

It is also possible to get a referral from your GP for a psychologist. After the referral you can contact a psychologist yourself and typically get a course of counselling with a number of interviews.
With a referral from your GP you can get a subsidy towards the payment for your interviews, but you will most often have to pay an amount yourself.
Some private health insurances og trade unions subsidizes interviews with psychologists.
You can read more at: http://psykologeridanmark.dk/

Cancer counselling and the Cancer Line

If you would like to talk to an experienced counsellor, you may contact the Cancer Society in your municipality (see information on the back of this leaflet) or call the Cancer Line at 8030 1030

SR-Bistand

SR-Bistand can help with social-legal counselling; accompany you to meetings with social workers in the community.
http://sr-bistand.dk/
Tel: 3539 7197

Dentist

If you in the course of your treatment has had teeth removed you can apply for replacement of your teeth, usually as a denture. You will need to talk to your own dentist about this.
You can get more information in the leaflets (Tandbehandlingstilskud ved fokussanering og kæberesektion)

Smoking cessation

If you wish to get support for smoking cessation you may contact the Stop Line at http://stoplinien.dk/.
There you will be able to find smoking cessation programmes in your own municipality. You may also call the Stop Line at tel: 8031 3131

Alcohol

If you wish to get support to reduce your drinking of alcohol and follow the recommendations of the Danish Health authority, which is 7 units a week for women and 14 units a week for men, you may contact the anonymous counselling at Alco Line at http://www.alkolinjen.dk/
Or tel: 80 200 500

Ethnic Resource Team

If you wish to talk to a person of your own ethnic or religious background, you may contact the Ethnic Resource Team, where volunteers of different ethnic and religious background, offer counselling and discussion with patients and carers of similar backgrounds.
You may read more here: http://ressourceteam.dk/
Or contact Tel: 3545 4206

Priest

If you would like to talk to a priest, you may contact the hospital chaplains at following phone number:

Tel: 3545 1613 or 3545 1612

The priest can provide contact to other denominations, if you wish.

Imam

If you wish to talk to an imam, you may call at tel: 3545 4206

Appendix 11: Questionnaires

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: |__|__|__|__|
Your birthdate (Day, Month, Year): |__|__|__|__|__|__|__|__|
Today's date (Day, Month, Year): 31 |__|__|__|__|__|__|__|__|

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

EORTC QLQ - H&N35

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very much**
31. Have you had pain in your mouth?	1	2	3	4
32. Have you had pain in your jaw?	1	2	3	4
33. Have you had soreness in your mouth?	1	2	3	4
34. Have you had a painful throat?	1	2	3	4
35. Have you had problems swallowing liquids?	1	2	3	4
36. Have you had problems swallowing pureed food?	1	2	3	4
37. Have you had problems swallowing solid food?	1	2	3	4
38. Have you choked when swallowing?	1	2	3	4
39. Have you had problems with your teeth?	1	2	3	4
40. Have you had problems opening your mouth wide?	1	2	3	4
41. Have you had a dry mouth?	1	2	3	4
42. Have you had sticky saliva?	1	2	3	4
43. Have you had problems with your sense of smell?	1	2	3	4
44. Have you had problems with your sense of taste?	1	2	3	4
45. Have you coughed?	1	2	3	4
46. Have you been hoarse?	1	2	3	4
47. Have you felt ill?	1	2	3	4
48. Has your appearance bothered you?	1	2	3	4

Please go on to the next page

During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very much**
49. Have you had trouble eating?	1	2	3	4
50. Have you had trouble eating in front of your family?	1	2	3	4
51. Have you had trouble eating in front of other people?	1	2	3	4
52. Have you had trouble enjoying your meals?	1	2	3	4
53. Have you had trouble talking to other people?	1	2	3	4
54. Have you had trouble talking on the telephone?	1	2	3	4
55. Have you had trouble having social contact with your family?	1	2	3	4
56. Have you had trouble having social contact with friends?	1	2	3	4
57. Have you had trouble going out in public?	1	2	3	4
58. Have you had trouble having physical contact with family or friends?	1	2	3	4
59. Have you felt less interest in sex?	1	2	3	4
60. Have you felt less sexual enjoyment?	1	2	3	4

During the past week:	**No**	**Yes**
61. Have you used pain-killers?	1	2
62. Have you taken any nutritional supplements (excluding vitamins)?	1	2
63. Have you used a feeding tube?	1	2
64. Have you lost weight?	1	2
65. Have you gained weight?	1	2

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PLEASE USE
BLACK INK PEN

Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials: ____________

Study Subject # ☐☐☐☐

Study Name: ______________________________

Protocol #: ______________________________

PI: ______________________________

Revision: 07/01/05

M. D. Anderson Symptom Inventory - Head & Neck (MDASI-HN)

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptom was as bad as you can imagine it could be) for each item.

	NOT PRESENT 0	1	2	3	4	5	6	7	8	9	AS BAD AS YOU CAN IMAGINE 10
1. Your **pain** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
2. Your **fatigue (tiredness)** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
3. Your **nausea** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
4. Your **disturbed sleep** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
5. Your feeling of being **distressed (upset)** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
6. Your **shortness of breath** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
7. Your problem with **remembering things** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
8. Your problem with **lack of appetite** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
9. Your feeling **drowsy (sleepy)** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
10. Your having a **dry mouth** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
11. Your feeling **sad** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
12. Your **vomiting** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
13. Your **numbness or tingling** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
14. Your problem with **mucus** in your mouth and throat at its WORST?	○	○	○	○	○	○	○	○	○	○	○
15. Your difficulty **swallowing/chewing** at its WORST?	○	○	○	○	○	○	○	○	○	○	○

Draft

Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials: ______________

Study Subject # ☐☐☐☐

PLEASE USE BLACK INK PEN

Study Name: ______________________________

Protocol #: ______________________________

PI: ______________________________

Revision: 07/01/05

	NOT PRESENT										AS BAD AS YOU CAN IMAGINE
	0	1	2	3	4	5	6	7	8	9	10
16. Your **choking/coughing** (food/ liquids going down the wrong pipe) at its WORST?	○	○	○	○	○	○	○	○	○	○	○
17. Your difficulty with **voice/speech** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
18. Your **skin pain/burning/rash** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
19. Your **constipation** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
20. Your problem with **tasting food** at its WORST?	○	○	○	○	○	○	○	○	○	○	○
21. Your **mouth/throat sores** at their WORST?	○	○	○	○	○	○	○	○	○	○	○
22. Your problem with your **teeth or gums** at its WORST?	○	○	○	○	○	○	○	○	○	○	○

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items in the last 24 hours:

	Did not interfere										Interfered Completely
	0	1	2	3	4	5	6	7	8	9	10
23. General activity?	○	○	○	○	○	○	○	○	○	○	○
24. Mood?	○	○	○	○	○	○	○	○	○	○	○
25. Work (including work around the house)?	○	○	○	○	○	○	○	○	○	○	○
26. Relations with other people?	○	○	○	○	○	○	○	○	○	○	○
27. Walking?	○	○	○	○	○	○	○	○	○	○	○
28. Enjoyment of life?	○	○	○	○	○	○	○	○	○	○	○

Appendix 12: Comparison of studies Hansson et al, 2017 and thesis

EH= Hansson 2017 AM= present thesis

Similarities	Differences	Strengths	Limitation
Studies conducted in a Scandinavian country	Incidence of HNC: Sweden (1400 annually/ population 10.3 million) (EH) Denmark (1300 annually/ population 5.8 million) (AM)		
Studies conducted in one centre with large catchment area			
	Different set-up re transfer from tertiary/secondary sector to primary		
Nursing consultation and nursing interventions	Intervention: Person-centred care (a specific method) - no use of tool (EH) Patient involvement in nursing consultation (inspired by specific method) – use of tool (AM)		Records on how well patients filled in care-plan (part of intervention method), not carried out (EH)
Randomized Controlled Trial	Power calculation: 80% power, 100 pt's 20% difference (EH) 80% power, 75 pt's 15% difference (AM)	Randomized to equal sized groups (AM)	Randomized to unequal sized groups 60% IG; 40 % CG (EH)
Excluded from study if participating in other studies	Excluded if diagnosed or treated with depression (EH) Excluded if diagnosed with unstable psychiatric illness (AM)		
	Inclusion period: 24 mth's – Spring 2012 – Spring 2014(EH) 15 mth's June 1, 2018 – August 31, 2019 (AM)		

Similarities	Differences	Strengths	Limitation
	CG – doctors consultation (EH) CG – nurses consultation (AM)		
Number of included pt's 96 (EH) 92 (AM)		5 pt's declined participation (EH)	56 pt's declined participation (AM)
		HPV status of pt's registered and HPV-pos pt's included in study (EH)	HPV status of pt's not registered. HPV-pos pt's not included in study (AM)
	Treatment: RT/CT starting 2 wks after MDT (EH) Surgery starting 1 – 2 wks after MDT (AM)		
	Treatment trajectory: 6 weeks of RT/CT with weekly controls by doctor (EH) Time of surgery one single event. Seen by doctor three times during 9 weeks in post-surgical period (AM)		
Intervention: Emphasis on patient-involvement Aspects of patient self-management	Intervention carried out by specialist nurses (EH) Main investigator or project nurse (AM)	Investigator and nurses carrying out intervention not the same (EH)	Risk of bias as main investigator carried out the main part of intervention consultation (AM)
	Intervention begins: Before start of treatment (EH) After start of treatment (AM)		Not entirely clear in description of intervention when nursing consultations took place, apart from pre-treatment consultation, but may have been at same time as doctors consultations (EH)
Outcome: Symptom burden/control and HRQoL			

Similarities	**Differences**	**Strengths**	**Limitation**
Primary outcome measurement tool: EORTC QlQ and HN35	Changes to 3 questions on HN35 (EH)		Response rate: Missing data during both studies (unanswered questionnaires) At 4 – 10 wks (EH) and at 9 wks (AM)
Pattern of change between and within groups rather similar during first year.	Measurement time-points: Pre-treatment; 4, 10, 18, 52 wks (EH) Discharge; 2 and 9 wks (AM)		
	Symptom peak: 4 – 10 wks (EH) 0 – 2 wks (AM)		
	Measuring effect: Between groups at each measuring time-point (EH) Between groups pre- and post-treatment (AM)		
No statistically significant difference in GHS/QoL at any measurement point	Statistically significant improvement between groups at 18 and 52 wks in relation to swallowing; social eating; feeling ill (EH)		
	Significant improvement in both groups at post measurement time for emotional functioning; pain and appetite loss (AM)		

Weeks = wks Months = Mths