Needs assessment and decision-making tool (NEAT-decision) integrated in clinical practice to enhance patient involvement in Head and Neck Cancer Rehabilitation - a randomised controlled trial

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Background

The global incidence of Head and Neck Cancer (HNC) is approximately 650,000 per year [1]. Prevalence in the Nordic Countries is 32,500 with an incidence of 4100 annually [2][3][4] and in Denmark there is a prevalence of 8800 with an incidence of 1300 annually [5][6][7]. The five year survival rate is 68% [8].

Head and neck cancer is a heterogenous disease, which involves tumors in the oral cavity, naso-, oro-, and hypopharynx and larynx [9]. More than 90% of malignancies affecting head and neck are squamous cell carcinomas [10]. Risk factors for HNC are primarily linked to lifestyle factors, such as excessive use of tobacco and alcohol [9][10] and HPV-positive oral cancer is linked to sexual behavior [11].Treatment for HNC is typically surgery, radiotherapy and chemotherapy. One modality or a combination may be used [10]. Treatment at an early stage is most effective, however many patients with head and neck cancers, especially oral cancer, are diagnosed at a late stage [12]. Due to the anatomical sites of the tumors and its treatment, functional abilities can be compromised affecting the patients' psychological and physical wellbeing and social functioning [13][14][15].

The most common complications and sequelae include pain and difficulties with nutrition, voice, swallowing, disfigurement, social life and psychological distress [16][17][18][19][20][21][22]. Artificial nutrition support and an artificial voice [18] may be indicated and the patient may suffer from facial disfigurement due to reconstructive surgery [23].

Patients will experience multiple symptoms occurring concurrently. One symptom may compound another or symptoms may be interrelated affecting quality of life (QoL) more negatively due to the synergistic effect of multiple symptoms [24]. Furthermore interrelatedness exists between the symptom burden, poorer physical functioning, social dysfunction and psychological distress [25]. Patients tend to withdraw from social life, due to disfigurement, problems with speech and eating in public or just interacting with partners, family and friends. Increased social isolation may be a risk factor for poorer physical recovery from the effects of the illness and treatment [26]. Some patients with HNC have a limited social network and/or no partner [27] and lower affiliation to the work force [28] 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 [29]. Two years after diagnosis, Danish HNC patients are among those with the highest symptom burden, compared to other cancer diagnoses [30]. Finally, HNC is found to be more emotionally traumatic than any other type of cancer [31] and there is a high prevalence of emotional or psychological distress in patients with head and neck cancer, again leading to poorer QOL [32].

Life as it was prior to the disease and treatment cannot be the same afterwards, yet prevention of sequela could give patients better QOL long term. Therefore, there is a need to prevent or alleviate symptoms and the early and late negative effects of the disease and its treatment. Symptoms that could lead to sequela need to be assessed and managed early by referral to specialist follow-up i.e. speech-language pathologist, physio-and occupational therapists, dietician, clinical nurse specialist and psychologist [33][34][35]. To a greater extent, patients with HNC come from backgrounds of short education and manual labour, which place them at risk for health disparity [36][37][38]. The type and quality of decision-making tools used to assess health and rehabilitation needs are important to consider in patients with low health literacy [39]. Acknowledgment of the importance of patient-involvement in needs assessments using Patient Reported Outcomes (PRO) is growing. However present PRO questionnaires have certain limitations. Firstly, they have been developed for research purposes, therefore little is known about how these can be applied in the clinical setting to obtain the patient's information on the symptoms experienced[40]. Secondly, PRO questionnaires do not incorporate needs assessments [40]. Finally, there is currently, a lack of knowledge

regarding which type of decision making assessment tool would be optimal in patients with short education and low health literacy.

Study hypothesis and objective

The study's *hypothesis* is that a disease-specific patient-reported needs assessment tool integrated in the clinical management of HNC will increase patient involvement in decision making, control the short and long term symptom burden and improve short and long term health related quality of life (HRQoL) in HNC patients, primarily surgically treated. The *purpose* of the study is to investigate whether a systematic patient reported needs and concerns assessment integrated prior to and during consultations with health care professionals (HCP), is feasible and safe, and will improve patient involvement in decision making during the consultation. Further, whether patient involvement will result in increased referral to the multi-disciplinary team and ultimately reduce the symptom burden, improve physical, mental and social wellbeing and global HRQoL.

Study designs and methods

Study *one* is a literature review exploring early and late physical and psychosocial effects of surgery. Study *two* is designed as a qualitative study exploring nurse-patient interactions during formal and systematic rehabilitation consultations. Study *three* is a randomized, controlled trial (RCT) on the effect of applying a disease-specific needs and concerns assessment instrument in the context of clinical nurse consultations assessing and managing the patient's rehabilitation needs. Prior to the RCT, a cross-cultural validation of the instrument Patient Concerns Inventory (PCI) will be carried out. The PCI was developed at Aintree University Hospital, Liverpool, Great Britain, specifically for HNC patients[41] and since the PCI functions with a touch screen solution, an IT solution will be developed. The randomized controlled study will include a control group (CG) and intervention group (IG) and take place at the Department of Otolaryngology, Head and Neck Surgery and Audiology, (Dept. ORL, H&N),Copenhagen University Hospital, Rigshospitalet.

Study one – Literature Review

Aim

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

Material and methods

Perform a systematic literature search in PubMed, Cinahl and PsycInfo, using the Boolean search operators and the search words: mouth neoplasms, rehabilitation, oral surgery, anxiety, body image, depression, distress, dysphagia, eating, pain, psychosocial, speech and swallowing. Include English language quantitative and qualitative articles published between January 2004 and January 2014 that investigates physical and psychosocial wellbeing in patients primarily surgically treated for oral cancer (non HPV-induced squamous cell carcinomas) at one or more time points along the treatment trajectory, including time of diagnosis. Exclude articles that includes samples of patients with diagnoses other than non-HPV induced squamous cell cancer of the oral cavity and/or only treated oncologically, as well as articles describing surgical procedures.

Methodological and statistical quality of the included studies will be assessed independently by two persons using a 7-item criteria checklist [42]. The number of articles accessed, screened and read, will be noted, as well as time of measurements; types of articles (quantitative or qualitative articles) and study

designs. Finally the key areas of the physical and psychosocial early and late effects of the surgical treatment for oral cancers and the factors that influence these effects will be summarised.

The literature review has been published (Mortensen, A; Jarden, M. "Early and late physical and psychosocial effects of primary surgery in patients with oral and oropharyngeal cancers: a systematic review," *Oral Surg. Oral Med. Oral Pathol. Oral Radiol.*, vol. 121, no. 6, pp. 583–594, 2016).

Study two – Qualitative study

Aim

To explore the nurse-patient interaction, patient involvement and communication practices during nurse consultations in post-surgical patients with head and neck cancer.

Methods and procedures

An exploratory and descriptive qualitative study informed by ethnographic fieldwork. The study will include nonparticipant observations during nurse consultations, individual patient interviews and focus group interviews with nurses performing nurse consultations, employing Interpretive Description [43][44].

Population and recruitment

Included are patients, who have been diagnosed and treated surgically for head and neck cancer, at stage T3 or T4, and able to speak and understand Danish. Excluded are patients treated surgically for thyroid or parotic cancers, patients referred to adjuvant radio – or chemotherapy and patients with unstable psychiatric illness.

Patients (n=15) will be informed about observational studies through posters in Dept. ORL, H&N on the observation days during June – July 2017 and January 2018. Using purposive sampling, patients (n=15) will be recruited for individual interviews after surgery for Head and Neck Cancer, from Dept. ORL, H&N, at the following three time points: before discharge, seven – ten days post-op and two months post-op in the period from December 2017 – February 2018. Nurses (n=4) who deliver nurse consultations will be recruited for a focus group interview at the Dept. ORL, H&N, through individual contact during February 2018.

Data analysis

The focus group interview and the individual interviews will be recorded digitally, transcribed verbatim and coded in the software program NVivo. Thematic analysis will follow a model where the transcriptions will be read and re-read, coded according to emerging themes, a clustering of themes and finally reaching a number of themes, which describes the patient's and nurses experiences with nurse-patient interactions [45]. Observations will be recorded as short field notes during observations and following this expanded as notes in a text-file. The field notes will follow the same analytic process as the interviews. Researcher triangulation will be applied.

A detailed project description for this part of the study is attached (Appendix I)

Study three – Randomized controlled trial

Aim

To evaluate the safety and effect of the PCI integrated in clinical practice. Specifically, to investigate whether patients and Health Care Professionals (HCP) find the PCI applicable and useful in assessing and managing care and rehabilitation needs. Furthermore, whether patients are referred more often to multi-disciplinary follow-up, which types of follow-up and whether the new needs assessment and decision-

making tool improves the interaction between HCPs and patients. Lastly, to explore whether patients experience a reduced symptom burden and improved HRQoL.

Linguistic and cross cultural validation of the PCI and Development of an IT-solution

Prior to the RCT, a linguistic and cross cultural validation of the PCI and development of an IT-solution within the context of a head and neck department in Denmark will be carried out. The PCI is a 57 item solution, where patients can select a range of items related to functional, emotional, social and existential areas [46] using touch screen buttons, which allows the patients to choose the items, they wish to discuss with the HCP. This enables the patient to express their concerns and symptoms and choose those items, they find important and meaningful to discuss. The PCI includes a brief electronic version of the University of Washington Quality of Life Questionnaire (UW-QoL), which aids the HCP in addressing needs that the patient may not be attentive to [41].

The IT-solution functions with 'buttons' on a touch-screen. Each 'button' corresponds to one item. Thus the solution makes it easy to attain an overview of the items [41].The solution has been approved by Center for It, Medico and Telephone (CIMT) of the Capital Region, who requires that the actual programming is done by a private company (I-r software a/s). A four step validation process will follow the EORTC-guidelines for cross-cultural adaptation of QoL questionnaires [47] and include *linguistic and cultural validation*, but not psychometric, as the PCI is not a QoL questionnaire: (1) forward and (2) backward translation, (3) pilot testing a paper version by HNC patients (n=10) and patients from patient networks (Dansk Landsforening for Hals- og Mundhuleopererede and Netværk for hals og mundhulekræft) . The testing will include interviews based on a brief structured questionnaire on the understand ability of the PCI [47]. (4) Finally, to ensure IT-solution suitability in clinical practice, it will be pilot tested by HNC patients (n=10), who will be interviewed on the basis of a brief questionnaire on the applicability and usefulness of the touch-screen solution. An in-depth validation protocol is attached (Appendix II). Two native Danish and English speaking persons will be asked to carry out the forward and backward translation. Patient recruitment for step 4 (n=10) and 5 (n=10) of the validation process will be identical. The inclusion and exclusion criteria are the same as in study two. The PCI and IT-solution will be tested and re-tested on new patients until problems with comprehensiveness is resolved. A final translation report will be sent to consultants at Aintree Hospital, Liverpool for approval.

Design and methods (Figure 1 attached)

The study is designed as a two arm randomized controlled study with a control group (CG) and intervention group (IG). Patients will be randomized via Research Electronic Data Capture (REDCap), an electronically based system for keeping research data, containing a randomisation module. Patients will be randomly assigned 1:1 to either CG or IG, stratified according to newly diagnosed and recurrences. The assignments will not be blinded to either investigator or patients.

Population and recruitment

Total study population (n=128).CG (n=64) and IG (n=64) will be recruited consecutively during hospital admission post-surgery from April 2018 - March 2019. The inclusion and exclusion criteria will be the same as in study two.

Statistics

The sample size of this study (n=128) is based on a power calculation with an SD of 20; effect size 10 and power of 0,8. SD is based on similar studies on Head and Neck patients [48] and effect size on recommendations from EORTC [49], further the sample size is based on previous research in the Department of ORL H&N, Copenhagen University Hospital. To account for an expected dropout rate and non-recruitment rate of approximately 20% [50][51], the number of patients included in the study will be 160. Furthermore, based on the ratio between newly diagnosed patients and recurrences, we will stratify each study arm as follows; newly diagnosed (n=43) and recurrences (n=21).

Procedures

CG will receive standard care according to the Danish Health and Medicine Board's follow-up programme for HNC patients [52], which requires all patients have their physical, emotional, social and existential needs assessed by interview with a HCP, at three time-points post-treatment. At present this is done at the Dept. of ORL, H&N during the admission period post-surgery, two weeks and two months post-surgery, by a staff nurse who is a member of the rehabilitation team who perform nurse consultations. These consultations take place after the appointment with the surgeon. The nurse refers the patient to physical rehabilitation if needed.

IG will receive the PCI intervention integrated in clinical practice in accordance with present requirements as stated by the Danish Health and Medicine Board follow-up program for HNC patients [52]. The main investigator (AM) or the research assistant (a nurse from the rehabilitation team), will carry out the nurse consultation in 6 steps: 1. Welcoming the patient; 2. Introducing the patient to the PCI and guide in the use of this; 3. Starting with the symptoms and concerns the patient has highlighted in the PCI, the consultation will be based on these; 4. Follow up on the patients symptoms, concerns and emotional reactions or problems from a professional point of view; 5. Accompany and support the patient during the appointment with the surgeon and in cooperation with the patient and the surgeon ensure that problems arising from the nurse consultation needing medical attention are focused on; 6. Continue the consultation after the appointment with the surgeon; refer the patient to multi-disciplinary team members when needed. The nurse consultations will take place during the admission period post-surgery, two weeks and two months post-surgery. The management of symptoms arising from the needs assessment using the PCI, will be based on an evidence-based manual prepared for this purpose. In preparation of the intervention, the HCP multidisciplinary staff will be introduced to the intervention, including the use of the PCI, through written and oral information. The research assistant will be formally trained in the use of the PCI and interviewing patients with physical and emotional needs.

Outcome measures

Quantitative outcomes: The primary outcome will measure the effect of the intervention by PRO quality of life and symptom questionnaire EORTC QLQ-H&N35. H&N35 is a 35-item questionnaire to be used with a core questionnaire[53]. The H&N module particularly measures oral pain, nutritional and voice problems. Patients will be asked to complete the EORTC QLQ-H&N35 at four time-points, 1) baseline (before randomisation) 2) between discharge and first follow-up in OPD 3) 7 days after first and 4) second post-surgical appointments – by telephone. Presence and severity of symptoms will be evaluated by MDASI-HN (MD Anderson Symptom Inventory) which is a multi-symptom patient-reported outcome measure for clinical and research use ([54]). MDASI-HN is a 28-item questionnaire which measures symptoms of HNC patients. Finally the patients physical activity level will be measured according to the Saltin-Grimby Physical Activity Level Scale, which

is a four-item questionnaire measuring the patients activity level [55]. MDASI-HN and Saltins will be used at four time-points – baseline (before randomization); before discharge; at first and second post-surgical appointment. Demographic and medical data (age, sex, diagnosis) will be registered at baseline and the types and number of multi-disciplinary referrals will be registered at each follow-up. The outcomes and items patients choose on the PCI will be registered. Finally the acceptance and adherence to the study will be assessed by registering the number of patients recruited and participating in the study and the attrition rate.

Qualitative outcomes: Qualitative interviews and focus group interviews will be carried out at the second post-surgical appointment to explore patient and HCP perspectives regarding the use of PCI. The interviews will be based on semi-structured interview guides. For the qualitative individual interviews, patients from IG (n= 15) will be recruited at the OPD, at the two-week appointment, from August to September 2018 and carried out October to November 2018 For the focus group interview, doctors and nurses (n=6-8) will be recruited at the Department from January - February 2019 and carried out March 2019.

Data and analysis

The baseline demographic, medical data and number and types of referrals to multi-disciplinary team will be compared between the two trial arms using the chi-square test for categorical variables, the Student's t-test for normally distributed continuous variables, and the Mann-Whitney test for non-parametric variables. Descriptive data will be presented as means with standard deviations, medians with inter-quartile ranges or frequencies with percentage depending on the distribution of the variable. For the intervention group; feasibility, acceptance, adherence, attrition (and reasons) and safety will be calculated in mean and percentage. Data from the PRO questionnaires will be keyed in a database, compared across groups using SAS program to evaluate for statistical difference and effect size, by two-sample t-test. Analysis of covariance (ANCOVA) will be applied for comparisons of groups adjusted for, e.g. smoking and alcohol consumption status or sex.

Qualitative: The focus group interview and the individual interviews will be recorded digitally, transcribed verbatim and coded in the software program NVivo. Thematic analysis will follow a model where the transcriptions will be read and re-read, coded according to emerging themes, a clustering of themes and finally reaching a number of themes, which describes the patient's or HCP's experiences with the PCI in the new model of care [45]. Researcher triangulation will be applied.
A detailed project description for this part of the study will be developed.

Ethical considerations

Patients will receive oral and written information that participation is voluntary and that they may withdraw at any time without affecting treatment and care. Written informed consent will be obtained from patients participating at time of recruitment. The Regional Ethics Committee of the Capitol Region of Denmark has been approached regarding approval of the study. They have assessed this and deemed an approval unnecessary (Jr. no: 16036032)
The study has been approved by the Danish Data Protection Agency (RH-2017-264 ,I-Suite no: 05781) and will be sought registered at ClinicalTrials.com. The study will be carried out in accordance to the Helsinki Declaration and published according to Vancouver guidelines.

Clinical Perspectives
This study has the potential to be a new model of care incorporated in the head and neck surgery department, by allowing the patient to set the agenda at nurse consultations and strengthening the needs assessments of the head and neck cancer patient. In collaboration with the health care professionals it may strengthen the referral to multi-disciplinary follow-up, thus having the potential to prevent the late effects of treatment for head and neck cancer, physically, emotionally, socially and existentially. It is designed pragmatically to fit into the existing clinical practice setting, enabling implementation. The new model of care with head and neck patients could be implemented with other patient groups and within an international framework.

Network:
This study is part of Models of Cancer Care Research Program, at Finsen Centre, Copenhagen University Hospital, Rigshospitalet

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Time Plan (Appendix III)
GANTT-chart

Dissemination

Publications: Four publications are planned: 1) Literature review: 'Early and late physical and psychosocial effects of primary surgery in patients with oral and oropharyngeal cancers: a systematic review' (published) 2) Qualitative study: An exploration of nurse-patient communication and interactions during rehabilitation consultations with Head and Neck cancer patients 3) Randomised controlled study: 'Needs assessment and decision-making tool integrated in clinical practice to enhance patient involvement in Head and Neck Cancer Rehabilitation' and 4. Qualitative findings: Feasibility and patient experiences of new needs assessment and decision-making tool integrated in clinical practice to enhance patient involvement in Head and Neck Cancer Rehabilitation. The articles will be published according to Vancouver guidelines in peer reviewed scientific journals as Head & Neck; Oral Oncology; Support Care Cancer; Cancer Nursing; European Journal of Cancer Care.

Conferences: The results will be presented at international conferences: Society of Otolaryngology, Head-Neck nurses (SOHN) annual congress; International Head and Neck Cancer Quality of Life Conference; Annual meeting on supportive care in cancer (MAASC), and national conferences: Nationalt Symposium for Fagligt Selskab for ØNH-kirurgiske sygeplejersker and Landskursus for Fagligt Selskab for Kræftsygeplejersker.

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Appendix I

An exploration of nurse-patient interactions during nurse consultations with Head and Neck cancer patients - a qualitative study

1. **Background:**

   Nurse-patient interaction is at the core of nursing care and may be planned with a therapeutic purpose or may occur spontaneously (in practice) (Evans 2016) involving physical, psychological, social and professional aspects as well as informative/instructional actions (Evans 2016). The interaction is often based on verbal as well as non-verbal communication, as many nursing interactions and procedures can be performed without verbal interaction (Evans 2016). Studies have shown that nurses tend to direct the goals of nurse-led consultations, but allow for patient participation (Tobiano et al. 2016)(Mayor and Bietti 2017)(Brataas, Thorsnes, and Hargie 2010). Communication is an important and integral part of much nurse-patient interaction (Evans 2016).There is a growing number of studies investigating communication between nurses and patients and the degree of patient involvement in head and neck cancer (HNC). These show that nurses generally are skilful at informing about and responding to patient's questions related to medical issues (de Leeuw et al. 2014), but find it more difficult to respond to emotional cues (de Leeuw et al. 2014)(Sheldon, Hilaire, and Berry 2011). It has been found that nurses may acknowledge the cues, but choose to distance themselves from these in communication with the oncological or HNC patient (de Leeuw et al. 2014)(Sheldon et al. 2011). Sheldon etc. al. found it to be important to be able to identify psychosocial needs in order to care for these needs or refer patients to professional support (Sheldon et al. 2011).
   However, studies have also shown that HNC patients prioritize medical information above emotional support (Jabbour et al. 2017)(Salander et al. 2016). Furthermore the preferred modality of information differs depending on the patient's educational level, and it has been shown that those of higher education have a preference for obtaining information from the Internet. However, all HNC patients prefer one-on-one communication/information from a healthcare professional(Jabbour et al. 2017)(Papadakos et al. 2017).
   Finally studies have shown that patients coming from a background of short education, as some HNC patients do (Papadakos et al. 2017)(Olsen et al. 2015), are hesitant to express their own needs and need to be encouraged to do so (Protheroe et al. 2013). Nurse consultations take place in many settings in hospitals, however it is unclear what takes place in the interaction between the patient and nurse, during these consultations. Firstly it is not clear to which degree the patients find themselves involved in these consultations and secondly whether all patients, regardless of educational background, understand the information delivered during these consultations.

2. **Aim**

   To explore nurse-patient interaction, patient involvement and communication practices during rehabilitation consultations in post-surgical patients with Head and Neck cancer (HNC).

3. **Methods**

   An exploratory and descriptive qualitative study informed by ethnographic fieldwork. The study will include nonparticipant observations during nurse consultations (n=15), individual patient interviews (n=15) and focus group interviews with nurses performing nurse consultations (n=4), employing Interpretive Description (Thorne 2016)

Participants and setting:
Study participants will be recruited from Dept. ORL, H&N. Included are patients, who have been diagnosed and treated surgically for head and neck cancer, at stage T3 or T4, and able to speak and understand Danish. Excluded are patients treated surgically for thyroid or parotic cancers, patients referred to adjuvant radio – or chemotherapy and patients with unstable psychiatric illness.

Using purposive sampling, patients will be recruited in the post-treatment phase after surgery for Head and Neck Cancer in the bed ward before discharge, for interviews at three time points:
1. before discharge in the bed ward
2. 7 – 10 days post-operatively in the OPD
3. 2 months post-operatively in the OPD
Observations (n=5) and patient interviews (n=5) will be performed at each time point.

Procedure
Observations will be carried out by main investigator (AM), individual interviews by AM and research assistant (RM) and focus group interview by AM and research assistant (BN).Individual and focus group interviews will be based on separate semi-structured interview-guides. Interviews will be recorded digitally.
Observations will be recorded by AM as short handwritten field notes during observations and following this expanded as field notes in a text-file. AM will situate herself in the field as a researcher and be conscious about her own previous role as a clinical nurse specialist. In order to perform an inductive analytic process, AM will also make field notes on her own experiences as a researcher in the field (Thorne 2016)

Context - nurse rehabilitation consultations
In the Department of Otolaryngology, Head and Neck Surgery and Audiology, Rigshospitalet (Dept. ORL, H&N), formal nurse rehabilitation consultation takes place at three different time points post-surgically in Head and Neck cancer patients: 1. before discharge; 2. seven – ten days and 3. Two months postoperatively in the OPD. The purpose of the consultations are to evaluate the patient's need for rehabilitation after surgical treatment for HNC in the areas of physical, emotional, social and existential needs and refer patients to multi-disciplinary follow-up if needed.

Analysis
Data will be analysed using Interpretive Description (ID) (Thorne, Kirkham, and O'Flynn-Magee 2004) (Thorne 2016) which is an inductive analytic approach designed to create ways of understanding clinical phenomena that yield application implications. When applying ID a concurrent data collection and analysis will take place, inspired by ethnographic analysis.
The focus group interview and the individual interviews will be recorded digitally, transcribed verbatim, read and re-read in depth to get a preliminary understanding of the text, before coding in the software program NVivo (Bazeley and Jackson 2013). In order to conduct a constant comparative analysis using ID, the further sorting of interview – and observational data will apply systematic text condensation, using four steps: Total impression – from chaos to themes; Identifying and sorting meaning units - from themes to codes; Condensation – from code to meaning; Synthesizing – from condensation to descriptions and concepts (Malterud 2012).
Researcher triangulation will be applied.

4. Ethical issues

Based on the ethical guidelines provided by the Northern Nurses' Federation on nursing research in the Nordic countries (Federation 2003), the following ethical aspects of the project will be taken into consideration. The principles of autonomy; beneficence; non-maleficence and justice: this means that voluntary participation in the study will be ensured and any form of coercion avoided. Voluntariness will be based on oral and written information about the project. The information will be provided in such a manner that patients and nurses understand the purpose of the study and the consequences of their own participation, in this. Further is the self-determination of participants protected by ensuring that withdrawal from the project can take place without negative consequences.

The information/data patients and nurses provide through observations and interviews will be treated in (such a manner) that their integrity will be respected and anonymity provided and finally it is ensured that the research will not be harmful to the participants in any way.

Patients will be informed about observational studies through posters in Dept. ORL, H&N and individual patients will be asked to give oral consent to being observed prior to the observation. Nurses performing rehabilitation consultation will be informed through individual information and doctors and nurses through informational meetings and emails.

Patients who participate in individual interviews will receive oral and written information that participation is voluntary and they may withdraw at any time without affecting treatment and care. Written informed consent will be obtained prior to the interview. Nurses participating in focus group interview will receive oral and written information. Written informed consent will be obtained prior to the interview.

The study has been registered by The Regional Ethics Committee of the Capitol Region of Denmark (Jr. no: 16036032), the Danish Data Protection Agency (Jr. no: RH-2017-264, with I-Suite no: 05781) and will be registered with clinical trials.gov

The study will be carried out in accordance to the Helsinki Declaration.

5. Dissemination and outputs

Publication:

The study will be published according to Vancouver guidelines in peer reviewed scientific journals as Support Care Cancer; Cancer Nursing; European Journal of Cancer Care.

Conferences: The results will be presented at international conferences as Society of Otolaryngology, Head-Neck nurses (SOHN) annual congress; International Head and Neck Cancer Quality of Life Conference; Annual meeting on supportive care in cancer (MAASC), and national conferences: Nationalt Symposium for Fagligt Selskab for ØNH-kirurgiske sygeplejersker and Landskursus for Fagligt Selskab for Kræftsygeplejersker.

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Appendix II

Translation Protocol – Patient Concerns Inventory

1. Background

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 [1]

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 [2] . The PCI-H&N has been validated in several other languages, including Norwegian.

2. Aim

The aim of this translation procedure is to perform a correct linguistic and cultural forward-and-backward translation of the Patient Concerns Inventory for Head and Neck Cancer patients into the Danish language. Pre-testing will be carried out in 10 surgically treated Head and Neck cancer patients in Denmark.

The final Danish version should be comprehensible to Head and Neck cancer patients of all levels of education, culturally acceptable and inoffensive, reflect the wording and structure from the original source, as well as the standard layout and formatting for online survey including the paper-and-pen version.

3. Methods

The translation process will follow the guidelines of the EORTC [3]

3.2. Forward translation

For the forward translation process, two separate, independent persons will translate the PCI-H&N from English to Danish. The translation will be done by native speakers of Danish with a very good command of English (primary investigator AM and research assistant RM). They do not have to be professional translators.

The forward translators will receive the English original PCI. In the translation process they will make sure that the translations are correct regarding grammar, syntax, orthography and punctuation, that the language is of current use and comprehensible, and that the wording and structure of the translation follows the English original.

3.3 Reconciliation

The two forward translations are reconciled into one by MJ and AM. The aim of the reconciliation is to choose or build from the two forward translations an optimal translation of each item.

3.4 Back translation

The reconciled translation is translated back into English by two translators working independently of one another (VK and CS). Optimally they should be native speakers of English, but if there are difficulties finding

such people, the back translations can be done by people who are not native speakers but have a good command of English. They do not have to be professional translators.
The two translators should receive only the reconciled translation and should work independently and without knowledge of the original Inventory in English. In their translations they should follow the structure and wording as closely as possible in order to reflect the translation in an accurate way that allows MJ and AM to review the back translations.

3.5 Back translation report
The back translation report will be prepared by AM and include all five translations: two forward translations from English into Danish, the reconciled translation, the two back translations into English and any comments regarding the translations.

3.7 Pilot-testing
The translated PCI-H&N will be pilot-tested on a group of surgically treated Head and Neck cancer patients in order to check its comprehensibility in Danish. The group will comprise 10 patients and will be recruited from the Dept. Of Otorhinolaryngology, Head and Neck Surgery and Audiology, at Rigshospitalet, Copenhagen University Hospital. Patients may also be recruited from two patient head and neck associations : 'Netværk for hals – og mundhulekræft' and 'Dansk Landsforening for hals – og mundhuleopererede'.

Furthermore five health care staff will be asked to check the comprehensibility of the PCI-H&N in Danish. The staff will be recruited by AM from the Dept. Of Otorhinolaryngology, Head and Neck Surgery and Audiology, at Rigshospitalet, Copenhagen University Hospital.
All patients and health care staff should be native speakers of Danish and constitute a representative group in terms of socio-demographic characteristics (gender, age and education).

The pilot-testing step consists of two parts:
1. Patients and health care staff receive and complete the translated PCI-H&N.
2. AM discusses the translation with the patients and health care staff individually.

3.7.1 Pilot-testing interview
When discussing the translation, AM will go through each part of the PCI-H&N asking the patients or health care staff whether the translation was:
1. Difficult to answer
2. Confusing
3. Difficult to understand
4. Upsetting/offensive
A probe for general comprehension is the statement: How would you state this statement in your own words?
If there are any comments, the patients should be invited to reword the statement in a way that would be easier to understand, less confusing, upsetting or offensive.

3.7.2 Pilot-testing report

On the basis of the results of the pilot-testing, AM will compile a summary in the translation report. All items that elicited comments should be filled in with information on what the problem was, with the patients' or health care staff's comments translated into English, and analysis of the comments. If changes to the wording are suggested, they should be explained and the new version should be back translated into English.

An electronic copy of the PCI-H&N response sheets filled in by patients and health care staff should be added as an appendix to the report.

The pilot-testing report will then be sent to Simon Rogers.

3.7.3. Re-testing

If any items elicited comments because of problems with comprehensibility AM suggests a change in the wording that was approved and the item will be re-tested on a few patients, including the patients that reported the comprehension problems and some that did not report problems. The re-test serves to ensure that the problem has been solved and that the new version is understandable for everybody.

In the re-test, the interviewer should only check the items in question with the patients and not the whole inventory. The comments will be communicated to Simon Rogers as a written report.

When all issues have been solved and all changes approved, AM will prepare the final translation based on the wording agreed upon in the pilot-testing phase.

3.8 Final translation

The final translation will be sent to Simon Rogers for final approval. Once approved, AM will terminate the translation project, making the translation available for use, archiving the documentation from the translation process.

4. Copyrights of PCI-H&N and publication policy

The final Danish version of the PCI-H&N will be used for assessing needs of Head and Neck patients and facilitate patient involvement in out-patient clinics without cost. The methods of responding to the Danish PCI-H&N in the project will be by tablets. The Danish PCI-H&N will be handled as confidential material as part of the protocol. The project group does not own the Danish PCI-H&N and for use of the Danish PCI-H&N in another project or by other researchers, Edge Hill University and Professor Simon Rogers, University Hospital Aintree, Liverpool, Great Britain, will be contacted for approval and will decide whether the Danish PCI-H&N can be used in relation to their copyright policy.

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Appendix III

Project Timeplan