Needs Assessment In Patients Surgically Treated For Head And Neck Cancer – A Randomized Controlled Trial

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Abstract

Purpose:

Investigate whether a head and neck cancer specific needs assessment tool integrated in nursing rehabilitation consultations early in the post-surgical period would improve quality of life and symptom burden in patients surgically treated. Further, to assess the feasibility of carrying out needs assessments during consultations.

Methods:

92 surgically treated head and neck cancer patients at the Department of Otolaryngology, Head and Neck Surgery and Audiology, Copenhagen University Hospital, Denmark were enrolled.

A two-arm randomized controlled trial design was used. Both arms received nursing rehabilitation consultations before discharge, approximately two weeks and two months post-operative. Patients in the intervention group had their needs assessed using an assessment tool.

Primary outcome was quality of life. Secondary outcomes were symptom burden and referrals for multi-disciplinary rehabilitation follow-up.

Results:

No significant differences were found in quality of life or symptom burden. However, notable more patients in the intervention group were referred for rehabilitation.

Conclusion:

The intervention suggests that important needs were identified and addressed, especially emotional and existential needs, which were accommodated through referrals and professional advice. Nursing rehabilitation consultations using a needs assessment instrument may ensure that patient preferences and priorities are incorporated in their care.

Trial Registration

ClinicalTrials.com (NCT03443258). Date of registration: May 31st, 2018

Introduction

Patients who have undergone surgery for head and neck cancer (HNC) experience considerable adverse effects and significant symptom burden [1]. Surgical treatment alters functional anatomy [2], such that patients with HNC experience dysfunction across physical, functional, emotional, social, and existential domains [3]. Dysfunction can result in unmet needs being difficult for patients to express and for health care professionals (HCP) to identify [4]. A high proportion of patients with HNC have unmet needs [5], with some studies showing up to 60% [6], and if left unmanaged, may negatively impact quality of life (QoL), emotional wellbeing, and daily living [6]. Needs may present early or late in a patient's trajectory [1, 5]. Identification and intervention regarding these concerns can potentially reduce symptom burden and lead to improvement in health-related Quality of Life (HRQoL) [6].

Assessment of patient needs related to symptom management and rehabilitation is recommended after treatment to mitigate early and late detrimental effects [7]. The Danish Health Authority recommends assessing cancer patient needs early in the post-treatment phase, including physical, social, psychological, and existential needs [8]. The assessment may use national needs assessment instruments recommended by the Regions of Denmark [8]; however, these are generic and do not cater to specific needs of patients with HNC [9].

Head and neck nurse specialists play a key role in assessing patient needs. Advice, information, and support in managing physical symptoms and emotional reactions are recommended to be integrated in nursing consultations [11, 12]. Wider multidisciplinary team involvement is shown to have positive impact on patient HRQoL [12].

A variety of instruments are available to help identify the needs of patients with HNC [14–16]. Some instruments are based on HRQoL questionnaires linking poor outcomes or anxiety and depression to unmet needs [16]. Others are based on symptom burden questionnaires [17]. However, patient-reported outcome (PRO) measures developed for research purposes often measure HRQoL and may not be useful in identifying patient needs [3]. A systematic review and content comparison of self-report measures of unmet needs used in patients with HNC favoured the Patient Concerns Inventory (PCI) compared to 13 other tools [18]. PCI is a 56-item prompt list used in clinics to facilitate patients raising concerns that might otherwise be missed [19].

We hypothesized that an HNC needs assessment tool integrated in nursing rehabilitation consultations early in the post-surgical period would improve HRQoL and symptom burden. The aim was to investigate the effect of the HNC needs assessment tool on HRQoL, symptom burden and

types and numbers of follow-up referrals. Further, to assess the feasibility of carrying out needs' assessments during nursing rehabilitation consultations.

Methods

Sample and Settings

Designed as a two-arm randomized controlled trial (RCT) with a control group (CG) and an intervention group (IG), the study recruited patients from Department of Otolaryngology, Head and Neck Surgery and Audiology, Copenhagen University Hospital, Denmark (Dept. H&N), between June 1, 2018 and August 31, 2019. The inclusion criteria were: >18 years of age, either newly diagnosed or recurrent and operated for HNC within the last few days; able to speak and understand Danish. The exclusion criteria were: treated surgically for thyroid or parotic cancers, referred to adjuvant radio/chemotherapy, and diagnosed with unstable psychiatric illness.

Patients were randomized via Research Electronic Data Capture (REDCap), an electronic system for research data containing a randomization module [20]. Patients were randomly assigned 1:1 to either CG or IG, and stratified according to medical status; newly diagnosed or recurrence, and ASA classification [21]. Block randomization was applied. Assignments were not blinded to either investigator or patients, but the statistician was blinded to treatment allocation.

Study Context

The study was conducted at Dept. H&N, a tertiary, tax-funded, public health care facility with an uptake area of 2.6 million people. Post-operative assessment consultations are provided for all patients prior to discharge [8], while rehabilitation takes place in the primary sector [22]. In Denmark, nurse rehabilitation consultations include a formal, systematic needs assessment for symptom management and rehabilitation, but some aspects are done collaboratively with swallowing therapists and surgeons. Follow-up in the primary sector is multidisciplinary and may include referral to or advice about contacting, a speech pathologist, swallowing therapist, physiotherapist, psychologist or counsellor.

Procedures

CG received usual post-operative care, including three rehabilitation consultations by a nurse on the rehabilitation team, which did not include a needs assessment tool or follow any specific flow. Consultations took place immediately after the appointment with the surgeon, where the nurse had accompanied the patient. The nurse followed up on the surgeon's consultation and assessed the patient's needs based on hospital records and systematic questioning. Recommendations, referrals, and advice for follow-up at a hospital or in primary sector were decided upon and patients were handed a selection of leaflets, based on the nurses' professional perspective.

Consultations were offered prior to discharge (time-point 1), 7–10 days after discharge (time-point 2), and two months post-surgery (time-point 3).

IG received usual post-operative care, including three nursing rehabilitation consultations taking place at the same time-points as CG and conducted by primary investigator AM or a project nurse. The consultations applied PCI [23] as a needs assessment instrument, where patients select items they would like to discuss with the nurse related to functional, emotional, social, and existential areas. In addition to encouraging patients to express their needs, concerns, and symptoms, they can choose items they find important and meaningful to discuss. To promote integration of needs assessment and facilitate patient involvement in the consultations [24,25], these followed a certain sequence inspired by Smith's patient-centered interviewing [26]. Patients were informed about the purpose of the consultation at the outset and received guidance on completing the PCI on iPad. Nurse and patients briefly discussed results and identified needs or concerns patients wished to discuss with the surgeon. The nurse accompanied the patient to the surgeon's consultation and ensured chosen concerns were discussed. After the consultation with the surgeon, the nurse followed up on this and remaining needs and concerns based on the PCI were discussed. Any needs nurses deemed important from a professional perspective were added to the discussion. Finally, collaboratively with the patient, recommendations, referrals, and advice for follow-up at hospital or in primary sector was decided upon guided by a management manual.

Prior to commencement of the study, a management manual for discussing and acting on PCI items was developed, as well as a leaflet informing the patient on how to access support in the primary sector, e.g. psychologist, counsellor, smoking and alcohol cessation programs, chaplain, or other religious support. Further, a Danish linguistic validation of PCI was conducted, and an IT solution on iPad developed, easily allowing an overview of items. The Region's Centre for IT, Medical Technology and Telephony Services approved the solution.

Outcome Measurements

Primary outcome was HRQoL on European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ), and symptoms using EORTC QLQ–Head and Neck 35 (H&N35)[27]. The questionnaires have 35 items comprising a global QoL and global health status (GHS) scale, five functional and nine symptom scales on EORTC QlQ and 18 symptom scales the last five of which are binary on H&N35, with scores ranging from 0–100. HRQoL was measured using the GHS/QoL scale which consists of two items rating the overall health and overall QoL. When measuring changes over time, it is suggested changes above 10 points is considered clinically relevant [28]. EORTC QLQ–H&N35 was

completed at two time-points: baseline (before randomization) and seven days after the two-month post-treatment appointment, either electronically via email generated by REDCap or letter by regular mail. Patients rated scores based on past seven days.

The secondary outcomes included symptom prevalence and severity evaluated by MD Anderson Symptom Inventory–Head and Neck (MDASI–HN) module [29], a multi-symptom PRO measure for clinical and research use. The MDASI–HN module comprises a 28-item questionnaire measuring symptoms and their severity in patients with HNC using 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 [30]. When measuring changes over time, a minimum important difference is 0.98–1.21 [29]. MDASI–HN was completed at the same time-points as EORTC QIQ-H&N35. Patients rated scores based on past 24 hours.

The types and number of multidisciplinary referrals were registered at three time-points: before discharge, 7–10 days and two months post-treatment. Demographic, medical data and comorbidity using the Charlson Comorbidity Index [31] were registered at baseline. The outcomes and items chosen on the PCI were registered for IG.

Statistical Analysis

Sample size was based on results from studies with similar groups of patients reporting a standard deviation (SD) of size 20 on within-group changes of GHS/QoL on EORTC QLQ [32]. A between-group difference of 15 for changes from baseline to post-intervention was considered clinically relevant. Based on two-sample t-test, we found 29 patients in each group were required to obtain a power of 0.80. To account for an expected dropout of 20%, we decided to include at least 72 patients. Descriptive statistics was used to describe demographics and baseline characteristics of the two groups. For numerical variables, we reported mean and range, and for categorical variables, numbers and percentages. For EORTC QLQ-H&N35 and MDASI–HN we presented mean, SD, and number of data available at each assessment time for both groups. We used a linear mixed model 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, we reported estimated prevalence and standard error for each combination of assessment time and treatment group. 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, risk of reporting false positive results is high; hence, this should be regarded as an exploratory analysis. Types and number of referrals were reported for each group at each assessment time. For IG, PCI items chosen were calculated at each assessment time and reported. All statistical analyses were carried out using R [33].

Results

Of 244 eligible patients, 92 (38%) were included. Sixty-four patients were excluded for not meeting inclusion criteria, 32 were unreachable for inclusion, and 56 (23%) 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 (Fig. 1).

Groups were comparable, except for tumour sites, where CG had nine patients with tumours in larynx (23%) and eight in pharynx (21%), compared to IG, with five in larynx (16%) and two in pharynx (6%) (Table 1).

Table 1
Baseline demographic and medical characteristics

	Intervention (n = 44)	Control (n = 48)
Gender		
Women	12 (27%)	16 (33 %)
Men	32 (73%)	32 (67 %)
Age, years	64.4 (37–80)	64.9 (45–85)
Smoking status		
Never smoker	8 (18%)	10 (21%)
Previous smoker	28 (64%)	29 (60%)
Previous smoker package-years	35.7 (1–76.5)	41.9 (5–153)
Smoker	8 (18%)	9 (19%)
Smoker package-years	59.2 (8,4–112)	56.8 (36,8–90)
Alcohol		
No alcohol	7 (16%)	2 (4%)
Less than 7 units/wk.	13 (30%)	17 (35%)
7–14 units/wk.	12 (27%)	17 (35%)
More than 14 units/wk.	12 (27%)	12 (25%)
BMI	26.7 (18.3–38.1)	24.1 (17–33.4)
Partner		
Living alone	30 (68%)	33 (69%)
Cohabiting	13 (30%)	15 (31%)
Employment status		
Retired/early retirement	24 (55%)	27 (56%)
Years since last employment	Min: 1 Max: 43 Mean: 13.4	Min: 0 Max: 24 Mean: 8.8
Employed (part-time)	7 (16%)	3 (6%)
Employed (full-time)	12 (27%)	15 (31%)
Rehabilitation benefits	1 (2%)	1 (2%)
Social security	0	2 (4%)
Educational level, years		
Lower, 7–9	5 (11%)	7 (15%)
Middle, 12–15	32 (72%)	31 (65%)
Higher, 17–20	7 (16%)	10 (21%)
Diagnosis	n = 32	n = 39
Larynx	5 (16%)	9 (23%)

Legend:

Package years = No. of cigarettes daily x no of years/20; Units = 1 bottle beer, 1 glass wine, 1 glass dessert wine; 1 glass spirits;

PF0 = able to carry out all normal activity without restriction, PF1 = restricted in strenuous activity but ambulatory and able to carry out light work, PF2 = ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours, PF3 = symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden

	Intervention (n = 44)	Control (n = 48)
Pharynx (total)	2 (6%)	8 (21%)
Oral cavity	25 (78%)	22 (56%)
Tumour stage	n = 32	n = 39
Stage I	12 (38%)	19 49%)
Stage II	7 (22%)	4 (10%)
Stage III	10 (31%)	5 (13%)
Stage IV	1 (3%)	5 (13%)
Missing	2 (6%)	6 (15%)
Newly diagnosed	34 (77%)	36 (75%)
Recurrences	10 (23%)	12 (25%)
Comorbidities number (Charlson)		
0	20 (45%)	27 56%)
1	11 (25%)	11 23%)
2	7 (16%)	8 (17%)
3	3 (7%)	1 (2%)
4	3 (7%)	1 (2%)
Performance Status (PF)		
PF 0	7 (16%)	12 (25%)
PF 1	28 (64%)	32 67%)
PF 2	9 (20%)	3 (6%)
PF 3	0	1 (2%)
Legend:		
Package years = No. of cigarettes daily x no of years/20; Units = 1 bottle beer, 1 glass wine, 1 glass dessert wine; 1 glass spirits;		
PF0 = able to carry out all normal activity without restriction, PF1 = restricted in strenuous activity but ambulatory and able to carry out light work, PF2 = ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours, PF3 = symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden		

Primary Outcome

Primary outcome on EORTC QLQ, showed no statistically significant difference between within-group change on GHS/QoL: 3.8 (95% CI -10.7–18.4; p = 0.60). However, both groups showed statistically significant improvements over time (IG: P = 0.01, CG: P = 0.04). For EORTC QLQ, there were significant improvements in both groups for emotional functioning (CG: P < 0.01, IG: P < 0.01); for symptom scales pain (CG: P = 0.01, IG: P < 0.01) and appetite loss (CG: P = 0.03, IG: P = 0.05). Symptom scales for nausea/vomiting, dyspnoea, constipation, diarrhoea, and financial situation all showed mean scores below 20 (bottom fifth of the scale) with non-significant improvements over time in both groups. Symptom burden changed for one or both groups for following scales or items on H&N35: decreased pain (CG: P = 0.01, IG: P < 0.01); improved problems with senses (CG: P < 0.01); improved problems with speech (CG: P = 0.02); decreased felt ill (IG: P = 0.02); decreased use of painkillers (CG: P = 0.03, IG: P < 0.01) (Table 2).

Table 2. European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) and Head and Neck 35 (H&N35)

EORTC QLQ

	Baseline		Post		Linear mixed model					
	n	Mean (SD)	n	Mean (SD)	Change within	95% CI	P-value	Change between	95% CI	P-value
Global health status										
Control	46	59.4 (25.0)	29	70.1 (23.5)	10.7	0.6 - 20.7	0.04			
Intervention	41	57.1 (26.3)	27	72.2 (25.2)	14.5	4.0- 25.0	0.01	3.8	-10.7 - 18.4	0.60
Functional scales										
Physical functioning										
Control	48	83.0 (17.1)	29	85.7 (16.9)	2.4	- 3.6 – 8.3	0.43			
Intervention	42	80.0 (23.5)	27	86.7 (20.9)	4.7	- 1.5 - 11.0	0.13	2.4	- 6.2 - 11.0	0.59
Role functioning										
Control	48	81.6 (29.2)	29	80.5 (24.8)	-1.7	-11.9 – 8.4	0.73			
Intervention	41	78.5 (30.3)	27	79.6 (31.8)	2.6	-8.1 – 13.3	0.63	4.3	-10.4 – 19.0	0.56
Emotional functioning										
Control	46	70.8 (19.6)	29	81.9 (20.8)	11.9	3.9 – 19.9	<0.01			
Intervention	41	67.8 (26.8)	27	80.6 (27.0)	13.6	5.2 – 21.9	<0.01	1.6	-9.9 - 13.2	0.78
Cognitive functioning										
Control	47	86.2 (18.2)	29	89.1 (18.0)	4.1	-2.2 – 10.4	0.19			
Intervention	41	75.6 (28.2)	27	82.7 (26.3)	5.8	-0.9 – 12.4	0.09	1.6	-7.5 – 10.8	0.72
Social functioning										
Control	47	87.9 (21.1)	29	88.5 (17.9)	1.0	-6.9 – 8.9	0.80			
Intervention	40	89.2 (19.4)	27	87.0 (24.2)	-1.8	-10.1 – 6.6	0.68	-2.8	-14.3 – 8.7	0.63
Symptom scales										
Fatigue										
Control	48	27.9 (27.7)	29	24.5 (22.9)	-4.9	-13.8 – 3.9	0.27			
Intervention	43	31.9 (27.2)	27	25.1 (23.6)	-6.4	-15.6 – 2.9	0.17	-1.4	-14.2 – 11.4	0.83
Nausea and vomiting										
Control	48	3.1 (8.9)	29	1.1 (4.3)	-1.3	-5.8 – 3.3	0.57			
Intervention	43	7.4 (17.6)	27	7.4 (14.9)	0.3	-4.4 – 5.0	0.89	1.6	-4.9 – 8.1	0.62
Pain										
Control	48	26.0 (26.4)	29	8.6 (13.1)	-17.5	-26.9 – (-8.1)	<0.01			
Intervention	43	23.6 (24.7)	27	10.5 (17.4)	-12.3	-22.2 – (-2.5)	0.01	5.2	-8.4 – 18.8	0.45
Dyspnoea										
Control	46	13.8 (23.9)	29	14.9 (22.9)	1.9	-6.3 – 10.1	0.65			
Intervention	39	17.1 (27.4)	27	11.1 (22.6)	-8.3	-16.9 – 0.3	0.06	-10.2	-22.1 – 1.7	0.09
Insomnia										
Control	47	30.5 (30.2)	29	24.1 (26.6)	-8.5	-19.2 – 2.3	0.12			
Intervention	42	34.1 (33.3)	27	25.9 (33.8)	-9.7	-20.9 – 1.5	0.09	-1.3	-16.8 – 14.3	0.87
Appetite loss										

Control	48	22.2 (33.2)	29	10.3 (20.1)	-11.1	-21.1 – (-1.0)	0.03			
Intervention	43	22.5 (31.5)	27	8.6 (23.7)	-10.4	-20.9 – 0.0	0.05	0.6	-13.8 – 15.1	0.93
Constipation										
Control	48	11.8 (26.2)	29	9.2 (19.7)	-2.8	-12.9 – 7.2	0.57			
Intervention	42	15.1 (27.7)	27	7.4 (16.9)	-7.0	-17.5 – 3.6	0.19	-4.1	-18.7 – 10.4	0.57
Diarrhoea										
Control	47	10.6 (19.8)	29	11.5 (24.0)	0.5	-7.5 – 8.5	0.90			
Intervention	40	10.8 (23.1)	27	7.4 (16.9)	-4.6	-13.0 – 3.9	0.28	-5.1	-16.7 – 6.5	0.38
Financial situation										
Control	47	5.7 (18.8)	27	9.9 (18.1)	3.1	-4.4 – 10.7	0.41			
Intervention	41	12.2 (26.6)	27	12.3 (29.5)	0.0	-7.7 – 7.7	1.00	-3.1	-13.9 – 7.7	0.56

H&N35

	Baseline		Post		Linear mixed model					
	n	Mean (SD)	n	Mean (SD)	Change within	95% CI	P-value	Change between	95% CI	P-value
Pain										
Control	46	21.6 (21.4)	29	10.8 (13.3)	-10.2	-18.1 - -2.3	0.01			
Intervention	42	32.5 (28.3)	26	11.6 (15.3)	-19.1	-27.4 - -10.9	<0.01	-8.9	-20.4 – 2.5	0.12
Swallowing										
Control	47	13.7 (22.7)	29	10.1 (18.0)	-2.7	-10.8 – 5.4	0.51			
Intervention	42	15.6 (25.7)	26	8.7 (16.7)	-5.9	-14.5 – 2.6	0.17	-3.2	-15.1 – 8.6	0.58
Senses										
Control	47	9.6 (18.6)	29	26.4 (32.6)	16.7	7.9 – 25.5	<0.01			
Intervention	40	17.1 (30.0)	26	16.0 (25.6)	-0.9	-10.3 – 8.5	0.85	-17.6	-30.5 – (-4.7)	0.01
Speech										
Control	44	13.4 (19.0)	29	24.1 (26.4)	9.1	1.4 – 16.7	0.02			
Intervention	39	13.8 (19.5)	26	12.8 (20.3)	-1.0	-9.1 – 7.2	0.81	-10.0	-21.2 – 1.2	0.08
Social eating										
Control	44	14.8 (26.8)	29	10.6 (20.5)	-3.3	-12.5 – 5.9	0.48			
Intervention	38	14.8 (21.2)	26	11.3 (26.4)	-1.2	-11.2 – 8.7	0.81	2.1	-11.5 – 15.6	0.76
Social contact										
Control	45	3.8 (8.6)	29	5.7 (11.1)	2.3	-3.5 – 8.1	0.43			
Intervention	39	7.1 (15.4)	26	6.1 (17.5)	-0.5	-6.8 – 5.7	0.86	-2.8	-11.4 – 5.7	0.51
Less sexuality										
Control	39	33.3 (40.5)	27	38.3 (36.9)	-1.4	-15.4 – 12.6	0.84			
Intervention	29	19.0 (33.5)	23	16.7 (34.1)	1.8	-14.0 – 17.6	0.82	3.2	-17.9 – 24.4	0.76
Teeth										
Control	44	5.3 (12.3)	29	6.9 (16.4)	2.1	-5.3 – 9.5	0.58			
Intervention	38	14.0 (32.5)	25	5.3 (18.5)	-2.8	-10.8 – 5.2	0.49	-4.9	-15.7 – 6.0	0.37
Mouth opening										
Control	47	7.1 (16.9)	29	10.3 (20.1)	3.3	-7.1-13.6	0.53			
Intervention	42	11.9 (28.3)	26	6.4 (21.1)	-5.5	-16.4-5.4	0.32	-8.7	-23.8-6.3	0.25
Dry Mouth										
Control	47	22.0 (28.9)	29	18.4 (27.6)	-4.3	-16.7-8.2	0.50			
Intervention	40	36.7 (38.3)	26	26.9 (26.7)	-9.0	.-22.3-4.3	0.18	-4.8	-23.0-13.5	0.60
Sticky saliva										
Control	45	16.3 (26.2)	29	19.5 (22.7)	4.1	-7.0-15.3	0.46			
Intervention	39	20.5 (28.2)	26	16.7 (28.7)	-3.3	-15.1-8.6	0.58	-7.4	-23.7-9.0	0.37
Coughing										
Control	45	28.9 (29.0)	29	18.4 (19.1)	-9.4	-18.6-(-0.2)	0.05			
Intervention	41	22.0 (24.3)	26	24.4 (29.1)	1.9	-7.8-11.6	0.70	11.3	-2.1-24.6	0.10
Felt ill										

Control	46	15.9 (26.0)	28	9.5 (17.8)	-6.2	-17.0-4.6	0.25			
Intervention	39	19.7 (27.3)	25	5.5 (12.5)	-14.4	-25.9-(-2.8)	0.02	-8.2	-24.0-7.7	0.30
Binary items	**n**	**Mean (SE)**	**n**	**Mean (SE)**	**Change within**		**P-value**			
Pain killers										
Control	45	51.1 (7.5)	29	24.1 (7.1)			0.03			
Intervention	36	66.7 (7.9)	26	19.2 (7.7)			<0.01			
Nutritional supplements										
Control	43	21.9 (6.2)	29	27.6 (8.3)			1.00			
Intervention	36	8.3 (4.6)	25	24.0 (8.5)			0.37			
Feeding tube										
Control	46	8.7 (4.2)	29	3.4 (3.4)			0.48			
Intervention	35	5.7 (3.9)	26	3.8 (3.7)			1.00			
Weight loss										
Control	45	33.3 (7.0)	29	13.8 (6.4)			0.11			
Intervention	37	24.3 (7.1)	26	15.4 (7.1)			1.00			
Weight gain										
Control	46	6.5 (3.6)	29	37.9 (9.0)			0.03			
Intervention	36	8.3 (4.6)	25	28.0 (9.0)			0.13			

Mean scores and SD are based on raw data. Change scores and CI are based on linear mixed model. For last five binary items the table displays estimated prevalence (in %) and corresponding standard error instead of mean and SD. Within-group changes are based on McNemar's test

The response rate to EORTC QLQ-H&N35 post-time dropped by 6 (17 %) for CG and 3 (10 %) for IG.

Secondary Outcomes

Changes in symptom prevalence and severity measured by MDASI-HN did not show significant differences between groups. Overall range for mean scores of core symptoms was 0.2–4.7, with highest scores in fatigue; disturbed sleep; being distressed; drowsy/sleepy; dry mouth and sadness. Overall range for mean scores of head and neck-specific symptoms was 0.3–4.9, with highest scores in problems with mucus in mouth/throat; difficulty with swallowing/chewing; and difficulty with voice/speech. Significant improvements over time were observed in many areas in both groups. Overall range of mean scores for interference symptoms was 1.0–5.3, with highest scores in activity, mood, and work, with slight improvements in both groups over time (Table 3). The response rate to MDASI–HN dropped by 2 (6%) in CG and 2 (7%) for IG at post-treatment assessment.

Table 3. MD Anderson Symptom Inventory–Head & Neck

	Baseline		Post		Linear mixed model					
	n	Mean (SD)	n	Mean (SD)	Change within	95% CI	P-value	Change between	95% CI	P-value
Core symptom										
Pain										
Control	46	4.7 (3.1)	33	1.1 (2.2)	-3.6	-4.8 - -2.4	0.00			
Intervention	41	4.6 (2.7)	28	1.7 (2.7)	-2.9	-4.2 - -1.6	0.00	0.7	-1.0 - 2.4	0.38
Fatigue										
Control	47	4.7 (3.4)	30	2.5 (3.0)	-2.2	- 3.2 – -1.2	0.00			
Intervention	39	4.7 (2.6)	27	1.9 (2.5)	-2.9	- 3.9 - -1.7	0.00	-0.7	- 2.2 - 0.9	0.45
Nausea										
Control	45	1.8 (3.1)	33	0.3 (0.8)	-1.6	-2.6 - -0.6	0.00			
Intervention	41	1.8 (2.8)	26	0.5 (1.9)	-1.3	-2.4 - -0.2	0.03	0.3	-1.2 – 1.9	0.67
Disturbed sleep										
Control	48	3.7 (3.4)	33	2.2 (2.9)	-1.5	-2.7 - -0.4	0.01			
Intervention	39	4.3 (3.3)	28	1.8 (2.7)	-2.6	-3.9 - -1.2	0.00	-1.0	-2.8 – 0.8	0.26
Being distressed										
Control	48	3.3 (3.2)	31	2.2 (2.7)	-1.5	-2.5 - -0.6	0.00			
Intervention	40	3.2 (3.1)	28	1.6 (2.5)	-1.6	-2.7 - -0.6	0.00	-0.1	-1.6 – 1.3	0.87
Shortness of breath										
Control	48	1.6 (2.2)	33	0.9 (1.8)	-0.6	-1.4 – 0.2	0.14			
Intervention	40	1.2 (2.1)	28	0.9 (1.8)	-0.4	-1.2 - 0.5	0.40	0.2	-0.9 – 1.4	0.69
Difficulty remembering										
Control	47	1.5 (2.3)	32	0.9 (1.4)	-0.7	-1.5 – 0.0	0.06			
Intervention	39	1.5 (2.3)	28	0.9 (1.8)	-0.5	-1.3 – 0.3	0.22	0.2	-0.9 – 1.3	0.71
Lack of appetite										
Control	45	3.1 (3.7)	33	0.9 (1.8)	-2.2	-3.4 - -1.0	0.00			
Intervention	36	2.2 (2.7)	28	1.0 (2.5)	-1.2	-2.5 – 0.1	0.07	1.0	-0.7 – 2.8	0.24
Drowsy (sleepy)										
Control	47	4.2 (3.2)	33	2.0 (2.4)	-2.2	-3.2 - -1.2	0.00			
Intervention	41	3.7 (2.9)	28	1.8 (2.8)	-2.0	-3.1 - -0.9	0.00	0.2	-1.3 – 1.6	0.84
Dry mouth										
Control	48	3.5	30	1.3	-2.4	-3.5 - -1.3	0.00			

		(3.1)		(1.6)							
Intervention	42	3.8 (3.3)	28	2.2 (2.9)	-1.7	-2.8 - -0.6	0.00	0.7	-0.8 – 2.3	0.36	
Sadness											
Control	47	3.4 (3.1)	32	1.9 (2.7)	-1.7	-2.7 - -0.6	0.00				
Intervention	40	3.1 (3.3)	27	1.3 (2.4)	-1.8	-2.9 – -0.6	0.00	-0.1	-1.7 – 1.5	0.92	
Vomiting											
Control	47	0.9 (2.6)	33	0.2 (0.7)	-0.8	-1.6 – 0.1	0.06				
Intervention	40	0.4 (1.5)	28	0.4 (1.5)	-0.0	-0.9 – 0.9	0.95	0.8	-0.4 – 2.0	0.19	
Numbness/tingling											
Control	48	2.4 (3.2)	33	1.9 (2.5)	-0.6	-1.5 – 0.3	0.21				
Intervention	39	1.7 (2.4)	28	1.7 (2.1)	-0.3	-1.3 – 0.8	0.61	0.3	-1.1 – 1.7	0.64	
Head and neck symptoms											
Problem with mucus in mouth throat											
Control	48	3.2 (3.1)	33	1.9 (1.9)	-1.2	-2.4 - -0.1	0.04				
Intervention	39	3.5 (3.2)	28	1.6 (2.4)	-2.0	-3.3 - -0.8	0.00	-0.8	-2.5 – 0.9	0.35	
Difficulty with swallowing/chewing											
Control	39	4.9 (3.8)	32	1.8 (2.4)	-3.2	-4.6 - -1.8	0.00				
Intervention	39	4.5 (3.3)	27	2.1 (3.3)	-2.3	-3.7 - -0.9	0.00	0.9	-1.1 – 2.8	0.38	
Coughing/choking											
Control	41	1.4 (2.5)	33	0.8 (1.7)	-0.7	-1.7 – 0.4	0.21				
Intervention	39	1.7 (2.9)	28	0.8 (2.1)	-0.9	-2.1 – 0.2	0.11	-0.2	-1.8 – 1.3	0.75	
Difficulty with voice/speech											
Control	41	3.2 (3.2)	30	2.7 (2.6)	-0.7	-1.9 – 0.6	0.28				
Intervention	40	3.9 (3.3)	26	1.2 (1.6)	-2.9	-4.2 - -1.6	0.00	-2.2	-4.0 - -0.4	0.02	
Skin pain/burning/rash											
Control	45	0.4 (1.1)	32	0.4 (1.2)	-0.0	-0.6 – 0.6	0.98				
Intervention	40	0.5 (1.5)	26	0.5 (1.1)	0.1	-0.6 – 0.7	0.87	0.1	-0.8 – 0.9	0.89	
Constipation											
Control	43	1.6 (2.9)	32	0.3 (0.6)	-1.3	-2.4 - -0.2	0.02				
Intervention	38	1.7 (2.9)	25	0.6 (1.8)	-1.1	-1.4 – 1.9	0.08	0.2	-1.4 – 1.9	0.79	

Problem with tasting food										
Control	38	1.2 (2.8)	30	1.5 (2.3)	-0.4	-0.7 – 1.4	0.48			
Intervention	31	1.8 (2.9)	25	1.8 (2.6)	-0.3	-1.4 – 0.8	0.61	-0.6	-2.2 – 0.9	0.39
Mouth/throat sores										
Control	41	2.4 (2.9)	32	0.4 (1.1)	-2.0	-3.3 - -0.8	0.00			
Intervention	37	3.6 (3.5)	24	0.5 (1.7)	-3.1	-4.4 - -1.7	0.00	-1.0	-2.9 – 0.8	0.26
Problem with teeth and gums										
Control	43	1.1 (2.5)	32	0.7 (1.2)	-0.4	-1.3 – 0.5	0.41			
Intervention	38	1.6 (2.9)	26	0.6 (1.5)	-1.0	-2.0 – - 0.0	0.04	-0.6	-1.9 – 0.7	0.34
Interference										
Activity										
Control	46	4.3 (3.2)	31	3.0 (2.6)	-1.3	-2.6 - -0.1	0.04			
Intervention	38	4.5 (3.3)	25	2.5 (2.8)	-2.0	-3.5 - -0.6	0.01	-0.7	-2.6 – 1.2	0.47
Mood										
Control	45	3.4 (2.8)	29	2.1 (2.9)	-1.4	-2.5 - -0.4	0.01			
Intervention	38	3.0 (2.6)	25	2.1 (2.8)	-1.2	-2.3 – 0.0	0.05	0.3	-1.3 – 1.9	0.72
Work										
Control	33	4.2 (4.5)	31	2.5 (2.9)	-1.8	-3.5 - -0.1	0.04			
Intervention	30	5.3 (4.4)	26	2.6 (2.8)	-2.9	-4.8 - -1.2	0.00	-1.2	-3.6 – 1.3	0.36
Relations with others										
Control	46	2.0 (2.8)	31	1.4 (2.1)	-0.6	-1.7 – 0.5	0.26			
Intervention	37	2.2 (3.0)	26	1.8 (2.8)	-0.6	-1.8 – 0.6	0.32	-0.0	-1.6 – 1.6	0.98
Walking										
Control	44	1.3 (2.6)	31	1.0 (2.4)	-0.3	-1.3– 0.8	0.62			
Intervention	40	1.3 (2.4)	25	1.3 (2.7)	-0.0	-1.2 – 1.2	0.98	0.3	-1.3 – 1.9	0.73
Enjoyment of life										
Control	44	2.0 (2.8)	30	1.3 (2.2)	-0.7	-1.9 – 0.4	0.21			
Intervention	40	2.4 (3.2)	26	1.5 (2.6)	-1.0	-2.3 – 0.2	0.11	-0.3	-1.9 – 1.5	0.76

Mean scores and SD are based on raw data. Change scores and CI are based on linear mixed model.

There was a notable difference between groups regarding referrals in the emotional domain, where more IG patients (n = 28) were advised to contact a psychologist than CG (n = 7), or a counsellor (IG: n = 51; CG: n = 25). There were in total 183 referrals in IG compared to 119 in CG (Table 4).

Table 4
Referrals

		Time point 1			Time point 2			Time point 3			
Type of referral	Group	In hospital (n)	Primary sector (n)	Advised about (n)	In hospital (n)	Primary sector (n)	Advised about (n)	In hospital (n)	Primary sector (n)	Advised about (n)	Total no of referrals
Swallowing Therapist	CG	1	22	4	6	0	3	0	0	0	36
	IG	2	18	4	1	2	5	1	0	3	36
Speech Pathologist	CG	0	2	2	0	7	1	0	5	3	20
	IG	0	5	9	0	10	6	0	3	3	36
Physiotherapist	CG	0	3	0	0	2	0	0	0	0	5
	IG	0	3	0	0	1	0	1	1	3	9
Dietician	CG	0	0	0	1	0	0	0	0	0	1
	IG	0	0	0	0	0	0	0	0	0	0
Dentist	CG	0	0	0	0	0	3	0	1	0	4
	IG	0	0	1	0	0	1	0	0	1	3
Dental hygienist	CG	0	0	0	0	0	0	0	0	0	0
	IG	0	0	0	0	0	0	0	0	1	1
Sexologist	CG	0	0	0	0	0	0	0	0	0	0
	IG	0	0	0	0	0	1	0	0	0	1
Psychologist	CG	0	0	4	0	0	0	0	0	3	7
	IG	0	0	9	0	0	11	0	0	8	28
Counsellor	CG	0	0	19	0	0	3	0	0	3	25
	IG	0	1	28	0	0	10	0	0	12	51
Spiritual counsellor	CG	0	0	0	0	0	0	0	0	0	0
	IG	0	0	0	0	0	0	0	0	2	2
Cancer rehabilitation	CG	0	2	6	0	4	5	0	1	1	19
	IG	0	2	3	0	2	0	0	2	2	11
Oral rehabilitation team	CG	0	0	0	2	0	0	0	0	0	2
	IG	0	2	0	1	1	0	0	1	0	5
Nursing rehabilitation team	CG	23	0	4	1	0	0	0	0	0	28
	IG	32	0	5	2	0	1	0	0	0	40
Homecare nurse	CG	1	1	0	1	0	0	0	0	0	3
	IG	0	3	1	0	1	0	0	0	0	5
Welfare officer	CG	0	0	0	0	1	0	0	0	0	1
	IG	0	0	0	0	0	0	0	0	0	0
Patient support group	CG	0	0	2	0	0	0	0	0	0	2
	IG	0	0	4	0	0	7	1	0	0	12
Patient counsellor	CG	0	2	1	0	1	0	0	0	0	4
	IG	0	2	1	0	0	0	0	0	0	3

Legend: TP = Timepoint; TP1 = Before discharge; TP2 = 7–10 days post-op; TP3 = 2 mths post-op. CG = Control Group. IG = Intervention Group

In-hospital: Patients referred to specialised follow-up; Primary sector: Patients referred to follow-up in Municipality/primary care; Advised about: Patient cannot be referred by the hospital but is advised about how to get referred or how to obtain support. Counsellor: a counsellor with special knowledge about cancer.

		Time point 1			Time point 2			Time point 3			
	IG	0	2	0	0	1	0	0	0	1	4
Alcohol cessation	CG	0	0	2	0	0	1	0	0	0	3
	IG	0	0	0	0	0	0	0	0	0	0
Smoking cessation	CG	0	1	14	0	3	8	0	0	6	32
	IG	0	0	10	0	0	5	0	0	3	18
Legend: TP = Timepoint; TP1 = Before discharge; TP2 = 7–10 days post-op; TP3 = 2 mths post-op. CG = Control Group. IG = Intervention Group											
In-hospital: Patients referred to specialised follow-up; Primary sector: Patients referred to follow-up in Municipality/primary care; Advised about: Patient cannot be referred by the hospital but is advised about how to get referred or how to obtain support. Counsellor: a counsellor with special knowledge about cancer.											

Five most frequently chosen subjects on PCI by IG at time-point 1 were fear of cancer coming back (FCC) (37.2%), swallowing (27.9%), dental health/teeth (27.9%), chewing/eating (27.9%), and activity (27.9%). Five most frequently chosen subjects for time-point 2 were: chewing/eating (50%), cancer treatment (41.7%), wound healing (33.3%), FCC (33.3%), dental health/teeth (33.3%), and four most frequently chosen subjects at time-point 3 were: FCC (30.8%), chewing/eating (23.1%), dry mouth (19.2%), and cancer treatment (19.2%). Four other subjects were also chosen with a frequency of 15.4%: swallowing, sleeping, mood, and energy levels (Fig. 2).

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 PCI at any time-point, but data for four patients were lost to follow-up due to IT-problems at time-point 3.

Discussion

To our knowledge, this is the first time PCI has been integrated in a nursing rehabilitation consultation, although it has been used routinely by individual oncologists or teams of oncologists and clinical nurse specialists in oncology clinics [34]. Nursing consultations using PROs in patients with cancer, or HNC specifically, have proven successful and aided in not only uncovering needs, but also facilitated discussion with the patient [12, 35].

This study was an RCT investigating the effect of applying an HNC-specific needs assessment tool, in clinical management and rehabilitation of patients with HNC early in the post-surgical period on HRQoL, and control of symptom burden. We did not find statistically significant differences between groups on GHS/QoL, and symptom burden. The study population already performed well in several areas post operatively, with only small improvements over time; however, there was a clinically relevant change for better in both groups over time on EORTC QLQ-H&N35: GHS/QoL, emotional functioning, pain and appetite. Further, the magnitude of all symptoms on the MDASI–HN were mild and improving over time for both groups.

Other studies have shown that patients with HNC reported similar results to our study on GHS/QoL post-treatment [36, 37], while pain, appetite, swallowing, social eating, social contact, teeth and mouth opening all scored better (> 10-point difference) in our study [37]. Several studies have investigated the effect of a nurse-led intervention to improve HRQoL in patients with HNC [11, 12]. These have all had some effect on QoL long-term (6–24 months). The short-term symptom burden was highest in the early post-treatment period (4–10 weeks) with non-significant differences between groups [11]. A cohort study confirms that patients with HNC have a high symptom burden which peaks during treatment and need for symptom management during this period in the patient's trajectory [38]. This may indicate the need to look more in-depth at challenges surgically treated patients face in the short-term post-operative phase.

Using PCI during nurse consultations identified functional needs and concerns about cancer treatment and activity. Other studies on PCI in doctor's consultations have shown similar results [34]. Further, we found needs in emotional/existential areas, in particular the item FCC, as HNC cancer research has shown [39]. Fear of cancer recurrence (FOR) is common among patients with HNC [40]. Patients are reluctant to talk about emotional needs and FOR with HCPs [41] and are among those cancer patients most reluctant to ask for support [42], yet need support to talk about concerns around cancer recurrence [6]. As FCC was a highly chosen item on PCI, it could suggest patients need an opportunity or option for talking about existential or emotional needs and may be the reason more patients in IG were referred to emotional support. Thus, PCI could function as an avenue to address these subjects and support patient's in alleviating concerns or guide them to seek psychological or spiritual/existential assistance.

The PCI resulted in 64 (35%) more referrals in IG compared to CG. Although our study did not attempt to measure the potential benefit of this, it is notable that more patients in IG were advised by the nurse to see a psychologist or counsellor for emotional support as a result of the chosen items. The majority of patients were advised based on the management manual to contact a counsellor at discharge, just as most patients were advised to contact a psychologist one to two weeks post-operatively. It is recognized that patients with HNC have complex needs, which can be

addressed through multidisciplinary follow-up [6]. Since standard care does not require nurses to record identified needs, the number and type of referrals are assumed to indicate the nurse identified an unaddressed need in CG. Further, we do not know how many patients made use of these opportunities and thus benefitted from them. We believe this type of nursing rehabilitation consultation, can ensure patient preferences and priorities are incorporated in care aimed at improving HRQoL in patients with HNC.

Strengths And Limitations

Linguistic validation of the Danish version of PCI in cooperation with patients makes the future use of this instrument feasible in a larger Danish population of patients with HNC.

However, there are some limitations. Although 23% declined to participate, other studies have shown even higher rates. Kjaer et al. [43] found in a study of Danish patients with HNC less than 50% of the study population agreed to participate. Those who declined had a higher symptom burden, lower income, and less healthy lifestyle than participants. In this study, only a few patients (IG 11%, CG 15%) had a low educational background or were unemployed. Generally, the proportion of patients with HNC in Denmark and internationally with a low socioeconomic background is higher than other cancer populations [44, 45]. As a result, it is possible that a high proportion of patients with middle to higher education in our study could explain why this group had lower symptom burden from the onset. The dropout and exclusion rate increased over time, as well as the amount of missing data, especially towards the end of the study. The latter may be due to patients independently completing the questionnaire at home seven days after their last visit to the out-patient department. Further, the final test time-point was approximately nine weeks after surgery, and patients may have needed more time to act on and benefit from consultations and advice given [12], particularly in terms of emotional and existential needs, to have an effect on HRQoL. Lastly, the multiple elements of the intervention may pose a risk when interpreting results. Future research should investigate whether nursing consultations using PCI in a larger study sample with a longer follow-up period, such as 6–24 months, could strengthen patient self-efficacy, reduce symptom burden, and improve HRQoL. Furthermore, qualitative research exploring patient experiences and satisfaction with nurse consultations using needs assessment tools may identify additional beneficial ways to employ them.

Conclusion

The study found applying an HNC needs assessment tool within nursing rehabilitation consultations over a nine-week period did not improve HRQoL or reduce symptom burden. However, the intervention suggests that important needs were identified and addressed, especially emotional and existential needs, which were accommodated through referrals and professional advice. In addition, nursing rehabilitation consultations using PCI can ensure that patient preferences and priorities are incorporated in their care.

Declarations

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Conflict of interest

The authors declare they have no conflict of interest.

Availability of data and material

The corresponding author has full control of all primary data and agrees to allow the journal to review their data if requested.

Code availability

Software application: R.

Authors' contributions

Annelise Mortensen: Conceptualization, Methodology, Formal analysis, Investigation, Resources, Writing - Original Draft, Project administration, Funding acquisition **Irene Wessel:** Conceptualization, Methodology, Formal analysis, Writing - Review & Editing, Supervision **Simon Rogers**:

Conceptualization, Methodology, Formal analysis, Writing - Review & Editing, Supervision **Anders Tolver**: Formal analysis and investigation, Writing - review and editing **Mary Jarden:** Conceptualization, Methodology, Formal analysis, Writing - Review & Editing, Supervision, Funding acquisition.

Compliance with ethical standards

Ethics approval

The study was carried out in accordance with the Helsinki Declaration, Regional Ethics Committee of the Capitol Region of Denmark (16036032) and approved by Danish Data Protection Agency (2012-58-0004-05781).

Consent to participate

Informed consent was obtained from all participants included in the study.

Consent to publish

The participants provided informed consent regarding publishing data in this article.

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Figures

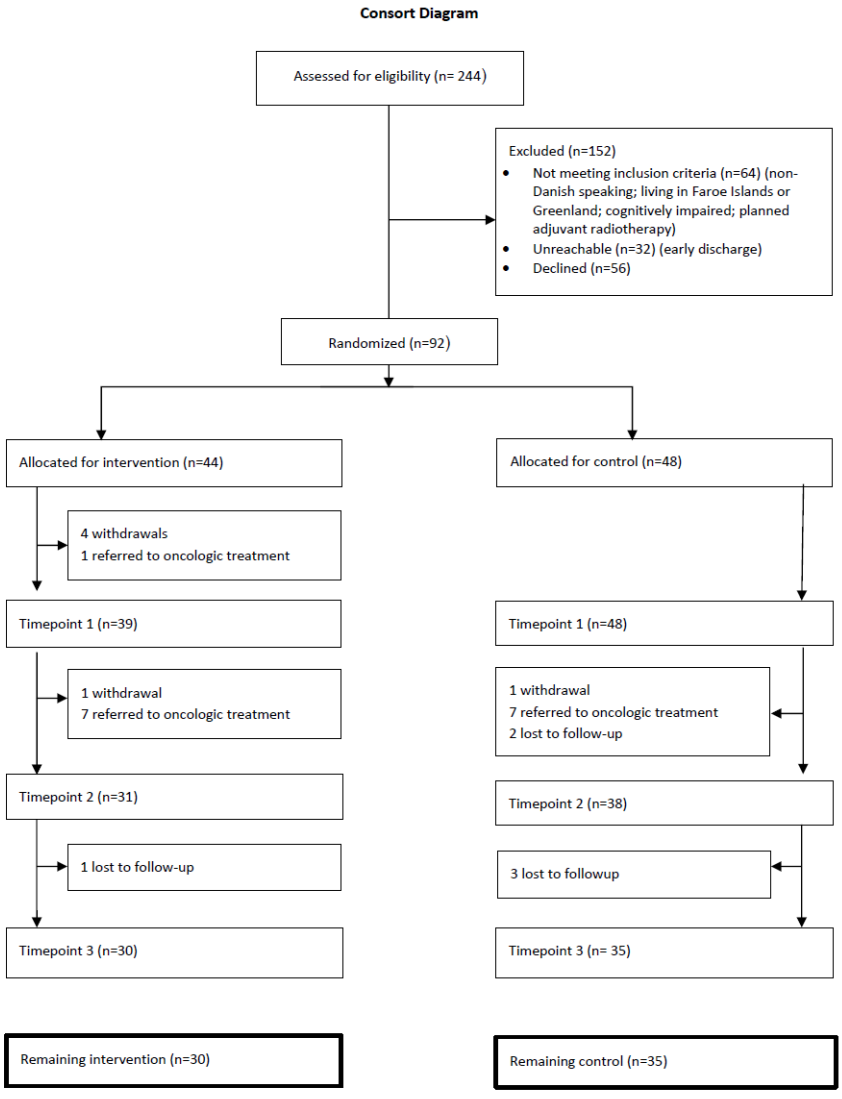

Figure 1

Consort Diagram

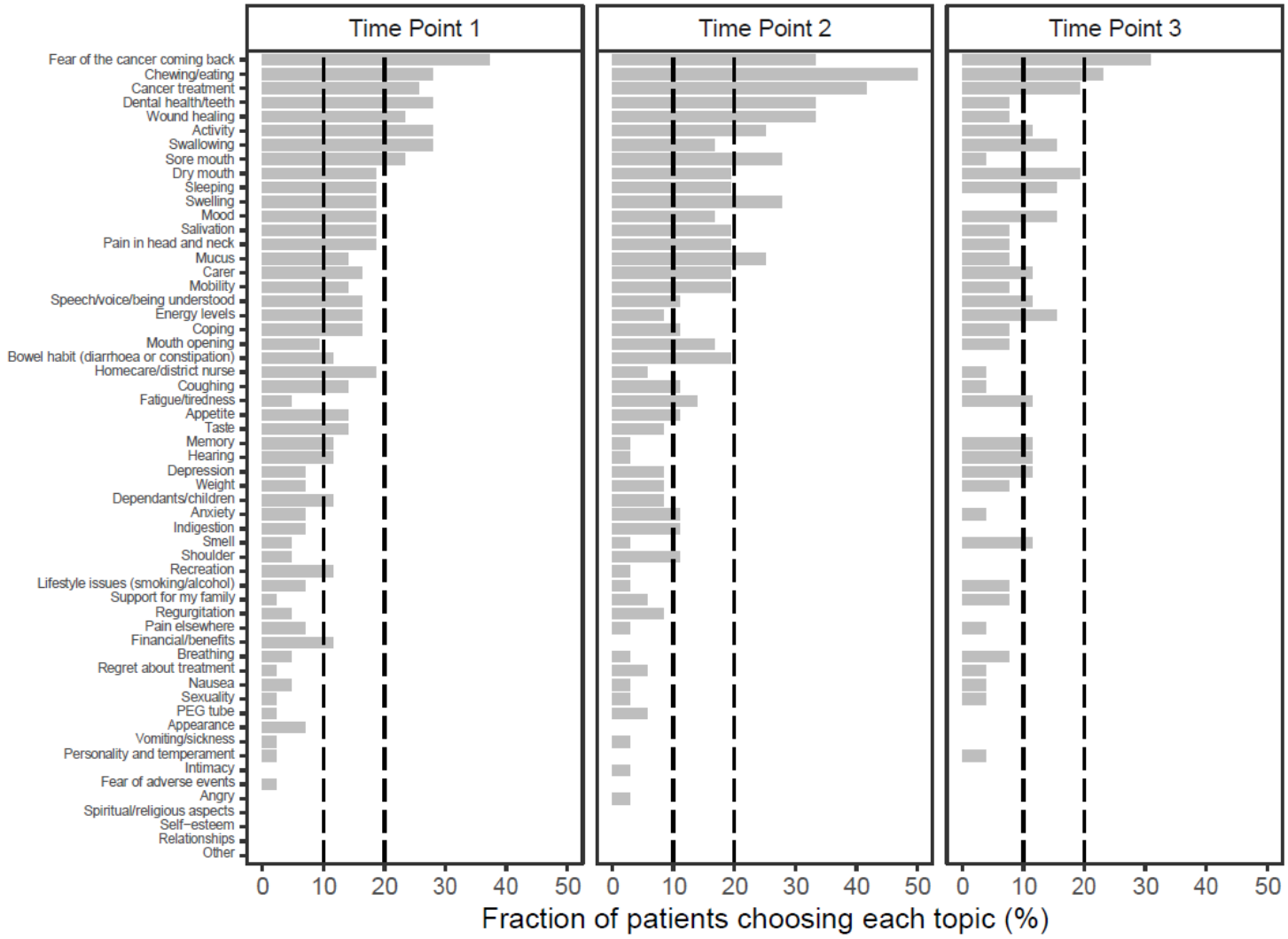

Figure 2

Five most frequently chosen subjects on PCI by IG at time-point 1 were fear of cancer coming back (FCC) (37.2%), swallowing (27.9%), dental health/teeth (27.9%), chewing/eating (27.9%), and activity (27.9%). Five most frequently chosen subjects for time-point 2 were: chewing/eating (50%), cancer treatment (41.7%), wound healing (33.3%), FCC (33.3%), dental health/teeth (33.3%), and four most frequently chosen subjects at time-point 3 were: FCC (30.8%), chewing/eating (23.1%), dry mouth (19.2%), and cancer treatment (19.2%). Four other subjects were also chosen with a frequency of 15.4%: swallowing, sleeping, mood, and energy levels