INGEBORG VAN DER MEULEN

NURSE-LED PSYCHOSOCIAL INTERVENTIONS

IN FOLLOW-UP CARE FOR HEAD AND NECK CANCER PATIENTS

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Nurse-led psychosocial interventions in follow-up care for head and neck cancer patients

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Nurse-led psychosocial interventions in follow-up care for head and neck cancer patients

Psychosociale interventies geleid door verpleegkundigen tijdens de nazorg voor hoofd-hals kankerpatiënten

(met een samenvatting in het Nederlands)

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General introduction

Epidemiology of head and neck cancer

Head and neck cancer includes cancer in the oral cavity, pharynx and larynx (Figure 1). Worldwide, there were 599.000 new cases of head and neck cancer and 325.000 deaths in 2012, both accounting for 4% of all new cases and deaths in cancer [1]. In the Netherlands, 2.721 new head and neck cancer diagnoses were reported in 2012 [2] representing 4% of all new cancer patients.

The incidence of cancer in the oral cavity and pharynx increased in the Netherlands over the past two decades. Incidence of laryngeal cancer decreased, though only in males [3]. It is estimated that in 2025, 819.764 people worldwide will be diagnosed with head and neck cancer of which 3.339 in The Netherlands [2]. Moderate improvements in five-year survival rates were found, strongly varying by tumor site [3,4]. Current five-year survival for all sites in the Netherlands is about 58%.

Head and neck cancer is more common among males than among females. Sex ratios vary from 2:1, 4:1 to 7:1 for cancer in the oral cavity, pharynx and larynx, respectively [1]. Mean age at diagnosis varies between 60-65 years and tobacco use, excessive alcohol intake and infection with human papilloma virus are the three known major risk factors [5-7].

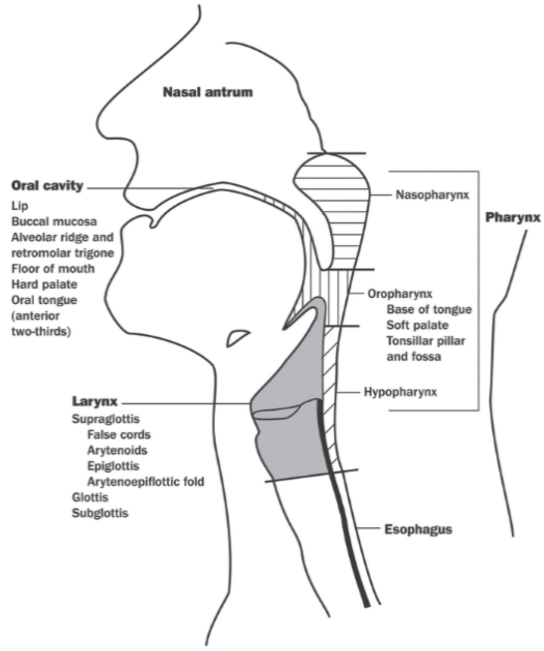

Figure 1: Anatomic sites of head and neck cancer.

NB: Cancer in the nasal cavity was not included in this thesis.

Consequences of head and neck cancer and treatment

The list of consequences due to head and neck cancer and its treatment is long. Physical problems that are typical for head and neck cancer, like dry mouth, difficulty eating or impaired speech, can occur depending on the stage, localization, size of the tumor and kind of treatment (Figure 2). Besides, more general physical problems like fatigue and pain can exist. In many patients, the physical problems are visible and have strong negative impact on diverse functions and psychosocial wellbeing [8]. Though physical problems can improve in the period directly after end of treatment, many problems are irreversible and are persisting in the long-term.

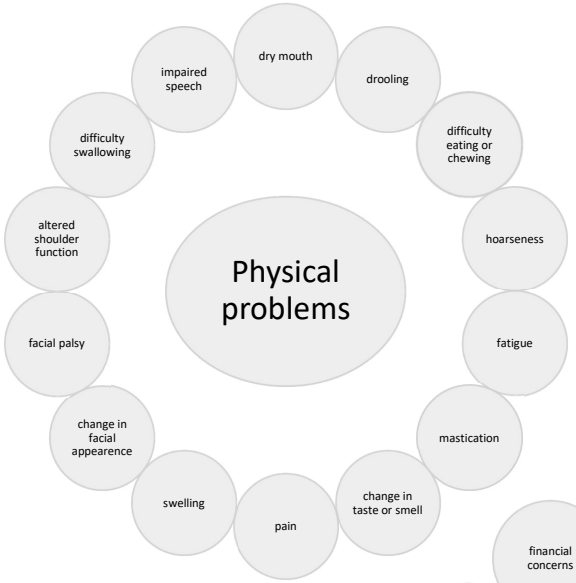

Figure 2: Physical problems in head and neck cancer patients

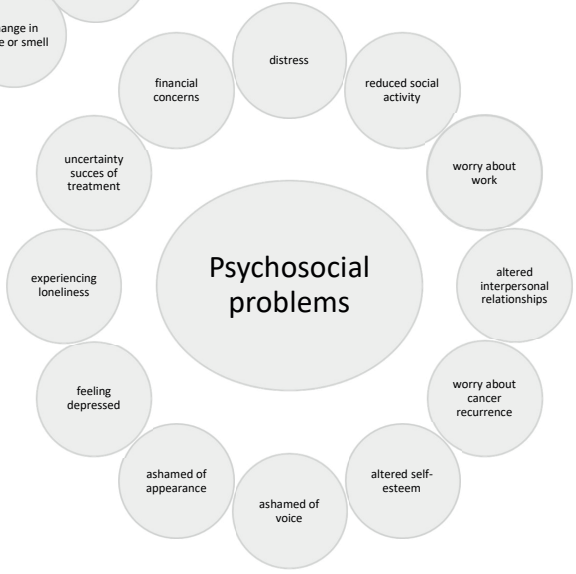

Figure 3: Psychosocial problems in head and neck cancer patients

Partly because of the persisting physical problems, head and neck cancer patients often suffer from psychosocial problems (Figure 3). At diagnoses, 28-29% of the Dutch head and neck cancer patients reports depressive symptoms [9]. The symptoms are persisting in 28-39% of the patients after six months [9,10] and in 20% after one year [11]. In addition, depressive symptoms at diagnoses are known to be predictive of a poor HRQoL 1-3 years later [12,13]. Head and neck cancer patients experience deterioration of HRQoL, including worse emotional functioning or impaired speech directly after start of treatment [14], which can persist even up to ten years after completion of treatment [15,16]. Head and neck cancer patients are at higher risk and suffer of greater distress than patients diagnosed with any other form of cancer because of the impact of impairments in functioning [17,18]. Prevalence rates of elevated distress in head and neck cancer patients are 35% and 41% pre- and post-treatment (up to one year after treatment), respectively [19]. In Dutch head and neck cancer patients a prevalence of 29% was found during follow-up care [20]. Head and neck cancer patients with elevated levels of distress often report lower quality of life [21-23].

Treatment and follow-up care in head and neck cancer patients in the Netherlands.

According to the guidelines of the Netherlands Comprehensive Cancer Organization (IKNL) [24] the main treatment for head and neck cancer consists of surgery, radiation therapy, chemotherapy, targeted therapy, or a combination of treatments. The duration of treatment can be several days when a single operation suffices or reach up to several months when multiple radiation therapy sessions and/or chemotherapy sessions are needed. After completion of treatment, follow-up care starts, which includes medical consults at the outpatient clinic by head and neck cancer specialists. Follow-up appointments are planned every two months in the first year after cancer treatment, every three months in the second year and every four to six months in the following years. After five years, the follow-up can be continued once a year if there is an increased risk of tumor growth and/or late morbidity [24]. The medical consults are primarily focused on detection of recurrences or second primary tumors and treatment of physical side effects. On average, the appointment lasts about 10 minutes during which the patient is physically examined, their medical history is reviewed, and additional tests are arranged if necessary. If the patients indicate to have psychosocial problems, referral to psychosocial aftercare is possible.

Psychosocial care in the follow-up period

Traditionally, follow-up care was focused on evaluating the physical condition of the patient. In addition, survival and tumor response parameters were the conventional outcome measures of interest in research [25,26]. In the recent years, the importance of the psychosocial wellbeing of a patient in addition to physical aspects has been acknowledged in research as well as in clinical practice. Psychosocial care is now increasingly recognized as part of a good and effective treatment [27]. Examples of psychosocial care are psycho-education, individual psychotherapy, cognitive behavioral training and group interventions [28].

In head and neck cancer patients, various efforts are made to develop interventions to combat the psychosocial problems. Some studies suggest beneficial effects [29-31]. The studies, all including head and neck cancer patients with elevated levels of distress, indicated positive outcomes on various aspects of psychosocial wellbeing. However, the studied interventions were relatively intensive with two to six sessions of 90 minutes at the patients home [29], seven sessions given weekly [31] or 12 sessions in six months [30]. In addition, the intervention was led by a clinical nurse specialist or clinical psychologist. Yet, in a review of psychosocial interventions in patients with cancer the importance of cheap interventions requiring few professional resources was emphasized [32]. In addition, combining the intervention with existing medical care is shown to be effective [31], can be efficient in terms of patients' time and might reduce noncompliance. So far, only one intervention was incorporated within usual medical care [31]. In addition, the studies had methodological weaknesses due to lack of a control group, and/or long term findings, and due to small sample sizes. In line, a large Cochrane review assessing the effectiveness of psychosocial interventions in head and neck cancer patients concluded that the evaluated studies generated insufficient evidence to conclude on effectiveness due to small number of studies and methodological shortcomings [33]. Further research is needed to develop relatively low-intensive interventions combined with the medical care where attention is paid to physical problems and psychosocial wellbeing and to study its effectivity in well-designed studies.

Role for nurses

It is known that even if patients with cancer experience high distress, high depressive symptoms scores or low HRQoL scores, referral rates to a psychologist or psychiatrist are low [34]. This could be partly due to the stigma that is still attached to a psychologist or psychiatrist. Psychosocial care provided by nurses might be more easily accessible for patients as compared to consulting a psychologist or psychiatrist since no stigma is attached to nurses. Thereby, nurses are in a key position to deliver a psychosocial

intervention in cancer patients [35,36]. Nurses can have the necessary communication skills, knowledge about the medical and practical aspects of head and neck cancer treatments and its consequences and, moreover, they are already involved in patient care. Considering the relation between the physical and psychosocial problems it is beneficial to embed a professional that can address both types of problems. Thereby, it is more and more common that nurses coordinate patient's care. Working in close cooperation with physicians, nurses contribute to screening, assessment of psychosocial problems, management of symptoms, providing information and support and give education [37-40]. Moreover, nurse-led interventions have proven to be effective in cancer patients in reducing depressive and physical symptoms, improved coping with physical impairments and reducing emotional distress [41-44].

Additional training for nurses is, however, required to enlarge the skills needed in delivering the intervention in an uniform and right manner [45]. Where nurses traditionally have a direct approach in solving problems as they are mentioned or occur, training can enable nurses to listen more carefully and to encourage patients and close ones to talk about his/her problems.

The study projects

The studies conducted in this thesis are specifically aimed at low intensive, nurse-led interventions, combined with medical care and their effectiveness during the follow-up period in head and neck cancer patients. Three different interventions were investigated varying in intensity and content: the Nurse Cancer and After Intervention (NUCAI), the Distress Thermometer and Problem List + (DT&PL+) intervention and the educational intervention.

The NUCAI was designed to support head and neck cancer patients in managing the physical and psychosocial consequences of their disease and its treatment in the first year after completion of cancer therapy. The NUCAI consists of three fixed components: evaluating current mental status with the Hospital Anxiety and Depression Scale (HADS), discussing current problems and systematically asking about physical problems and functioning. In addition, three components could be added if indicated: providing the Adjustment to Fear, Threat or Expectation of Recurrence (AFTER) intervention, providing general medical assistance and advice or referring patients to psychological aftercare. Patients received six counseling sessions of 45-60 minutes during one year given by a trained nurse in the outpatient clinic. The counseling session was always combined with the patient's 2-monthly medical consult. The effectivity of the NUCAI on depressive

symptoms (primary outcome) and HRQoL was evaluated in a randomized controlled trial in head and neck cancer patients from the outpatient clinic at the University Medical Center Utrecht.

The DT&PL+ intervention was designed as a short intervention to screen and provide immediate support, advice, information or referral, if necessary. The intervention consists of three components: screening with de Distress Thermometer and Problem List, discussing outcome of the screening and identification of problems and, if indicated, offering basic psychosocial care, minor nursing interventions or referral to other health care providers or patient program. Patients received three to four sessions of 20 minutes during 1 year given by a trained nurse in the outpatient clinic. The session was always combined with the patient's 2-montly medical consult. The feasibility and effectiveness of the DT&PL+ intervention was evaluated in a randomized controlled trial in head and neck cancer patients from the outpatient clinic at the University Medical Center Utrecht.

The educational intervention was designed in order to prepare the head and neck cancer patients for the period at home after finishing surgical treatment by providing comprehensive information in a structural manner. The intervention consisted of a discharge interview where systematically six domains were discussed, knowing: general information, wound care, physical problems, psycho-social problems, work & finances and information and support after discharge. Verbal information was supported with written material if appropriate. Duration of the interview was 30 minutes and the interview was given by a nurse from the ward the day before discharge. The educational intervention was evaluated in a quasi-experimental study in surgical head and neck cancer patients at the University Medical Center Utrecht.

Objective and outline of this thesis

The overall objective of this thesis was to evaluate several nurse-led psychosocial interventions, which vary by intensity and content, for head and neck cancer patients aimed at improving psychosocial wellbeing in the years after completion of cancer treatment. Three study projects were conducted and are presented in the following chapters. **Chapter 2** describes the primary results of the NUCAI study, i.e. the effect of the nurse-led intervention on patients' depressive symptoms one year after completion of cancer treatment. In **Chapter 3** the results of the NUCAI on depressive symptoms and HRQoL two years after completion of cancer treatment are presented. To differentiate between head and neck cancer patients who benefit most from the NUCAI and those who do less, several potential moderators like age, smoking or emotional functioning were investigated and the results are presented in **Chapter 4**. **Chapter 5** describes the DT&PL+ intervention study which explored if a less intensive intervention than the

NUCAI also has a positive effect on depressive symptoms and HRQoL in head and neck cancer patients. To prepare head and neck cancer patients for the period at home after finishing surgical treatment the educational intervention was evaluated and results are described in **Chapter 6**. **Chapter 7** contains the general discussion and future perspectives. The overall summary of this thesis is given in **Chapter 8**.

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2

One-year effect of a nurse-led psychosocial intervention on depressive symptoms in patients with head and neck cancer

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Abstract

Background. Many patients with head and neck cancer (HNC) experience depressive symptoms after treatment. This randomized controled trial investigated the effects of a psychosocial nurse counseling and after intervention (NUCAI) versus usual care on depressive symptoms of patients with HNC at 1 year after diagnoses.

Methods. A total of 205 patients HNC were randomly assigned to either the intervention (n = 103) or usual care (n = 102), with stratification for gender and tumor stage. The NUCAI, which consisted of six bimonthly 45-minute counseling sessions, was a problem-focused intervention aimed at helping patients to manage the physical, psychological, and social consequences of HNC and its treatment. It was nurse-led and offered in combination with regular medical follow-up visits at the University Medical Center Utrecht, the Netherlands. Depressive symptoms at 1 year after diagnosis were the primary outcome. Analyses were performed on an intention-to-treat basis for the total sample and for a predefined subgroup of patients with raised levels of depressive symptoms (Center for Epidemiologic Studies-Depression score ≥ 12; n = 91) at baseline using mixed-effect models.

Results. One year after HNC treatment, levels of depressive symptoms were significantly lower in the intervention group than in the control group in the total sample and in the subgroup of patients with raised levels of depressive symptoms.

Discussion. The NUCAI was feasible and effective in reducing depressive symptoms in patients with HNC 1 year after HNC treatment, and especially in patients with raised levels of depressive symptoms. The results of this study need to be confirmed in future studies before the NUCAI can be used in daily clinical practice.

Implications for Practice

Head and neck cancer patients are prone to physical problems, depressive symptoms and decreased quality of life. The Nurse Counseling and After Intervention (NUCAI) is a nurse-led psychosocial intervention. The NUCAI has shown to be effective in decreasing depressive symptoms and tumor and treatment related symptoms at one year after treatment in head and neck cancer patients, and especially in patients with raised levels of depressive symptoms. This nurse-led intervention is less intensive compared to other psychosocial interventions, and is easy to combine with regular medical follow up. It is therefore promising to implement in daily clinical practice.

Introduction

Treatment of head and neck cancer (HNC) frequently results in long-term physical problems, such as changes in taste and smell, dry mouth, sticky saliva [1,2], and problems with mastication [3]. In part because of these physical and functional impairments, HNC patients are prone to depressive symptoms [4]. The prevalence of depressive symptoms in patients with HNC varies from .05% to 48% [5,6], and the proportion of patients with possible depression ranges from 27-28% at diagnosis to 9-20% at 36 months after treatment [2,7-9]. Even though the risk of depressive symptoms slowly decreases, it remains substantial 3 years after treatment. Depression is strongly associated with, and is a major predictor of, a decreased quality of life [10-13] and is accompanied by anxiety disorders [4] and fear of recurrence [14,15]. Unfortunately, HNC patients are not yet routinely screened for depressive symptoms.

Several meta-analyses and reviews have shown that psychosocial interventions are effective in diminishing depressive symptoms in the general cancer population [16-19]. Examples of such interventions include cognitive behavioral therapy [17,19], counseling/psychotherapy [20], counseling/relaxation [21], computer-based assessment and individually tailored care plans [22,23], supportive interventions [24-26], and multicomponent interventions [27,28]. There is no evidence that one intervention is superior to another. Four studies reported psychosocial interventions, aimed at coping behavior, to be fairly successful in decreasing depressive symptoms in HNC [29-32]. Literature suggests that it might be appropriate to offer such therapies only to those cancer patients with a significant psychological burden [19,33].

Psychosocial interventions are usually given by psychologists [20], mental health professionals [24], social workers [34], or nurses [22,23,26]. While the intervention and standard care are usually offered separately, one study showed the combination to be effective [21]. It might be advantageous, in terms of time and compliance, to incorporate the intervention in the medical follow-up of HNC patients, with the intervention being administered by nurses who are familiar with the care and problems of HNC patients. Working in close cooperation with attending physicians, these nurses can have an important role in the management of symptoms, assessment of depressive symptoms, and in providing support and education about depression and its effects [35]. In the past, interventions for cancer patients led by nurses have proven effective in reducing depressive symptoms [27,28,30] and physical symptoms, in helping patients cope with physical impairments, and in reducing emotional distress [22,36].

The primary aim of this randomized, controlled trial was to investigate the effectiveness of a comprehensive nurse-led intervention focused on decreasing depressive symptoms in HNC patients following their cancer treatment. The secondary aim was to investigate the effect of the intervention on physical symptoms. We hypothesized that patients in the intervention group would show fewer depressive symptoms and fewer physical symptoms than patients in the control group 1 year after HNC treatment.

Materials and methods

Design

This randomized controlled trial (RCT) evaluated the 1-year effect of a comprehensive nurse-led intervention on depressive symptoms and HNC-related physical symptoms in patients treated for HNC and in a subgroup of patients with raised levels of depressive symptoms.

Sample

Recruitment took place between January 2005 and September 2007. Patients were enrolled by the researcher before the start of cancer treatment, and the NUrse, Counseling and After Intervention (NUCAI) was started after completion of treatment. Eligibility criteria included a primary diagnosis of squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, or larynx; treatment with curative intent; ability to complete questionnaires; and ability to participate in the intervention. Patients were excluded if they had a previous or concomitant malignancy and/or were being treated for depression, diagnosed according to DSM-IV-TR criteria, as stated in their medical record [37].

Ethical approval and procedure

The study was approved by the Medical Ethics Committee of the University Medical Center Utrecht. The trial is registered as ISRCTN06768231. Before randomization, each patient received written information about the study, in which they were told that two different types of aftercare were being investigated but that medical care would remain the same. Each participant signed the informed consent form and received general information about post-cancer treatment care, but no specific information about the NUCAI. After the completion of cancer treatment, the patients were randomized, using an open block procedure, to receive NUCAI or care as usual, stratified by gender and

tumor stage. Participant received a letter by the researcher which type of care they would receive, but did not know whether this treatment was the control or intervention treatment.

Participants completed five questionnaires at home and returned them using a prepaid return envelope at baseline, before the start of cancer treatment, and at 3, 6, 9, and 12 months after the completion of cancer treatment. The primary endpoint was 12 months after completion of cancer treatment; the other measurements were taken to gain insight into the pattern of change in depressive and physical symptoms.

Care as usual

Care as usual was provided by HNC specialists and was primarily aimed at the treatment of complications and the detection of recurrences or second primary tumors. Patients were seen at 2-month intervals during a 10-minute appointment, during which they were examined, their physical history was reviewed, and ancillary tests were ordered, if necessary. If the patient had psychosocial problems, the HNC specialist could refer the patient to psychological aftercare.

Intervention

The NUCAI was designed to help patients manage the physical, psychological, and social consequences of their disease and its treatment, by means of restructuring cognitions and beliefs (part of the AFTER intervention), educational and behavioral training and advice, and provision of emotional support. The NUCAI is problem focused and patient-led.

A manual was developed to help nurses to structure the counseling sessions and to assist them in discussing problems and in choosing appropriate nursing interventions. The nurses kept a treatment file for each of their patients, in which they recorded the topics discussed, namely, the home situation, physical functioning, social functioning, mental functioning, and nursing interventions. Patients received six counseling sessions of 45 to 60 minutes during 1-year given by a trained nurse in the outpatient clinic. The counseling session was always combined with the patient's 2-month medical check-up, and each patient saw the same nurse in all six sessions. If needed, the patient could continue counseling after the first year.

The NUCAI consists of six components, namely, (1) evaluating current mental status with the HADS; (2) discussing current problems; (3) systematically asking about physical problems and functioning in six relevant life domains; (4) providing the AFTER intervention, if indicated; (5) providing general medical assistance and advice,

if indicated; and (6) referring patients to psychological aftercare, if indicated. Before each counseling session, the patients completed the Hospital Anxiety and Depression Scale (HADS) [38,39] at home. Nurses used the HADS score to screen for anxiety and/or depressive symptoms (cut-off >10 points). The outcome was used to gain insight into the needs of the patient, and discussing the results of the HADS often made it easier for patients to talk about their problems. For example: *'I reviewed your answers on the questionnaire (HADS) and they show that you sometimes feel down, in despair, or worried. Is this correct – do you feel down or worried?'* Furthermore, the nurse checked the patient history to screen for the presence of psychosocial morbidity. This information was used to guide counseling.

The session started with a discussion of current problems and topics brought up by the patient. Patients were then systematically asked about physical problems related to HNC, such as mastication, swallowing, shoulder function, sense of taste or smell, breathing, restrictions in speech, pain and fatigue (e.g., "*Some patients feel that their shoulder is painful and stiff after surgery. Is your shoulder painful or stiff?")*. Then patients were asked about their functioning in six relevant life domains, namely, home situation, (resuming) work, household and leisure activities, mood and emotional distress, partner relation and intimacy, family and social life (e.g., "*Has your relationship with your partner/family changed since your treatment?*"). When indicated, the nurse gave information and advice, provided minor medical and/or behavioral treatment, and offered support in accordance with the Dutch oncological nursing guidelines [40], the cancer clinical practice guidelines of the Dutch Association of Comprehensive Cancer Centers [41], and the guidelines of the Nurse Intervention Classification [42]. For example, the nurses taught patients a relaxation exercise. If necessary, patients were referred to physicians, health care professionals specialized in psychosocial problems (e.g. psychologist or social worker), or to a relevant patient program (e.g., oncological rehabilitation or patient support groups). If indicated, the Adjustment to Fear, Threat or Expectation of Recurrence (AFTER) [43] intervention was carried out. This cognitive behavioral intervention, which is based on Leventhals' self-regulation model [44], was designed to reduce irrational thoughts and to help patients with orofacial cancer to handle excessive fear of recurrence and psychological distress. It consist of four components: expressing fear of recurrence, identifying beliefs about sensations and their interpretation as recurrence, evaluating the function of self-examination and reducing excessive checking behavior, and relaxation.

Training

Three experienced oncology nurses were selected from the oral maxillofacial and the otorhino-laryngology department of the University Medical Center Utrecht. Before the start of the study, the nurses were intensively trained by two psychologists (R.L. and W.R.) and one of the investigators (M.O.) to carry out the NUCAI, by learning on the job. They also completed a comprehensive 1-day training, given by an expert, in how to administer the AFTER intervention [43], to ensure that the intervention was given in a standardized way. During the intervention period, the nurses, the psychologists, and the investigator reviewed selected tape-recorded intervention sessions every 2 months, to monitor and, where necessary, improve the quality of the intervention sessions. No midcourse corrections and/or adaptions were needed.

Measures

Information about age, gender, educational level, and social status was collected by means of self-report questionnaires. Information about treatment, tumor type and stage was obtained from the medical records. Depressive symptoms were measured with the Center for Epidemiologic Studies-Depression (CES-D) scale [45,46], with a cut-off score of 16 or higher being considered indicative of clinical depression [47]. This 20-item self-report questionnaire has shown good psychometric properties in medically ill populations[48] and cancer populations [49,50] including HNC [1,51]. The CES-D mean (±SD) score in the Dutch population is 8.2±7.2 [52]. Because a difference of half a standard deviation may be interpreted as a clinically relevant raised level of depressive symptoms [53], a CES-D score ≥ 12 was used in this study as indicative of a raised level of depressive symptoms. As a secondary outcome, physical symptoms were assessed using the head and neck module of the Quality of Life Questionnaire (QLQ) of the European Organization for Research and Treatment of Cancer (EORTC).The EORTC QLQ-H&N35 is a widely used and validated questionnaire [54]. For all functional items, high scores indicate more problems. In addition each counseling session, the nurse recorded if the following topics were discussed for each patient: home situation, physical functioning, social functioning, psychological functioning and nursing interventions.

Analysis

The primary endpoint was depressive symptoms and the secondary endpoint was physical symptoms at 12 months after completion of cancer treatment. The sample size was based on the prevalence of patients with raised levels of depressive symptoms (CES-D ≥ 12). Power analysis for ANOVA procedures showed that assuming an effect size of .32 with a two-sided test, a sample size of 45 patients with raised levels of depressive symptoms in each arm would suffice (power = 80%, alpha = .05). Data from our previous

study [55] showed that 56% of patients had a CES-D score ≥12 before cancer treatment. Therefore a minimum of 160 HNC patients would be needed; 205 were enrolled to allow for study dropout.

The effect of the intervention in the total group and in the predefined 'depressive' subgroup was assessed on an intention-to-treat basis (all patients with complete data at baseline and at least one follow-up measurement), using a linear mixed model approach. As some 1-year data were missing, we also included data for 3, 6, and 9 months after HNC treatment in the model to estimate the 1-year effect. In these analyses, the program accounts for missing data based on observed data by maximum likelihood estimations [56]. Pearson's correlation coefficients were used to explore the correlation between depressive and physical symptoms at baseline and 12 months after treatment and the relation between changes from baseline to 12 months. To verify the comparability of prognostic factors in the depressive subgroup between the intervention and control conditions, Student's T and Mann-Whitney tests were used for continuous data and Chi-Square tests for categorical data. Results for the subgroup were controlled for any between-group differences in baseline characteristics. Two-sided significant tests were used ($\alpha<.05$). Statistical analyses were performed using R software, version 2.10.0. (www.r-project.org) and SPSS, version 20.

The content of 10 treatment files kept by the nurses was systematically analyzed in order to determine whether the intervention had been carried out as intended and to identify the topics discussed.

Results

Demographic variables and study compliance

A total of 328 eligible patients were identified, of which 205 (62.5%) were eligible for participation. Reasons for non-participation are shown in Figure 1. In total, 103 patients were randomized to the intervention and 102 patients to the control group. At 12 months, 55 patients were lost to follow-up, 33 of whom had died. At baseline, the intervention and control groups were comparable in terms of demographic variables, clinical characteristics, and baseline CES-D scores (Table 1). Baseline demographic values for the subgroup of patients with raised levels of depressive symptoms were not statistically different, with the exception that patients in the intervention group had a higher educational level than the patients in the control group ($p = .05$) (Table 2).

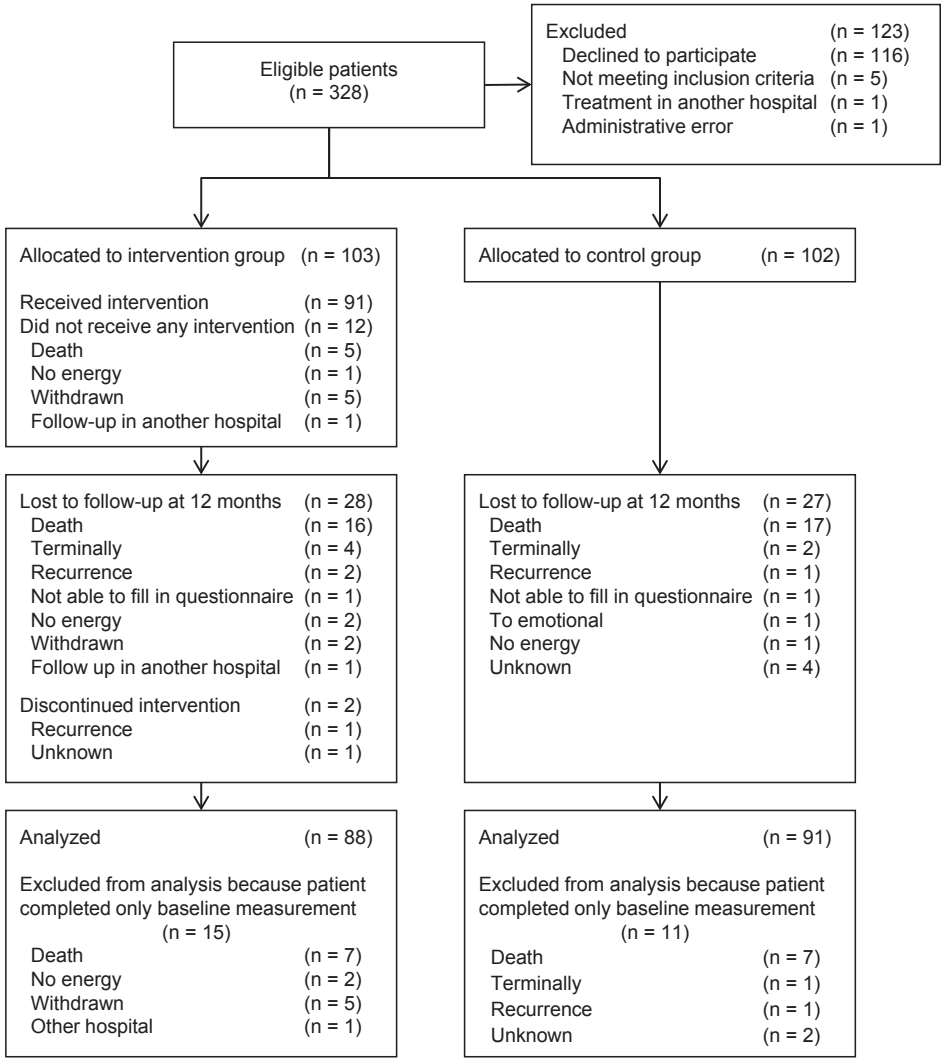

Figure 1. Diagram of participants' progress through the study.

Significant differences were found between patients who were lost to follow-up (n = 55) and patients who completed the study (n = 150): patients who were lost to follow-up were older (p = .019), higher educated (p = .011), and had an advanced tumor stage (p = .026). There were no differences in sociodemographic variables, clinical variables, and depressive symptoms between patients lost to follow-up in the intervention and control groups, indicating that loss was not selective. Antidepressant medication was

used by one patient at baseline, by two patients at 6 months, and by three patients at 12 months in the intervention group, and by one, five, and six patients in the control group, respectively.

Table 1. Demographics and clinical characteristics at baseline by study arm

Characteristic	Intervention group	Control group
n	88	91
Age, year		
Mean (sd)	60.1 (9.8)	60.7 (9.8)
Range	25.6 – 88.1	26.8 – 83.1
Sex		
Male	62 (70.5)	64 (70.3)
Female	26 (29.5)	27 (29.7)
Educational level		
Low	37 (42.0)	37 (40.7)
Middle	32 (36.4)	41 (45.1)
High	19 (21.6)	13 (14.3)
Social status		
Married/living together	63 (71.6)	67 (73.6)
Single	25 (28.4)	24 (26.4)
Type of cancer		
Larynx	20 (22.7)	22 (24.2)
Oral cavity	41 (46.6)	44 (48.4)
Oropharynx	16 (18.2)	17 (18.7)
Hypo pharynx	11 (12.5)	7 (7.7)
Unknown primary	0	1 (1.1)
Tumor stage[b]		
I-II	51 (58.0)	54 (59.3)
III-IV	37 (42.0)	36 (40.0)
unknown	0	1 (1.1)
Type of treatment		
Surgery	22 (25.0)	29 (31.9)
Radiotherapy	25 (28.4)	24 (26.4)
RT/CH	12 (13.6)	12 (13.2)
Combination	29 (33.0)	26 (28.6)
CES-D, continuous		
Mean (sd)	12.9 (9.1)	12.8 (9.8)
Range	0–39	0–44

Data are *n* (%) unless noted and include participants who completed a minimum of two measurements.
Abbreviations: CES-D, Center for Epidemiologic Studies – Depression scale; SD, standard deviation; CH, chemotherapy; RT, radiation therapy.

Table 2. Subgroup of patients with a CES-D score ≥ 12 at baseline

Characteristic	Intervention group	Control group (n = 42)	*p* value
n	49	42	
Age, year Mean (sd) Range	 59.2 (10.1) 25.6 – 84.0	 59.9 (10.) 37.2 – 83.1	.75
Sex Male Female	 35 (71.4) 14 (28.6)	 28 (66.7) 14 (33.3)	.62
Educational level Low Middle High	 18 (36.7) 20 (40.8) 11 (22.4)	 18 (42.9) 22 (52.4) 2 (4.8)	.05
Social status Married/living together Single	 31 (63.3) 18 (36.7)	 31 (73.8) 11 (26.2)	.28
Type of cancer Larynx Oral cavity Oropharynx Hypo pharynx	 12 (24.5) 20 (40.8) 10 (20.4) 7 (14.3)	 11 (26.2) 19 (45.2) 9 (21.4) 3 (7.1)	.76
Tumor stage I-II III-IV	 27 (55.1) 22 (44.9)	 25 (59.5) 17 (40.5)	.67
Type of treatment Surgery Radiotherapy RT/CH Combination	 8 (16.3) 14 (28.6) 7 (14.3) 20 (40.8)	 15 (35.7) 11 (26.2) 8 (19.0) 8 (19.0)	.07
CES-D, continuous Mean (sd) Range	 19.0 (7.2) 12–39	 21.0 (8.3) 12–44	.24

Data are n (%) unless noted and include participants who completed a minimum of two measurements.
Abbreviations: CES-D, Center for Epidemiologic Studies – Depression scale; SD, standard deviation; CH, chemotherapy; RT, radiation therapy.

Intervention adherence

Of the 103 patients allocated to the intervention group, 12 (11.7%) did not attend any of the counseling sessions. Reasons for nonattendance are presented in Figure 1. Of the 91 (88.3%) patients who received counseling, 15 (16.5%) attended 1-2 sessions, 39 (42.9%) 3-4 sessions, and 37 (40.7%) 5-6 sessions. Three patients did not consider it necessary to complete the intervention and stopped after 4 (n = 1) or 5 sessions (n = 2). At 12 months, 65 patients (63.1%) still had 1 or more counseling sessions planned.

The counseling sessions were sometimes delayed because it was not always possible for physicians to hold follow-up visits at 2-month intervals, and the NUCAI was always given in combination with these appointments.

At 12 months, one participant in the intervention group and five participants in the control group had seen a psychologist. Two participants in the intervention group and two in the control group had received religious guidance.

Content of the intervention

The analyses of a random selection of 10 patient treatment files showed that the nurses followed the manual, implementing the six components of the intervention. The treatment files also showed that patients were quite open and frank in discussing their history and emotions with the nurses. In some cases, the nurses provided minor medical assistance, such as prescribing an oral gel for dry mouth or giving information about stopping or cut down smoking if smoking was a problem. The sessions were homogenous in content, although the first sessions focused more on physical symptoms, whereas the later sessions concentrated more on emotional, relational, and social problems. Patients' fear of reoccurrence was discussed in all sessions, if relevant. If indicated, patients were referred to a social worker or psychologist.

Depressive symptoms

Intention-to-treat analysis revealed that the decrease in depressive symptoms was significant in the intervention group compared with the control group (-2.8, 95% confidence interval -5.2 to -0.3) at 12 months after treatment (Table 3). On average, depressive symptoms in the intervention group decreased from 12.9 (sd 9.1) at baseline to 10.9 (sd 9.1) at 12 months, whereas symptoms increased in the control group from 12.8 (sd 9.8) to 13.8 (sd 12.3). Changes in depressive symptoms over 12 months for the total study sample are shown in Figure 2. For the depressive subgroup of patients (CES-D ≥12), analysis revealed a significant decrease in depressive symptoms in the intervention group compared with the control group at 12 months (-5.2, 95% confidence interval -9.1 to -1.2) (Table 3). After adjustment for the between-group difference in baseline educational level, depressive symptoms decreased significantly from 19.0 (sd 7.3) at baseline to 13.8 (sd 10.1) in the intervention group but increased from 21.0 (sd 8.3) to 22.0 (sd 12.6) in the control group at 12 months. Changes in depressive symptoms over 12 months in the subgroup are shown in Figure 3.

Table 3. Depressive symptoms and head and neck related physical symptoms during the 12-month study period

		Baseline[a]				12 months posttreatment				Between- group change,
		Intervention		Control		Intervention		Control		
		Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean (95% CI)
Total group										
Primary outcome (CES-D)		12.9	(9.1)	12.8	(9.8)	10.9	(9.1)	13.8	(12.3)	-2.8 (-5.2 to -0.3)[a]
Secondary outcome (EORTC-H&N35)	Pain	36.0	(26.1)	31.1	(24.4)	16.1	(17.9)	21.1	(20.9)	-9.9 (-17.0 to -2.9) [a]
	Swallowing	22.7	(26.0)	18.1	(22.5)	16.4	(22.7)	19.7	(25.2)	-8.0 (-14.8 to -1.3) [a]
	Senses	9.9	(19.2)	7.7	(14.3)	17.8	(25.4)	19.8	(22.5)	-3.7 (-10.6 to 3.1)
	Speech	23.0	(27.5)	22.8	(26.3)	16.6	(20.5)	19.5	(25.4)	-2.7 (-9.9 to 4.5)
	Teeth	23.0	(31.0)	23.8	(31.1)	19.0	(29.3)	26.0	(33.0)	-4.5 (-14.7 to 5.8)
	Opening mouth	19.2	(32.4)	17.4	(30.5)	14.6	(25.5)	27.0	(34.3)	-14.6 (-24.0 to -5.2)*
	Dry mouth	16.3	(26.7)	18.7	(28.6)	35.6	(31.1)	39.6	(35.2)	0.6 (-9.2 to 10.4)
	Sticky salvia	19.0	(27.8)	15.8	(26.0)	31.5	(31.4)	33.3	(30.9)	-5.4 (-14.9 to 4.1)
	Coughing	22.4	(25.1)	25.3	(28.3)	26.0	(25.6)	18.5	(26.5)	10.9 (2.2 to 19.5)*
Subgroup										
Primary outcome (CES-D)		19.0	(7.3)	21.0	(8.3)	13.8	(10.1)	22.0	(12.6)	-5.2 (-9.1 to -1.2) [a]
Secondary outcome (EORTC-H&N35)	Pain	42.9	(24.7)	41.5	(26.0)	17.0	(20.1)	27.8	(24.4)	-9.7 (-20.7 to 1.2)
	Swallowing	30.4	(28.9)	27.0	(23.8)	19.7	(25.5)	14.0	(26.6)	-6.6 (-16.8 to 3.6)
	Senses	11.2	(19.4)	13.5	(17.0)	21.4	(28.1)	26.8	(23.2)	-1.2 (-11.6 to 9.3)
	Speech	31.1	(28.1)	33.1	(27.0)	22.5	(23.2)	27.8	(29.9)	-0.4 (-11.6 to 10.8)
	Teeth	28.5	(34.4)	28.6	(33.4)	22.5	(34.3)	36.4	(34.7)	-10.6. (-26.0 to 4.8)
	Opening mouth	29.3	(36.4)	24.6	(34.6)	16.2	(29.5)	34.3	(34.8)	-23.2 (-37.8 to -8.7) [a]
	Dry mouth	21.8	(30.8)	27.0	(31.4)	40.2	(30.8)	45.5	(34.2)	4.2 (-10.1 to 18.5)
	Sticky salvia	25.7	(30.9)	26.2	(30.8)	38.5	(34.7)	41.4	(30.1)	-1.3 (-15.3 to 12.6)
	Coughing	28.6	(25.5)	32.5	(30.8)	28.2	(27.1)	25.3	(30.1)	10.5 (-2.5 to 23.5)

Intervention total group: $n = 88$ at baseline and $n = 73$ at 12 months; Control total group: $n = 90$ at baseline and $n = 74$ at 12 months; Intervention subgroup: $n = 49$ at baseline and $n = 39$ at 12 months; Control subgroup: $n = 42$ at baseline and $n = 33$ at 12 months. The intention-to-treat method was used for analyses (intervention group: $n = 88$ and control group: $n = 91$; Intervention subgroup: $n = 49$ and control subgroup: $n = 42$).

[a] $p \leq .05$.

Abbreviations: CES-D, Center for Epidemiologic Depression Scale; EORTC H&N35, European Organization for Research and Treatment of Cancer head and neck module.

Physical symptoms

Overall, physical symptoms decreased in the intervention group compared with the control group, with there being significant decreases in pain, swallowing, and opening mouth ($p>0.05$). Symptoms of dry mouth and coughing increased in the intervention group compared with the control group, but the increase was significant for coughing only. Similar results were obtained for the depressive subgroup (CES-D ≥12), but only the decrease in opening mouth was significant. Detailed data for both groups are given in Table 3.

Overall, depressive symptoms were significantly associated with HNC-related symptoms at baseline and 12 months after treatment and with changes from baseline to 12 months after treatment. Correlation coefficients ranged from .18 to .58; only the correlation between changes from baseline to 12 months for dry mouth was not significant (r= .024, p=.8). Detailed data are given in supplemental file 1.

Discussion

In this RCT, we evaluated the effectiveness of a comprehensive nurse-led counseling intervention (NUCAI) in reducing depressive and HNC related physical symptoms in HNC patients. Twelve months after completion of cancer treatment, depressive symptoms were significantly lower in the intervention group than in the control group, and physical symptoms generally decreased, showing the effectiveness of the NUCAI.

Our results are in agreement with the findings of a systematic review showing that psychotherapeutic interventions are effective in reducing depressive symptoms in general cancer patients [19]. Williams et al. [19] suggested that insignificant findings in trials might be due to the inclusion of all cancer patients instead of only cancer patients with meaningful levels of depressive symptoms. We found that the nurse-led intervention significantly decreased depressive symptoms in the total group of HNC patients, but the effect of the intervention was greater in the subgroup of patients with raised levels of depressive symptoms. Depressive symptoms appeared to be related to physical symptoms, i.e. patients with more physical problems also had higher levels of depressive symptoms. The change in physical symptoms from baseline to 12 months after treatment was also related to changes in depressive symptoms.

The intervention also had beneficial effects on physical symptoms, such as pain, swallowing, and opening mouth. Unexpectedly, symptoms coughing were higher in the intervention group. The intervention was carried out as intended and the patients were, if indicated, referred to other psychological healthcare professionals. However, few patients actually saw a psychologist or psychiatrist.

Four studies have reported beneficial effects in HNC patients [29-32]. Allison et al. [29] used a small group intervention, which consisted of individual contact with a therapist and materials for use at home. Fifty HNC patients were treated in 2-3 sessions of 2 hours over a period of 4 weeks. Semple et al. [30] used a combined intervention in a quasi-experimental study involving 54 HNC patients. The intervention consisted of 2-6 sessions of 90 minutes given by a clinical nurse specialist at the patients' home. Both studies reported a decrease in depressive symptoms with the intervention, but had methodological shortcomings, such as a nonrandomized and small sample, and/or lack of control group. The third study was a RCT showing that individualized psychological counseling significantly decreased depressive tendency in HNC patients with raised scores on the Personality Traits Inventory (PTI) (measures; e.g., dominance, emotional instability, depressive tendency) [31]. In total 47 patients received pre- and postoperative psychological counseling. If they still had a high PTI score 3 months postoperatively, they received another 12 sessions of individualized psychological counseling provided by a clinical psychologist over 6 months. However, the sample size was relatively small, depressive tendency was measured instead of symptoms, and the study took place in India, which makes it difficult to compare and generalize the findings. The fourth study, a pilot RCT (n=35), reported that early implementation of a cognitive-behavioral therapy program had a beneficial effect, compared with a supportive counseling intervention, on depressive symptoms in newly diagnosed and distressed patients with HNC [32]. The intervention comprised 6 weekly 90-minute sessions given by a clinical psychologist during radiotherapy and 1 session 4 weeks after completion of radiotherapy. The improvement in the distress status was sustained for 12 months. However, the study only included patients aged 18 to 70 years and the drop-out rate was relatively high (study results were based on intention-to-treat analyses), The latter two interventions [31,32] were intensive with more than 12 and 7 sessions, respectively, and were led by a clinical psychologist, whereas our intervention was less intensive with 5-6 sessions of 45 minutes and led by experienced nurses. Our intervention would be expected to be less expensive than a more intensive (12 sessions) intervention led by a clinical psychologist.

A review of psychosocial interventions for anxiety and depression in cancer patients also emphasized the importance of cheap interventions requiring few professional resources [16]. In addition, nurses are already involved in patient care and do not have the

stigma attached to them that a mental health provider might have. Hence, combining the intervention with the medical check-up is efficient in terms of patient time and might reduce noncompliance. As the intervention is dependent on the time schedule of the physician, there were occasionally longer than intended intervals between the counseling sessions. Therefore, not all participants received the same number of counseling sessions; however, there were no significant differences in the decrease in depressive symptom levels between the participants who received different numbers of counseling sessions (data not shown). It could be argued that a nurse-initiated review, not in combination with the medical follow-up, might be beneficial in patients with more severe depressive symptoms, who could then be seen at shorter intervals, as determined by the nurse. This remains to be investigated.

Given that only two patients dropped out of the intervention group, and that the overall dropout rate of 27% was mainly due to death, we can conclude the intervention is feasible for patients who need or want counseling after cancer treatment. The dropout rate in the control group was similar.

The characteristics of the patients in our sample at baseline were comparable to those of other HNC samples (mean age 60 years, 74–78% male, 70–77% living together, [29,30,57] oral cavity as main tumor site (48%), and a baseline CES-D score of 12.4 [57], which supports the generalizability of the results to other Dutch HNC samples. Further strengths of the study were its randomized controlled design with intention-to-treat analyses; the supervised, standardized, theory-based, and nurse-led intervention; and the regular screening for depressive symptoms using a validated instrument. In addition, the participants did not know the nature of the aftercare they would receive, which reduced the possibility of contamination.

Conclusions

This RCT showed that the NUCAI is feasible and effective for reducing depressive symptoms of patients with HNC, particularly for patients with raised levels of depressive symptoms. In addition, HNC-specific physical symptoms decreased. The results of this study need to be confirmed in future studies so that the NUCAI can be implemented in daily clinical practice.

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3

Long-term effect of a nurse-led psychosocial intervention on health related quality of life in patients with head and neck cancer

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Abstract

Background: Head and neck cancer patients are prone to have a poor health-related quality of life after cancer treatment. This study investigated the effect of the nurse counselling and after intervention (NUCAI) on the health related quality of life and depressive symptoms of head and neck cancer patients between 12 and 24 months after cancer treatment.

Methods: Two hundred and five head and neck cancer patients were randomly allocated to NUCAI ($N = 103$) or usual care ($N = 102$). The 12-month nurse-led NUCAI is problem focused and patient driven and aims to help head and neck cancer patients manage with the physical, psychological and social consequences of their disease and its treatment. Health related quality of life was evaluated with the EORTC QLQ-C30 and QLQ H&N35. Depressive symptoms were evaluated with the CES-D.

Results: At 12 months the intervention group showed a significant ($P < 0.05$) improvement in emotional and physical functioning, pain, swallowing, social contact, mouth opening and depressive symptoms.. At 18 months, global quality of life, role and emotional functioning, pain, swallowing, mouth opening and depressive symptoms were significantly better in the intervention group than in the control group, and at 24 months emotional functioning and fatigue were significantly better in the intervention group.

Conclusion: The NUCAI effectively improved several domains of health related quality of life and depressive symptoms in head and neck cancer patients and would seem a promising intervention for implementation in daily clinical practice.

Introduction

Head and neck cancer (HNC) patients experience a deterioration of health-related quality of life (HRQoL) directly after they start treatment and up to 1 year after treatment [1], and possibly for much longer (8-11 years) after treatment completion [2,3]. HRQoL is multidimensional and includes generally experienced QoL, functioning (e.g. emotional and physical functioning), general cancer symptoms (e.g., fatigue and pain), and cancer-specific symptoms (e.g., in HNC problems with swallowing and dry mouth). Depressive symptoms at diagnosis are known to be predictive of a poor HRQoL 1–3 years later [4,5]. The need for effective interventions to improve HNC patients' HRQoL has been emphasized in the literature [6-8], but there have been few high-quality studies investigating the long-term effect of interventions on HRQoL in HNC patients.

Nurses are in a key position to deliver an intervention to improve HRQoL [9,10]. They are already involved in patient care and have the necessary skills and knowledge about the medical and practical aspects of HNC treatment and its consequences. In addition, nurses can provide information, support and coaching to HNC patients [7,11,12]. We therefore designed a longitudinal randomised controlled trial (RCT) to investigate the effectiveness of a comprehensive 1 year nurse-led intervention, the nurse counselling and after intervention (NUCAI), in HNC patients. We previously reported on the beneficial short-term effects of the NUCAI on depressive symptoms and HNC-related physical symptoms in HNC patients 1 year after the completion of cancer treatment [13]. In this article, we report on the effect of the NUCAI on HRQoL, as secondary outcome of the trial, and depressive symptoms up to 2 years after cancer treatment. We hypothesised that the NUCAI would improve HRQoL and depressive symptoms in HNC patients 1–2 years after cancer treatment.

Patients and methods

Sample, ethical considerations and randomisation

Patients were enrolled by a researcher (M.O.) between January 2005 and September 2007 from the outpatient oral maxillofacial and the otorhino-laryngology clinics of a Dutch university hospital before the start of cancer treatment. Inclusion criteria were primary diagnosis of squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, or larynx, treatment with curative intent, ability to complete questionnaires in Dutch and ability to participate in the intervention. Patients were excluded if they had a previous

or concomitant malignancy and/or were being treated for depression, diagnosed according to Diagnostic and Statistical Manual of Mental Disorders criteria [14], as stated in their medical record.

According to the Zelen design, patients received general information about the goal of the study and that they would be randomised to one of two groups. They were also given written assurance that the post-cancer care provided by the doctors would be the same in both groups. They were not given specific information about the intervention.

The study was approved by the Medical Ethics Committee of the University Medical Centre Utrecht and is registered under number ISRCTN06768231. After informed consent and the completion of cancer treatment, participants were randomised to the intervention or control group, using a web-based computer program with an open block procedure stratified for sex and tumour stage. All researchers were blinded to the block sizes. For the duration of the study, participants were not informed which treatment they received.

Care as usual

Care as usual was provided bimonthly by HNC specialists and was primarily aimed at the treatment of complications and the detection of recurrences or second primary tumours. During the 10-minute medical follow-up visit, patients were examined, their physical history was reviewed, and ancillary tests were arranged as necessary. If the patient had psychosocial problems, the HNC specialist could refer the patient to psychological aftercare.

Intervention

The NUCAI aims to help patients manage the physical, psychological, and social consequences of their disease and its treatment by giving advice, emotional support, education and behavioural training. The intervention is problem focused and patient driven, and was provided by trained nurses. Patients received a maximum of six counselling sessions of 45–60 minutes every 2 months over a period of 1 year, starting 6 weeks after the completion of cancer treatment. The counselling session was always combined with the patient's bimonthly medical check-up at the outpatient clinic.

The NUCAI can be divided into six components, which are:

Evaluating current mental status with the Hospital Anxiety and Depression Scale (HADS): Before each counselling session, the patients completed the HADS [15,16] at home. Nurses used the HADS score to screen for anxiety and/or depressive symptoms (cut-off >10

points), to gain insight into the psychological status of the patient. Moreover, discussion of the results of the HADS often made it easier for patients to talk about their problems. The nurse screened the patient's history for the presence of psychosocial morbidity; this information was used to guide counselling.

Discussing current problems: The session started with a discussion of current problems and topics raised by the patient. Patients were then systematically asked about physical problems related to HNC, such as mastication, swallowing, shoulder function, sense of taste or smell, breathing, restrictions in speech, pain and fatigue.

Discussing life domains: Then patients were systematically asked about their functioning in six relevant life domains, namely, home situation, (resuming) work, household and leisure activities, mood and emotional distress, partner relation and intimacy, family and social life.

Providing the AFTER intervention: If indicated, the Adjustment to Fear, Threat or Expectation of Recurrence (AFTER) [17] intervention was carried out. This cognitive behavioural intervention, which is based on Leventhals' self-regulation model [18], was designed to reduce irrational thoughts and to help patients with orofacial cancer to handle excessive fear of recurrence and psychological distress. The AFTER intervention consists of four components, namely, expressing fear of recurrence, identifying beliefs about sensations and their interpretation as recurrence, evaluating the function of self-examination and reducing excessive checking behaviour, and relaxation.

Providing general medical assistance and advice: When indicated, the nurse gave information and advice, provided minor medical and/or behavioural treatment, and offered support in accordance with the Dutch oncological nursing guidelines [19], the cancer clinical practice guidelines of the Dutch Association of Comprehensive Cancer [20], and the guidelines of the Nurse Intervention Classification [21].

Referring patients to psychological aftercare: If necessary, patients were referred to a psychiatrist or other doctor, a healthcare professional specialised in psychosocial problems (e.g. psychologist or social worker), or a relevant patient programme (e.g., oncological rehabilitation or patient support groups).

A manual was developed to assist the nurses in structuring the counselling sessions, discussing problems and choosing the appropriate nursing interventions. In addition, the nurses kept a treatment file for each of their patients, in which they recorded the

content of the session. The following topics were given to structure the record: home situation, physical functioning, social functioning, mental functioning, and nursing interventions.

Trained nurses

Three experienced oncology nurses were selected from the oral maxillofacial and the otorhino-laryngology department of a Dutch university hospital. Before the start of the study, the nurses were intensively trained to deliver the intervention. During the intervention period, sessions were evaluated with the nurses to monitor the quality of the intervention. More details about training can be found elsewhere [13]. The nurses continued to work on the ward as normal and received compensation for their additional duties, based on their normal salary.

Measures

Participants completed seven questionnaires at home, namely, at baseline, i.e. before the start of cancer treatment, and at 3, 6, 9, 12 (i.e., completion of NUCAI), 18, and 24 months after completion of cancer treatment. Endpoints of interest were those recorded at 12 and 24 months after completion of cancer treatment. Measurements performed during the intervention phase were taken to gain insight into the pattern of change in HRQoL and depressive symptoms.

HRQoL was assessed with the EORTC QLQ-C30 version 3.0 [22] and the head and neck module QLQ H&N35 [23]. Both are widely used and have good psychometric properties in HNC patients [23,24]. A range of 0–100 is used and a difference of 10 points is considered to be clinically significant [25]. Depressive symptoms were measured with the CES-D [26]. This 20-item self-report questionnaire gives a total score ranging from 0 to 60. A high score reflects a high level of depression. The CES-D has shown good psychometric properties in Dutch HNC patients [27]. In addition, information was collected about age, sex, education level, and social status by means of self-report questionnaires. Information about treatment, tumour type, and stage was obtained from medical records. All outcome data were collected by an independent researcher.

Statistics

The sample size was based on the prevalence of patients with raised levels of depressive symptoms (CES-D ≥ 12) established in previous analyses [13]. Power analysis for ANOVA procedures showed that, assuming an effect size of .32 with a two-sided test, a sample size of 45 patients with raised levels of depressive symptoms in each arm would suffice

(power = 80%, alpha = 0.05). Data from our previous studies [28,29] showed that 56% of patients had a CES-D score ≥12 before cancer treatment. Therefore a minimum of 160 HNC patients would be needed and 205 were enrolled to allow for study dropout.

Analyses followed the intention-to-treat principle (all patients with data at baseline and at least one follow-up measurement were included in analyses) and were performed using a linear mixed model approach. In these analyses, missing data were replaced by observed data, using maximum likelihood estimations [30]. Two-sided significant tests were used ($\alpha < 0.05$). Statistical analyses were performed using R software, version 2.10.0. (www.r-project.org).

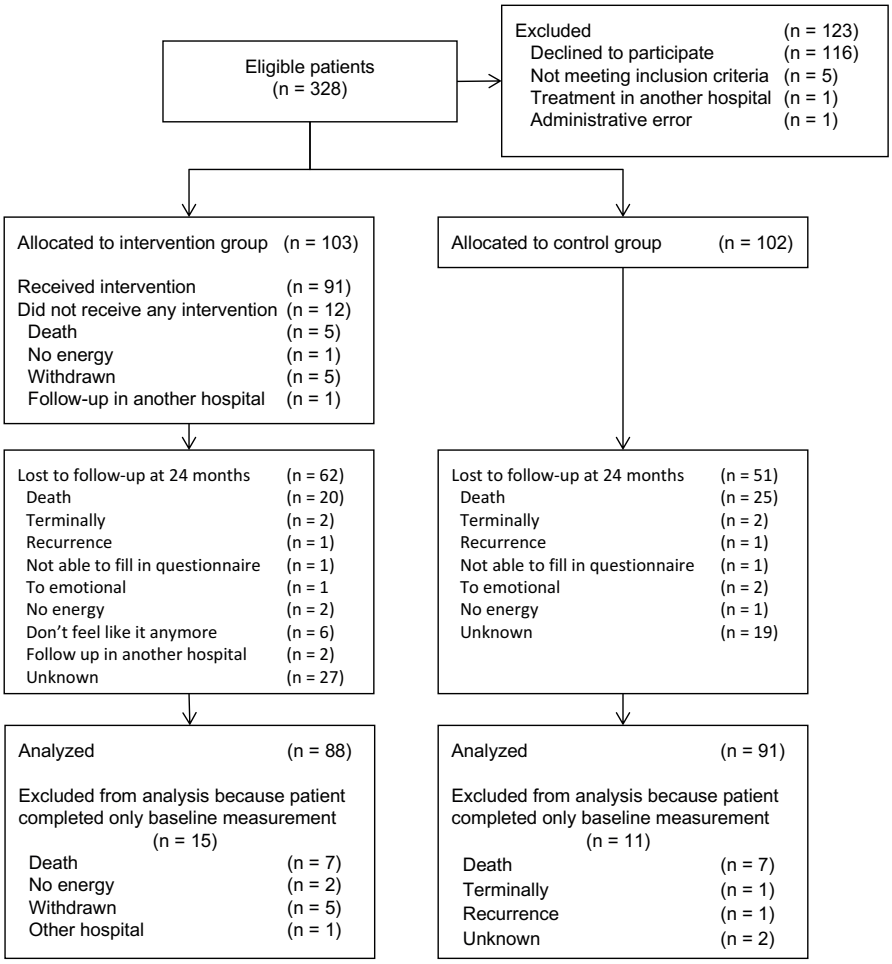

Figure 1. CONSORT flow chart.

Results

Patients

Of 328 eligible patients, 205 (62.5%) participated. Reasons for non-participation are shown in Figure 1. In total, 103 patients were randomized to the intervention group and 102 patients to the control group. At baseline, the intervention and control groups were comparable (*P > 0.05)* in terms of demographic variables and clinical characteristics (Table 1). At 24 months after the completion of cancer treatment, 113 (50%) patients were lost to follow-up (intervention *n* = 62; control *n* = 51), 49 (43%) of whom had died or were terminally ill.

Patients who were lost to follow-up had a significantly higher TNM status (*P* = 0.03) and lower QoL (*P* = 0.05) at baseline than did patients who completed the study. No differences were found in sociodemographic, clinical, global QoL, or depressive symptoms between patients lost to follow-up in the intervention and control groups (see Table 2).

Compliance

Of the 103 patients allocated to the intervention group, 12 (11.7%) did not attend any of the counselling sessions. Reasons for non-attendance are presented in Figure 1. Of the participants who completed the assessment at 12 months, 49% had received ≥ 5 counselling sessions; at 18 months the proportion was 91% and at 24 months 95%. Two patients, one at 18 and one at 24 months, received an additional seventh counselling session. The counselling sessions were sometimes delayed because it was not always possible for physicians to hold follow-up visits at 2 monthly intervals, and the NUCAI was always given in combination with these appointments.

Health-related quality of life and depressive symptoms

The longitudinal results of the EORTC-C30, EORTC-H&N35 and depressive symptoms are presented in Tables 3&4. Table 3 shows the descriptive mean scores and standard error for patients by randomization status. Table 4 presents the between-group differences following the intention-to-treat method.

Table 1. Demographics and clinical characteristics at baseline by study arm.[a]

	Intervention group (*N* = 88)	Control group (*N* = 91)
Age		
Years (mean (s.d.))	60.1 (10)	60.7 (10)
Sex (no. (%))		
Male	62 (70)	64 (70)
Female	26 (30)	27 (30)
Educational level (no. (%))		
Low	37 (42)	37 (41)
Middle	32 (36)	41 (45)
High	19 (22)	13 (14)
Social status (no. (%))		
Married/living together	63 (71.6)	67 (74)
Single	25 (28.4)	24 (26)
Working status (no. (%))		
Employed	31 (35)	34 (37)
Not employed	29 (33)	34 (37)
Retired	19 (22)	21 (23)
Unknown	9 (10)	2 (2)
Type of cancer (no. (%))		
Larynx	20 (23)	22 (24)
Oral cavity	41 (47)	44 (19)
Oropharynx	16 (18)	17 (48)
Hypo pharynx	11 (13)	7 (8)
Unknown primary	-	1 (1)
Tumor stage[b] (no. (%))		
I-II	51 (58)	54 (59)
III-IV	37 (42)	36 (40)
Unknown	-	1 (1)
Type of treatment (no. (%))		
Surgery	22 (25)	29 (32)
Radiotherapy	25 (28)	24 (26)
RT/CH	12 (14)	12 (13)
Combination	29 (33)	26 (29)
Coping style (mean (s.d.))		
Task oriented	18 (6)	17 (5)
Emotion oriented	12 (5)	13 (5)
Avoidance	12 (5)	12 (3)

Abbreviations: CH = chemotherapy; RT = radiation therapy; s.d. = standard deviation.
[a] Data is given of participants who completed a minimum of 2 measurements (n=179).
[b] Tumor stage according to the TNM Classification of Malignant Tumors.

Table 2. Demographics and clinical characteristics at baseline for patients lost to follow up by study arm.[a]

	Patients lost to follow up in the intervention group (*N* = 62)	**Patients lost to follow up in the control group (*N* = 51)**	***P- value***
Age Years (mean (s.d.))	61 (11)	62 (10)	0.87
Sex (no. (%)) Male Female	47 (76) 15 (24)	36 (71) 15 (29)	0.54
Educational level (no. (%)) Low Middle High	20 (32) 28 (45) 14 (23)	16 (31) 27 (53) 8 (16)	0.66
Social status (no. (%)) Married/living together Single Unknown	46 (74) 15 (24) 1 (2)	36 (71) 15 (29) -	0.64
Working status (no. (%)) Employed Not employed Retired Unknown	22 (36) 20 (32) 14 (23) 6 (10)	13 (26) 22 (43) 12 (24) 4 (8)	0.69
Type of cancer (no. (%)) Larynx Oral cavity Oropharynx Hypo pharynx Unknown primary	14 (23) 28 (45) 10 (16) 10 (16) -	10 (20) 25 (49) 12 (24) 3 (6) 1 (2)	0.90
Tumor stage[a] (no. (%)) I-II III-IV	33 (53) 29 (47)	23 (45) 28 (55)	0.39
Type of treatment (no. (%)) Surgery Radiotherapy RT/CH Combination	14 (23) 17 (27) 10 (16) 21 (34)	12 (24) 12 (24) 10 (20) 17 (33)	0.95
Coping style (mean (s.d.)) Task oriented Emotion oriented Avoidance	18 (5) 12 (4) 12 (4)	19 (5) 13 (5) 12 (5)	0.35 0.54 0.34
Global QoL (mean (s.d.))	66 (22)	60 (25)	0.14
Depressive symptoms (mean (s.d.))	12 (8)	13 (9)	0.60

Abbreviations: CH = chemotherapy; RT = radiation therapy; s.d. = standard deviation. [a] Data is given of participants who completed a minimum of 2 measurements (n=179). [b] Tumor stage according to the TNM Classification of Malignant Tumors.

QLQ C30

At 12 months after treatment completion, the intervention group had a significantly improved physical functioning (4.9, 95% confidence interval (CI): 0.6 to 9.3) and emotional functioning (9.9, 95% CI: 3.6 to 16.2) and diminished pain (-9.9, 95% CI: -17.0 to -2.9) compared with the control group. At 18 months, significant differences were found for global QoL (6.7, 95% CI: 0.1 to 13.3), role functioning (11.3, 95% CI: 1.9 to 20.7), emotional functioning (9.4, 95% CI: 2.4 to 16.4) and pain (-12.6, 95% CI: -21.4 to -3.8). At 24 months, the emotional functioning of patients in the intervention group was still significantly better (9.7, 95% CI: 2.3 to 17.1) and they were significantly less fatigued (-9.4 95% CI: -17.8 to -1.1) than the patients in the control group.

QLQ H&N35

At 12 months, the intervention group reported significantly fewer problems with pain (-9.9, 95% CI: -17.0 to -2.9), swallowing (-8.1, 95% CI: -14.8 to -1.3), social contact (-7.6, 95% CI: -12.4 to -2.9) and mouth opening (-14.6, 95% CI: -24.0 to -5.2) than the control group. However, the intervention group reported significantly more problems with coughing than did the control group (10.9, 95% CI: 2.2 to 19.5). At 18 months, the beneficial effects of the NUCAI on pain (-8.3, 95% CI: -16.1 to -0.5), swallowing (-7.5, 95% CI: -14.9 to -0.0) and opening mouth (-17.0, 95% CI: -27.4 to -6.6) were still present, but at 24 months there were no between-group differences in any HNC-related symptom.

Depressive symptoms

Depressive symptoms were significantly diminished at 12 months in the intervention group compared with the control group (-2.8, 95% CI: -5.2 to -0.3) and this improvement was still seen at 18 months (-3.7, 95% CI: -6.4 to -1.0). At 24 months, depressive symptoms were still lower, although non-significantly, in the intervention group (-2.6, CI: -5.5 to 0.2).

Table 3. Descriptives of health related quality of life, head and neck cancer specific health related quality of life and depressive symptoms over the 24-month study period[a]

		BL		12M		18M		24M	
		mean	(SE)	mean	(SE)	mean	(SE)	mean	(SE)
EORTC QLQ-C 30[b]									
Global QoL	I	67.3	(2.3)	73.6	(2.4)	77.8	(2.7)	77.5	(2.8)
	C	66.2	(2.3)	68.1	(2.4)	71.1	(2.5)	74.5	(2.6)
Physical functioning	I	84.4	(2.2)	81.5	(2.2)	83.2	(2.4)	82.4	(2.5)
	C	87.0	(2.1)	79.1	(2.2)	81.3	(2.3)	80.5	(2.4)
Role functioning	I	76.3	(3.0)	79.4	(3.2)	83.2	(3.6)	82.8	(3.8)
	C	77.7	(3.0)	78.6	(3.2)	73.2	(3.3)	77.8	(3.5)
Emotional functioning	I	64.8	(2.4)	82.8	(2.5)	85.6	(2.8)	84.9	(3.0)
	C	66.9	(2.4)	75.0	(2.5)	78.3	(2.6)	77.2	(2.8)
Cognitive functioning	I	83.9	(2.2)	83.1	(2.4)	87.7	(2.6)	84.7	(2.8)
	C	84.2	(2.2)	82.8	(2.3)	85.1	(2.4)	83.8	(2.6)
Social functioning	I	83.1	(2.5)	87.1	(2.7)	88.9	(3.1)	88.5	(3.2)
	C	83.1	(2.5)	80.0	(2.6)	85.0	(2.8)	85.1	(3.0)
Fatigue	I	27.9	(2.7)	25.7	(2.9)	20.4	(3.2)	19.9	(3.4)
	C	25.9	(2.7)	29.9	(2.8)	24.8	(3.0)	27.1	(3.1)
Nausea and vomiting	I	3.4	(1.3)	1.2	(1.4)	2.3	(1.7)	1.3	(1.8)
	C	4.2	(1.3)	6.4	(1.4)	4.1	(1.5)	4.9	(1.7)
Pain	I	27.8	(2.8)	14.0	(3.0)	10.0	(3.4)	11.4	(3.6)
	C	26.4	(2.7)	22.3	(2.9)	21.1	(3.1)	17.8	(3.3)
Dyspnoea	I	11.7	(2.7)	14.6	(2.8)	13.1	(3.1)	13.2	(3.3)
	C	12.8	(2.7)	17.0	(2.8)	15.3	(2.9)	18.5	(3.1)
Insomnia	I	28.4	(3.1)	19.2	(3.3)	18.5	(3.9)	12.7	(4.1)
	C	28.2	(3.1)	19.5	(3.3)	21.4	(3.5)	19.6	(3.8)
Appetite loss	I	11.7	(2.8)	13.1	(2.9)	10.1	(3.4)	6.4	(3.6)
	C	19.0	(2.7)	17.8	(2.9)	15.8	(3.1)	14.2	(3.3)
Constipation	I	7.6	(2.0)	7.9	(2.1)	8.1	(2.4)	6.4	(2.6)
	C	5.5	(1.9)	8.0	(2.1)	8.6	(2.2)	8.4	(2.4)
Diarrhoea	I	3.0	(1.9)	12.6	(2.1)	12.3	(2.5)	12.4	(2.7)
	C	4.4	(1.9)	15.0	(2.1)	12.5	(2.3)	16.4	(2.5)
Financial difficulties	I	9.1	(2.5)	11.5	(2.6)	8.5	(2.9)	11.1	(3.1)
	C	9.6	(2.5)	10.9	(2.6)	9.9	(2.7)	11.2	(2.8)

Table 3. (continued)

		BL		12M		18M		24M	
		mean	(SE)	mean	(SE)	mean	(SE)	mean	(SE)
EORTC QLQ-H&N35[b]									
Pain	I	36.0	(2.4)	17.3	(2.5)	15.5	(2.9)	15.1	(3.1)
	C	31.1	(2.3)	22.3	(2.5)	19.0	(2.6)	15.6	(2.8)
Swallowing	I	22.7	(2.5)	18.8	(2.7)	18.3	(3.0)	17.2	(3.2)
	C	18.1	(2.5)	21.3	(2.6)	21.2	(2.8)	15.7	(2.9)
Senses	I	9.8	(2.6)	18.9	(2.7)	18.1	(3.0)	24.0	(3.2)
	C	7.7	(2.5)	20.4	(2.7)	20.9	(2.8)	19.4	(3.0)
Speech	I	23.0	(2.6)	18.2	(2.7)	17.0	(3.1)	16.2	(3.3)
	C	23.4	(2.6)	21.3	(2.7)	19.8	(2.8)	18.8	(3.0)
Social eating	I	9.8	(2.8)	18.9	(2.9)	18.1	(3.2)	24.0	(3.4)
	C	7.7	(2.7)	20.4	(2.9)	20.9	(3.0)	19.4	(3.1)
Social contact	I	7.6	(1.8)	8.0	(1.9)	8.1	(2.1)	7.7	(2.2)
	C	6.2	(1.8)	14.2	(1.9)	11.2	(2.0)	10.6	(2.1)
Sexuality	I	27.1	(3.8)	27.2	(4.0)	24.3	(4.5)	22.3	(4.7)
	C	25.8	(3.7)	32.0	(3.9)	29.8	(4.1)	26.0	(4.3)
Teeth	I	23.0	(3.3)	20.4	(3.6)	18.5	(4.1)	17.5	(4.3)
	C	23.8	(3.2)	25.7	(3.5)	21.4	(3.7)	15.6	(4.0)
Opening mouth	I	19.0	(3.2)	15.1	(3.4)	8.8	(3.9)	13.0	(4.1)
	C	17.6	(3.1)	28.2	(3.4)	24.3	(3.6)	18.1	(3.8)
Dry mouth	I	16.3	(3.5)	36.8	(3.7)	35.8	(4.2)	33.4	(4.5)
	C	18.7	(3.5)	38.6	(3.7)	35.0	(3.9)	32.8	(4.1)
Sticky saliva	I	19.5	(3.3)	32.7	(3.5)	28.6	(4.0)	23.8	(4.3)
	C	15.8	(3.3)	34.4	(3.5)	30.8	(3.7)	26.5	(3.9)
Coughing	I	22.3	(3.0)	27.4	(3.2)	23.7	(3.6)	23.7	(3.8)
	C	25.3	(2.9)	19.5	(3.1)	22.9	(3.3)	23.6	(3.5)
Felt ill	I	17.8	(2.6)	9.0	(2.8)	8.6	(3.3)	7.3	(3.5)
	C	18.7	(2.6)	14.1	(2.8)	15.7	(3.0)	11.2	(3.2)
CES-D									
Depressive symptoms	I	12.9	(1.1)	11.3	(1.1)	9.5	(1.2)	10.6	(1.3)
	C	12.9	(1.0)	14.1	(1.1)	13.2	(1.1)	13.2	(1.2)

Abbreviations: BL = baseline, C = control group, I = intervention group, M = months, SE = standard error.
[a] Data is given following the intention to treat principles (n = 179 : intervention group n= 88 ; control group n = 91)
[b] A high score for a functional scale/global QoL represents a high level of functioning/global QoL whereas a high score for a symptom scale represents a high level of problems. Symptom scales are presented below the dotted line.

Table 4. EORTC QLQ C30, H&N35 and depressive symptoms - between group differences[a,b]

	12M	18M	24M
EORTC QLQ-C30 [c]			
Global QoL	5.5 (-0.5 to 11.4)	**6.7 (0.1 to 13.3)***	3.0 (-4.0 to 10.0)
Physical functioning	**4.9 (0.6 to 9.3)***	4.4 (-0.4 to 9.3)	4.5 (-0.6 to 9.7)
Role functioning	5.2 (-3.3 to 13.7)	**11.3 (1.9 to 20.7)***	6.3 (-3.7 to 16.3)
Emotional functioning	9.9 (3.6 to 16.2)*	9.4 (2.4 to 16.4)*	9.7 (2.3 to 17.1)*
Cognitive functioning	0.6 (-5.3 to 6.5)	2.9 (-3.6 to 9.4)	1.2 (-5.7 to 8.2)
Social functioning	7.1 (-0.1 to 14.3)	3.9 (-4.1 to 11.9)	3.3 (-5.2 to 11.9)
Fatigue	-6.5 (-13.6 to 0.6)	-6.7 (-14.5 to 1.1)	**-9.4 (-17.8 to -1.1)***
Nausea or vomiting	4.4 (-0.4 to 9.1)	1.0 (-4.2 to 6.3)	2.8 (-2.7 to 8.4)
Pain	**-8.9 (-16.9 to -1.0)***	**-12.6 (-21.4 to -3.8)***	-7.9 (-17.2 to 1.4)
Dyspnoea	-7.8 (-1.3 to 5.2)	-1.1 (-8.3 to 6.1)	-4.2 (-11.9 to 3.4)
Insomnia	-0.4 (-9.9 to 9.0)	-3.2 (-13.7 to 7.3)	-7.1 (-18.3 to 4.1)
Appetite loss	2.6 (-5.7 to 10.9)	1.7 (-7.5 to 10.9)	-0.5 (-10.3 to 9.2)
Constipation	-2.1 (-8.2 to 3.9)	-2.6 (-9.3 to 4.1)	-4.1 (-11.2 to 2.9)
Diarrhoea	-1.0 (-8.2 to 6.1)	1.2 (-6.7 to 9.0)	-2.6 (-11.0 to 5.7)
Financial difficulties	1.1 (-5.2 to 7.5)	-1.0 (-8.0 to 6.0)	0.4 (-7.1 to 7.8)
EORTC QLQ-H&N35[c]			
Pain	**-9.9 (-17.0 to -2.9)***	**-8.3 (-16.1 to -0.5)***	-5.4 (-13.7 to 2.9)
Swallowing	-8.1 (-14.8 to -1.3)*	-7.5 (-14.9 to -0.0)*	-3.1 (-11.0 to 4.8)
Senses	-3.7 (-10.6 to 3.1)	-4.9 (-12.5 to 2.7)	2.4 (-5.6 to 10.5)
Speech	-2.7 (-9.9 to 4.5)	-2.3 (-10.3 to 5.6)	-2.2 (-10.6 to 6.2)
Social eating	-5.6 (-12.4 to 1.2)	-3.6 (11.1 to 4.0)	-0.5 (-8.5 to 7.5)
Social contact	**-7.6 (-12.4 to -2.9)***	-4.5 (-9.8 to 0.7)	-4.3 (-9.9 to 1.3)
Sexuality	-6.0 (-15.9 to 3.9)	-6.8 (-17.7 to 4.2)	-4.9 (-16.5 to 6.6)
Teeth	-4.5 (-14.7 to 5.8)	-2.1 (-13.4 to 9.2)	2.8 (-9.2 to 14.8)
Opening mouth	**-14.6 (-24.0 to -5.2)***	**-17.0 (-27.4 to -6.6)***	-6.6 (-17.6 to 4.5)
Dry mouth	0.6 (-9.2 to 10.4)	3.1 (-7.7 to 14.0)	3.0 (-8.5 to 14.6)
Sticky saliva	-5.4 (-14.9 to 4.1)	-6.0 (-16.5 to 4.6)	-6.5 (-17.7 to 4.7)
Coughing	**10.9 (2.2 to 19.5)***	3.8 (-5.8 to 13.4)	3.0 (-7.2 to 13.1)
Felt ill	-4.2 (-12.6 to 4.2)	-6.2 (-15.5 to 3.1)	-2.9 (-12.9 to 7.0)
CES-D[c]			
Depressive symptoms	**-2.8 (-5.2 to -0.3)***	**-3.7 (-6.4 to -1.0)***	-2.6 (-5.5 to 0.2)

Bold values indicate significant findings. [a] Data are mean differences with a confidence interval (CI) of 95% with baseline score as reference. [b] Data is given following the intention to treat principles (n = 179 : intervention group n= 88 ; control group n = 91). [c] A high score for a functional scale/ global QoL represents a high level of functioning/ global QoL whereas a high score for a symptom scale represents a high level of problems. Symptom scales are presented below the dotted line.
* Significant difference with a CI 95%.

Discussion

General discussion

This RCT showed the effectiveness of a comprehensive 12-month nurse-led psychosocial intervention in improving HRQoL and depressive symptoms in HNC patients. Significant improvements were found in physical and emotional functioning, pain, swallowing, social contact, mouth opening and depressive symptoms 12 months after the completion of cancer treatment in the intervention group. At 18 months, patients in the intervention group reported improvements in global QoL, role and emotional functioning, pain, swallowing, mouth opening and depressive symptoms. At 24 months emotional functioning and fatigue were better in the intervention group than in the control group. Most of the significant findings showed a substantial difference of almost, or more than, 10 points, which can be considered clinically relevant [25].

The intervention did not have a significant effect on nausea and vomiting, or constipation and diarrhoea, possibly because few patients experienced these problems (scores <10 points). However, the intervention also did not have a significant effect on sexuality, dry mouth and sticky saliva, aspects that the patients did consider problematic. Two recently published Cochrane reviews of RTCs on interventions for dry mouth [31,32] showed that saliva substitute sprays are beneficial and that a gel-releasing device worn in the mouth and a mouth care system are potentially promising treatments [32]. Acupuncture, as non-medical treatment, was not found to better than placebo for alleviating the problems of dry mouth and sticky saliva [31]. Overall, the quality of the studies was rather poor and the studies provided insufficient evidence to guide clinical care [32]. One small pilot study with institutionalised elderly individuals described lemon-lime sorbet to be effective against dry mouth [33]. Concerning sexuality problems, Kagan [10] emphasised the complexity of problems with sexuality in older cancer patients and the complexity of tailored interventions. They recommended integrating standards of practice for intimacy and sexuality as advised for younger adults in any intervention for older individuals, together with information about issues unique to older people [10]. As there is little available information, future studies should focus on effective strategies to combat these specific problems in HNC patients. Findings can then be integrated into the NUCAI, to improve HRQoL in all domains. To our knowledge, no RCTs have been published that evaluated interventions to increase HRQoL in HNC patients. Instead, often quasi-experimental designs were used [7,34] and/or small study samples [8,34]. The results of a quasi-experimental study [7] (n=160), using an intervention comparable to the NUCAI, showed that most HRQoL scores improved in the intervention group compared with the control group 6 and 12 months after

treatment. Another small study [8] (n=54) reported improvements in social functioning and QoL scores compared with control 3 months after a problem-focused psychosocial intervention consisting of 2-6 sessions led by a nurse specialist at the patient's home. A feasibility study (n=50) showed a psycho-educational intervention to have some beneficial effects on HRQoL and depressive symptoms [34]. Our results, coming from a study with a robust design and long follow-up, are in line with these findings. A recently published Cochrane review [35] included seven RCTs or quasi-RCTs (which also included unpublished results) that evaluated QoL and/or psychological distress found there to be insufficient evidence to support the use of psychosocial interventions for HNC patients (the results of the current study were not included in the meta-analysis). Semple and colleagues [35] mentioned numerous difficulties in reviewing the studies, such as the small number of studies, low power, and heterogeneous interventions and outcome measures. Overall, the results of our and another study [36] suggest that interventions that are structured, theoretically based and skills-focused are promising in terms of improving HRQoL and decreasing depressive symptoms [36]. Multicentre trials are needed to ensure sufficient numbers of patients [35,37].

The involvement of nurses in patient aftercare may necessitate a change in traditional study designs. Although we did not explicitly investigate the cooperation between doctors and nurses, it went well, but it should be remembered that the NUCAI was additional to standard medical follow-up, unlike other nurse-led interventions [12]. A small survey conducted by Urquhart *et al* [38] showed that 67% of interviewed clinicians were against nurse-led clinics, at least in England. This means that the necessary attention should be paid to the cooperation between clinicians and nurses, and to the role of a nurse-led intervention in the aftercare of HNC patients.

Limitations and strengths

Some difficulties arose during the intervention, such as the delay in counselling sessions with the result that 51% of the patients had received 4 sessions or less at 12 months. Outpatient clinics are a busy and challenging environment, and it is therefore of great importance that the intervention is integrated into the organisation of the clinic and that counselling sessions are given in a friendly, quiet and accessible room near to where the doctors are working. The study had some uncontrollable variables, such as the patient or doctor being ill or the patient forgetting his/her appointment. An important strength of the study is the educational training given to the nurses before the start of the study and their supervision during the study. Nurses traditionally have a direct approach to solving problems as they are mentioned or occur, but the training and supervision enabled the nurses to listen more carefully and to encourage the patient to

talk about his/her problems. It is important that the nurses who give the intervention have extensive experience in the care for HNC patients, have good communication skills, are self-reliant and are able to work closely with other professionals, as was the case for the nurses who led the intervention in this study.

Most participants had early, stage I-II cancer, which possibly reflects the ability of general practitioners to recognise the disease and to refer patients on to an HNC specialist in a timely fashion. However, the study population was generally comparable to that of our previous study [29], which strengthens the extent to which findings can be generalised to the Dutch population of HNC patients. Although we performed a number of analyses, which increases the chance of false positive findings, we think it is unlikely that the beneficial effects of NUCAI on HRQoL were due entirely to chance, given the pattern of findings. Compared with other, more intensive, interventions [39,40], we consider the NUCAI to be a relatively low-cost intervention, given its nurse-led approach and the relatively few sessions involved. Moreover, findings suggest that it can be implemented in the follow-up care for HNC patients, although the overall costs and feasibility of the intervention remain to be investigated. Overall, the study design, an RCT with a long follow-up, strengthens the findings of the study, especially because of the lack of other RCTs of interventions to improve HRQoL in HNC patients.

Conclusion

This RCT showed that the nurse-led NUCAI is feasible and effective in HNC patients and improved physical and emotional functioning, pain, swallowing, social contact, mouth opening and depressive symptoms 12 months after the completion of cancer treatment. Improvements in global QoL, role and emotional functioning, pain, swallowing, mouth opening and depressive symptoms were seen at 18 months, and improvements in emotional functioning and fatigue at 24 months. The NUCAI is a valid intervention, thanks to its structured, theory-based, problem-focused, and nurse-led nature, and appears to be a promising to implement in daily practice.

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4

Moderators of the response to a nurse-led psychosocial intervention to reduce depressive symptoms in head and neck cancer patients

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Abstract

Purpose Little is known about the variables that moderate the response to psychosocial interventions to decrease depressive symptoms in cancer patients. The purpose of this study was to determine whether variables associated with depressive symptoms in cancer patients in general moderate the response to a nurse-led psychosocial intervention in patients with head and neck cancer.

Methods This study is a secondary analysis of a randomized controlled trial evaluating the effect of the Nurse Counseling and After Intervention (NUCAI) on depressive symptoms 12 months after cancer treatment in patients with head and neck cancer. Of 205 patients, 103 received the NUCAI and 102 care as usual. Twenty-one variables were selected for analysis and a linear regression analyses including interaction terms was performed for each variable separately. Significant moderators were post-hoc probed.

Results Four moderators were found: marital status, global quality of life, emotional functioning, and social functioning. Patients who were married/living together or had low scores for global quality of life, emotional- or social functioning at baseline benefited more from the NUCAI than patients who were single or with high scores for global quality of life, emotional- or social functioning.

Conclusions Marital status, global quality of life, emotional - and social functioning of head and neck cancer patients should be evaluated to determine whether they might benefit from a psychosocial intervention to combat depressive symptoms. Further research is necessary to replicate results and to contribute to the knowledge needed to make screening and personalized patient care possible.

Introduction

Head and neck cancer is the sixth most common cancer worldwide [1] with approximately 690,000 new cases annually worldwide, which accounts for 4.9% of the total cancer incidence [2]. Patients diagnosed with head and neck cancer face unique challenges, because the effects of the cancer and its treatment are in many cases visible and have a strong negative impact on diverse functions. Impaired speech, drooling, difficulty chewing, altered facial appearance are just a few examples, and these changes can influence social interactions and alter patients' self-esteem [3]. In addition, of the patients recently diagnosed with head and neck cancer 28-29% is experiencing depressive symptoms [4], which is 28–39% after 6 months [4,5] and 20% at 1 year after treatment [6]. Several interventions have proven effective in decreasing depressive symptoms in these patients [7-11]. We recently found that the Nurse Counseling and After Intervention (NUCAI), a psychosocial intervention, effectively decreased depressive symptoms 1 year after treatment of head and neck cancer [11]. Although this intervention is currently offered to all patients, it might not be effective in some patients. In order to gain more insight into which patients might benefit from the intervention, knowledge is needed of the variables that moderate the effect of the intervention [12].

A recent systematic review [13] identified 14 significant variables that moderate the outcomes of interventions in patients with cancer. For example, patients with a poor global quality of life (QoL), poor interpersonal relationships, and high emotional expressiveness appeared to benefit more than other patients. However, the review included a rather broad range of interventions, such as psychosocial, psycho-educational, and mind-body interventions aiming to increase psychosocial well-being. Less is known about which variables moderate depressive symptoms in patients with head and neck cancer. In a literature search, we found younger age [14,15], female gender [16], lower educational level [17,18], living alone and unemployment [19], higher tumor stage [14,20], adjuvant chemotherapy [16], smoking and daily drinking [17], avoidance and helpless coping [4,21,22], lower social support [23,24], lower global QoL [15,19,25,26], lower physical functioning [27], lower emotional functioning [28], lower social functioning [27], higher level of pain [29,30], more intrusive thoughts [31], lower self-esteem [32], and lower self-efficacy [32,33] to influence depressive symptoms in patients with cancer. The purpose of the current study was to investigate whether these variables, which are associated with depressive symptoms in cancer patients, moderate the response to a nurse-led psychosocial intervention [11] for the treatment of depressive symptoms in head and neck cancer patients.

Materials and Methods

This study is a secondary analysis of a randomized controlled trial (RCT) evaluating the effect of the NUCAI, a psychosocial intervention, in patients with head and neck cancer (registration number: ISRCTN06768231). Newly diagnosed patients were randomly allocated to an intervention or control group. Patients in the control group received care as usual, which consists of a 10-minute medical check-up by a specialist in head and neck cancer in the outpatient clinic every 2 months during the first year after cancer treatment. In addition to care as usual, patients in the intervention group received the NUCAI, which consists of six counseling sessions of 60 minutes during the first year after cancer treatment, given by a trained nurse. The 2-monthly sessions were combined with the medical check-up. Participants completed seven questionnaires at home, before the start of cancer treatment which is considered as baseline measurement, and at 3, 6, 9, 12, 18, and 24 months after cancer treatment. The primary endpoint was depressive symptoms 12 months after completion of cancer treatment; the other measurements were taken to gain insight into the pattern of change in depressive and health-related QoL variables.

Results showed that the NUCAI decreased depressive symptoms and improved physical functioning, emotional functioning, and pain 12 months after the completion of cancer treatment [11]. More details and other, long-term findings are previously published elsewhere [11,34].

Patients

Participants were recruited between January 2005 and September 2007 from the outpatient oral maxillofacial and the otorhinolaryngology clinics of a Dutch university hospital before the start of cancer treatment. Eligibility criteria were a primary diagnosis of squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, or larynx; treatment with curative intent; ability to complete questionnaires; and ability to participate in the intervention. Patients were excluded if they had a previous or concomitant malignancy and/or were being treated for depression at time of enrollment or before. Depression was diagnosed according to Diagnostic and Statistical Manual of Mental Disorders [35], as stated in the patients' medical record. Note that patients without ongoing treatment for depression were eligible for the trial. After completion of cancer treatment, participants were randomized to the intervention or control group, stratified by gender and tumor stage. Of the 328 eligible patients 63% (n=205) agreed to participate, 103 participants in the intervention group and 102 participants in the control group. At 12 months 28 participants were lost to follow up in the intervention group and 27 participants in the control group. Mean reasons were death (n=16 in

intervention group, n=17 in control group) and being terminally ill (n=4 in intervention group, n =2 in control group). A total of 146 participants had complete data for analyses. The study was approved by the Medical Ethics Committee of the University Medical Centre Utrecht. Eligible patients received verbal and written information about the study and all participants provided written informed consent.

Measures

Sociodemographic, disease and treatment related variables

Information on age (continuous), gender (male, female), education level (low (i.e. elementary and lower vocational education), middle (i.e. secondary and secondary vocational education), high (i.e. higher vocational and university education)), marital status (married/living together, single), employment status (employed, not employed, retired, unknown), smoking (yes, no) and daily drinking (<3 units alcohol a day, >3 units alcohol a day) was collected by means of self-report questionnaires. Information about type of cancer (oral cavity/oropharynx, hypopharynx/larynx), tumor stage (I-II, III-IV) and treatment (surgery, radiotherapy, chemoradiation, combination) was obtained from medical records.

Depressive symptoms

Depressive symptoms were measured with the CES-D [36]. This 20-item self-report questionnaire gives a total score ranging from 0 to 60. A high score reflects a high level of depression. The CES-D has shown good psychometric properties in Dutch patients with head and neck cancer [4].

Health-related quality of life (HRQoL)

Global QoL, physical -, role -, emotional -, cognitive - and social functioning were assessed with the EORTC QLQ-C30 version 3.0 [37] and pain with the head and neck module QLQ H&N35 [38]. A range of 0–100 is used and a high score reflects a high level of functioning or a high level of pain. Both are widely used and have good psychometric properties in patients with head and neck cancer [38,39].

Coping strategy

Coping was assessed with the shortened Dutch version of the Coping Inventory for Stressful Situations (CISS) [40]. This 21-item self-report questionnaire measures three dimensions of coping: task-oriented, emotion-oriented, and avoidance-oriented coping. Item scores range from 1 (not at all) to 5 (very often). A higher score on each dimension reflects a higher probability of using that coping strategy. The CISS demonstrated good

psychometric properties in Dutch patient with internal diseases [41].The Chronbach's alpha in the present sample was 0.83 for the task-oriented scale, 0.83 for the emotion-oriented scale and 0.71 for the avoidance-oriented scale.

Social support Social support was measured with the short version of the Social Support List–Interactions (SSL 12-I) [42]. This questionnaire assesses the extent of perceived received social support by means of social interactions with members of the primary social network. It consists of 12 items with possible item scores ranging from 1 (seldom or never) to 4 (very often) with a higher score reflecting more social support. The SSL 12-I has shown good psychometric properties in Dutch elderly [42] and Dutch patients with rheumatoid arthritis [43]. The Chronbach's alpha in the present sample was 0.91.

Potential moderators

The following variables were entered in the analyses: age, gender, educational level, marital status, employment status, tumor stage, type of treatment, smoking, daily drinking, task-, emotion- and avoidance coping, social support, global QoL, physical functioning, emotional functioning, social functioning, and pain. These variables have been reported in the literature to be associated with depressive symptoms. We additionally included the variables assessed in the NUCAI study, namely, head and neck cancer specific tumor site, role-, and cognitive functioning, even though there is no evidence in the literature that these variables have a moderating effect. The variables intrusive thoughts, self-esteem, and self-efficacy, which showed to be associated with depressive symptoms, could not be included in the moderator analyses because we did not collect these variables in the NUCAI study. Overall, 21 variables were selected for analysis.

Statistics

To determine whether there were differences in potential moderators between the intervention and control groups, we performed t-tests for continuous variables and X^2 tests for categorical variables. The variance of the residuals was tested by a scatterplot to examine homoscedasticity and linearity. A linear regression analysis was performed for each moderator separately to identify whether the selected variable moderated the effect of the intervention on depressive symptoms at 12 months after cancer treatment. Continuous potential moderators were centered to reduce multicollinearity and for the categorical potential moderators, educational level, employment status, and type of treatment, dummies were created. The first category was used as reference. The linear regression model contained the continuous depressive symptom score at

12 months as dependent variable. Group (intervention versus control), the centered potential moderator at baseline, the group by moderator interaction, and the centered continuous baseline depressive symptoms score were entered as independent variables. All participants who completed the baseline and the 12-month assessments were included in the full-case analyses.

In addition to the full-case an intention to treat analyses was performed. Participants who did not complete the 12-month assessment but who minimally completed the baseline and 3-month assessments were included. To determine whether there were differences in potential moderators between the participants in the full-case analyses and the additional participants who entered the intention-to-treat analyses, t-tests were performed for continuous variables and X^2 tests for categorical variables. Missing values were imputed in the intention-to-treat sample. Multiple imputation (10x) was carried out for missing 12 months post cancer treatment score for depressive symptoms as well as missing baseline scores of, coping strategy, social support, cognitive functioning and depressive symptoms. Constraints were given for each variable. All other variables were used as indicator.

The linear regression analyses were repeated and the pooled outcome of the 10 imputation datasets was used as result.

Effect sizes (ES) were calculated for each regression model in order to estimate the variance explained by the interaction term. Therefore, the proportion of variance accounted for in the model with the interaction term was subtracted from the model without the interaction term. Cohen's [44] cut off points were used to indicate a small (ES=0.02), medium (ES=0.15) or large (ES=0.35) effect. In addition, the achieved power for each regression model was calculated using the statistical software of G*Power [45].

Finally, the significant moderators were post-hoc probed to determine if the relation between depressive symptom and group (intervention vs control) is significant for the categories of the moderators. For the continuous moderators the categories -1SD, mean and +1SD score were generated. For categorical moderators the existing categories were used. The statistical software PROCESS of A. Hayes [46] was used for the post-hoc probing analyses. All analyses were, unless otherwise stated, performed using SPSS version 21. Statistical significance was set at $p < 0.05$ (two-tailed).

Results

Baseline characteristics

In total, 103 participants were randomized to the intervention group and 102 to the control group. A minimum of two assessments were available for 88 participants in the intervention group and 91 participants in the control group (intention-to-treat analyses), and 73 participants in the intervention group and 73 participants in the control group completed the 12-month post cancer treatment assessment (full-case analyses) (Table 1). The intervention and control groups were similar in terms of sociodemographic, disease and treatment related characteristics and potential moderators. In addition, there were no significant differences between the full-case participants (n=146) and the additional participants who entered the intention-to-treat analyses (n=33) (all p >0.05).

Moderator analyses

The data was considered to be normally distributed, homoscedastic and linear for all potential moderators. In the full-case analyses, the linear regression analyses identified four significant moderators: marital status (*b*=-6.75, *p*=0.04), global QoL (*b*=-0.14, *p*=0.03), emotional functioning (*b*=-0.14, *p*=0.02), and social functioning (*b*=-0.13, *p*=0.04) (Table 2). In the intention-to-treat analyses, emotional functioning (*b*=-0.14, *p*=0.02) and social functioning (*b*=-0.15, *p*=0.03) were identified as moderators. A trend to significance was found for marital status (*b*=-5.96, *p*=0.08) and global QoL (*b*=-0.14, *p*=0.05) (Table 2).

Effect sizes ranged from 0.00 to 0.25 and achieved power from 0.05 to 0.56 for gender in the full-case analyses and emotional functioning in the intention-to-treat analyses, respectively (Table 2).

Table 1. Participant characteristics at baseline

	Full-case analyses n = 146 [a]		Intention-to-treat analyses n = 179 [a]	
	Intervention group (*n* = 73)	Control group (*n* = 73)	Intervention group (*n* = 88)	Control group (*n* = 91)
Age				
Years (mean (SD))	59.5 (8)	59.9 (9)	60.1 (10)	60.7 (10)
Gender (no. (%))				
Male	53 (73)	55 (75)	62 (70)	64 (70)
Female	20 (27)	18 (25)	26 (30)	27 (30)
Educational level (no. (%))				
Low	32 (44)	33 (45)	37 (42)	37 (41)
Middle	26 (36)	29 (40)	32 (36)	41 (45)
High	15 (21)	11 (15)	19 (22)	13 (14)
Marital status (no. (%))				
Married/living together	54 (74)	53 (73)	63 (71.6)	67 (74)
Single	19 (26)	20 (27)	25 (28.4)	24 (26)
Employment status (no. (%))				
Employed	25 (34)	30 (41)	31 (35)	34 (37)
Not employed	23 (32)	25 (34)	29 (33)	34 (37)
Retired	16 (22)	17 (23)	19 (22)	21 (23)
Unknown	9 (12)	1 (1)	9 (10)	2 (2)
Tumor site (no. (%))				
Oral cavity & oropharynx	46 (63)	48 (66)	57 (65)	61 (67)
Hypopharynx & larynx	27 (37)	25 (34)	31 (35)	29 (32)
Unknown primary	-	-	-	1 (1)
Tumor stage [b] (no. (%))				
I-II	43 (59)	47 (64)	51 (58)	55 (60)
III-IV	30 (41)	26 (36)	37 (42)	36 (40)
Type of treatment (no. (%))				
Surgery	17 (23)	26 (36)	22 (25)	29 (32)
Radiotherapy	21 (29)	21 (29)	25 (28)	24 (26)
Chemoradiation	11 (15)	8 (11)	12 (14)	12 (13)
Combination	24 (33)	18 (25)	29 (33)	26 (29)
Smoking (no. (%))				
Yes	29 (40)	33 (45)	33 (38)	37 (41)
No	44 (60)	40 (55)	55 (63)	54 (59)
Daily drinking (no. (%))				
Yes	26 (36)	22 (30)	27 (31)	27 (30)
No	47 (64)	51 (70)	61 (69)	64 (70)
Coping strategy (mean (s.d.)) [c,d]				
Task oriented	18 (6)	18 (5)	18 (6)	17 (5)
Emotion oriented	12 (5)	13 (5)	12 (5)	13 (5)
Avoidance	12 (5)	12 (3)	12 (5)	12 (3)

Table 1. (continued)

	Full-case analyses n = 146 [a]		Intention-to-treat analyses n = 179 [a]	
	Intervention group (*n* = 73)	**Control group (*n* = 73)**	**Intervention group (*n* = 88)**	**Control group (*n* = 91)**
Social support (mean (SD)) [c, d]	2.9 (.6)	2.6 (.5)	2.9 (.6)	2.7 (.5)
Global quality of life (mean (SD))	68 (23)	68 (22)	67 (23)	66 (23)
Physical functioning (mean (SD))	84 (19)	88 (16)	84 (16)	87 (18)
Role functioning (mean (SD))	76 (28)	78 (29)	76 (28)	78 (29)
Emotional functioning (mean (SD))	64 (25)	67 (25)	65 (25)	67 (23)
Cognitive functioning (mean (SD)) [d]	82 (22)	85 (21)	84 (22)	84 (22)
Social functioning (mean (SD))	82 (23)	84 (21)	83 (22)	83 (21)
Pain (mean (SD))	35 (26)	32 (25)	36 (26)	31 (24)
Depressive symptoms (mean (SD)) [d]	12 (9)	13 (11)	13 (9)	13 (10)

SD standard deviation

[a] Data is given of participants who completed a minimum of 2 measurements (n=179)

[b] Tumor stage according to the TNM Classification of Malignant Tumors

[c] Incomplete baseline data for participants in full-case analyses: task-oriented coping (n=129), emotion-oriented coping (n=131), avoidance coping (n=132) and social support (n=137)

[d] Incomplete baseline data for participants in intention-to-treat analyses: task-oriented coping (n=154), emotion-oriented coping (n=157), avoidance coping (n=159), social support (n=165), cognitive functioning (n=178) and depressive symptoms (n=178)

Table 2. Potential moderators of the intervention effect in full-case analyses and intention-to-treat analyses

	BL – 12M					BL – 12M				
	Full case analyses (n=146)					Intention-to-treat analyses (n=179)				
Potential moderators	*P*	**CI 95%**	**Unstand. β**	**ES[c]**	**Power**	*P*	**CI 95%**	**Unstand. β**	**ES[c]**	**Power**
Demographic & clinical characteristics										
Age	0.28	-0.51 to 0.15	-0.18	0.005	0.14	0.55	-0.48 to 0.26	-0.11	0.005	0.16
Gender	0.79	-5.51 to 7.23	0.68	0.000	0.05	0.69	-4.94 to 7.50	1.28	0.001	0.07
Education				0.004	0.12				0.002	0.09
low vs middle	0.54	-8.19 to 4.33	-1.93			0.94	-6.87 to 6.38	-0.24		
low vs high	0.38	-11.65 to 4.49	-3.58			0.83	-9.85 to 7.91	-0.97		
Marital status	0.04*	-13.02 to -0.48	-6.75	0.019	0.38	0.08	-12.59 to 0.67	-5.96	0.018	0.43
Employment status				0.016	0.31				0.013	0.31
employed vs not employed[a]	0.11	-1.22 to 12.11	5.45			0.33	-3.70 to 10.86	-3.58		
employed vs retired[a]	0.12	-1.57 to 13.25	5.84			0.21	-3.06 to 13.59	5.27		
Tumor site	0.27	-2.58 to 9.14	3.28	0.005	0.14	0.61	-4.55 to 7.69	1.57	0.002	0.09
TNM status	0.68	-4.65 to 7.07	1.21	0.001	0.07	0.81	-5.37 to 6.88	0.75	0.001	0.07
Treatment				0.006	0.15				0.002	0.09
surgery vs radiotherapy	0.26	-3.14 to 11.73	4.30			0.83	-6.92 to 8.68	0.88		
surgery vs chemoradiation	0.52	-6.42 to 12.55	3.06			0.96	-9.95 to 10.43	0.24		
surgery vs combination	0.51	-5.07 to 10.22	2.58			1.00	-7.65 to 7.66	0.01		
Smoking	0.07	-.34 to 11.06	5.36	0.014	0.29	0.24	-2.42 to 9.59	3.59	0.007	0.20
Daily drinking	0.58	-7.75 to 4.36	-1.69	0.001	0.07	0.46	-8.84 to 3.97	-2.44	0.003	0.11
Coping strategy										
Task coping[b]	0.97	-0.52 to 0.55	0.01	0.000	0.05	0.92	-0.55 to 0.49	-0.03	0.001	0.07

Table 2. (continued)

	BL – 12M					BL – 12M				
	Full case analyses (n=146)					Intention-to-treat analyses (n=179)				
Potential moderators	*P*	**CI 95%**	**Unstand. β**	**ES [c]**	**Power**	*P*	**CI 95%**	**Unstand. β**	**ES [c]**	**Power**
Coping strategy										
Emotion coping [b]	0.20	-0.21 to 0.97	0.38	0.008	0.17	0.28	-0.30 to 1.01	0.36	0.007	0.20
Avoidance coping [b]	0.60	-0.57 to 0.99	0.21	0.001	0.07	0.76	-0.67 to 0.93	0.13	0.002	0.09
Social support[2]	0.06	-10.94 to 0.24	-5.35	0.016	0.31	0.54	-7.95 to 4.17	-1.89	0.004	0.13
EORTC-QLQ-C30 & H&N35 variabels										
Global quality of life	0.03*	-0.26 to -0.02	-0.14	0.021	0.41	0.05	-0.28 to 0.00	-0.14	0.024	0.54
Physical functioning	0.55	-0.21 to 0.11	-0.05	0.001	0.07	0.50	-0.23 to 0.11	-0.06	0.003	0.11
Role functioning	0.24	-0.16 to 0.04	-0.06	0.005	0.14	0.26	-0.16 to 0.05	-0.06	0.007	0.20
Emotional functioning	0.02*	-0.25 to -0.02	-0.14	0.024	0.46	0.02*	-0.26 to -0.02	-0.14	0.025	0.56
Cognitive functioning	0.18	-0.22 to 0.04	-0.09	0.007	0.17	0.32	-0.20 to 0.07	-0.07	0.004	0.13
Social functioning	0.04*	-0.26 to -0.01	-0.13	0.018	0.36	0.03*	-0.27 to -0.02	-0.15	0.022	0.51
Pain	0.31	-0.06 to 0.17	0.06	0.004	0.12	0.18	-0.04 to -0.20	0.08	0.010	0.27

BL baseline measurement, *CI* confidence interval, *Unstand.* β unstandardized beta, *ES* effect size

* *p* value is < 0.05

[a] Patients whose employment status was unknown were not included in analyses

[b] Incomplete data in full-case analyses: task-oriented coping (n=129), emotion-oriented coping (n=131), avoidance coping (n=132) and social support (n=137)

[c] Cohen's (1988) cut off points were used to indicate a small (ES = 0.02), medium (ES = 0.15) or large (ES = 0.35) effect

Post-hoc probing analyses revealed a significant group difference in marital status in favor of patients who were married or living together (*b*=-4.25, *p*=0.01) compared to patients who were single. Furthermore, patients with low (-1SD) baseline scores on global QoL (*b*=-5.65, *p*=0.01), emotional functioning (*b*=-5.99, *p*=0.00) and social functioning (*b*=-5.41, *p*=0.01) differed significantly from patients with mean or high (+1SD) baseline scores (Table 3). This indicates that patients who were married or living together, and patients with low baseline scores on global QoL, emotional functioning and social functioning responded better to the NUCAI than patients who were single or had mean or high baseline scores. Regression lines for each relationship between group (control vs NUCAI) and depressive symptom score at 12 months post-cancer treatment as moderated by marital status , global QoL, emotional functioning or social functioning are given in Figure 1. Age, gender, educational level, employment status, tumor stage, type of treatment, smoking, daily drinking, task-, emotion- and avoidance coping, social support, physical functioning, pain, tumor site, role functioning, and cognitive functioning did not moderate the effect of the NUCAI on depressive symptoms 12-months post treatment.

Table 3. Post hoc probing of the significant moderators

		Moderator baseline value	*P*	95 % CI	B value
Marital status	Married / living together	-	0.01*	-7.49 to -1.01	-4.25
	Single	-	0.36	-2.86 to 7.86	2.50
Global quality of life	- 1 SD	45.52	0.01*	-9.61 to -1.70	-5.65
	mean	68.26	0.08	-5.25 to 0.31	-2.47
	+ 1 SD	91.01	0.72	-3.23 to 4.65	0.71
Emotional functioning	- 1 SD	40.30	0.00*	-9.96 to -2.01	-5.99
	mean	65.26	0.07	-5.38 to 0.20	-2.59
	+ 1 SD	90.22	0.69	-3.12 to 4.73	0.80
Social functioning	- 1 SD	60.70	0.01*	-9.39 to -1.44	-5.41
	mean	83.11	0.08	-5.26 to 0.32	-2.47
	+ 1 SD	100	0.89	-3.75 to 3.25	-0.25

Analyses were performed in the full-case group (n=146)
CI confidence interval, β beta, *SD* standard deviation
* *p* value is <0.05

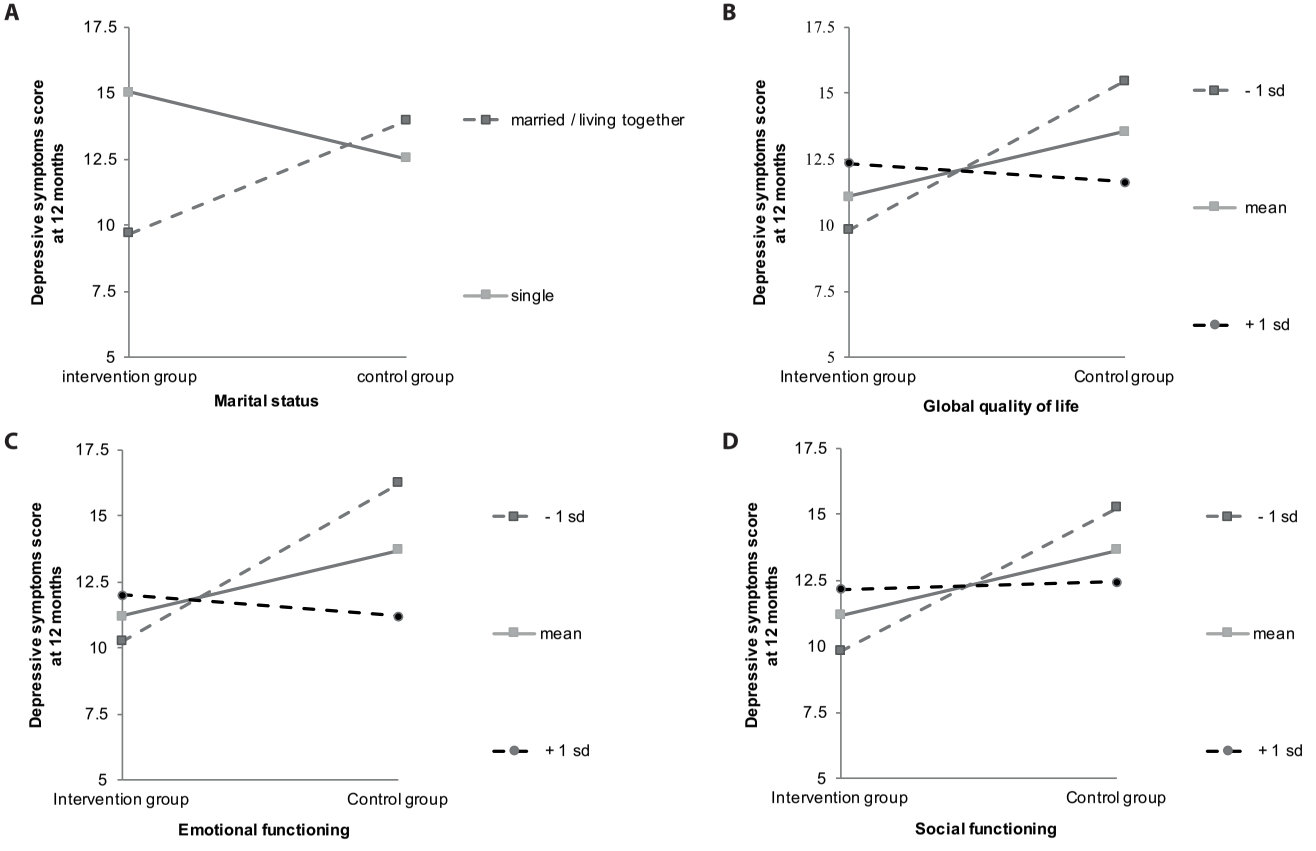

Figure 1. Regression lines for the relationship between group (intervention vs control) and depressive symptom score at 12 months post cancer treatment, as moderated by marital status (part **a**), global quality of life (part **b**), emotional functioning (part **c**) or social functioning (part **d**).

Discussion

The present study investigated moderators of the response to a nurse-led psychosocial intervention, the Nurse Counseling and After Intervention (NUCAI). The NUCAI has been found to decrease depressive symptoms 1 year after treatment of head and neck cancer [11]. In this secondary analysis, we found that patients who were married/living together, had low baseline scores on global QoL, emotional- or social functioning benefitted more of the NUCAI, resulting in lower depressive symptom scores 12 months post treatment, than patients who were single or had mean or high baseline scores on global QoL, emotional- or social functioning.

Patients with low baseline scores for emotional functioning showed a statistical significant improvement of almost 6 points on the depressive symptoms scale. Although a minimal clinically important difference of the CES-D is not yet established, we considered this difference as clinical significant, according to Norman et al. who showed that a change of half a standard deviation indicates a clinical relevant difference [47]. Only one study was found in the literature that explored the moderating effect of emotions in patients with cancer. Manne et al. [28] showed, in a large RCT involving women with gynecological cancer, that women who were more expressive of positive emotions benefitted more from a supportive counseling intervention than women who were less expressive of positive emotions. Results for negative emotions were not computed because of the low internal consistency of the data. Our results are inconsistent with those of Manne et al. [28], which could be due to the different types of cancer studied and the gender of the participants (solely women versus 70% men in our study). In addition, Gamper et al. [48] recently defined emotional functioning as a variable that covers aspects of anxiety, depression and general distress, which is much broader than expression of emotions alone.

We also found that patients with head and neck cancer who had low scores for social functioning at baseline responded statistically and clinically significantly better, with a decrease of 5.4 points on the depressive symptoms scale, to the NUCAI than patients with high scores for social functioning. Balderson et al. [27] reported that social/family well-being was related to lower psychological distress in patients with prostate cancer, which is in line with our results.

The full-case analyses showed that patients who were married/living together had fewer depressive symptoms (a decrease of 4.3 points) 1 year after cancer treatment than patients who were single and thus benefited more from the NUCAI. The intention-to-treat analyses showed the same trend. It should be mentioned that, with the NUCAI,

patients are encouraged to bring their partners to intervention sessions. Mikoshiba et al. [19] found that living alone was associated with an increased likelihood of depressive symptoms in patients with liver cancer. Perhaps if a partner follows the intervention with the patient, he/she can discuss the intervention with the patient at home and might stimulate and support the patient.

A poorer global QoL at baseline was also found to be a moderator of the effect of the NUCAI in both the full-case and intention-to-treat analyses, with patients with a worse global QoL at baseline responding better (a decrease of 6.7 points on the depressive symptoms scale) to treatment than patients with a better global QoL. While we did not find any articles in the literature that expressly investigated this, several studies have shown that higher depressive symptom scores or depression are related to a lower global QoL in cancer patients [19,25,26]. Overall, no significant improvements were found for patients who had high (+1SD) global QoL, emotional functioning and social functioning scores. The CES-D is found to be sensitive to changes in depressive symptoms after intervention [49], however, it could be that these patients with high scores had little room to improve and therefore only minor changes in depressive symptoms could be established. This should be considered when offering the NUCAI to patients.

Other studies have shown that social demographic variables (age, gender, educational level, working status), disease-related variables (tumor stage, type of treatment) or health behavior-related variables (smoking, drinking) are related to increased levels of depressive symptoms [13,14,16-19]. We did not find these variables to moderate the response to the NUCAI. The NUCAI is patient driven and it is possible that the nurses personalized the intervention on the basis of these variables, thereby providing a tailored intervention. Overall, there is no evidence at this point that clinical variables should be used when selecting patients with head and neck cancer for a psychosocial intervention. Hence, the NUCAI seems to be of most benefit for head and neck cancer patients who have poor scores on emotional functioning, social functioning, and global QoL. In addition, patients who are single should be given extra attention and should be encouraged to bring a relative or friend to the intervention sessions.

Interestingly, the European Organisation for Research and Treatment of Cancer (EORTC) is developing a computerized adaptive testing measure based on an item bank for, among others, emotional functioning, to be used as a screening tool in cancer patients [48]. This extensive project is in its last phase and seems to be promising for future screening possibilities and could be extended with the other moderators found in this study.

Our findings represent a first step to distinguishing between patients with head and neck cancer who might or might not benefit from a psychosocial intervention. However, the results are secondary analyses and the following limitations should be considered when interpreting outcome. First, this study was not powered for moderator analyses but for the efficacy of the intervention. The effect sizes of the significant moderators varied between 0.018 and 0.024 which is considered to be a small effect [44]. In addition, the power varied between 0.36 and 0.46 which implicate that a larger sample size is needed to detect a relationship between the moderator and the intervention effect without committing a type II error. In addition, because of the explorative nature of the study, the p-values were not adjusted for multiple testing. Lastly, not all the variables that are associated with depressive symptoms could be incorporated in the analyses because they were not measured in the NUCAI study.

In conclusion, little is known about the variables that moderate the response to a psychosocial intervention in head and neck cancer patients. Analyses showed that patients who had poor scores for emotional functioning, social functioning, and global QoL at baseline and who were married or living together benefitted more from the NUCAI than patients with high scores and who were single. We suggest that the screening of patients with head and neck cancer for eligibility for a psychosocial intervention should be based on patients' global QoL and emotional and social functioning, with extra attention being paid to patients who are single. Because of the explorative nature of this study further, well powered, research is necessary to replicate our results and to provide personalized patient care, so that available resources (time, staff, and money) can be used in the best possible way.

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5

The utilization of a Distress Thermometer intervention to improve depressive symptoms and health related quality of life in head and neck cancer patients

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Abstract

Objectives: This study investigated the feasibility of the DT&PL+ intervention and the effect on depressive symptoms, health-related quality of life (HRQoL) and worry of cancer, in head and neck cancer (HNC) patients.

Design: Two-arm randomized controlled trial.

Setting: Outpatient clinic of an university hospital.

Sample: 110 HNC patients.

Methods: Patients were randomized to care as usual (n=57) or the DT&PL+ intervention (n=53) consisting of screening with the Distress Thermometer and Problem List plus nurse-guided follow-up lasting about 20 minutes, three to four times in the 12 months following inclusion. Intention-to-treat analysis was performed using linear mixed models with outcomes at 6 months and 12 months and baseline adjustment.

Main Research Variables: Depressive symptoms (primary outcome), HRQoL and worry of cancer.

Findings: The intervention showed moderate compliance and acceptable session duration. Intervention participants were satisfied with nurses' care. Depressive symptoms, HRQoL and worry of cancer were not significantly different in the two treatment groups (all $p>0.05$).

Conclusion:. The DT&PL+ intervention seemed feasible in clinical practice but more effort is needed to achieve optimal implementation. No effect on patient outcomes could be shown.

Implications for Nursing: Trained nurses have the necessary skills to deliver the DT&PL+ intervention and patients appreciate the opportunity to discuss their problems with them.

Knowledge Translation: Psychosocial care is an essential component of the HNC patients' aftercare. The DT&PL+ intervention is relatively short and feasible to implement in daily clinical practice; however, at the moment it does not seem to improve patient outcomes.

Introduction

Dependent on the location of the tumor and the type of treatment, patients with head and neck cancer (HNC) will have visible disfigurement, physical dysfunction, and psychological problems [1-3]. Many HNC patients experience considerable distress, defined as 'a multifactorial unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social, and/or spiritual nature that may interfere with the ability to cope with cancer, its physical symptoms and its treatment' [4]. Worldwide, between 35% and 41% of HNC patients experience high levels of distress [5,6]; the prevalence of distress is 29% among Dutch HNC patients [7]. These patients often have a poor quality of life [5,8,9]. Screening for distress is becoming a standard component of post-treatment care, and a commonly used instrument for this is the Distress Thermometer (DT), often combined with the Problem List (PL) [10,11]. The DT is a visual analogue scale to rate emotional distress and the PL assesses practical, family, and social, emotional, religious or spiritual, and physical problems. The National Comprehensive Cancer Network guideline on distress management recommended that the DT should be used in conjunction with the PL [4].

However, the overall effectiveness of screening for distress is debated. There have been few rigorously designed studies and various screening tools and implementation methods have been used. While it is assumed that screening improves communication between patient and healthcare provider [12], there is no conclusive evidence that screening alone improves recognition of problems and treatment of distress [13]. Screening for distress alone is not enough [14] and may even increase anxiety if nothing is done as a consequence of the screening [15,16]. Screening needs to be followed by support and/or referral [17], which might also improve the acceptability of screening [18].

The aim of this study was to investigate the feasibility of screening with the DT&PL+ combined with short nurse-guided follow-up session and the effectiveness on depressive symptoms (primary outcome), health-related quality of life (HRQoL), and worry about cancer in patients with HNC. We hypothesized that, 1 year after inclusion, HNC patients in the intervention group would exhibit fewer depressive symptoms, better HRQoL, fewer physical symptoms, and worry less about cancer than HNC patients in a control group.

Methods

Design and sample

To study the feasibility of the DT&PL+ intervention and its effect on depressive symptoms, HRQoL and worry of cancer in patients with HNC, we carried out a two-arm randomized controlled trial over 6 months. All patients who visited the outpatient clinic of oral maxillofacial surgery and otorhinolaryngology of the University Medical Center Utrecht, the Netherlands before and up to 6 months after cancer treatment were enrolled by the physician between April 2012 and September 2012. The study was performed preceding the implementation of nurse-guided follow-up as standard care at the outpatient clinic from October 2012 onwards. Inclusion criteria were diagnosis of squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, or larynx; ability to complete questionnaires in Dutch; and ability to participate in the intervention. Each patient received verbal and written information about the study. After giving their informed consent, participants were randomized to the DT&PL+ intervention or care as usual using a block procedure, stratified by gender, cancer site (oral/oropharyngeal cancer versus hypopharyngeal/laryngeal cancer) and treatment status (new patients, 0–3 months after cancer treatment, and 4–6 months after cancer treatment).

All participants were asked to complete questionnaires at baseline (i.e., 0–6 months after cancer treatment) (M1), 6 months (M2), and 12 months (M3) after baseline. Participants received the questionnaires at home and returned them using a prepaid return envelope. The study was reviewed and registered by the medical ethics committee of the University Medical Center Utrecht, under number 12-029/C. Participants could withdraw their consent at any time without giving a reason.

Care as usual

Patients received care provided by their HNC specialist or physician at 2-month intervals in the first year after cancer treatment and at 3-month intervals in the second year. The 10-minute appointments were primarily aimed at the treatment of complications and the detection of recurrences or secondary primary tumors. No formal time was reserved to discuss the patients' psychosocial concerns. However, if the patient was considered to be in need of psychosocial support, the HNC specialist could refer the patient to psychosocial care.

Intervention

The DT&PL+ intervention is a screening for distress combined with a short nurse-guided follow-up to identify distress in HNC patients, with a view to providing immediate support, advice, information, or referral if necessary. The DT measures the severity of distress on a 0 to 10 visual analogue scale, the thermometer. The DT has been validated and is sensitive (0.85) and specific (0.67) in Dutch cancer patients, including HNC patients [19]. A score of 5 or higher is considered as an elevated distress score [19]. The DT is used in conjunction with the Problem List (PL), which assesses (47 items) practical, family, and social, emotional, religious or spiritual, and physical problems (Appendix 1). The patient can tick whichever problem they experience. The PL has been validated and shows a good internal consistency (Cronbach's alpha 0.90) [19]. At the end of the PL, there is a question 'Would you like to talk to a professional about your problems?', which can be answered with yes/maybe/no.

The intervention consisted of three to four sessions of 20 minutes during 1 year. An intervention session contains three components. First, the patient completes the DT&PL+ at home and brings the filled DT&PL+ to the outpatient clinic. Second, the patient has an appointment with a trained nurse directly after his/her medical appointment with the HNC specialist at the outpatient clinic and the outcome of the DT&PL+ is discussed and problems are identified. Third, if indicated, basic psychosocial care, minor nursing interventions or referral to other health care providers or patient program was arranged. Basic psychosocial care encompasses providing education about the disease and its treatment, providing emotional support, attempting to resolve symptoms and complaints, providing support with regard to making decisions about treatment possibilities, and arranging referral based on observed problems. Minor nursing interventions are for example, prescribing mouth gel or giving advice about supplementary feeding. The outcome of the DT&PL+, important details, and the care provided were reported in the patients' medical record. Family or significant others were encouraged to join the sessions and were involved in the discussion and information provision.

Before the start of the study, six oncology nurses received a 3-hour training, including theoretical background, process details, and role-playing. In addition, periodic consultation sessions were organized to discuss difficulties and to ensure that the intervention was offered in a uniform manner.

Measures

The primary outcome, depressive symptoms, was measured with the Center for Epidemiological Studies – Depression scale (CES-D) [20,21].This 20-item self-report questionnaire gives a total score ranging from 0 to 60 [22]. A high score reflects a high level of depression. A cut-off score of 16 or higher is regarded as being indicative of clinical depression. The CES-D has good psychometric properties in cancer populations [23,24] including HNC patients [25,26].

HRQoL was measured with the Quality of Life Core Questionnaire version 3.0 (QLQ – C30) [27] of the European Organization for Research and Treatment of Cancer (EORTC) and the tumor specific EORTC Head and Neck module (QLQ-H&N35) [28]. The EORTC-C30 is widely used and has been validated for many types of cancer including HNC. Both are widely used and have good psychometric properties [29,30]. The instruments use a score scale 0–100, where a high score reflects a high level of functioning or a high level of symptoms or problems.

Worry of cancer recurrence was measured with the Worry of Cancer Scale [31]. This questionnaire contains 4 items, scored 0–10, with a high score reflecting a high level of concern. The scale has been validated in breast cancer patients [31].

Patient satisfaction with the intervention was measured with a modified version of the EORTC- IN PATSAT 32 [32] and the CQ-index questionnaire 'Care for cancer patients, experiences of cancer patients with hospital care' version 2.0 [33]. Nine topics were rated on a 5-point Likert scale (poor, moderate, good, very good, excellent).

DT&PL+ outcomes were registered in the patient record by the nurses who delivered the intervention. The nurses also documented the content of the intervention, that is, the duration of each appointment, presence of family or significant others, topics discussed, advice and/or intervention given, and referral.

Lastly, information was collected about age, gender, educational level, and social status by means of self-report questionnaires. Information about the type of cancer, tumor stage, and type of treatment was obtained from the medical records.

Sample size calculation

The number of patients to be approached was based on the expected change in CES-D scores after 1 year. In our previous study [34] investigating the effect of a nurse-led psychosocial intervention in HNC patients, a significant difference ($p<0.05$) of 2.9 points (SD 10.0) in depressive symptoms was found in favor of the

intervention group compared with the control group. This difference corresponds with an effect size of 0.29. Using a two-sided t-test with an alpha of 0.05 and a power of 80%, a sample size of 144 patients per group was considered appropriate. Since the mixed model analysis used in the present study was adjusted for baseline CES-D values, the correlation (ρ) of 0.54 between the baseline and follow-up CES-D scores found in our previous study [34] was taken into account in the sample size calculation. Therefore the number of subjects was multiplied by ($1- \rho^2$), plus one extra patient per group [35], giving a final sample size of 103 patients per group (($(1-.54^2) \times 144 +1$). On the basis of our previous studies [34,36], we expected that 70% of eligible patients would be included. Therefore, at least 288 patients were approached.

Statistical analysis

The effect of the DT&PL+ intervention was assessed on an intention-to-treat basis, using a linear mixed model. The model for the between-group analysis contained depressive symptoms at 6 and 12 months as dependent variables. Measurement and group (intervention versus control) were entered as independent variables and baseline depressive symptom score as covariate. All participants who had completed at least the 6 and/or 12-month assessments were included in the between-group analysis. The model for the within-group analysis followed the same structure; however, no covariate was used and all participants who completed at least the baseline assessment were included. Primary outcomes were the between-group differences at 12 months. Two-sided significant tests were used ($\alpha<0.05$). Statistical analyses were performed using SPSS software version 23.

Results

Sample

In 6 months, 213 patients were invited to participate in the study, of whom 110 (51.6%) were enrolled. The majority of the 103 patients who declined gave as main reason that they felt no need to participate (37.8%). Other reasons are shown in Figure 1. Patients who declined were significantly ($p<0.05$) older, more often had TNM status I–II, and were more often recruited in the first 3 months after the end of treatment (data not shown). Included participants had a mean age of 63.5 (SD 11.4) years, were mainly male (74.5%), and were married or living together (77.3%). The baseline characteristics of patients in the intervention and control groups were comparable (Table 1).

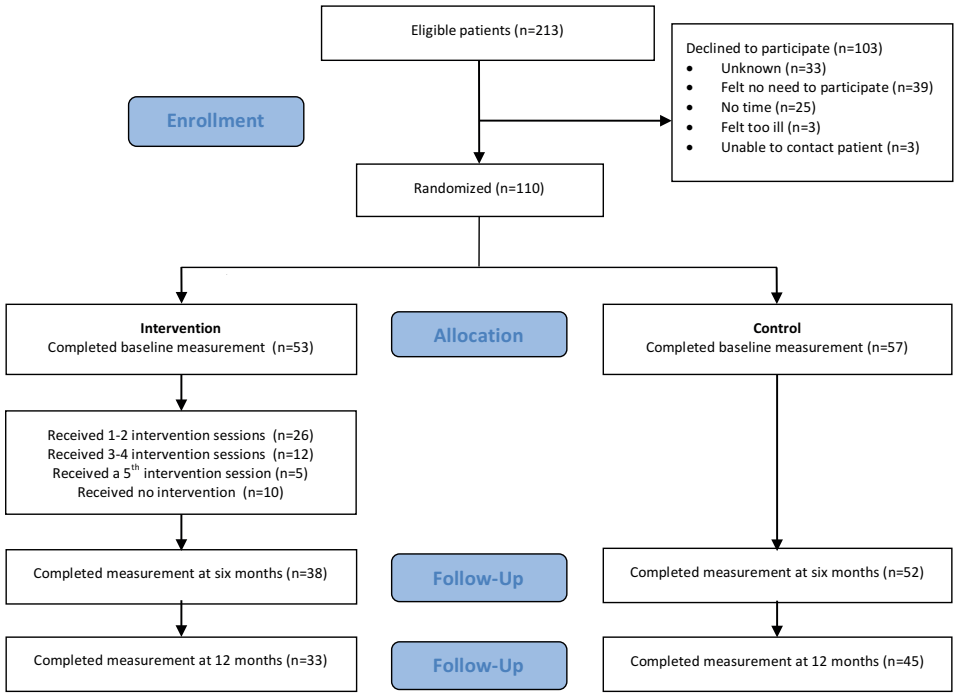

Figure 1. CONSORT Flow Diagram

Significant differences ($p<0.05$) were found between the 35 (31.8%) participants who were lost to follow-up and the 75 (68.2%) participants who completed the study. Participants who were lost to follow-up had a higher level of depressive symptoms, a lower HRQoL, and lower scores on all EORTC-C30 functioning scales at baseline. In addition, these participants had more problems on all EORTC-C30 and H&N35 problem scales (except for insomnia, loss of appetite, constipation, diarrhea, sexuality, and teeth). They were also more often not employed and were more often included in the intervention group (data not shown). During the study period, two participants in the intervention group and four participants in the control group visited a psychologist.

Table 1. Baseline characteristics of the participation head and neck cancer patients.

	Intervention group (*n*=53)		**Control group (*n*=57)**	
	Mean	**SD**	**Mean**	**SD**
Age (years)	62.4	11.5	64.5	11.3
	n	**%**	**n**	**%**
Gender				
Male	40	75.5	42	73.7
Female	13	24.5	15	26.3
Educational level				
Low	25	47.2	17	29.8
Middle	20	37.7	26	45.6
High	8	15.1	14	24.6
Marital status				
Married/living together	39	73.6	43	80.7
Single	14	26.4	9	19.3
Employment status				
Employed	18	34.0	16	33.3
Not employed	19	35.8	15	29.8
Retired	16	30.2	20	36.8
Tumor site				
Oral cavity & oropharynx	37	69.8	38	75.4
Hypopharynx & larynx	16	30.2	14	24.6
Tumor stage[a]				
I-II	33	62.3	37	70.2
III-IV	20	37.7	15	29.8
Type of treatment				
Surgery	14	26.4	14	26.3
Radiotherapy	20	37.7	19	36.8
Chemoradiation	7	13.2	3	5.3
Combination	12	22.6	16	31.6
Smoking				
Yes	11	20.8	10	21.1
No	42	79.2	42	78.9
Daily drinking				
Yes	12	22.6	9	19.3
No	41	77.4	43	80.7
Comorbidity				
Yes	31	58.5	24	49.1
No	22	41.5	28	50.9

Data is given of participants who completed a least the first and second measurement (n=110)
[a]Tumor stage according to the TNM Classification of Malignant Tumors

Intervention

Of the 53 participants allocated to the intervention group, 26 (49%) received 1–2 sessions, 12 (23%) received 3–4 sessions, and 5 (9%) received 5 sessions. Ten participants (19%) received no intervention, due to administrative errors (n=7), failure to show (n=2), or severe illness (n=1).

The mean DT score remained relatively stable over time with a score of 3.8 at the start and 3.7 at session 4. On average, one third of the participants in the intervention group reported every session a DT score of 5 or higher. Emotional problems were reported by 40–60% of participants, most often tension/nervousness. Physical problems were reported by 64–90%, most often eating and mouth sores, and 24–41% percent reported other problems. Of the patients who reported one or more problems, 3–21% wanted to talk with an expert. More information and details are given in Table 2. The first session took on average 16.5 minutes, whereas session 4 took on average 12.2 minutes. Family or significant others were present in 17–49% of the sessions. Most discussed topics were physical problems (13–59%) and family or social problems (30–41%). Nurses provided information (14–33%) and gave advice on oral hygiene (8–17%). Referral to a psychologist (8%) or social worker (3–17%) was suggested (Table 3). In general, participants in the intervention group were satisfied (scoring good, very good, or excellent) with the nurses' knowledge; attention paid to physical, emotional and social problems; personal attention; support and information received; human qualities; and duration of the conversation. On average, the nurses received (on a 1–10 scale) a score of 7.9 (SD 2.2) and 7.6 (SD 1.6) at M2 and M3, respectively.

Group comparisons

In general, no significant between-group differences were found in depressive symptoms at 6 and 12 months (Table 4). Of all the EORTC QLQ- C30 and EORTC QLQ-H&N35 items, the variable pain at 6 months and speech at 12 months showed a significant difference between groups in favor of the control group [MD 10.2; 95% CI 0.9 to 19.5; ES 0.40] and [MD 11.3; CI 3.5 to 19.1; ES 0.55], respectively. While the pain score remained at the same level in the intervention group [MD -0.7; CI-8.4 to 6.9], it decreased in the control group (MD -9.7; CI -16.5 to -3.0]. Likewise, the speech score in the intervention group remained the same [MD -0.9; CI -7.5 to 5.6] and decreased in the control group [MD -11.8; CI -17.6 to -6.0]. No significant between-group differences were found with regard to worry about cancer at both time points (Table 4).

Table 2. Outcome Distress Thermometer and Problem List

	Session 1 (n=43)				Session 2 (n=33)				Session 3 (n=17)				Session 4 (n=10)			
	Mean	**(SD)**	**n[b]**	**(%)**	**Mean**	**(SD)**	**n[b]**	**(%)**	**Mean**	**(SD)**	**n[b]**	**(%)**	**Mean**	**(SD)**	**n[b]**	**(%)**
Distress thermometer score	3.6	(2.4)			3.4	(2.4)			2.8	(1.8)			3.7	(2.3)		
No. of Distress thermometer score ≥ 5.0			15	(35)			8	(24)			5	(29)			4	(40)
Distress thermometer score	6.3	(1.4)			6.6	(1.7)			5	(0)			6	(1.2)		
Any emotional problem[a]			26	(60)			14	(42)			8	(47)			4	(40)
No. of emotional problems	2.4	(2.7)			1.2	(1.6)			1.5	(2.1)			1.7	(2.9)		
Most frequent emotional problem																
tension/nervousness			20	(47)			8	(24)			5	(29)			4	(40)
keeping emotions under control			17	(40)			5	(15)			4	(24)			1	(10)
self confidence			13	(30)			6	(18)			2	(12)			2	(20)
fears			13	(30)			8	(24)			3	(18)			3	(30)
depression			11	(26)			3	(9)			4	(24)			2	(20)
Any physical problem[a]			36	(84)			22	(64)			14	(82)			9	(90)
No. of physical problems	5.4	(4.6)			2.9	(3.4)			3.8	(4.1)			6	(5.2)		
Most frequent physical problem																
eating			22	(51)			8	(24)			7	(21)			5	(50)
mouth sores			21	(49)			13	(39)			8	(24)			6	(60)
condition			20	(47)			8	(24)			7	(21)			7	(70)
fatigue			20	(47)			3	(9)			6	(18)			6	(60)
weight change			16	(37)			7	(21)			4	(12)			4	(40)
muscle strength			15	(35)			5	(15)			5	(15)			6	(60)

Table 2. (continued)

	Session 1 (n=43)				Session 2 (n=33)				Session 3 (n=17)				Session 4 (n=10)			
	Mean	**(SD)**	**n[b]**	**(%)**	**Mean**	**(SD)**	**n[b]**	**(%)**	**Mean**	**(SD)**	**n[b]**	**(%)**	**Mean**	**(SD)**	**n[b]**	**(%)**
pain			14	(33)			7	(21)			5	(15)			6	(60)
speech/talking			14	(33)			9	(27)			5	(15)			7	(70)
taste			12	(28)			5	(15)			1	(3)			5	(50)
Any other problem[a]			16	(37)			8	(24)			7	(41)			3	(30)
No. of other problems	0.9	(1.5)			0.5	(1.1)			0.9	(1.3)			0.7	(1.3)		
Most frequent other problem																
transportation			6	(14)			3	(9)			3	(17)			2	(20)
financial			5	(12)			2	(6)			3	(17)			2	(20)
meaning of life			6	(14)			1	(3)			0	(0)			0	(0)
Want to talk with an expert?																
yes			9	(21)			2	(6)			1	(3)			2	(20)
maybe			4	(9)			5	(15)			4	(12)			1	(10)

[a]Number of participants who reported at least one problem.
[b] Number and percentage are calculated over the number of participants who reported at least one problem.
NB: Five participants received a fifth session (data not shown).

Table 3. DT&PL+ intervention details[1]

	Session 1 n=37	Session 2 n=32	Session 3 n=15	Session 4 n=6
	Mean (SD) range	**Mean (SD) range**	**Mean (SD) range**	**Mean (SD) range**
Duration session (minutes)	16.5 (8.8) 5 - 30	13.0 (6.3) 5 - 25	14.1 (6.6) 5 - 30	12.2 (7.4) 3 - 20
	No (%)	No (%)	No (%)	No (%)
Presence family or significant others	18 (49)	14 (44)	6 (40)	1 (17)
Topics discussed				
physical problems	22 (59)	19 (59)	2 (13)	3 (50)
family / social problems	11 (30)	13 (41)	6 (40)	-
emotional problems	8 (22)	10 (31)	5 (33)	1 (17)
general wellbeing / coping situation	8 (22)	10 (31)	1 (7)	1(17)
treatment / reconstructive surgery	5 (14)	5 (16)	5 (33)	1(17)
work / financial situation	4 (11)	7 (22)	2 (13)	-
other[2]	10 (27)	10 (31)	5 (33)	4(67)
Nursing interventions				
providing information	5 (14)	4 (13)	2 (13)	2 (33)
advice mouth care / prescription mouth gel	3 (8)	1 (3)	-	1 (17)
providing information leaflets	2 (5)	1 (3)	2 (13)	2 (33)
giving advice supplementary feeding	1 (3)	1 (3)	1 (7)	-
Proposed referral				
psychologist	3 (8)	-	-	-
social worker	3 (8)	1 (3)	1 (7)	1 (17)
general practitioner	2 (5)	1 (3)	1 (7)	-
Other[3]	6 (16)	4 (13)	1 (7)	-

[1] Incomplete data due to missing or incomplete records.
[2] For example; concern of recurrence, leisure activities, DT-intervention, needing extra help.
[3] For example; dietitian, physiotherapist, dentist.
NB: Five participants received a fifth session (data not shown).

Table 4. The DT&PL+ intervention effect on depressive symptoms, health related quality of life and worry of cancer

		Baseline	Baseline to 6 months					Baseline to 12 months				
			Within-group difference		Between-group difference			Within-group difference		Between-group difference		
		Mean (SD)	Mean	[95 % CI]	Mean	[95 % CI]	ES	Mean	[95 % CI]	Mean	[95 % CI]	ES
CES-D												
Depressive symptoms	C	12.4 (8.8)	-1.6	[-0.3 to 0.3]		Reference		-1.5	[-3.5 to 0.5]		Reference	
	I	11.8 (8.6)	-0.3	[-2.5 to 1.9]	1.1	[-1.7 to 3.9]	0.14	0.4	[-1.9 to 2.6]	1.6	[-1.36 to 4.6]	0.08
EORTC QLQ-C30												
Global QoL	C	69.9 (18.4)	4.0	[-0.6 to 8.6]		Reference		3.3	[-1.6 to 8.2]		Reference	
	I	66.2 (20.0)	2.6	[-2.6 to 7.9]	-2.8	[-9.5 to 3.8]	-0.15	4.5	[-1.0 to 10.0]	-0.0	[-7.1 to 7.1]	0.00
Physical functioning	C	78.1 (20.1)	1.4	[-2.3 to 5.2]		Reference		1.0	[-2.9 to 5.0]		Reference	
	I	75.9 (19.8)	1.3	[-2.9 to 5.9]	-0.8	[-6.7 to 5.1]	-0.04	0.9	[-3.6 to 5.4]	-0.3	[-6.5 to 5.8]	-0.01
Role functioning	C	71.9 (27.3)	5.6	[-1.7 to 12.9]		Reference		7.1	[-0.6 to 14.8]		Reference	
	I	64.5 (31.0)	10.6	[2.4 to 19.8]*	0.2	[-9.9 to 10.3]	0.01	10.8	[2.1 to 19.5]*	0.7	[-9.8 to 11.2]	0.04
Emotional functioning	C	79.3 (20.3)	2.9	[-2.7 to 8.4]		Reference		2.6	[-3.2 to 8.5]		Reference	
	I	73.9 (27.4)	3.1	[-3.2 to 9.4]	-2.2	[-10.6 to 6.2]	-0.10	2.0	[-4.7 to 8.6]	-2.2	[-10.9 to 6.6]	-0.12
Cognitive functioning	C	88.3 (15.7)	-1.6	[-7.2 to 3.9]		Reference		-0.6	[-6.4 to 5.2]		Reference	
	I	78.6 (26.2)	2.3	[-3.9 to 8.6]	-1.5	[-9.7 to 6.7]	-0.08	3.6	[-3.0 to 10.2]	0.7	[-9.2 to 7.8]	0.04
Social functioning	C	75.1 (25.6)	7.8	[1.4 to 14.3]*		Reference		7.9	[1.0 to 14.7]*		Reference	
	I	78.6 (22.5)	2.7	[-4.6 to 10.1]	-3.2	[-11.6 to 5.2]	-0.13	2.6	[-5.1 to 10.4]	-3.3	[-12.2 to 5.7]	-0.16
Fatigue	C	35.9 (25.7)	-10.7	[-16.8 to -4.6]*		Reference		-11.8	[-18.2 to -5.3]*		Reference	
	I	41.9 (27.7)	-11.6	[-18.5 to -4.6]*	2.1	[-6.8 to 11.1]	0.08	-13.6	[-20.9 to 6.3]*	-0.2	[-9.1 to 9.5]	-0.01
Nausea or vomiting	C	8.5 (20.4)	-2.6	[-6.0 to 0.7]		Reference		-1.9	[-5.4 to 1.6]		Reference	
	I	8.5 (19.8)	-0.8	[-4.7 to 3.0]	2.0	[-3.1 to 7.1]	0.15	0.6	[-3.5 to 4.6]	2.2	[-3.1 to 7.6]	0.13

Table 4. (continued)

		Baseline	Baseline to 6 months					Baseline to 12 months				
			Within-group difference		Between-group difference			Within-group difference		Between-group difference		
		Mean (SD)	Mean	[95 % CI]	Mean	[95 % CI]	ES	Mean	[95 % CI]	Mean	[95 % CI]	ES
EORTC QLQ-C30												
Pain	C	23.4 (26.1)	-9.7	[-16.5 to -3.0]*		Reference		-10.8	[-17.9 to -3.6]*		Reference	
	I	25.5 (31.3)	-0.7	[-8.4 to 6.9]	10.2	[0.9 to 19.5]	0.40	-1.3	[-9.4 to 6.8]	8.8	[-0.8 to 18.3]	0.36
Dyspnoea	C	15.5 (24.6)	2.2	[-3.7 to 8.1]		Reference		3.7	[-2.5 to 10.0]		Reference	
	I	17.0 (26.7)	3.3	[-3.4 to 9.9]	1.8	[-7.0 to 10.3]	0.08	1.2	[-5.9 to 8.2]	-2.4	[-11.6 to 6.8]	-0.11
Insomnia	C	28.0 (32.9)	-4.4	[-11.5 to 2.6]		Reference		-4.1	[-11.5 to 3.3]		Reference	
	I	22.6 (32.5)	-0.9	[-8.8 to 7.0]	1.7	[-8.4 to 11.8]	0.06	-3.2	[-11.6 to 5.1]	-1.4	[-12.0 to 9.2]	-0.07
Appetite loss	C	23.8 (31.6)	-13.2	[-20.8 to -5.5]*		Reference		-12.9	[-20.6 to -4.4]*		Reference	
	I	24.8 (32.6)	-8.0	[-16.8 to 0.8]	4.4	[-4.8 to 13.7]	0.15	-5.6	[-14.8 to 3.5]	7.7	[-2.1 to 17.4]	0.35
Constipation	C	14.0 (22.7)	-4.6	[-10.6 to 1.4]		Reference		-4.9	[-11.2 to 1.5]		Reference	
	I	21.4 (30.7)	-6.7	[-13.5 to 0.1]	2.6	[-5.6 to 10.8]	0.11	-8.1	[-15.3 to -0.9]*	1.5	[-6.9 to 9.9]	0.08
Diarrhoea	C	7.6 (19.9)	-2.7	[-7.2 to 1.9]		Reference		-1.0	[-5.8 to 3.7]		Reference	
	I	9.4 (20.0)	0.2	[-4.9 to 5.3]	3.5	[-2.0 to 9.1]	0.23	-1.3	[-6.6 to 4.1]	0.8	[-4.9 to 6.6]	0.03
Financial difficulties	C	12.3 (25.7)	-0.9	[-6.4 to 4.6]		Reference		-4.5	[-10.3 to 1.4]		Reference	
	I	19.5 (28.1)	-4.5	[-10.7 to 1.7]	0.8	[-6.6 to 8.2]	0.03	-3.2	[-9.8 to 3.3]	5.3	[-2.4 to 13.0]	0.27
EORTC QLQ-H&N35												
Pain	C	30.7 (25.3)	-11.3	[-17.0 to -5.5]*		Reference		-14.6	[-20.7 to -8.5]*		Reference	
	I	30.0 (25.5)	-6.3	[-13.0 to 0.4]	4.4	[-3.1 to 11.9]	0.18	-7.5	[-14.4 to 0.5]*	6.6	[-1.3 to 14.4]	0.28
Swallowing	C	26.5 (23.6)	-9.0	[-15.8 to -2.2]*		Reference		-11.5	[-18.5 to -4.5]*		Reference	
	I	27.6 (26.7)	-13.3	[-20.9 to -5.7]*	-1.7	[-10.0 to 6.6]	-0.07	-8.7	[-16.8 to -0.6]*	2.3	[-6.3 to 10.8]	0.13

Table 4. (continued)

		Baseline	Baseline to 6 months					Baseline to 12 months				
			Within-group difference		Between-group difference			Within-group difference		Between-group difference		
		Mean (SD)	Mean	[95 % CI]	Mean	[95 % CI]	ES	Mean	[95 % CI]	Mean	[95 % CI]	ES
EORTC QLQ-H&N35												
Senses	C	23.7 (27.6)	-4.8	[-10.5 to 0.9]		Reference		-5.1	[-11.1 to 0.9]		Reference	
	I	19.2 (29.0)	-5.2	[-11.8 to 1.4]	-1.5	[-9.9 to 6.9]	-0.05	-3.8	[-10.7 to 3.1]	-1.1	[-9.8 to 7.7]	-0.06
Speech	C	25.2 (22.5)	-9.7	[-15.3 to -4.2]*		Reference		-11.8	[-17.6 to -6.0]*		Reference	
	I	28.2 (28.0)	-8.2	[-14.5 to -1.9]*	4.6	[-2.9 to 12.2]	0.18	-0.9	[-7.5 to 5.6]	11.3	[3.5 to 19.1]*	0.55
Social eating	C	27.5 (25.7)	-7.7	[-14.4 to -1.0]*		Reference		-10.6	[-17.6 to -3.7]*		Reference	
	I	29.6 (26.2)	-4.5	[-12.1 to 3.0]	5.7	[-3.6 to 14.9]	0.24	-3.2	[-11.1 to 4.7]	6.9	[-2.7 to 16.5]	0.33
Social contact	C	9.0 (12.5)	-0.0	[-3.7 to 3.6]		Reference		-1.0	[-4.9 to 2.8]		Reference	
	I	11.7 (15.8)	0.1	[-4.2 to 4.3]	1.7	[-4.1 to 7.5]	0.13	2.7	[-1.7 to 7.1]	3.5	[-2.4 to 9.5]	0.17
Sexuality	C	35.0 (31.5)	-6.3	[-14.2 to 2.7]		Reference		-4.9	[-14.2 to 4.5]		Reference	
	I	26.7 (33.5)	4.4	[-5.4 to 14.2]	6.7	[-5.6 to 19.1]	0.22	-4.6	[-15.0 to 5.9]	-2.8	[-16.0 to 10.4]	-0.12
Teeth	C	24.7 (37.9)	-6.5	[-14.9 to 1.8]		Reference		-1.4	[-10.3 to 7.6]		Reference	
	I	20.4 (29.5)	-0.2	[-9.6 to 9.2]	3.5	[-7.2 to 14.1]	0.11	-0.3	[-10.3 to -9.8]	-2.4	[-13.8 to 9.1]	-0.10
Opening mouth	C	29.8 (35.5)	-8.6	[-15.5 to -1.8]*		Reference		-4.8	[-11.9 to 2.4]		Reference	
	I	29.4 (33.8)	-3.7	[-11.7 to 4.2]	5.1	[-4.9 to 15.2]	0.15	-3.2	[-11.5 to 5.1]	1.7	[-8.7 to 12.0]	0.07
Dry mouth	C	45.0 (37.0)	-6.1	[-15.1 to 3.0]		Reference		-8.1	[-17.6 to 1.4]		Reference	
	I	48.7 (36.4)	-6.8	[-17.3 to 3.6]	1.4	[-11.0 to 13.8]	0.04	-9.2	[-20.1 to 1.7]	0.8	[-12.2 to 13.7]	0.04
Sticky saliva	C	38.0 (36.4)	-5.5	[-13.8 to 2.9]		Reference		-8.3	[-17.0 to 0.4]		Reference	
	I	41.0 (35.9)	-8.6	[-18.1 to 0.9]	-0.9	[-12.3 to 10.4]	-0.03	-8.5	[-18.5 to 1.4]	0.9	[-10.9 to 12.6]	0.05

Table 4. (continued)

		Baseline	Baseline to 6 months					Baseline to 12 months				
			Within-group difference		Between-group difference			Within-group difference		Between-group difference		
		Mean (SD)	Mean	[95 % CI]	Mean	[95 % CI]	ES	Mean	[95 % CI]	Mean	[95 % CI]	ES
EORTC QLQ-H&N35												
Coughing	C	32.2 (29.5)	-4.3	[-10.5 to 2.0]		Reference		-9.4	[-15.9 to -2.8]*		Reference	
	I	32.1 (30.2)	-3.3	[-10.5 to 3.9]	1.0	[-8.4 to 10.4]	0.04	-3.5	[-11.0 to 4.0]	6.7	[-3.1 to 16.4]	0.34
Felt ill	C	21.6 (24.8)	-6.9	[-14.4 to 0.7]		Reference		-11.4	[-19.1 to -3.6]*		Reference	
	I	23.7 (33.2)	-15.3	[-23.8 to -6.8]*	-6.9	[-15.7 to 1.9]	-0.26	-9.7	[-18.5 to 0.8]*	2.9	[-6.3 to 12.1]	0.20
WOCS												
Worry of cancer scale	C	4.0 (2.0)	0.1	[-0.3 to 0.6]		Reference		0.2	[-0.3 to 0.7]		Reference	
	I	4.0 (2.2)	0.4	[-0.1 to 0.9]	0.3	[-0.3 to 0.9]	0.15	0.2	[-0.3 to 0.7]	0.0	[-0.7 to 0.7]	0.0

SD standard deviation *CI* confidence interval *ES* effect size

* p-value is < 0.05

Baseline scores and within group differences were based on all patients who minimally completed the first measurement (n=110)

Between group effects were based on all patients who completed the first, second and/or third measurement (n=93).

A high score on Global QoL or functional scale represents a high level of QoL or functioning, whereas a high score on depressive symptoms or health related symptom scales represents the presence of a high level of (depressive) symptoms. A high score on the WOCS represents a high level of concerns.

Discussion

This study investigated the effect of the DT&PL+ intervention on depressive symptoms, HRQoL, and worry about cancer in HNC patients in a randomized controlled trial. No beneficial effects of the intervention on depressive symptoms, HRQoL, or worry about cancer at 6 or 12 months after inclusion could be shown. About one third of the participants in the intervention group had raised levels of distress (DT score ≥ 5), and most participants reported at least one emotional or physical problem. The intervention showed moderate compliance and acceptable session duration. Intervention participants were satisfied with nurses' care.

This is one of the few studies to assess the effectiveness of the DT&PL+ intervention on patient outcomes over 1 year [11,13] and the first to include HNC patients. As outlined in the review of Fitch [18], there are multiple challenges to successfully implementing an intervention and to improving patient outcomes. Although several strategies were used to ensure that the study ran smoothly, such as training of staff, engaging stakeholders, and providing feedback audits, the busy day-to-day reality was that the intervention was sometime delayed. The DT&PL+ intervention seems feasible in terms of integration in standard care, duration of sessions, and patient satisfaction, but several practical difficulties concerning the scheduling of sessions and the reporting of sessions need to be improved in order to achieve optimal implementation.

Fewer patients than estimated were eligible for the study, and instead of the expected 70% only 50% of the patients were willing to participate, resulting in reduced statistical power. Thirty-eight percent of the patients who declined participation felt no need to participate. Patients were invited by their physician at the end of the appointment in the outpatient clinic. Perhaps time was too short to thoroughly inform the patient and emphasize the importance of the study. However, considering the small differences in outcome between the intervention and control groups and a larger sample size would presumably not change the overall conclusion. Moreover, in general the participants in the intervention group reported relatively few complaints and the overall mean Distress score was 3.4 whereas a score > 5 is implicating elevated distress. As a consequence only a minority of patients were in need for additional care or referral. This makes it more difficult to detect any intervention effect.

The nurses who delivered the intervention were experienced in the care of HNC patients and had received training with follow-up consultation sessions, to increase the quality of the intervention and to positively influence patient outcomes [12]. Even though the nurse-led sessions were scheduled directly after the medical check-up, 40% of the participants

in the intervention group were lost to follow-up, some because of planning difficulties and some because participants said that they did not feel the need to continue. Perhaps the intervention format did not fit patients' expectations and desires or the appointment with the nurse was felt as an extra burden. The participants who dropped out reported on average more depressive symptoms and lower HRQoL scores at baseline. This is in line with the findings of Hollingworth [11], who reported that participants with better scores at baseline benefitted more from a DT&PL intervention than patients with worse scores at baseline in a group of cancer patients. It might be that patients with severe problems need a more structured, intensive intervention. Indeed, in our previous study [34,37], we found that an intervention consisting of 6 counseling sessions of 45–60 minutes given by trained nurses in the outpatient clinic had a significant beneficial effect on the depressive symptoms of HNC patients. This intervention was problem-focused and started with a short screening with the Hospital Anxiety and Depression Scale [38], followed by discussion of current problems and giving advice, emotional support, education, and behavioral training. HNC patients with raised depressive symptom scores (> 12 CES-D) at baseline especially benefited from the intervention. A recent review showed that interventions such as exercise interventions, cognitive behavioral therapy, and complementary therapy reduce distress in cancer patients [39]. However, the review included mainly studies of breast cancer patients, which makes the interpretation and generalization of findings to HNC patients, who are on average older, lower educated, and who have a higher consumption of tobacco and alcohol, difficult.

The HNC patients in our study often indicated that, if referral was discussed, they did not want to be referred to a psychologist of psychiatrist (data not shown). Little is known about referral rates or the wishes of HNC patients. Verdonck-de Leeuw [40] reported a referral rate of 21%; however, it is not known how many patients actually received psychological care. Research showed that only 28% of referred cancer patients accepted the referral [41]. Referral rates to a psychologist or social worker in our study varied between 3% and 17%. Because referral rates and acceptance are low, a structured nurse-led intervention integrated into standard aftercare seems to be a promising way to meet patients' needs. Evidently, referral for those in need remains a component of that aftercare.

Further research is needed to identify patient subgroups that would benefit the most from an intervention. Therefore, large-scale studies are needed to ensure sufficient power for subgroup analysis. The involvement of family or significant others, as occurred in this study, is important because they also suffer from distress [42]. Moreover, their

support is important to the recovery of patients [2]. Therefore, in future studies explicit attention should be paid to of family or significant others in the implementation and evaluation of a DT&PL+ intervention.

Implications for Practice and Conclusion

The DT&PL+ intervention seems feasible in clinical practice and aids the identification of possible distress in patients with HNC cancer, but more attention needs to be paid to the optimal scheduling of sessions and patient follow-up. Trained nurses are competent to deliver the intervention. We found no positive intervention effects on depressive symptoms, HRQoL, and worry about cancer but participants in the intervention group were highly satisfied with nurses' care. More research is needed to investigate interventions of different intensity in order to be able to offer HNC patients tailored interventions that meet their psychosocial needs.

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6

Educational intervention for patients with head and neck cancer in the discharge phase

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Abstract

Purpose: The consequences of head and neck cancer (HNC) treatment have great impact on patients' lives. Despite the importance of preparing patients for the period after discharge, patients frequently experience a lack of information. Aims of the study were to develop a nurse-led educational intervention to provide information during a discharge interview and to investigate the effects of the intervention on informational needs and satisfaction with information in HNC patients.

Methods: A total of 48 patients participated in this quasi-experimental study. The control group (n = 26) received standard care, which included a short interview using the patients' discharge letter dictated by the nurse. The intervention group (n = 22) received the educational intervention, namely a discharge interview where trained nurses used a checklist to inform patients about: general information, wound care, physical-social problems, work and finances. Effects associated with discharge interview were measured with the Patient Information Need Questionnaire (PINQ) and the Satisfaction with Cancer Information Profile.

Results: The findings showed that patients need information concerning: illness, treatment, side-effects, physical fitness, impact on functioning, duration of recovery time and impact on quality of life. The educational intervention had no significant effect on the informational needs or the level of satisfaction with information.

Conclusions: A nurse-led intervention to provide discharge information was developed however no effects on patient outcomes were found. Nurses need to use an instrument to assess the informational needs of patients prior to the discharge interview. The effects of the educational intervention need to be tested in a larger group of patients.

Introduction

Head and neck cancer (HNC) is the sixth most common cancer worldwide[1], representing 5% of the population of all cancer patients [2]. HNC itself may cause difficulty swallowing and eating, pain and hoarseness, depending on the stage, localisation and size of the tumour. Lifestyle factors, such as smoking and alcohol consumption, are generally known as important determinants for developing HNC [3-5].

The main treatment for HNC is removing the tumour by surgery, although surgery is often combined with radiation or chemotherapy [6,7]. Treatment leads to substantial problems in the lives of HNC patients. Generally problems identified described in literature concern three areas. Firstly, patients experience physical problems, such as pain, restrictions in speech, mastication, swallowing, shoulder function, sense of taste or smell, and breathing. Patients also describe changes in appearance, (partial) facial palsy, nausea and vomiting and fatigue [7-9]. Secondly, patients experience psychological and social problems, like reduced social activity or functioning, emotional stress, worrying about work, interpersonal relationships, day to day tasks, concerns about cancer, lack of self-confidence [7,10]. Patients report being ashamed of their voice and appearance, feeling depressed, experiencing loneliness and living in uncertainty about the success of treatment [7,8,10-12]. The third area concerns, financial problems which may occur as a consequence of health care costs and or reduced physical capacity to work [11,12].

Given that patients experience dramatic changes in their lives after discharge, it is important to provide patients with information to prepare them for the period after discharge [13,14]. Informational need has been defined as an experience of inadequate information concerning a life domain [15]. Various studies have explored the informational needs of HNC patients, showing that they prefer to receive information concerning physical problems as described above. Patients also want information on ability to work [7,16], financial issues [11,12] social and emotional support [16,17], side-effects, duration of recovery, Quality of Life (QoL) after one-year [16], symptoms of recurrence, and lifestyle factors that increase the risk of recurrence [17].

The literature shows that HNC patients who are unsatisfied with the information received experience high levels of fear and depression, and low QoL [7,15,18]. Patients' level of satisfaction with the received information can be improved by providing information in the identified areas [19]. To prepare the patient for the period after discharge, it is important to give the patient adequate information before discharge. However, the literature does not report any effective intervention that meets the informational needs of HNC patients after discharge. Nevertheless, literature exists concerning the manner

in which HNC patients would like to receive information. Patients prefer to receive verbal and written information and they want to be informed at the right time, on the right place and by a professional on an individual basis [20,21]. During the hospital stay, it can be difficult for patients to comprehend the received information and to consider it as meaningful [20,22]. It has, however, been reported that the meaning becomes apparent during the recovery period at home [22,23]. Furthermore, the provision of information about the combination of the problems to be expected is of great importance to HNC patients [10]. Many different health care professionals, including social workers, nurses or doctors provide information to patients in all stages of the disease and recovery. However, studies show that nurses are important for providing information and support, and for coordinating the care [24-26]. For example, a RCT showed that a nurse-led follow-up provided more continuity of care and that the nurses were better able to detect psychological problems than doctors in the case of breast cancer patients [27]. Furthermore, [23] emphasised that nurses must provide relevant and useful discharge information to surgical patients.

In conclusion, HNC patients face all kinds of difficulties after treatment and there is an indicated need for comprehensive information and thorough preparation. An effective and efficient nurse-led educational intervention that meets the informational needs of the patient is the next step in the care for HNC patients [7,16,20-22]. The aims of this study were firstly to develop a nurse-led educational intervention to provide information for the period after discharge, and secondly to investigate the effect of the intervention on the informational needs and level of satisfaction with the information among HNC patients.

Method

Methods for Aim one

The first aim of this study was to develop an intervention focussing on how to provide information to patients with HCN cancer.

Design

The intervention was developed using a seven step procedure, which included searching the literature for cancer patient interventions and tailoring the intervention to the needs of patients with HCN cancer.

Intervention development

Step 1. A literature search for educational interventions for cancer patients. A structure was needed for the intervention on how to provide information to patients. Two studies were found in the literature which described educational interventions for cancer patients [28,29]. One of these studies described an intervention using a specific topic list to provide structural information in breast cancer patients [28], while the other study described an intervention using a checklist to provide structural information to patients who were receiving chemotherapy [29]. In these interventions nurses provided verbal and written information during a 30-45 min structured conversation with each patient. In addition, the checklist and topic list were used to ensure that the information provided was complete and consistent. Nurses found the checklist helpful and it made them feel confident when providing information [29]. Based on these two studies, the format of a checklist was adopted for this study.

With a view to adapting the topics of the checklist for HNC patients, the following steps were undertaken by the researcher and two research assistants, both of whom were fourth year nursing students and experienced in caring for HNC patients.

Step two: Interviews were conducted with experts in the care and treatment of HNC patients. The experts included a social worker, dietician, physical therapist, outpatient clinic nurse and a specialist nurse. They were asked to indicate what information they provide during the hospital stay, which problems, from their perspective, were experienced by patients at home and which professional should be assigned to manage these problems.

Step three: All existing and relevant written material from the departments of oral maxillofacial surgery and otorhinolaryngology was collected. In addition, a nurse from another hospital specialised in caring for HNC patients was consulted concerning their provision of discharge information.

Step four: All the information gathered was categorized and a draft version of the checklist was created with six sections, namely general, wound care, physical problems, psycho-social problems, work and finance and sources for additional information/ professional help.

Step five: For the completeness of the written material, five informational pages were written on the following topics: a) information focussing on websites for accurate additional information, b) availability of professionals after discharge, c) the consequences of alcohol use and smoking cessation (two different pages), d) and practical advice for living with a gastric tube.

Step six: A second expert group consisting of eight nurses and a Clinical Nurse Specialist (CNS) reviewed the draft version of the checklist and the written material for accuracy and feasibility and they also provided input for improvement.

Step seven: The intervention and written materials were adapted in line with the comments made by these experts. The final version of the intervention included a. instructions for the discharge interview, b. five informational pages and c. a checklist for nurses including 18 major topics and 61 detailed points, all shown in Figure 1.

Procedure of the intervention

A few days before discharge the nurse made an appointment with the patient for the day before discharge from the hospital. Patients were encouraged to invite relatives to participate. This enabled patients to think about what they would like to know. On the day of discharge the nurse determined the educational needs based on the type of operation the patient had received and the patients' personal situation. Suitable written material was collected. The discharge interview lasted approximately 30 min and took place in a quiet room. These 'instructions' are also noted on the front-page of the checklist, that was used to structure the interview (Figure 1A).

The discharge interview started with the patient being given an opportunity to ask questions. This allowed the patient to receive information about the topics they identified. In addition, the nurse used the checklist to add information by discussing the major topics which are underlined in the checklist. The other more detailed points were discussed if the nurse considered them to be appropriate. The checklist is shown in Figure 1C. The verbal information was complemented with written material that was handed out and discussed with the patient during the discharge interview.

A Instructions discharge interview

Preparation	**Appointments**
○ Select date and time with patient ○ Encourage presence family ○ Encourage bringing received written material to conversation	Name nurse: Date interview: Family present: yes/no Date discharge:

Provision of the educational intervention:

- ○ Reflect on the operation and personal situation (gastronomic tube, smoking, cannula, etc)
- ○ Collect written materials (booklets, pamphlets, informational pages)
- ○ Secure a 'quiet room' for the interview without distraction
- ○ Plan adequate time (a minimal length of interview is 30 minutes)
- ○ Give information by using the checklist
- ○ Support verbal information with written materials (hand it out during the interview)

Comments:

B Informational pages

○ Websites	information focusing on websites for accurate additional information
○ Disciplines	information concerning available professionals after discharge
○ Alcohol	information discussing consequences of alcohol use and options for alcohol cessation
○ Smoking	information discussing consequences of smoking and options for smoking cessation
○ Gastronomic tube	information giving practical advice for living with a gastric tube

Figure 1. Educational intervention

C Checklist discharge interview

The checklist is a tool to facilitate discussion of important topics with the patient during the nurse discharge interview.

General

Knowledge and expectations treatment
- results treatment, pathology report
- further treatment (radiotherapy, reconstruction, dentist)
- treatment plan clear? Advise: write down questions for outpatient clinic visits

Medication
- effect and side-effects
- prescriptions

Appointments
- received appointment outpatient physician visit?
- appointment nurse specialist; if necessary
- who to contact for questions or for immediate help. Telephone number department (refer to discharge note)

Advise and rules for daily living at home
- regarding activities of daily living, housekeeping, physical exercise

Woundcare

Materials, care, inspection and observations concerning:
- cannula, fistula, laryngectomy
- gastric tube
- appointment CNS
- donor wound, thiersch's plastic, other wounds
- nursing care plan in discharge letter

Homecare
- which organisation, when is the first visit
- what care will be provided

Physical problems

Swallowing & diet
- problems with diet/eating
- possible referral to a speech therapist
- dietary advise clear, what is and is not allowed
- weight loss, advice to weigh once a week
- possible referral to a dietician

Speech
- communication problems
- possible referral to a speech therapist

Oral/dental hygiene
- problems (during radiotherapy)
- significance of oral hygiene after discharge (consequences for the mouth)
- prescription rinse
- possible referral to a dental hygienist

Fatigue
- discuss expected duration
- finding balance between relaxation and activity, exercise, 'listen to your body'

Level of consciousness
- drowsiness; negative influence on driving, reading, following conversations, memory
- influence operation and medication

Mobility
- complaints neck, shoulder, arm of leg
- oedema therapy
- possible referral to a physical therapist

Psycho-social problems

Change in appeareance
- (negative) influence on self-image, selfconfidence, emotions
- other possible reactions
- influence on work and social contacts

Emotions
- uncertainty
- fear of recurrence, life-threatening disease, dying
- how to handle these emotions
- possible referral to social worker or mental health facility

Intimacy
- change in personal contact (i.e. kissing)
- change in sexual experiences / intimacy with partner
- possible referral to specialist in sexuality

Home situation
- increased dependency, reduced ability to help in i.e. household maintenance
- social acceptance
- how to maintain social contacts and give meaning to them
- discuss problems with family and friends

Work and finances
- (temporarily) unable to work
- insurance / financial assistance
- financial compensation transport to radiotherapy
- possible referral to social worker

Source of information / support after discharge
- informational pages
- brochures (available on the ward)
- walk-in help centres
- patient support groups (individual experiences, not always generalizable)
- internet; NB not all sites are accurate, use the supplemental written information)

Figure 1. (continued)

Implementation of intervention

A single implementation strategy was used [30]. Eight experienced nurses took part in an interactive educational workshop and training in how to deliver the intervention. The workshop took 1.5 h. The importance and purpose of the intervention was explained and the leading and central role of the patients' needs was emphasized. The nurses were trained in using the checklist by means of a role play and discussed the usefulness and completeness of the checklist.

Outcome

With a view to enabling a quick evaluation of the intervention, space was provided on each checklist to record comments and experiences of the patient or the nurse (see Figure 1A, 'comments').

Methods for Aim two

The second aim of this study was to evaluate the effects of the intervention on the information needs of patients with HCN cancer and their level of satisfaction with information.

Design

The study conducted used a posttest-only design with nonequivalent groups [31]. The control group received care as usual. The intervention was then implemented with nurses receiving training and education on how to provide the intervention. Finally, the patients in the intervention group received the educational intervention from the trained nurses. Accordingly, patients gave informed consent before participation and could withdraw their consent at any time. The study was registered by the local medical ethics committee under number: 09-348/C.

Participants

Patients were included from departments of oral maxillofacial surgery and otorhinolaryngology at a Dutch academic hospital. A convenience sample was used and patients were included if they: 1) had a surgical treatment for head and neck cancer; 2) were able to read and speak Dutch. Patients were excluded if they 1) suffered from severe memory loss; 2) only underwent an endoscopy; 3) were admitted to hospital for two days or fewer. From November 2009 to March 2010, 82 patients were screened for eligibility. Of these patients, 18 patients were excluded for not meeting the inclusion criteria and four patients declined to participate. Although 60 patients agreed to

participate,12 did not complete the questionnaire and this resulted in 48 patients being included in the study. Of these, 26 patients were included in the control group, while 22 patients were included in the intervention group.

As regards the characteristics of the included patients, more men than women participated in both the control group and intervention group (15 compared to 11 and 15 compared to 7 respectively). The average age of people in the control group was 69, and that of people in the control group was 64 (Table 1).

Procedure

Control group: During the first two and a half months, 26 participants received care as usual. Care as usual included information provided by a nurse in a discharge interview with the patient and using the patients' discharge letter which was dictated by the nurse and which provides practical information such as wound care, medication, and outpatient appointment. The content of the information provided was determined by the nurse. Most discharge interviews took place on the day of discharge. However, no specific appointment was made with the patient for the exact time of the discharge interview.

Intervention group: During the second two and a half months, 28 participants received the educational intervention from trained nurses. The educational intervention was provided as described above. The intervention enabled the nurses to give information in a structurally and timely matter. The discharge interview took place in a separate, quiet room and lasted at least 30 minutes. Family members were invited to attend and written material which was thought to be suitable was collected. The intervention allowed the information to be provided in a more standardized way, focussing on the needs of each patient.

Outcome and measures

The following characteristics of participants were collected: gender, age, marital status, educational level, patient type, tumour classification status, radiation status.

Informational needs were measured using the Patient Information Need Questionnaire (PINQ) [15]. This 17 item instrument consists of two scales, a) a disease-oriented scale including nine items to indicate the need for information on HNC and treatment, and an action-oriented scale which includes eight items to indicate the need for information on access to help and on solving practical problems. Informational need was rated by

patients using four-point Likert scales. The score range for the scales is 9-36 and 8-32 respectively, with a high score implying a greater need for information. The PINQ showed good internal consistency; Chronbach's alphas were 0.88-0.92 [15].

The satisfaction with information was measured using the Satisfaction with Cancer Information Profile (SCIP) [20]. This 21 item instrument focuses on HNC patients and measures satisfaction with the amount of information (14 items) using a four-point Likert scale with a range of 1-14, and satisfaction with type and timing of information (7 items) using a five-point scale with a range of 7-35. A high score reflects a high degree of satisfaction. Both scales demonstrated good internal consistency. Chronbach's alphas were 0.89 and 0.87 respectively [20].

Translation

Both the PINQ and the SCIP were translated from English to Dutch using the forward and backward method [32]. In general the translation went well. However a few items showed some differences compared to the original version. For example, the word 'consequences' was translated with the word 'effects'. The differences were again translated using the forward and backward method and after that consensus was achieved on all items of both instruments.

Data collection

Each patient, in the control group as well as in the intervention group, was informed by the researcher or a research assistant about the study through verbal and written information 2-3 days before discharge from hospital. After an informed consent form had been signed, demographic, social and clinical data was collected from medical and nursing records. The patients received both the PINQ and the SCIP questionnaires on the day of discharge from the hospital. This gave the participants the opportunity to read the questionnaires before they received the telephone call, and simplified the process of answering the questionnaire by phone. Five days after discharge the researcher or the research assistant contacted the patient for a structured telephone interview. The active involvement of the patient meant that a better response was expected. Both research assistants were trained in administering questionnaires and Cohen's Kappa was used to evaluate interrater reliability between the researcher and the RA, which resulted in optimal agreement +1 ($p = 0.00$). However, if participants were physically unable to use a phone or objected to being contacted by phone, they were asked to fill in the written questionnaire and to return it within a week using a self-addressed envelope.

Data analysis

Concerning aim one: the experiences of patients and nurses with the intervention were analysed using thematic content analysis [33]. Practical information was compared with information on content and the number of negative and positive comments was counted. Concerning aim two: patients' characteristics, informational needs and satisfaction with information were analysed using descriptive statistics. The group differences on baseline characteristics were evaluated using the Mann-Whitney test. The normality of the data was measured with the Shapiro-Wilk test. Since the data was not normally distributed and the sample was relatively small, the Mann-Whitney test was conducted to analyse the effect of the educational intervention. Finally, a post-hoc power analyses was performed. A p-value equal to or less than 0.05 was considered significant. The data was analysed using Statistical Package for the Social Sciences (SPSS), version 17.

Results

Aim one

Intervention development

A nurse-led educational intervention was developed to provide HNC patients with information for the period after discharge, see Figure 1. The intervention was provided in addition to care as usual and included instructions for the discharge interview, written informational pages and a checklist to structure the information provided by nurses.

Comments from nurses and patients concerning the intervention used

Of the 28 discharge interviews conducted with the nurses, the nurses registered, in 25 interviews, their own comments and experiences, or those of the patient, with regard to the educational intervention. In eight cases, the comments were purely practical, for example: "supplied information leaflets" or "conversation went well". The comments in the other 17 interviews contained information about the content of the intervention. Thirteen of the comments were positive and emphasised that the discharge interview was helpful in structuring the information and that both the patients and the nurses found it to be a pleasant experience. One patient remarked that she missed this kind of education in the interview the last time she was admitted to the hospital. There were four less positive comments, for example: "it was already clear to the patient" or that the interview was difficult because "the patient did not want to let his emotional guard down". Both these comments were made by a nurse. No comments were made which indicated a need to modify the structure or elements of the checklist or the discharge interview.

Table 1. Participant characteristics.

Variable	Control (n = 26)		Intervention (n = 22)	
	n	%	n	%
Gender				
Male	15	57	15	68
Female	11	42	7	32
Average age	69	-	64	-
Marital status				
Married/cohabiting	12	46	15	68
Divorced	3	12	1	5
Single	4	15	4	18
Widowed	7	27	2	9
Highest education				
Primary school	2	8	2	9
Secondary school	10	39	9	41
Trade school	6	23	5	23
University	6	23	6	27
Missing	2	8	-	-
Type patient				
Newly diagnosed	20	77	16	73
Recurrence	6	23	6	27
TN (M) status[a]				
T0N 1-3	2	8	0	0
T1N0	4	15	7	32
T2N0	8	31	4	18
T2, 3N0, 1	3	12	3	14
T2-4 N0-3	7	27	4	18
Missing	2	8	4	18
Radiotherapy				
Yes	11	42	5	23
No	2	8	3	14
Unknown	13	50	14	64

[a] The TNM Classification is an anatomically based system that records the primary (T) and regional (N) nodal extent of the tumour and the absence or presence of metastases (M).

Aim two

Sample characteristics

There was no significant difference between the groups with respect to the demographic, social and clinical data. In the intervention group questionnaire data was collected from nine patients by telephone and 13 returned the questionnaire by post (for the control group this was 15 and 11, respectively). No significant differences in responses were found.

Effect of the intervention

Data collected using the PINQ was normally distributed for the 'disease-oriented' scale ($p = 0.07$) and was not normally distributed for the 'action-oriented' scale ($p = 0.02$). The Cronbach's alpha was 0.92 for the 'disease-oriented' scale and 0.79 for the 'action oriented' scale. No significant differences were found between the control and intervention group for either the 'disease-oriented' scale ($p = 0.98$) or the 'action-oriented' scale ($p = 0.44$), see Table 2. No significant differences in responses by telephone or questionnaire were found. Data collected using the SCIP was not normally distributed for the 'amount of information' scale ($p = 0.005$) and the 'type and timing information' ($p = 0.002$). The Cronbach's alpha was 0.86 for the 'amount of information' scale and 0.87 for the 'type and timing' of information scale. No significant differences were found between the control and intervention group for either the 'amount of information' scale ($p = 0.39$) and the 'type and timing information' scale ($p = 0.74$), see Table 2. No significant differences in responses by telephone or questionnaire were found.

Table 2. Differences in informational needs and satisfaction with the received information between the control group and the intervention group.

	Control group (n = 26)		Intervention group (n = 22)		Effect size (ES)
	Mean	**Std. deviation**	**Mean**	**Std. deviation**	
Informational needs - PINQ					
Disease oriented scale	21	7.6	21.1	8.6	0.01
Action oriented scale	14.9	5.2	15.9	5.5	0.19
Satisfaction with information – SCIP					
Amount of information	9.5	3.7	8.5	4.2	0.25
Type and timing information	27.3	4.5	26.9	5.1	0.08

Post-hoc power analyses

The post-hoc power analysis showed an effect size of 0.01 with a power of 0.05 for the 'disease-oriented' scale and an effect size of 0.19 with a power of 0.1 for the 'action-oriented' scale of the PINQ. For the SCIP the post-hoc power analysis showed an effect size of 0.25 with a power of 0.14 for the 'amount of information' scale and an effect size of 0.08 with a power of 0.06 for the 'type and timing information' scale.

Discussion

This study described the development of a nurse-led educational intervention and determined the effect of this intervention on the informational needs and satisfaction with information in Head and Neck Cancer (HNC) patients.

With regard to the study's first aim, a nurse-led educational intervention was developed and comments of nurses and patients were overall positive. In general the nurses found the intervention helpful in structuring information. One patient remarked that she missed this kind of education in the interview the last time she was admitted to the hospital. With regard to the study's second aim, the intervention had no significant effect on the informational needs and had no effect on the level of satisfaction with information.

Several steps were undertaken during the development to strengthen the educational intervention, such as reviewing the literature and using other known interventions. In addition, only experienced nurses carried out the discharge interviews, and they received interactive training and feedback on the content and utility of the checklist. Furthermore, the use of validated questionnaires specific to the HNC patients strengthened our study [15,16]. Given the method used for translation and that fact that the translation went well, we believe that the Dutch versions are equivalent to the originals.

It is possible that the development process and the content of the educational intervention may not have been strong enough to lead to significant results. The post-hoc power analyses showed a low effect size on both scales of the PINQ and the SCIP, assuming that the intervention needs to be improved. Furthermore, nurses who performed the intervention were only trained once and the knowledge of the nurses including the intervention fidelity was not measured. Only the 'amount of information' scale of the SCIP showed an effect size of 0.25 which can be considered as a small effect [34]. The associated power of 0.14 is low, but with a bigger sample size the results of the 'amount of information' scale might have been significant. However, a similar discharge intervention with one contact and small sample size (n = 50) improved outcome of

cardiac patients [35]. We assume that a combination of improving the intervention and enlarging the sample size should be undertaken to gain significant results on both the informational needs and satisfaction with information. Finally, one may question whether the educational intervention provided upon discharge can produce results five days later.

In connection with the data collection, telephone interviews were conducted with a good interrater reliability. Telephone interviews are a recommended strategy for assessing whether patients need further information [23], are widely used and are considered to be appropriate and efficient [33,36]. Nevertheless, the authors question whether the participants in this study evaluated the information they received as intended, in order to prepare themselves for the period after discharge. During each telephone call it was emphasised that the focus would be on the information given with regarding to the period after discharge, received in the period after the operation. Nevertheless, several participants gave the impression that they were evaluating information received during the whole hospital admission. In addition, 50% of the patients in this study were not willing or able to receive a telephone call because of difficulty speaking. No differences in the outcome of the PINQ and the SCIP were found between responses by telephone interviews or self-report questionnaires. Offering options such as face-to-face interviews or internet surveys may be a more efficient way of interviewing patients with HCN and should be considered in future research with this group of patients.

The characteristics of our sample are similar to other studies previously conducted with the same questionnaires [15,16]. Furthermore, the participants in our study are equally satisfied with the information received as the participants in the study by [16]. However, our control group was more satisfied than the intervention group, although the results were not significant. By contrast, participants in our study reported less informational needs than reported by [15] with a score of 21 versus 28 on the 'disease oriented' scale and a score of 15 versus 20 on the 'action-oriented' scale, respectively. It is possible that the relatively low average score in our study made it more difficult to measure the effect of the intervention because more participants already felt that they had received sufficient information.

There is some evidence to indicate that actively involving the patient and caregiver in the provision of information can have clinical benefits [37]. One can assume that actively involving patient and caregiver in information provision may also be beneficial for cancer patient. This, however, needs to be further investigated. We recommend that nurses in clinical practice use the PINQ as a standard assessment tool to evaluate the patients need for information prior to the discharge interview and to provide the

patient with information prior to discharge based on this assessment. In this way the intervention can be tailored even more effectively to patients' needs. Further research focussing on the intervention should adopt a model for intervention developments, for example 'The Utrecht model' [38]. A model can be used to develop the intervention in more detail. In particular, the experiences of nurses as providers of information and patients as recipients of the intervention can generate useful data. We also suggest expanding the intervention, where possible, to include a planned follow-up with the patient to evaluate the given information and to provide more information as necessary. This has been shown to be effective in a review by Smith et al. [37]. In addition, new methods of how to supply information, for example a web based computer program can be considered [39]. This needs to be further explored for HNC patients. Although there is a lack of studies focussing on these new methods with HNC patients, one can assume that using web based interventions may be beneficial because HNC patients often have difficulties with verbal communication. However, patients need to have access to a computer and skills in how to use one.

In summary, this study responded to the need for a comprehensive intervention to meet the informational needs of HNC patients [7,40]. A structured approach to determine informational needs was used and a nurse-led intervention to provide information was developed. However, no significant effects were found. Further development of the intervention and furthermore comprehensive research is needed to investigate its effects in a larger group of patients.

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7

General discussion

General discussion

Head and neck cancer and its treatment frequently results in long-term physical problems, for example dry mouth, difficulty eating, impaired speech and/or altered shoulder function. In part because of these persisting problems head and neck cancer patients are prone to deteriorated psychosocial wellbeing. Psychosocial problems like depressive symptoms or distress are present in up to 20% and 41% of patients one year after completion of cancer treatment, respectively [1,2]. At 36 months after cancer treatment even 9-20% of the patients still experiences depressive symptoms [1]. Declined Health Related Quality of Life (HRQoL), which includes physical and psychosocial aspects, can persist even up to ten years after completion of treatment [3,4]. Hence, interventions are needed to support head and neck cancer patients in the period after completion of cancer treatment in order to decrease physical problems, or learn to cope with them, and increase psychosocial wellbeing.

The studies, so far, that suggest beneficial effects of interventions addressing psychosocial care led by a clinical nurse specialist or psychologist [5-7], were relatively intensive in terms of time and number of session and were not combined with medical follow-up. Moreover, no specific attention was given to the physical problems. It is also known that even if cancer patients experience deteriorated psychosocial wellbeing, referral rates to a psychologist or psychiatrist are low [8]. This could partly be due to the stigma that is still attached to a psychologist or psychiatrist. Therefore, the existing interventions are less appropriate for head and neck cancer patients. The interventions presented is this thesis were low-intensive, combined with the medical follow-up and focused on physical as well as on psychosocial problems. Moreover, the interventions were led by a nurse because nurses are already involved in patients' care, have the necessary knowledge of physical and psychosocial problems and do not have a stigma attached.

Main findings

Three different interventions were designed, varying in intensity and content: the Nurse Cancer and After Intervention (NUCAI), the Distress Thermometer and Problem List + (DT&PL+) intervention and the educational intervention. The feasibility and effectivity of the interventions were studied.

The NUCAI was the most intensive intervention of the three and designed to support head and neck cancer patients in managing the physical and psychosocial consequences of their disease and its treatment in the first year after cancer treatment. Patients received six counseling sessions of 45-60 minutes during one year given by a trained

nurse in the outpatient clinic. The counseling sessions were always combined with the patient's 2-monthly medical consult. The NUCAI was feasible in clinical practice and effective in reducing depressive symptoms in patients with head and neck cancer at one year after cancer treatment, and especially in patients with raised levels of depressive symptoms at baseline. This effect sustained up to 18 months in the total group. NUCAI also improved several domains of HRQoL at 12 - 24 months. The less intensive DT&PL+ intervention was designed as a short intervention to screen and provide immediate support, advice, information or referral, if necessary. Patients received three to four sessions of 20 minutes during one year given by a trained nurse in the outpatient clinic. The session was always combined with the patient's 2-monthly medical consult. The DT&PL+ intervention showed moderate feasibility and patients were satisfied with nurses' care. However, no significant effect was found in reducing depressive symptoms or improving HRQoL in head and neck cancer patients at 6 or 12 months after study inclusion. Finally, we evaluated an educational intervention to prepare head and neck cancer patients for the period at home after finishing surgical treatment by providing comprehensive information in a structural manner. Duration of the interview was 30 minutes and the interview was given by a nurse from the ward the day before discharge. Results show that patients are in need for information about several topics but no beneficial outcomes were found for the intervention group compared to the control group.

Current practice: screening and referral

Screening for distress is upcoming and in the Netherlands the DT&PL is the centre of an evidence based guideline 'Screening for psychosocial distress' developed by a multidisciplinary group of experts[9]. This guideline is implemented in almost every hospital in the Netherlands, primarily in the care for breast cancer patients. Primary goal of the guideline is screening and in case of an elevated distress score a referral to the appropriate psychosocial and/or (para)medical care provider. There is an ongoing debate whether screening for distress and the possibility for referral of cancer patients improves recognition and the treatment of detected problems. Studies with rigorous designs are scant and methods of screening are divers, which makes it difficult to create a solid argumentation to integrate screening in standard care [10]. The current lack of strong evidence for a relationship between screening for distress and improvement in well-being [11,12] might be partly explained by low referral rates, as we also experienced in the DT&PL+ intervention study (Chapter 5). In general cancer patients with elevated levels of distress, only 25% of patients accepted referral [13]. In Dutch head and neck cancer patients, with and without elevated levels of distress, referral rates vary between 3 – 21% [14,15]. There seems to be a differences between screened need and actual desire

for psychosocial support [16]. Not all patients who have elevated levels of distress want to be referred, as is demonstrated by the mentioned percentages. On the other hand, it is also reported that 25% of the patients who screened negative for distress, requested referral [17]. The same conclusion was drawn in a qualitative study where 56 head and neck cancer patients were interviewed at 6, 12 and 24 months post treatment about how they lived their lives [18]. Results show that 20 (36%) patients labelled their life as 'changed for the worse' and the researchers believe that screening would not have made a difference in the lives of these patients. Partly because of the diversity of motives for seeing psychosocial services but also because of the complexity of the cases. They further suggest that the integration of a 'simple' question to outline possible distress and the possibility for referral, into the clinical dialogues during cancer trajectory would be more suitable than screening [18]. Altogether, it seems that the goal of screening, i.e., improving psychosocial wellbeing in cancer patients, is not met by screening and the possibility for referral alone.

Offering additional psychosocial care

Additional immediate psychosocial care, as provided in the NUCAI and DT&PL+ intervention, seems to be needed to improve psychosocial wellbeing in cancer patients. The NUCAI and DT&PL+ intervention were developed to provide psychosocial care for head and neck cancer patients combined with their standard medical consults in the follow-up period. This combination is bridging the gap between screening and referral. It takes a minimum of extra time and information received in the medical consult can be further discussed during the intervention session with the nurse. In addition, the interventions focus on psychosocial as well as on physical aspects as they are related to each other and both relevant for the patient in follow-up care.

The NUCAI and DT&PL+ intervention were both offered to all head and neck cancer patients and the NUCAI was effective in decreasing depressive symptoms and increasing HRQoL in the total group of patients (Chapter 2 & 3). In addition, subgroup analysis showed that patients with elevated levels of depressive symptoms at baseline benefitted more from the NUCAI than the total group (Chapter 2). Contrary, more patients with worse baseline scores on depressive symptoms and HRQoL prematurely stopped with the DT&PL+ intervention and no effects on depressive symptoms and HRQoL were found (Chapter 5). Compared with the NUCAI, the DT&PL+ intervention is less intensive concerning number and duration of sessions. Exact reasons for early drop out were not administered because patients could withdraw from the study without giving argumentation. However, it might be possible that the DT&PL+ intervention format did not meet their needs and/or expectations. In line, Hollingworth et. al. [11] found

that patients with better baseline scores benefitted more from the DT&PL+ intervention than patients with worse scores at baseline. No differences in psychosocial problems at baseline were found in patients who dropped out in the NUCAI study. This indicates that patients with low or high depressive symptoms or distress scores at baseline respond different to an psychosocial intervention. Elaborating on that thought it might be beneficial to start with a low intensive intervention and if needed extending the intervention with more or different care. Krebber et. al. [19] investigated a stepped care program for cancer patients with elevated distress scores. In stepped care all patients are offered the same low intensity treatment as a first step. Only those patients who do not recover, step up to a more intensive treatment [20]. In the study of Krebber et. al. [19] patients with head and neck (n=147) or lung cancer (n=9) and with elevated level depressive or anxiety symptoms were randomized to an 2 – 14 week intervention or care as usual. The stepped care program consisted of watchful waiting (step 1), guided self-help (step 2), problem-solving therapy (step 3), and psychotherapy and/or psychotropic medication (step 4). Results show that the stepped care group had better distress scores post-treatment and at 9 months follow-up compared to care as usual. In addition, the effect of stepped care was stronger for patients with a depressive or anxiety disorder compared with patients with an elevated level depressive or anxiety symptoms [19]. The largest group of patients (n=50) received the relatively light intervention of guided self-help (step 2), most comparable to the DT&PL+ intervention, but 60% dropped out at that stage. Fifty percent of the patients discontinued the step due to lack of motivation or experiencing the self-help program as stressful. Furthermore, only 11 patients received step 3, most similar to the NUCAI, of which one patient recovered after that step. The same pattern seems to appear in the DT&PL+ intervention study where patients drop-out during a relatively light intervention. This underlines that head and neck cancer patients are a specific group with specific needs that are probably not met with a self-help program or a low-intensive intervention like the DT&PL+ intervention. Furthermore, also in the stepped care program patients with severe problems respond different to the intervention. A more personalized and active approach seems to be needed.

Matching patients and psychosocial care

In line, a vision on psychosocial oncology care is described in 2014 by an association of six organisations, among others the Netherlands Comprehensive Cancer Organisation and The Dutch Cancer Society [21]. They propose a matched care model consisting of a systematic screening to gain insight in problems and possible need of care in combination with indicating which intervention or referral is appropriate. With this matched care model efficient and purposeful psychosocial care can be provided [21]. In

order to determine which intervention is most beneficial for a patient more information is needed about patient variables that influence the response to an intervention. In line, in this thesis effort is made to identify moderators that influences the success of the NUCAI. Results show that patients who had worse scores for global HRQoL, emotional functioning or social functioning at baseline benefitted more from the NUCAI than patients with better scores on these variables (Chapter 4). In addition, subgroup analysis in the NUCAI study (Chapter 2) revealed that patients with elevated levels of depressive symptoms benefited more from the NUCAI than patients with low depressive symptoms at baseline. This indicates that NUCAI is especially advantageous for patients with worse psychosocial wellbeing at baseline. In addition, patients who were married/living together benefitted more than patients who were single. We assume that if the partner follows the intervention with the patient, he/she can discuss the intervention with the patient at home and might stimulate and support the patient. In order to offer patients effective interventions and use resources in the best possible manner it is of great value to know which patients benefits of an intervention. The moderators found in this thesis are a start to guide matched psychosocial care, however, more research is needed to confirm our results.

Evaluating the role of nurses during the intervention

In delivering the intervention the nurses played a crucial role by leading the conversation during the intervention and coordination of care. Nurses gave content to the intervention by making decisions which questions they asked, which information they provided, which intervention to start, etc. In all the studies presented in this thesis the nurses were trained before the start of the intervention. Training differed from 1,5 hour in the educational-intervention to several days in the NUCAI study. In addition, in the NUCAI and DT&PL+ intervention periodic consultations and supervision meetings were organized during the intervention period to discuss difficulties, improve quality of the intervention sessions and to ensure that the intervention was offered in an uniform matter. These elements contributed to the intervention fidelity [22]. Horner et al. emphasized the great value of training and monitoring intervention delivery during the study period because the quality of the given interventions can influence the study outcome [23]. To gain insight in the actual delivered components of the interventions nurses were asked to keep a record of intervention details. However time was reserved for this purpose, the nursing records brought a considerable workload and therefore information was lacking. Perhaps that other methods, like audiotaping, would provide this information without adding extra workload for the nurses. During the studies presented in this thesis there were no signals that patients felt stigmatized by attending the nurse-led intervention, which might have had a

positive influence on the acceptance and adherence of the intervention. This was strengthened by the integration of care in the medical follow-up, the continuity of care patients received from the nurses and the focus on physical and psychosocial problems. Furthermore, patients were highly satisfied with the care delivered. From personal communication and outcome of the periodic consultations during the intervention period (NUCAI and educational intervention) it became clear that patients appreciated nursing care and the possibility to 'just tell their story'. In the DT&PL+ intervention patient satisfaction was measured and the nurses received, on average, a 7.8 score on a 1-10 scale [15]. In addition, the nurses themselves enjoyed providing the intervention, felt their nursing profession to be broadened and appreciated that they could continue patientcare after end of cancer treatment (unpublished data). The role and content of the nurse profession is still evolving and a nurse is given more responsibilities in indicating which care a patient needs [24]. Elaborating on the discussed matched care model trained nurses have the necessary skills to indicate which patient needs which intervention and can be the continues caregiver for the head and neck cancer patient during his treatment and follow-up period.

Future perspectives

To build further on the existing knowledge to provide head and neck cancer optimal, in terms of amount and content, psychosocial care during the follow-up period more research is needed, so psychosocial care can ultimately be integrated in standard care. High quality randomized controlled trials with sufficient power are needed to investigate predefined subgroups and to detect clinical significant differences. This implies that multi-center trials are needed to include enough participants. Then, researchers can define subgroups of patients with different levels of distress at baseline to find out which care is appropriate to decrease depressive symptoms and improve HRQoL in the long-term. In line, more information is needed on mediators and moderators of beneficial interventions to personalize the interventions for patients with head and neck cancer. Although in all the studies presented in this thesis family or close-ones were encouraged to join the intervention session(s), more attention can be given to their experiences with the intervention. The disease and its treatment does not only affect the patient but also the partner, children, family or other close-ones. Systematic evaluation how their needs can be met is challenging but can be of great value for their wellbeing as is can be for the patient itself. No cost effectiveness measures were assessed in the studies presented in this thesis. Implementing the psychosocial intervention has as goal to decrease the psychosocial burden of patient after end of cancer treatment and to restore their normal live in

the best way that is possible. However, gaining insight in the cost effectiveness of the intervention is relevant and needed in negotiations with health care insurance companies who have a rising voice in determining which care is offered to patients.

Conclusion

Head and neck patients are prone to persisting physical and psychosocial problems in the period after cancer treatment. Current care does not suffice as screening and referral alone provides an incomplete outcome and the majority of patients do not want to be referred to a mental health care professional. The results of the present thesis show that an intervention that is led by nurses, integrated with follow-up medical care, and provides immediate interventions focussing on physical as well as psychosocial problems beneficially affects depressive symptoms and health-related quality of life. Future research should focus on specific interventions tailored to sub-groups of patients with different levels of psychosocial problems to provide effective psychosocial care in the follow-up period.

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8

Summary
Samenvatting
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Summary

Head and neck cancer and its treatment frequently results in long-term physical problems, such as dry mouth, difficulty eating, impaired speech and/or altered shoulder function. In part because of these persisting problems, head and neck cancer patients are prone to deteriorated psychosocial wellbeing. Psychosocial problems like depressive symptoms or distress are present in up to 20% and 41% of patients one year after completion of cancer treatment, respectively. At 36 months after cancer treatment even 9-20% of the patients still experiences depressive symptoms. Declined health-related quality of life, which includes physical and psychosocial aspects, can persist even up to ten years after completion of treatment. Hence, interventions are needed to support head and neck cancer patients in the period after completion of cancer treatment in order to decrease physical problems or learn to cope with them, and increase psychosocial wellbeing.

The objective of this thesis was to evaluate three nurse-led psychosocial interventions, which vary by intensity and content, for head and neck cancer patients aimed at improving psychosocial wellbeing in the years after completion of cancer treatment. The Nurse Cancer and After Intervention (NUCAI) was nurse-led, combined with the standard 2-monthly medical follow-up and aimed at helping patients to manage the physical and psychosocial consequences of the disease and its treatment. Patients received six counseling sessions of 45-60 minutes during one year given by a trained nurse in the outpatient clinic. The Distress and Problem List + (DT&PL+) intervention was nurse-led, combined with the standard 2-monthly medical follow-up and aimed to screen and provide immediate support, advice, information or referral, if necessary. Patients received three to four sessions of 20 minutes during one year given by a trained nurse in the outpatient clinic. The educational intervention was designed to prepare head and neck cancer patients for the period at home after finishing surgical treatment by providing comprehensive information in a structural manner. The intervention comprised a discharge interview of 30 minutes given by a nurse on the ward the day before discharge.

Chapter 2 describes the effectiveness of the NUCAI on depressive symptoms in head and neck cancer patients one year after cancer treatment using a two-arm randomized controlled trial (RCT) with the NUCAI as intervention and care as usual as control group. A total of 205 head and neck cancer patients participated in the study. One year after cancer treatment, levels of depressive symptoms were significantly lower in the NUCAI group than in the control group. This effect was even stronger in the group of patients with raised levels of depressive symptoms at baseline.

Chapter 3 presents the long-term effects of the NUCAI study on health-related quality of life and depressive symptoms. Patients in the NUCAI group significantly improved in emotional and physical functioning, pain, swallowing, social contact, mouth opening and depressive symptoms at 12 months compared to the control group. At 24 months, emotional functioning and fatigue were significantly better in the intervention group.

Chapter 4 contains a secondary analysis of the NUCAI study to differentiate between patients who benefit most from the NUCAI and those who do less. Twenty-one variables associated with depressive symptoms in cancer patients were investigated. Results show that head and neck cancer patients who were married/living together, had low scores for global quality of life, and emotional or social functioning at baseline benefited more from the NUCAI than patients who were single or with high scores for global quality of life and emotional or social functioning. These variables can guide the decision making which patient might benefit from a psychosocial intervention to combat depressive symptoms.

Chapter 5 describes DT&PL+ intervention study which explored if a less intensive intervention than the NUCAI also has a positive effect on depressive symptoms and health-related quality of life in head and neck cancer patients. In a two-arm RCT including 110 head and neck cancer patients the DT&PL+ intervention was compared with care as usual. The intervention seemed feasible in clinical practice and participants were satisfied with nurses' care. No effect was found in reducing depressive symptoms or improving health-related quality of life at 6 or 12 months after study inclusion.

Chapter 6 presents the educational intervention study where a total of 48 patients participated in a quasi-experimental study where the educational intervention was compared to care as usual. Results show that patients indicated to need information concerning illness, treatment, side-effects, physical fitness, impact on functioning, duration of recovery time and impact on quality of life. However, the educational-intervention had no effect on the informational needs or the level of satisfaction with information in the intervention group compared with the control group.

Chapter 7 discusses the main findings of this thesis in relation with the current developments in clinical practice and literature. Screening for distress in cancer patients is upcoming in the Netherlands, however, it seems that the goal of screening, i.e., improving psychosocial wellbeing of cancer patients, is not met by screening and possibility for referral alone. Additional immediate psychosocial care, as provided in the NUCAI and DT&PL+ intervention, seems to be needed. The more intensive NUCAI effectively improved psychosocial wellbeing, but the DT&PL+ intervention did not. In

addition, not all head and neck cancer patients responded the same to the intervention. Subgroup analysis showed that patients with worse baseline scores on depressive symptoms benefitted more from the NUCAI than the total group. Contrary, more patients with worse baseline scores on depressive symptoms and HRQoL prematurely stopped with the DT&PL+ intervention. This implicates that head and neck cancer patients have specific needs that are probably not met with a self-help program or a low-intensive intervention like the DT&PL+ intervention. A more personalized and active approach seems to be needed. In order to offer patients effective interventions and use resources in the best possible manner it is of great value to know which patients benefits of an intervention. More research is needed to confirm our results, however, the moderators found in this thesis are a start to guide personalized psychosocial care. Trained nurses have the necessary skills to indicate which patient needs which intervention and can be the continues caregiver for the head and neck cancer patient during his treatment and follow-up period. Future research should focus on specific interventions tailored to sub-groups of patients with different levels of psychosocial problems to provide effective psychosocial care in the follow-up period.

Samenvatting

Hoofd-hals kanker en de behandeling ervan resulteert vaak in langdurige fysieke problemen zoals een droge mond, moeite met eten of spreken en/of veranderde functie van de schouder. Deels vanwege deze aanhoudende problemen hebben hoofd-hals kankerpatiënten een verhoogde kans op een verminderd psychosociaal welzijn. Psychosociale problemen zoals depressieve symptomen of distress zijn respectievelijk aanwezig bij 20% en 41% van de patiënten één jaar na afloop van de behandeling van kanker. Zesendertig maanden na de behandeling van kanker ervaart 9-20% van de patiënten nog steeds depressieve symptomen. Verminderde kwaliteit van leven, zowel op fysiek als op psychosociaal gebied, kan zelfs tot tien jaar na afronding van de behandeling aanhouden. Het inzetten van interventies is nodig om hoofd-hals kankerpatiënten in de periode na de behandeling te ondersteunen om de fysieke problemen te verminderen, of hen te leren met deze problemen om te gaan, en hun psychosociaal welzijn te verhogen.

Het proefschrift had als doel om drie psychosociale interventies te evalueren die werden uitgevoerd door verpleegkundigen. De interventies varieerden in intensiteit en inhoud maar waren alle gericht op het verbeteren van psychosociaal welzijn na afloop van de behandeling van kanker. De NUrse CAncer and After Intervention (NUCAI) was gekoppeld aan de standaard tweemaandelijkse follow-up afspraak met de arts en was gericht op het ondersteunen van patiënten in het omgaan met de fysieke en psychosociale gevolgen van de ziekte en de behandeling ervan. Patiënten kregen zes counseling gesprekken van 45-60 minuten op de polikliniek gedurende één jaar gegeven door een daarvoor getrainde verpleegkundige. De Distress and Problem List + (DT&PL+) interventie (Lastmeter) was eveneens gekoppeld aan de standaard tweemaandelijkse follow-up afspraak met de arts en was gericht op het screenen en het bieden van directe steun, advies, informatie of verwijzing, indien nodig. Patiënten kregen drie tot vier gesprekken van 20 minuten op de polikliniek gedurende één jaar gegeven door een daarvoor getrainde verpleegkundige. De educatie interventie was ontworpen om hoofd-hals kankerpatiënten voor te bereiden op de periode thuis na het afronden van de chirurgische behandeling door het verstrekken van uitgebreide informatie op een structurele wijze. De interventie bestond uit een eenmalig gesprek van 30 minuten op de afdeling gegeven door een daarvoor getrainde verpleegkundige een dag voor ontslag.

Hoofdstuk 2 beschrijft de effectiviteit van de NUCAI op depressieve symptomen bij hoofd-hals kankerpatiënten één jaar na de behandeling van kanker. Daarvoor is een gerandomiseerde en gecontroleerde studie (RCT) met twee groepen uitgevoerd

waarbij de NUCAI als interventie is ingezet en de bestaande zorg als controle. In totaal namen 205 hoofd-hals kankerpatiënten deel aan de studie. Eén jaar na de behandeling van de kanker was het niveau van depressieve symptomen significant lager in de NUCAI groep dan in de controlegroep. Dit effect bleek sterker in de groep patiënten met een verhoogd niveau van depressieve symptomen bij de start van de studie.

Hoofdstuk 3 presenteert de effecten van de NUCAI studie op langere termijn op kwaliteit van leven en depressieve symptomen. Patiënten in de NUCAI groep verbeterden aanzienlijk op emotioneel en fysiek functioneren, pijn, slikklachten, sociale contacten, mondopening en depressieve symptomen na 12 maanden in vergelijking met de controlegroep. Na 24 maanden waren emotioneel functioneren en vermoeidheid significant verbeterd in de interventie groep.

Hoofdstuk 4 bevat een secundaire analyse van de NUCAI studie om te differentiëren in patiënten die het meest van de NUCAI profiteerden en degenen die minder profijt hadden. Eenentwintig variabelen waarvan bekend is dat ze verband houden met depressieve symptomen bij kankerpatiënten werden onderzocht. Resultaten laten zien dat getrouwde of samenwonende patiënten en patiënten die bij aanvang van de studie laag scoorden op kwaliteit van leven, emotioneel- en/of sociaal functioneren meer baat hadden bij de NUCAI dan patiënten die alleenstaand waren of hoge scores hadden op kwaliteit van leven, emotioneel- en/of sociaal functioneren. Aandacht voor deze variabelen kan helpen bij het selecteren van patiënten die baat kunnen hebben bij een psychosociale interventie gericht op het verminderen van depressieve symptomen.

Hoofdstuk 5 beschrijft de DT&PL+ interventie studie waarin is onderzocht of een minder intensieve interventie dan de NUCAI ook een positief effect heeft op depressieve symptomen en kwaliteit van leven bij hoofd-hals kankerpatiënten. In een RCT met twee groepen zijn 110 hoofd-hals kankerpatiënten geïncludeerd en werd de DT&PL+ interventie vergeleken met de bestaande zorg. De interventie lijkt uitvoerbaar in de klinische praktijk en deelnemers waren tevreden met de verpleegkundige zorg. Er is geen effect gevonden in het verminderen van depressieve symptomen of het verbeteren van kwaliteit van leven op 6 of 12 maanden na de start van de studie.

Hoofdstuk 6 presenteert de evaluatie van de educatie interventie waaraan 48 patiënten hebben deelgenomen. Het betrof een quasi-experimentele studie waarin de educatie interventie werd vergeleken met de bestaande zorg. Resultaten tonen aan dat patiënten behoefte hebben aan informatie over de ziekte, behandeling, bijwerkingen,

fysieke gezondheid, invloed op functioneren, duur van herstel en de impact op kwaliteit van leven. De educatie interventie had geen aantoonbaar effect op de behoefte aan informatie of de tevredenheid over de informatie.

Hoofdstuk 7 bespreekt de belangrijkste bevindingen van dit proefschrift in relatie tot de huidige ontwikkelingen in de klinische praktijk en de literatuur. Screenen op distress bij patiënten met kanker neemt toe in Nederland. Het lijkt er echter op dat het doel van de screening, het verbeteren van psychosociaal welzijn bij kankerpatiënten, niet behaald wordt door alleen het screenen en het aanbieden van mogelijkheden voor verwijzing naar andere zorgverleners. Aanvullende directe psychosociale zorg, zoals gegeven bij de NUCAI en DT&PL+ interventie, lijkt nodig te zijn. De intensievere NUCAI is effectief in het verbeteren van psychosociale welzijn, maar de DT&PL+ interventie niet. Bovendien, niet alle hoofd-hals kankerpatiënten hebben op dezelfde manier gereageerd op de interventie. De subgroep analyse toonde aan dat patiënten met een verhoogd niveau van depressieve symptomen bij de start van de studie meer baat hebben gehad bij de NUCAI dan de totale groep. Daarentegen waren het juist deze patiënten met een verhoogd niveau van depressieve symptomen en lage scores op kwaliteit van leven, die voortijdig stopten met de DT&PL+ interventie. Dit impliceert dat hoofd-hals kankerpatiënten specifieke behoeften hebben die waarschijnlijk niet vervuld worden met een zelfhulp-programma of een laag-intensieve interventie zoals de DT&PL+ interventie. Een meer persoonlijke en actieve benadering lijkt nodig te zijn. Om patiënten effectieve interventies te bieden en middelen op de best mogelijke wijze te benutten is het van belang om te weten welke patiënten baat hebben bij een interventie. Hoewel er meer onderzoek nodig is om onze resultaten te bevestigen, zijn de gevonden moderende variabelen in dit proefschrift een aanzet voor gepersonaliseerde psychosociale zorg. Getrainde verpleegkundigen beschikken over de benodigde vaardigheden om te indiceren welke patiënt welke interventie nodig heeft. Daarbij kan de verpleegkundige de zorgverlener zijn die continuïteit biedt aan de hoofd-hals kankerpatiënt gedurende de behandeling en de periode daarna. Vervolg onderzoek dient zich te richten op interventies op maat voor verschillende groepen kankerpatiënten met verschillende niveaus van psychosociale problemen om effectief psychosociale zorg te kunnen verlenen in periode na de behandeling.

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Ingeborg

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Curriculum Vitae

Ingeborg Catharina de Goeij was born on the 22nd of February 1987 in Alphen aan den Rijn, The Netherlands. After graduating from secondary school at the Groene Hart Lyceum, she obtained her bachelor degree in Nursing at the University of Applied Sciences Utrecht in 2008. During the last two years of her bachelor she followed and obtained the pre-master Nursing Science at the Utrecht University. She started working as a registered nurse in 2008 at the Oral and Maxillofacial Surgery and Otorhinolaryngology ward at the University Medical Center Utrecht. Besides her work on the ward, she started her master study Nursing Science and she obtained her master degree in 2010. While continuing her work as a nurse, she started her PhD research at the departments of Oral and Maxillofacial Surgery, Otorhinolaryngology and Julius Center for Health Sciences and Primary care of the University Medical Center Utrecht. Since 2015, Ingeborg is working as a lecturer at the School of Nursing of the Hanzehogeschool Groningen. Ingeborg is married to Taco van der Meulen and is blessed with three children, Amélie, Jozua and Hylke.