The effect of comprehensive counseling by a nurse specialist on depressive symptoms and quality of life: A prospective randomized study in patients with head and neck cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23760

Source
NTR

Brief title
NUCAI

Health condition

- Comprehensive counseling by a nurse specialist (intervention group)
- care as usual (control group)

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: Dutch Cancer Society (KWF Kankerbestrijding)

Intervention

Outcome measures

Primary outcome

Depression will be measured with the Center for Epidemiological Studies-Depression Scale (CES-D) (Radloff 1977, Bouma 1988, Hanewald 1992). The CES-D consists of 20 items with a 4 point Likert scale, resulting in a total score ranging from 0 to 60 (Bouma 1988). A high score reflects a high level of depression. A cut-off point of 16 can be used, patients with a score of 16 or more being classified as being a possible case of depression.
This questionnaire has been developed for research in the general, non-psychiatric population, it contains 20 items and has been used in Duch cancer research (Komproe 1995, de Graeff 2000, de Leeuw 2000)

Secondary outcome

1. Quality of Life with the EORTC Core Questionnaire (QLQ-C30, version 3.0)(Aaronson 1993) and the EORTC Head and Neck Module (QLQ-H&N35) (Bjordal 1999, Bjordal 2000). The QLQ-C30 contains five functional scales, three
symptom scales, a global QoL scale and six sin-gle-items.
It has been tested in an international study in which Dutch patients participated, contains 33 items concerning global quality of life, functional capacity, physical and psychological symptoms, and daily activities;

2. The QLQ-H&N35 measures tumour-specific and treatment related symptoms.
This questionnaire has also been tested in an international study in which Dutch patients participated and contains seven symptom scales (pain, swallowing, senses (taste/smell), speech, social eating, social con-tacts, and sexuality) and six single items (teeth problems, trismus, dry mouth, sticky saliva, cough, and feeling ill);

3. Concern with recurrence of cancer will be measured with the Worry of Cancer Scale (Easterling, 1989). This questionnaire contains 5 items measuring the fear of cancer recurrence;

4. Uncertainty is measured with the Uncertainty in Illness Scale (Michel, 1981), containing 30 items measuring ambiguity and unpredictability.

Study description

Background summary

In previous research, we have shown that there is a high degree of depressive symptoms in patients with head and neck (H&N) cancer prior to treatment. After treatment, there is a partly temporary and partly permanent increase of physical symptoms. Despite this, there is a gradual improvement of psychological functioning and global quality of life (QoL). However,

one to three years after treatment there still is a high level of depressive symptoms and approximately 20% of all patients are possible cases of depressive disorder.
Depressive symptoms at baseline have been shown to be a major predictor of physical symptoms and depressive symptoms after treatment. Furthermore, many cancer patients experience fear of recurrence after treatment which is associated with uncertainty and anxiety and there is a need for appropriate interventions to assist cancer patients with the fears of recurrence and uncertainty surrounding the effectiveness of treatment. Although physicians may be considered to be experts in diagnosis and treatment of complications of treatment, and in the detection of a recurrence or second primiary tumours, it may be questioned whether they are the most appropriate professionals to support patients in psychosocial and quality of life issues (couseling).
Physicians are often primarily directed to the cure aspects of the disease and the more medical-technical aspects of treatment policies, whereas patients are more oriented on care issues with respect to quality of life and integrating the illness in daily life Moreover, physicians generally are in lack of time to provide psychosocial support in coping with symptoms, mutilations and impairments after treatment, and in regaining daily life activities.

- The aim of the present study is to investigate the effect of comprehensive counseling by a nurse specialist on depressive symptoms and quality of life in patients treated for squamous cell carcinoma of the mouth, pharynx or larynx.
- The primary endpoint of the study are depressive symptoms; secondary endpoints are QoL, uncertainty fear of recurrence. A total number of 200 patients will be included in the study during a period of two years. All patients will be followed for 24 months from the start of treatment. They will complete the EORTC QLQ-C30 and QLQ-H&N35 the CES-D the Uncertainty in Illness Scale and the Worry of Cancer Scale) before treatment and at 3, 6, 9, 12, 18 and 24 months after the completion of treatment. The questionnaires before treatment and at 6, 12, 18 and 24 months after the completion of treatment also contain items about cancer locus of control, social support and coping to examine whether these variables change in the experimental group as compared with the control group.

All participating patients will be randomized between care as usual (control arm) and comprehensive couseling (experimental arm) and both treatment arms will be seen by a different nurse specialist. The aim of the counseling intervention by the specialized nurse is to help the patient to deal with physical symptoms and impairments, to reduce emotional distress, uncertainty and concern of recurrence and to improve QoL. Patients will be stratified for gender, site (oral/oropharyngeal cancer versus hypopharyngeal/laryngeal cancer) and AJCC-stage (0/I/II versus III/IV). All patients will complete the questionnaire at the same timepoints during the study period.
Comprehensive counseling will be given by a nurse specialist, especially trained for this purpose. The nurse specialist will see the patient shortly before and after treatment to provide information needed about the tumour and the treatment. Two months after the completion of treatment, the nurse specialist sees the patient every 2 months for one year. The intervention is patient centered and the 6 sessions of it are structured according to the AFTER intervention (Adjustment to Fear, Threat or Epectation of Recurrence) which is designed to reduce fears of recurrence and psychological distress in patients with orofacial

cancer. During the second year, the patient will receive the same type of care as the patients in the control arm. Before each session of the intervention patients will complete the HADS to screen for serious psychosocial morbidity which might need special attention. Patients with an indication for depression or anxiety are referred to a psychologist for additional diagnosis and/or treatment.

If the results of this study indicate a positive effect of the intervention on depressive symptoms and QOL of patients with H&N cancer after treatment, psychological counselling by nurses may be implemented in daily practice for this patient group.

If the results of this study indicate a positive effect of the intervention on depressive symptoms and QoL of patients with H&N cancer after treatment, comprehensive support and screening by nurses may be implemented in daily practice for this patient group.

Study objective

1. After treatment, patients of the experimental group will show less depression;

2. After treatment, patients of the experimental group will show better quality of life;

3. After treatment, patients of the experimental group will show less uncertainty and;

4. After treatment, patients of the experimental group will show less concern for cancer recurrence one year after the start of treatment.

Intervention

Comprehensive counseling will be given by a nurse specialist, especially trained for this purpose.
The patient will be referred for a short contact before the start of surgery or before the start of primary radiotherapy. All patients who receive a combined treatment are also seen by the nurse specialist at 2 weeks after surgery, prior to postoperative radiotherapy. Furthermore, all patients are shortly seen by the nurse, 2 weeks after the overall completion of treatment. The nurse specialist will see the patient every 2 months during the year after the completion of treatment.
The duration of each sessoin 45 to 60 minutes and all sessions will be combined with a regular medical check-up at the outpatient clinic. At 12 months after the completion of treatment, the intervention will be discontinued, but the nurse specialist remains available for the patients.
To guarantee continuity of available support in the experimental group, patients of the experimental group will be urged to contact the nurse specialist when in need of additional information or support.
During the second year, the patient will receive the same type of care as the patients in the control arm.

- The aim of the counseling intervention by the specialized nurse is to help the patient to deal with physical symptoms and impairments, to reduce emotional distress and to improve morale, coping ability and sense of control. The intervention consists of 6 sessions during the period of one year.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx or larynx, receiving treatment with surgery and/or radiotherapy with curative intent;

2. No previous or synchronous malignancies, with the exception of:
adequately treated squamous cell or basal cell carcinoma of the skin or in situ carcinoma of the cervix
synchronous second squamous cell carcinoma of oral cavity, pharynx or larynx which can also be treated with curative intent;

3. Ability to complete the questionnaire and expected cooperation of the patient, as reflected by a completed baseline questionnaire.

Exclusion criteria

No further exclusion criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2003
Enrollment:	154
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL220
NTR-old	NTR257
Other	: UU 2003-2782
ISRCTN	ISRCTN06768231

Study results

Summary results
N/A