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

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 10/04/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UU 2003-2782; NTR257

Study information

Scientific Title

Acronym
NUCAI

Study objectives
After treatment, patients of the experimental group will show:
1. Less depression
2. Better quality of life
3. Less uncertainty
4. Less concern for cancer recurrence one year after the start of treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Head cancer, neck cancer, tumour

Interventions
Comprehensive counselling will be given by a nurse specialist, specially 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 two weeks after surgery, prior to post-operative radiotherapy. Furthermore, all patients are shortly seen by the nurse, two 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 session 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 counselling intervention by the specialised 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 six sessions during the period of one year.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Depression will be measured with the Center for Epidemiological Studies-Depression Scale (CES-D). The CES-D consists of 20 items with a 4-point Likert scale, resulting in a total score ranging from 0 to 60. 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 Dutch cancer research.

Secondary outcome measures
1. Quality of Life with the EORTC Core Questionnaire (QLQ-C30, version 3.0) and the EORTC Head and Neck Module (QLQ-H&N35). 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. 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).
2. Concern with recurrence of cancer will be measured with the Worry of Cancer Scale. This questionnaire contains five items measuring the fear of cancer recurrence.
3. Uncertainty is measured with the Uncertainty in Illness Scale, containing 30 items measuring ambiguity and unpredictability

Overall study start date
01/12/2003

Completion date
01/12/2009

Eligibility

Key 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:
2.1. Adequately treated squamous cell or basal cell carcinoma of the skin or in situ carcinoma of the cervix
2.2. 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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
154

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/12/2003

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Utrecht
Utrecht
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Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

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Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Charity

Funder Name
The National Cancer Fund (Koningin Wilhelmina Fonds [KWF]) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/02/2014		Yes	No