

Efficacy of a course "Living with head and neck cancer" in patients with head and neck cancer and their spouses

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To obtain insight in the usefulness and efficacy of psychosocial intervention for HNC patients and their spouses by performing a pilot study.

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON30153

Source

ToetsingOnline

Brief title

Living with head and neck cancer

Condition

- Miscellaneous and site unspecified neoplasms benign
- Adjustment disorders (incl subtypes)

Synonym

distress, head and neck cancer

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: distress, head and neck cancer, psychosocial intervention, spouses

Outcome measures

Primary outcome

Hospital Anxiety and Depression Scale (HADS).

Secondary outcome

Health-related quality of life questionnaires:

EORTC QLQ-C30 and QLQ-H&N35 for the patients

the SF36 for the partners

Study description

Background summary

In the Netherlands approximately 2500 patients are diagnosed with primary head and neck cancer (HNC) every year. HNC patients have to deal with severe side effects of treatment: in addition to complaints as pain and fatigue and fear for tumour recurrence, patients are often confronted with changes in facial appearance, speech or swallowing problems and related psychological distress. A recent study at our Department revealed that approximately 30% of the patients and 20% of their spouses have clinical levels of distress and adaptation problems after treatment. Psychosocial intervention has proved to be beneficial in patients treated for cancer at various sites. Evidence on the efficacy of intervention in HNC patients is limited. Information on the efficacy of intervention in spouses of HNC patients is lacking completely. Because of the specific problems of head and neck cancer patients and their spouses, a tailored psychosocial intervention program is needed.

Study objective

To obtain insight in the usefulness and efficacy of psychosocial intervention for HNC patients and their spouses by performing a pilot study.

Study design

non-randomised prospective pilot study

Intervention

Psychosocial intervention: a course "Living with head and neck cancer"
6 sessions of 1 1/2 - 2 hours per session.

Study burden and risks

Patients and spouses will be asked to fill in questionnaires on distress and health related quality of life. If the intervention proves to be effective, patients and spouses will benefit immediately by improving their quality of life.

Contacts

Public

Vrije Universiteit Medisch Centrum

postbus 7057
1007 MB Amsterdam
Nederland

Scientific

Vrije Universiteit Medisch Centrum

postbus 7057
1007 MB Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

head and neck cancer
treatment > 3 months
psychological distress

Exclusion criteria

cognitive dysfunction
not speaking dutch

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-09-2006

Enrollment: 20

Type: Anticipated

Ethics review

Approved WMO

Date: 13-06-2006

Application type: First submission

Review commission: METC Amsterdam UMC

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
CCMO	NL11674.029.06