

# Cost-effectiveness of a stepped care strategy to improve symptoms of depression or anxiety in patients treated for head and neck cancer or lung cancer.

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To evaluate cost-effectiveness of a stepped care strategy to improve symptoms of depression or anxiety in patients treated for head and neck cancer or lung cancer.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON39087

### Source

ToetsingOnline

### Brief title

STEP-study

### Condition

- Other condition
- Respiratory and mediastinal neoplasms malignant and unspecified
- Anxiety disorders and symptoms

### Synonym

anxiety and depression; lung and head and neck neoplasms

### Health condition

psychische stoornissen: angststoornissen en -symptomen

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** anxiety and depression, cost-efficacy, disease management, head and neck neoplasms, Lung neoplasms, stepped care

## Outcome measures

### Primary outcome

Primary outcome is the Hospital Anxiety and Depression Scale (HADS) and costs (health care utilization and work loss (TIC-P and PRODISQ modules)).

### Secondary outcome

Secondary outcome measures are quality of life questionnaires (EORTC QLQ-C30, EORTC QLQ-HN35, EORTC QLQ-LC13) and patient satisfaction with care (EORTC QLQ-PATSAT).

## Study description

### Background summary

In the Netherlands over 10.000 patients are diagnosed with lung cancer (LC) or head and neck cancer (HNC) every year of whom 25-50% have comorbid anxiety or depression after treatment. Although there is evidence on efficacy of psychosocial cancer care in general, patients with poor survival rates (LC) or less prevalent tumours (HNC) are often not involved, while these patients are among the most distressed patients. Barriers to admission to psychosocial care are a lack of adequate screening instruments in oncology settings, and that traditional models of the delivery of psychosocial care do not meet current demands. A stepped care approach including a web-based self-help intervention has the potential to improve the efficiency of psychosocial care.

## Study objective

To evaluate cost-effectiveness of a stepped care strategy to improve symptoms of depression or anxiety in patients treated for head and neck cancer or lung cancer.

## Study design

Randomised controlled trial. Follow up at 3, 6, 9 and 12 months.

## Intervention

Stepped care model with 4 evidence based steps: 1. Watchful waiting, 2. Internet-based self-help, 3. Problem Solving Therapy applied by a nurse, and 4. Specialised psychological interventions and/or antidepressant medication. Control group patients receive care as usual which most often is no intervention or referral to specialised intervention.

## Study burden and risks

Risks are negligible and burden is low. In case of positive results, participating patients will benefit immediately from the stepped care approach.

## Contacts

### Public

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NL

### Scientific

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## Trial sites

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Treatment for UICC stage I-IV lung or head and neck carcinoma: ICD-10 C00-C14 (lip, oral cavity and pharynx), C32 (larynx), C33 (trachea), C34 (lung); psychological distress or possible or probable cases of depression or anxiety as assessed by the Hospital Anxiety Depression Scale (HADS-Anxiety subscale score  $> 7$  and/or HADS-Depression subscale score  $> 7$ , or total score on HADS  $> 14$ ). For more details, see page 11 of the research protocol.

### Exclusion criteria

Other (neurological) diseases causing cognitive dysfunction; no motivation to undergo psychosocial therapy; current treatment for a depressive or anxiety disorder; end of treatment for a psychiatric disorder less than two months ago, high suicide risk; psychotic and/or manic signs; too little knowledge of the Dutch language to fill out the questionnaires.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2009
Enrollment:	152
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-08-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	13-04-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	02-10-2013
Application type:	Amendment
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	NL28142.029.09