

Stepped care to improve depression and anxiety in cancer patients.

No registrations found.

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

Summary

ID

NL-OMON26555

Source

Nationaal Trial Register

Brief title

STEP-study

Health condition

Head and neck neoplasms; lung neoplasms; anxiety; depression; psycho-oncology
Hoofd-halskanker; longkanker; angst; depressie; psycho-oncology

Sponsors and support

Primary sponsor: VUmc

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Primary outcome is the Hospital Anxiety and Depression Scale (HADS).

Secondary outcome

Secondary outcome measures are quality of life questionnaires (EORTC QLQ-C30, EORTC QLQ-HN35, EORTC QLQ-LC13), patient satisfaction with care (EORTC QLQ-PATSAT), and costs (health care utilization and work loss (TIC-P and PRODISQ modules)).

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.

Objective of this study is 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 objective

In the Netherlands over 10.000 patients are diagnosed with head and neck cancer or lung cancer every year of whom 25-50% have comorbid anxiety or depression.

Is a stepped care strategy applied in an oncological setting more (cost-)effective to improve symptoms of anxiety and depression compared with care as usual?

Study design

0, 3, 6, 9 en 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;
4. Specialised psychological interventions and/or antidepressant medication.

Control group patients receive care as usual.

Contacts

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Eligibility criteria

Inclusion criteria

1. 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);
2. Depression (minor or major) or (generalized) anxiety disorder as assessed by the Composite International Diagnostic Interview (CIDI).

Exclusion criteria

1. Other (neurological) diseases causing cognitive dysfunction;
2. No motivation to undergo psychosocial therapy;
3. Current treatment for a depressive or anxiety disorder;

4. End of treatment for a psychiatric disorder less than two months ago;
5. High suicide risk;
6. Psychotic and/or manic signs;
7. 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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	176
Type:	Anticipated

Ethics review

Positive opinion	
Date:	18-06-2009
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	NL1758
NTR-old	NTR1868
Other	ZonMw : 60-82500-98-8043
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A