Supporting Resilience and Case Finding

No registrations found.

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

Summary

ID

NL-OMON26756

Source
Nationaal Trial Register

Brief title
SIGN

Health condition

Psychological distress
Cancer patients
Anxiety
Depression
Psychologische distress
Kankerpatiënten
Angst
Depressie

Sponsors and support

Primary sponsor: VUmc-GGZ inGeest
PO Box 74077, 1070 BB Amsterdam
Source(s) of monetary or material Support: VUmc-GGZ inGeest soma-psyche
PO Box 74077, 1070 BB Amsterdam
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Intervention

Outcome measures

Primary outcome

Primary outcome is the recognition of psychological distress after introduction of the new procedure. The diagnostic accuracy of the new procedure (study aim v-a) is determined by comparing information in the medical/nursing record about the presence of psychological distress with patient reported psychological distress (Distress Thermometer + Problem List, HADS). Sensitivity, specificity, false positives, false negatives, and positive and negative predictive value are determined.

Secondary outcome

- Evaluation of diagnostic accuracy of current clinical practice, which will be evaluated in an analogous way (study aim i).

- A comparison of the diagnostic accuracy of phase 1 (before) and phase 2 (after) (study aim v-b). The two phases are compared in terms of sensitivity and specificity, (negative and positive) predictive values, and likelihood ratios (of positive and negative results). This is tested in terms of the diagnostic odds ratio, being a single indicator of diagnostic test performance (25).

- A descriptive analysis of the level of psychological distress, patients' subjective need for treatment, and actual treatment of psychological distress, and separately for phase 1 (before) and phase 2 (after) (study aims ii, iii, iv, vi, vii and viii). Appropriate descriptive statistics will be used.
- A comparison between phase 1 (before) and phase 2 (after) of the level of psychological distress, patients' subjective need for treatment, and actual treatment of psychological distress (study aims vi, vii and viii). Multiple regression analysis (continuous measures) or logistic regression analysis (dichotomous measures) will be used.

Study description

Background summary

With this trial we want to improve psychosocial care for patients with cancer and adequately detect psychological distress in these patients. To achieve this, oncologists and nurses will receive a training aimed at communicating about emotions, including emphatically ending a conversation about emotions, and at targeted referral. Furthermore, based on predefined risk factors, patients will be divided into two groups: (a) patients with a low risk of developing psychological distress, and (b) patients with a high risk of developing psychological distress. Patients at high risk for distress will be monitored closely and care needs will be evaluated regularly. All adult cancer patients will be asked to participate, excluding patients participating in interfering trials, patients who are referred to our hospital for a second

opinion and patients with a life expectancy of less than three months.

Study objective

To evaluate the diagnostic accuracy (distress recognition) of the new procedure for detecting psychological distress in patients with cancer

Study design

3 months after start treatment

Intervention

Based on empirically derived predictors of poor resilience (‘yellow flags’), patients are divided into (I) a group with an elevated risk of experiencing psychological distress, and (II) a group with a normal risk.

Group I

(i) Within group I oncologists and nurses provide basic support in dealing with emotional and mental challenges inherent to illness and treatment, as well as supporting existing resilience and optimizing coping strategies. Training in counseling and supervision are provided to medical and nursing staff.

(ii) The oncologist and oncology nurse are alert to possible psychological distress (case finding): the patient’s psychological state is an explicit topic of conversation. The ‘Lastmeter’ and the PHQ4 are available to facilitate detection of psychological distress.

(iii) In case of psychological distress, the oncologist and/or oncology nurse explores the severity and nature of the problem, using the ‘Lastmeter’. The most appropriate assistance is determined, in deliberation with the patient.

Group II
(i) Within group II oncologists and nurses provide support (analogous to group I).

(ii) Oncologist and nurses rely on the usual approach in regular visits to detect psychological distress. The ‘Lastmeter’ and the PHQ4 are available to facilitate detection of psychological distress.

(iii) The most appropriate assistance is determined (analogous to group I).

Contacts

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Eligibility criteria

Inclusion criteria

• Patients with cancer, treated at the VU University Medical Center (VUmc), department of Medical Oncology (clinic and day treatment)

• Patients are enrolled, using a proportional stratified consecutive sample based on the cancer diagnoses in the population at the department of Medical Oncology. Each stratum is represented in the sample (both in the ‘before’ and ‘after’ phase) in the same proportion as in the population at the department of Medical Oncology

• Start with anti-tumor treatment

• Life expectation > 3 months

Exclusion criteria

• Age < 18 or > 85 years

• Second opinion

• Patients with head or neck cancer

• Patients who are participating in the TES-trial

• Insufficient command of the Dutch language

• No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	07-05-2015
Enrollment:	240
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-04-2015
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	NL5076
NTR-old	NTR5208
Other	VU University Medical Center : 2015.072

Study results