Supporting Resilience and Case Finding

Gepubliceerd: 30-04-2015 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26756

Bron
Nationaal Trial Register

Verkorte titel
SIGN

Aandoening

Psychological distress
Cancer patients
Anxiety
Depression
Psychologische distress
Kankerpatiënten
Angst
Depressie

Ondersteuning

Primaire sponsor: VUmc-GGZ inGeest
PO Box 74077, 1070 BB Amsterdam
Overige ondersteuning: VUmc-GGZ inGeest soma-psyche
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

3 months after start treatment

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	07-05-2015
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-04-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5076
NTR-old	NTR5208
Ander register	VU University Medical Center : 2015.072

Resultaten