Screening and treatment of psychological distress in colorectal cancer with metastasized disease: the TES-trial

No registrations found.

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

Summary

ID

NL-OMON24937

Source
Nationaal Trial Register

Brief title
TES-trial

Health condition

colorectal cancer, distress, anxiety, depression, colorectaal kanker, angst, depressie

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Alpe d'Huzes and KWF Kankerbestrijding

Intervention

Outcome measures

Primary outcome

Psychological distress:

- Hospital Anxiety and Depression Scale (HADS)

Secondary outcome

Quality of life:

- EORTC-QLQ-C30

- RAND-36

- EuroQol-5D

Patient evaluation of care:

- Client Satisfaction Questionnaire - 8

Recognition:

- Recognition of psychological distress by clinician.

Referral:

- Referrals related to psychological distress.

Process of care:

- A questionnaire is used to collect data on process of care

Costs

- All relevant costs will be measured prospectively.

Study description

Background summary

Background

Psychological distress, i.e an anxious or depressive mood occurs frequently in patients with metastasized colorectal cancer (CRC). Psychological distress is an unfavorable outcome in itself and is frequently overlooked. To improve detection of psychological distress, the use of screening instruments has been advocated; for example, the Dutch oncology guideline “Detecting the need for psychological care” advises to screen regularly for psychological distress.

However, recent reviews have shown that it cannot be assumed that the implementation of screening and treatment leads to improvement in detection, management or outcome of psychological distress.

Objective

We have developed the TES program, which involves Targeted selection (screening at 0, 10 and 18 weeks) and Enhanced care, delivered on the basis of Stepped care (from watchful waiting to psychotherapy). The primary study aim is to evaluate the effectiveness of the TES-program compared to usual care in reducing psychological distress (as assessed with the Hospital Anxiety and Depression Scale) in metastasized CRC patients.

Methods

Study design

The study is designed as a cluster randomized trial with 2 treatment arms in 10 hospitals. The treatment arms are: TES program for screening and treatment of psychological distress versus usual care. Outcomes are evaluated at the 1st cycle of chemotherapy (T0), after 3 weeks (T3), 10 weeks (T10), 24 weeks (T24) and 48 weeks (T48).

Study population

• Patients with metastatic colorectal cancer (CRC)

• Start of treatment with 1st line chemotherapy

• Life expectation > 3 months

Study objective

We hypothesize that the TES program is a cost-effective approach towards the screening and treatment of psychological distress in CRC patients with metastasized disease, in comparison to usual care.

Study design

Assessments are made at the 1st cycle of chemotherapy (T0), after 3 weeks (T3), 10 weeks (T10), 24 weeks (T24) and 48 weeks (T48).

Intervention

Targeted selection of patients with psychological distress. Enhanced care
by the clinical nurse specialist. Stepped care: The steps include: (i) Watchful waiting. (ii) If psychological distress persists, the guided self-help program. (iii) If psychological distress persists, a problem analysis is performed and an agreement is made with the patient on the next step; treatment consists of problem solving therapy (face-to-face). (iv) If psychological distress persists, psychotherapy, medication or a referral for other services (e.g. social work) is offered.

The TES intervention is compared to usual care.

Contacts

Public
Dept Rehabilitation Medicine and Dept of Psychiatry, VU University Medical Center, PO Box 7057
Joost Dekker
Amsterdam 1007 MB
The Netherlands
+31.20.44.40.763.
Scientific
Dept Rehabilitation Medicine and Dept of Psychiatry, VU University Medical Center, PO Box 7057
Joost Dekker
Amsterdam 1007 MB
The Netherlands
+31.20.44.40.763.

Eligibility criteria

Inclusion criteria

- Patients with metastatic colorectal cancer (CRC);

- Start of treatment with 1st line chemotherapy;

- Life expectation > 3 months.

Exclusion criteria

-Age < 18 or >85 years;

-Insufficient command of the Dutch language;

-Recent psychotherapy (< 3 months ago);

- Contra-indication for the stepped care approach (e.g. need for immediate hospitalization in mental health institute);

- No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-06-2013

Enrollment:	804
Type:	Anticipated

Ethics review

Positive opinion Date:	17-06-2013
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	NL3866
NTR-old	NTR4034
Other	NL39619.029.12 : VU 2011-5279
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A