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

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41458

Source
ToetsingOnline

Brief title
TES-trial

Condition

- Other condition
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Psychological distress. Anxious and depressive mood.

Health condition

gevoelens van angst en depressie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Alpe d'Huzes/KWF Dutch Cancer Society

Intervention

Keyword: Colorectal cancer, Psychological distress, Screening, Treatment

Outcome measures

Primary outcome

Primary outcome is the difference in treatment effect over time in

psychological distress, as assessed with the HADS.

Secondary outcome

Secondary outcomes include quality of life, patient evaluation of care,

recognition and management of psychological distress, and costs.

Study description

Background summary

Psychological distress occurs in approximately one third of colorectal cancer patients. In patients with metastasized diseased, the level of distress is even higher. Because of the improved life expectancy, providing treatment for psychological distress in CRC is an increasingly important issue.
Psychological distress 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.

Essential requirements for the implementation of a screening program include (i) a valid screening instrument, and (ii) effective treatment for psychological distress. These requirements are generally fulfilled, as several valid screening instruments and effective treatments are available. The third essential requirement is (iii) evidence on the (cost)effectiveness of the actual implementation of the screening program. Unfortunately, this third essential requirement is not fulfilled. Despite its intuitive appeal, the true benefit of screening and subsequent treatment of psychological distress is far

from being definitively proven. In fact, the recommendation of the Dutch guideline *Detecting the need for psychological care* to screen regularly for psychological distress is based on consensus among professionals and one qualitative study in oncology patients. Ideally, screening results in improved detection, management (e.g. counselling by the clinician; or referral to a nurse or mental health specialist) and outcome of psychological distress Recent reviews have shown that it cannot be assumed that implementing screening and treatment automatically leads to improvement in detection, management or outcome of psychological distress.

Reviews indicate that effective management of psychological distress seems to require targeted selection of patients and enhanced care. Targeted selection of patients involves administering and scoring of the screening instrument by someone other than the clinician; those with high scores are offered a referral for treatment. Enhanced care involves training of clinicians and support staff, participation of support staff, and several follow up contacts with the patient. Targeted selection and enhanced care require substantial investments in staff as well as clearly defined responsibilities of staff members. In attempting to control the costs of delivering psychological interventions, the stepped care approach has been strongly advocated as being potentially cost-effective. In this approach, less intensive interventions are tried first (e.g. a self help program), with more intensive and costly interventions reserved for those insufficiently helped by the initial intervention (e.g. face-to-face counseling).

Study objective

We have developed the TES program, which involves Targeted selection and Enhanced care, delivered on the basis of Stepped care (TES). The primary study aim is to evaluate the effectiveness of the TES-program compared to usual care in reducing psychological distress in metastasized CRC patients. Secondary aims include the evaluation of the impact of the TES-program on quality of life, patient evaluation of care, recognition and management of psychological distress, and to evaluate the cost-effectiveness of the TES-program.

Study design

The study is designed as a cluster randomized trial with 2 treatment arms in 16 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). These measurement points coincide with the transitions in stepped care in the experimental group.

Intervention

We have developed the TES program, which involves Targeted selection and Enhanced care, delivered on the basis of Stepped care (TES). The steps include: (i) Watchful waiting. (ii) If psychological distress persists, the guided self-help program (based on problem solving therapy) is offered to the patient; an internet based self-help program or a booklet and surface mail is used to deliver self help. (iii) If psychological distress persists, a problem analysis is performed and a contract is made with the patient on the next step; treatment consists of problem solving therapy (face-to-face).(iv) If psychological distress persists, psychotherapy or medication is offered.

Study burden and risks

The additional risk of participation in the TES trial is negligible. All instruments, procedures and treatmens used in the assessment are being used in care as usual: the added value of the TES intervention is in the highly structured approach in using these instruments (*targeted selection*). The same applies to the four steps of the intervention: watchful waiting; internet based self-help program (based on problem solving therapy); problem solving therapy (face-to-face); psychotherapy, medication or a referral for other services (e.g. social work). All steps are available in care as usual: the added value of the TES intervention is the highly structured approach in administering these interventions.

It will take patients ~60 minutes to complete questionnaires, per assessment. Questionnaires are completed at home.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with metastatic colorectal cancer (CRC); start of treatment with 1st line chemotherapy according to standard care, including fluoropyrimidine (e.g. fluorouracil or capecitabine), irinotecan, and oxaliplatin; life expectation > 3 months.

Exclusion criteria

Age < 18 or > 85 years; insufficient command of the Dutch language; recent psychotherapy (< 3 months ago, once every 2 weeks); severe psychopathology; no informed consent.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	30-07-2013
Enrollment:	715
Type:	Actual

Ethics review

Approved WMO Date:	12-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-06-2015
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	NL39619.029.12