The CORRECT-study

No registrations found.

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

Summary

ID

NL-OMON26232

Source
Nationaal Trial Register

Brief title
The CORRECT-study

Health condition

Cognitive behavioral therapy, e-health, psychological distress, colorectal cancer survivors

Cognitieve gedragstherapie, E-health, psychologische distress, colorectaal kanker

Sponsors and support

Primary sponsor: Radboud University Medical Center Nijmegen
VU University Medical Center Amsterdam
Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

Psychological distress as measured by the Brief Symptom Inventory (BSI-18)

Secondary outcome

General quality of life (EORTC-QLQ-C30), supplemented by a disease specific module quality of life module: (EORTC QLQ-CR38), Anxiety and depressive symptoms (Hospital Anxiety and Depression Scale, HADS), Fear of cancer recurrence (Cancer Worry Scale, CWS), Fatigue (Checklist Individual Strength, CIS).

Study description

Background summary

Up to 35% of colorectal cancer survivors (CRCS) experience high levels of psychological distress. Interventions for distressed CRCS are scarce. Therefore, we developed a blended therapy, combining face-to-face cognitive behavioral therapy (CBT) with online self-management activities. This enables patients to complete part of their treatment at home at their convenience and spend more time learning and practicing CBT skills to manage distress. The intervention consists of one generic module and three optional modules which are aimed at decreasing: 1) distress caused by physical consequences, 2) anxiety and fear of recurrence, 3) depressive mood. The intervention will be tailored to patients' individual needs.

In a two-arm randomized controlled trial the efficacy of blended care will be compared to treatment as usual in reducing psychological distress and improving quality of life. Treatment will be compared with a usual care control condition. The primary outcome is general distress. The efficacy of the intervention is evaluated in a randomized controlled trial carried out in the Netherlands.

Study design

Patients will be asked to complete questionnaires at three different time points; baseline (T0, before randomization), 4 months (T1) and 7 months (T2) after randomization.

Intervention

The intervention is based on cognitive behavior therapy (CBT) and consists of blended therapy, a combination of face-to-face CBT with a self-management interactive website. The intervention lasts four months and compromises of five individual face-to-face sessions, supplemented by three telephone contacts. Patients will have daily access to the self-management website. The CBT protocol is directed at changing cognitions and behavior related to distress. Treatment will be individually-tailored based on the presenting problems identified during clinical assessment and and the data gathered during baseline assessment. The intervention consists of one generic module and three optional modules. Three different types of distress will be addressed in the modules: 1) distress caused by physical consequences (e.g. post-cancer fatigue, gastrointestinal problems, urinary incontinence and sexual dysfunction), 2) anxiety and fear of recurrence, 3) depressive mood.

Contacts

Public
Radboudumc, Nijmegen
Sarah Döking
Nijmegen
The Netherlands
Scientific
Radboudumc, Nijmegen
Sarah Döking
Nijmegen
The Netherlands

Eligibility criteria

Inclusion criteria

- Colorectal cancer treated with curative intent (stage I, II and III)

- Completed cancer treatment at least 6 months and no more than 5 years

- Cancer-free at study-entry

- 18 years or older

- Distress Thermometer score of 5 or higher

- Sufficient comprehension of the Dutch language to fill out questionnaires

- Basic internet skills (e.g. possession of email address, internet access at home, weekly internet use and able to use internet without help of others)

- Able to travel to the hospital for the CBT intervention

Exclusion criteria

- No current psychological treatment or during the last month

- Inability to provide informed consent due to intellectual disability or cognitive impairment

- Diagnosis of Lynch Syndrome

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-08-2016
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	NL5759
NTR-old	NTR6025
Other	NL55018.091.15 CMO Arnhem-Nijmegen : 2015-2077

Study results