The CORRECT-study

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

Samenvatting

ID

NL-OMON26232

Bron
Nationaal Trial Register

Verkorte titel
The CORRECT-study

Aandoening

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

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

Ondersteuning

Primaire sponsor: Radboud University Medical Center Nijmegen
VU University Medical Center Amsterdam
Overige ondersteuning: Dutch Cancer Society

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-08-2016
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	NL5759
NTR-old	NTR6025
Ander register	NL55018.091.15 CMO Arnhem-Nijmegen : 2015-2077

Resultaten