Effectiveness of blended therapy for psychological distress in colorectal cancer survivors: The CORRECT multicenter trial

Published: 11-01-2016
Last updated: 19-04-2024

Intervention studies for distress in CRCS are scarce. The CORRECT intervention (COloRectal canceR distrEss reduCTion) will be aimed at decreasing psychological distress through participatory healthcare. The context of healthcare is rapidly changing…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON47176

Source
ToetsingOnline

Brief title
CORRECT study

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Adjustment disorders (incl subtypes)

Synonym
bowel cancer, colorectal cancer, rectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: Cognitive behavioral therapy, Colorectal cancer survivors, E-health, Psychological distress

Outcome measures

Primary outcome

The primary outcome of the study is general distress (measured with the Brief Symptom Inventory-18).

Secondary outcome

The secondary outcomes are Quality of Life (measured with the EORTC-QLQ-C30 and QLQ-CR38), fatigue (measured with the Checklist Individual Strength), anxiety and depressive symptoms (measured with the Hospital Anxiety and Depression Scale), fear of recurrence (measured with the Cancer Worry Scale), coping (measured with the Impact of Event Scale) and self-efficacy (measured with the Self-Efficacy Scale).

Study description

Background summary

Colorectal cancer is one of the most common cancer diagnoses worldwide affecting men and women almost equally. Population ageing and improved methods of early detection and treatment have led to rising numbers of patients surviving colorectal cancer. With the introduction of the national colorectal cancer screening program in the Netherlands, the incidence is expected to even further increase, especially for early stages. Approximately 60% of the patients survive 5 years or more without a cancer recurrence. Although the majority of colorectal cancer survivors (CRCS) are resilient and eventually

adjust well, a substantial minority experience high levels of distress that affect the patients' quality of life. The prevalence estimate of psychological distress in CRCS is about 35%.

Study objective

Intervention studies for distress in CRCS are scarce. The CORRECT intervention (COloRectal canceR distrEss reduCTion) will be aimed at decreasing psychological distress through participatory healthcare. The context of healthcare is rapidly changing, "patients shift from being mere passengers to responsible drivers of their health and medical care providers encourage and value patients as partners" (Society Participatory Medicine). Patients are expected to assume a greater role in managing their own care. The CORRECT intervention will stimulate participatory healthcare by combining face-to-face cognitive behavioral therapy with self-management activities at a secured website. This innovative approach is called blended therapy. By adding online activities to face-to-face therapy, patients can seek treatment at home at their convenience and spend more hours to learn new skills to manage distress. Moments of contact with the therapist will occur at fixed time points to support the survivor in his/her effort to self-manage distress and to communicate about progress and difficulties. The CORRECT intervention will stimulate and facilitate self-management by gradually decreasing therapist support and increasing self-management towards the end of the intervention period. In this way patients take charge of their own health and learn to cope with the challenges of the future as cancer survivor.
There is a growing body of research demonstrating that cancer patients tend to experience clusters of problems rather than a single problem in isolation. The CORRECT intervention will address key elements of psychological distress in CRCS 1) distress caused by physical consequences of colorectal cancer, e.g. postcancer fatigue, gastrointestinal problems, urinary incontinence, sexual dysfunction 2) anxiety and fear of recurrence, 3) depressive mood. As not all factors might be equally relevant for each patient, the intervention will be individually tailored to the survivors' needs.

Study design

An elaborate treatment-protocol will be written by experienced psychologists with patient participation. The interactive self-management website will be developed with use of the e-health application myTherapy. The content of the website will be adapted from existing websites developed by the Department Medical Psychology of the Radboudumc. The intervention exists of maximum 8 sessions (5 face-to-face, 3 e-consultations) with a total duration of four months. The website will be available to support the participant throughout the entire intervention, including psycho-education, assignments, assessments and video clips.

A multicentre randomized controlled trial will be conducted:
1.to test the effectiveness and cost-effectiveness of the CORRECT intervention compared to treatment as usual in decreasing distress (BSI-18)
2.to provide a more complete understanding of the usage of online activities by exploring in what amount and how CRCS use the interactive website and how online usage is associated with distress reduction

Assessments will take place at baseline (T1, time of inclusion). After four months the second assessment will take place (T2). Between T1 and T2 the CORRECT intervention will be carried out. The follow-up assessment (T3) will be administered at 3 months after the intervention (7 months after baseline).

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 CBT protocol is directed at change of cognitions and behavior related to key factors of distress.
Distressed colorectal cancer survivors (CRCS) who will be randomized to the intervention will be in different phases of their survivorship trajectory. Therefore, distress may be the result of different problems. Also the factors related to distress are not the same for each patient, so each treatment will be individually-tailored based on the distress analysis in the first session and the data gathered during baseline assessment. Three different types of distress will be differentiated in further tailoring the intervention: 1) distress caused by physical consequences (like post-cancer fatigue, gastrointestinal problems, urinary incontinence and sexual dysfunction, 2) Anxiety and fear of recurrence, 3) depressive mood

The control group has access to usual care and will not be offered the CORRECT intervention. In recent years, the need for psychosocial screening has been recognized, guidelines have been formulated and systematic screening has been implemented in hospitals in the Netherlands. If distress is detected during routine follow-up, TAU will be very diverse. Physicians or nurses may advise patients how to reduce distress or patients will be referred to their general practitioner or a psychologist. No restrictions will be made in the TAU condition to use internet, psychological or other interventions

Study burden and risks

There are no risks involved for the participating patients of this study. Only time investment is asked regarding the completion of the questionnaires and/or CBT treatment.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Colorectal cancer survivors 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, as defined by the absence of somatic disease activity parameters
- Distress Thermometer score equal or higher than 5 (validated cut-off score indicating high distress levels)
- Age of 18 years and older
- Sufficient understanding 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 therapeutic treatment or during the last month (e.g. counseling, cognitive behaviour therapy, group psychological treatment)
- Inability to provide informed consent due to intellectual disability or cognitive impairment
- Lynch Syndrome

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2016
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	11-01-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-06-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	01-08-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-12-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-09-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-11-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-01-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-04-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-05-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-10-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL55018.091.15