The SWORD-study: Managing fear of cancer recurrence.

No registrations found.

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

Summary

ID

NL-OMON27836

Source
Nationaal Trial Register

Brief title
The SWORD-Study

Health condition

fear of cancer recurrence in breast, colorectal and prostate cancer survivors.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Fear of cancer recurrence as measured with the cancer worry scale (CWS).

Secondary outcome

1. Disease specific quality of life (EORTC-QLQ-C30), supplemented by a disease specific

module: BR23 for breast cancer, CR29 for colorectal cancer or PR25 for prostate cancer.
2. Satisfaction with Life (Satisfaction With Life – Scale)

Study description

Background summary

Fear of Cancer Recurrence (FCR) is a normal and common concern for most cancer survivors. For up to 40% fear becomes a chronic problem. Few studies investigated interventions specifically designed for clinical levels of FCR. In a two-arm randomized controlled trial, among breast, prostate and colorectal cancer survivors, the efficacy of blended care will be compared to treatment as usual in managing FCR and thereby reducing related functional and psychological consequences. The intervention is based on principles of cognitive behavior therapy (CBT) and is directed at change of the cognitions and behaviors managing FCR. It is designed as blended care, combining face-to-face CBT with online activities (or workbook assignments). Primary and secondary outcome measures are severity of FCR, quality of life and satisfaction with life. At this moment, the effectiveness of the intervention is evaluated in a randomized trial carried out in the Netherlands.

Study design

Patients will be asked to complete the described questionnaires at four different time points; baseline (T0, before randomization), 3 (T1), 9 (T2) and 15 months (T3) after random assignment.

Intervention

The intervention is designed as blended care, combining traditional face-to-face cognitive behavior therapy (CBT) with online activities (psycho-education, assignments, assessments and therapist contact). If access to the website is not possible a workbook will be supplied instead. The CBT lasts three months and comprises five individual hourly face to face sessions, supplemented with three (15 minute) electronic consultations (‘e-consults’) or contact by telephone. The therapy protocol is based on a theoretical model by Lee-Jones (1997) which hypothesizes that an emotional reaction (fear) can be the result of interpretations and cognitions of the threat of cancer, triggered by perceptions of internal and/or external cues, leading to dysfunctional behavior and subsequently an increased fear response. The CBT is directed at change of the cognitions and behaviors managing FCR. It contains techniques commonly used in psychotherapy, such as cognitive reframing, exposure- and response prevention, psycho-education, mindfulness and relaxation exercises.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically proven breast, colorectal or prostate cancer.
2. Primary curative-intent cancer treatment is completed between six months and five years ago.
3. Patients are disease-free at moment of study inclusion, as defined by the absence of somatic disease activity parameters;.
4. Patients are at least 18 years of age at time of inclusion (therefore defined as ‘adult’ by Dutch law);
5. Cancer Worry Scale score of 14 or higher, indicating a high level of fear of cancer recurrence.
6. Have sufficient Dutch language skills to complete questionnaires and engage in active conversation.
7. Patients are able to travel to hospital for CBT.
8. Are willing and able to give written informed consent according to legal requirements.

Exclusion criteria

1. Primary curative-intent cancer treatment is completed less than 6 months ago.
2. Currently receiving psychological or psychiatric therapy for psychiatric co morbidity.

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):	02-02-2014
Enrollment:	108
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-02-2014
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	NL4280

Register	ID
NTR-old	NTR4423
Other	CMO Arnhem-Nijmegen : 2013/145 - NL41601.091.13

Study results