The sword of Damocles. Managing fear of cancer recurrence with the SWORD intervention study (Survivors' Worries of Recurrent Disease).

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Cognitive behavior therapy (CBT) seems a promising intervention to reduce FCR. The SWORD study (Survivors* Worries of Recurrent Disease) will examine the efficacy and cost-effectiveness of individual CBT compared to treatment as usual (TAU) in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON39571

Source
ToetsingOnline

Brief title
SWORD study

Condition

- Miscellaneous and site unspecified neoplasms benign
- Anxiety disorders and symptoms

Synonym
breast cancer, colorectal cancer, prostate cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cancer, Cognitive behavior therapy, E-health, Fear of recurrence

Outcome measures

Primary outcome

Severity of fear of cancer recurrence (measured with the Cancer Worry Scale).

Secondary outcome

1. Disease specific quality of life (QLQ-C30), supplemented by a disease specific module: BR23 for breast cancer, CR29 for colon cancer or PR25 for prostate cancer. .

2. Satisfaction with (Quality of) Life (Satisfaction With Life Scale)

3. Cost-effectiveness and health-status (EQ-5D and patient diaries).

Other:

Mediators and moderators: Body Vigilance (Body Vigilance Scale), aspects of fear of cancer recurrence (Fear of Cancer Recurrence Inventory) emotional wellbeing (Hospital Anxiety and Depression Scale). Personality factors (The Big Five Inventory) Optimism (Life Oriëntation Test), Social Support (Sociale Steun Lijst- Discrepanties), fatigue (Verkorte Vermoeidheids Vragenlijst - 8) and impact of events (Schokverwerkingslijst).

For both patient groups, also medical disease-specific data are collected.

Study description

Background summary

Fear of cancer recurrence (FCR) is a normal concern for cancer survivors who have completed treatment and are in remission. Fear might be constructive, e.g. keeping patients alert for symptoms indicating the possibility of recurrent disease. However, even though fear of recurrence appears to be universal, some survivors report more fear than others. This high level of fear is characterized by a perceived risk of recurrence that is disproportionate to the actual risk, functional impairment resulting from FCR, a long duration and greater severity of the problem, frequent self-examination and demands for medical tests for potential signs of recurrence. In literature, the percentages of cancer survivors experiencing high levels of FCR range from 9-34% and seems to become a chronic problem. Until now an evidence-based intervention especially designed to assist patients in dealing with FCR is lacking in the care for cancer survivors.

Study objective

Cognitive behavior therapy (CBT) seems a promising intervention to reduce FCR. The SWORD study (Survivors* Worries of Recurrent Disease) will examine the efficacy and cost-effectiveness of individual CBT compared to treatment as usual (TAU) in managing FCR and thereby reducing related functional and psychological consequences. Mediation analyses will be conducted to provide us a more complete understanding of the mechanisms through which the intervention might achieve its effect. In addition, moderators of treatment outcome will be determined.

Study design

In this 2-arm randomized controlled trial (RCT) patients who are willing to participate will be screened for the presence of high FCR by filling out a questionnaire. Provided that they meet the inclusion criteria (see study population) eligible patients will be randomly allocated to one of two conditions, cognitive behavior therapy (CBT) or treatment as usual (TAU). While both participants in the CGT and TAU condition will be asked to fill out questionnaires, patients in the CGT condition will also receive a CGT intervention. Assessments will take place at baseline (T1, time of inclusion). After 3 months the second assessment will take place (T2). Between T1 and T2 the CBT will be carried out. The follow-up assessment will be administered at 6 months (T3) and one year (T4) after the intervention.

Intervention

The intervention will be developed by researchers and psychologists of the department of Medical Psychology (UMC st. Radboud). Psychologists of this department are specialized in treating cancer patients for different kind of problems with CBT (depression, fatigue, anxiety). The proposed CBT intervention consists of 6 to 8 individual, one hour sessions within 3 months by a trained psychologist and is directed at change of cognitions and behaviour related to FCR. In the last sessions (6-8) shared decision-making will take place in how to continue therapy: face-to-face or by E-health.

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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Breast, colorectal and prostate cancer survivors up to 5 years after finishing primary treatment
- At the moment of the study disease-free, as defined by the absence of somatic disease activity parameters.
- Age of 18 and older.
- Cancer Worry Scale score of 14 or higher, indicating a high level of fear of cancer recurrence
- Sufficient understanding of the Dutch language to fill out questionnaires
- Able to travel to hospital for CBT intervention

Exclusion criteria

- Primary treatment completed less than 6 months ago.
- Currently in active (psychological/psychiatric) treatment for psychiatric comorbidity.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2014
Enrollment:	104
Type:	Actual

Ethics review

Approved WMO Date:	02-07-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-03-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-05-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-06-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-10-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-12-2014
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	NL41601.091.13