Investigating an online self-help training for fear of cancer recurrence in breast cancer patients.

No registrations found.

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

Summary

ID

NL-OMON24298

Source
Nationaal Trial Register

Brief title
CAREST

Health condition

breast cancer
fear of cancer recurrence
FCR
borstkanker
angst voor terugkeer van kanker

Sponsors and support

Primary sponsor: Helen Dowling Institute
Source(s) of monetary or material Support: Pink Ribbon

Intervention

Outcome measures

Primary outcome

Primary outcome measure will be fear of cancer recurrence. Fear of cancer recurrence will be assessed with the Fear of Cancer Recurrence Inventory (FCRI). The FCRI consist of the following seven subscales: triggers, severity, psychological distress, coping strategies, functioning impairments, insight, and reassurance. The severity-subscale is the first outcome measure in this study. The coping strategies- and functioning impairments-scale scores at baseline will be used in the predictor analysis.

Secondary outcome

Secondary outcomes will be healthcare costs and psychological distress. Healthcare costs will be assessed with the Medical Consumption Questionnaire (MCQ) and the EuroQol-5D (EQ-5D). Psychological distress will be assessed with the Fear of Cancer Recurrence Inventory (FCRI).

Study description

Background summary

(Version added 13-aug-2014):

Rationale for the study

The prevalence of patients living with breast cancer in the Netherlands has been estimated to rise to 140.000 in 2020. One third of all women who have had breast cancer suffer from fear of recurrence, which has a profound negative impact on their quality of life. This fear may also lead to higher healthcare costs and may compromise health outcomes. Breast cancer patients have indicated that they lack support in dealing with their fear of cancer recurrence. In light of the increasing prevalence of breast cancer and increasing health care costs, we are in urgent need of a form of support that is both easily accessible to a large group of patients and is cost-effective. The aim of this study is to determine the (cost-) effectiveness of an online self-help training for fear of cancer recurrence.

Research questions

1. Is online self-help for fear of cancer recurrence (cost-) effective?

2. Can we predict for whom online self-help is beneficial?

Methods / study design

The design of the study will be a multi-center, randomized-controlled trial, comparing online

self-help training with care as usual. Primary outcome measure will be fear of cancer recurrence.
Secondary outcome will be healthcare costs and distress. Patients will be randomized to either the online self-help or care as usual. Randomization will be carried out through the sealed envelope system, for each hospital separately. Patients will be recruited through hospitals in various regions in the Netherlands. Patients will be eligible if they have had a diagnosis of breast cancer between one and five years ago, have had curative treatment, have access to the internet and are capable of filling out questionnaires in Dutch. Assessments will take place at baseline (T0), and 3 (T1), 9 (T2) and 24 months later (T3). The aim of this study is to determine the (cost-) effectiveness of an online self-help training for fear of cancer recurrence.

Relevance

This project contributes to knowledge about potentially effective ways of reducing the fear of recurrence, which in turn is expected to lead to a better quality of life of patients and their loved ones. Also we expect this study to show that early and easily accessible online interventions are cost effective and may prevent development of high distress.

Study objective

The primary objective of this project is to study the (cost-) effectiveness of an online self-help training for fear of cancer recurrence. We expect that fear of recurrence severity, psychological distress, and healthcare costs wil reduce more in the online self-help condition compared to the usual care condition.

Online self-help for FCR is not expected to be effective for all participants. It is important to identify factors that predict whether a person does or does not benefit from treatment. This will be the second objective of this project

Study design

Patients will fill out questionnaires at baseline (T0), 3 months (T1), 9 months (T2) and 24 months (T3).

Intervention

Online self-help training for fear of cancer recurrence:

Participants start the training by filling out the Fear of Recurrence Inventory, after which they

get feedback about their scores and a suggestion about which modules to follow.

The two basic modules concern:

1. Psycho-education about FCR, its symptoms and learning to recognize symptoms of fear.

2. Teaching the basic principles of cognitive behavior therapy.

After these basic modules women can choose from the following 4 modules:

1. How to stop rumination, behavioral techniques to stop ruminating.

2. Action, making an action plan about what one can do when fear of recurrence pops up.

3. Relax, audio files with relaxation practices.

4. Reassurance, how and when to seek reassurance.

Each module consists of an informative part and a practical part in which participants are motivated to do exercises or assignments in daily life. Participants are advised to take a week for each module they follow, so most participants will need four to six weeks depending on how many modules they follow. It is explained that the more time they invest, the more effect they can expect from the training, but participants eventually choose themselves how much time is actually spent on the training.

The control group will receive care as usual.

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Eligibility criteria

Inclusion criteria

Part A

> Diagnosis of breast cancer, 1-5 years ago

> Curative treatment

> Capable of filling out questionnaires in Dutch

> Age at disease onset minimal 18 years

Part B

> All criteria of part A

> Access to the internet

> No actual recurrence or diagnosis of metastasis

Exclusion criteria

None

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2013
Enrollment:	454
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-08-2013
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	NL3953
NTR-old	NTR4119
Other	NL45768.101.13 : 2012.WO43.C158 Pink Ribbon
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A