(Cost-) effectiveness of online self-help training for fear of cancer recurrence in breast cancer patients.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41426

Source
ToetsingOnline

Brief title
CAREST

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
fear of cancer recurrence

Health condition

angst voor de terugkeer van kanker

Research involving
Human

Sponsors and support

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

Intervention

Keyword: effectiveness, FCR, fear of cancer recurrence, online self-help

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).

Other study parameters:

Baseline level of fear of recurrence severity, psychological distress, level of functioning impairment, and coping strategies will be assessed with the Fear of Cancer Recurrence Inventory (FCRI).

Psychosocial problems and risk factors will be assessed with the Psychosocial Distress Questionnaire-Breast Cancer (PDQ-BC). The PDQ-BC consists of nine subscales: trait anxiety, social support, state anxiety, depressive symptoms, social problems, physical problems, body image, financial problems, and sexual problems.

Self-efficacy will be assessed with an assembled questionnaire.

Study description

Background summary

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. Recently, an online self-help training for fear of cancer recurrence was developed.

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. 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.

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?

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. Patients will be recruited through hospitals in various regions in the Netherlands. Assessments will take place at baseline (T0), and 3 (T1), 9 (T2), 15 (T3) and 24 months later (T4).

Intervention

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.

Study burden and risks

This study involves capacitated adults and therapeutic research. Participation is free of charge. The pilot study indicates that no concrete risks are related to the intervention. Participating in this study can be time consuming, as participants will fill out several questionnaires at different time points. These questionnaires contain questions that might be confronting for the participant, as they confront the participant with her current situation. Though, we do not expect this to be harmful.

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

- Female
- Diagnosis of breast cancer, between one and five years ago (part A)
- No signs for local/regional recurrence or metastatic disease (part A)
- Capable of filling out questionnaires in Dutch (part A)
- Age at disease onset at least 18 years old (part A)
- Access to the internet (part B)

Exclusion criteria

- No exclusion criteria

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2014
Enrollment:	454
Type:	Actual

Ethics review

Approved WMO Date:	18-12-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	29-04-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	21-05-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	26-06-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-02-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-09-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL45768.101.13