Development and effectiveness of a webbased psycho-educational self-management intervention for breast cancer patients.

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

Summary

ID

NL-OMON33129

Source
ToetsingOnline

Brief title
BREAst cancer e-healTH: BREATH

Condition

- Miscellaneous and site unspecified neoplasms benign
- Mood disorders and disturbances NEC

Synonym
breast cancer, breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Stichting Pink Ribbon

Intervention

Keyword: breast cancer, psychological distress, self-management, webbased psycho-education

Outcome measures

Primary outcome

Psychological distress (SCL-90).

Secondary outcome

- Quality of life generally (EORTC QLQ C30) and specifically for breast cancer

patients (BR23).

- Anxiety and depression (HADS)

- Personality (BFI)

- Coping (Cope)

- Impact of events (SVL)

- Acceptance and helplessness (ZCL)

- Empowerment (NEV-bk)

For patients in the experimental group, also medical disease-specific data are

collected and technical data on the use of the Internet intervention, in

addition to the standardized questionnaires.

Study description

Background summary

In the Netherlands approximately 10,000 patients are newly diagnosed with breast cancer, of which 94% have curative treatment. The expected 10-year survival is over 70% in the period 2000-2002. Despite the increased life expectancy, women diagnosed with breast cancer often experience anxiety and depression. After the operation and diagnosis of abnormal cells in the lymph nodes both depression and anxiety reduce, and return to base level one year after the operation. Although breast cancer patients show a good adaptation of general distress after treatment, a part of the patients is at risk for persistent distress. Several years after surgery approximately one third of the women experience more anxiety and depression compared to peers without breast cancer. In this group of patients the impact of the disease does not decrease in the course of time.

The psychological distress of breast cancer patients after primary surgery plays a central role in predicting subsequent survival. Low levels of distress, low fatigue and low anxiety predicted longer relapse-free survival. Depending on the professional, individual specialized psycho-oncological care appears to have fair to good effect. It is scientifically demonstrated that psychological interventions with cognitive behavioral therapy through E-health is equally effective as psychological interventions with face-to-face contact, for example in the area of anxiety, depression or emotional processing problems. At this moment there are no comparable psychological treatments available online for patients with breast cancer.

Study objective

The purpose of this study is to develop a webbased intervention for breast cancer patients to reduce the impact of psychological problems that arise after the completion of medical treatment at an early stage. The question is whether this intervention compared with usual care is effective in reducing psychological distress.

Study design

In a randomized controlled trial (RCT), two groups will be compared. In the experimental group usual care will be supplemented with the use of the BREATH intervention on a protected website. The control group only uses usual care and reflects the natural course of treatment. The latter group may freely use information on breast cancer on the Internet, as in daily practice is possible, but does not have access to the protected website with the BREATH intervention. By comparing the experimental group and the control group, the effect of the intervention will be identified. During hormonal therapy patients report mood swings and increased fatigue, which can be expected to influence the relationship between the intervention and the outcome variable. Therefore,

after stratification for the use of hormonal therapy a randomized block design will be used. After stratification patients will be randomized according to a predetermined procedure and random allocation to the two research groups will take place.

Intervention

The Internet intervention will focus on information and treatment of psychological problems (such as anxiety and depression), emotional processing issues, social problems (such as work resumption and reactions fo the environment), and physical problems (such as pain, fatigue and sexuality), which can all be influenced by psychological factors. With short-term cognitive behavioral therapy patients are offered the opportunity to successively go through several treatment modules for psychological, social or physical problems. Each cognitive behavioral module contains exercises or homework to promote behavioral change.
The intervention will be developed by the Department of Medical Psychology of the UMC St Radboud. This department has a long experience in developing e-health programs for medical and psychological treatment (eg IVF, young people with diabetes, rheumatoid arthritis, psoriasis and cardiac patients).

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. In addition, patients in the experiment group have access to an additional psychoeducational website (BREATH website), in addition to standard treatment. No condictions are attached to the use, and correspondingly, the time investment of the intervention, this is done at the initiative of the patient.
It is up to the patient to what extent they use the website. The aim of the research is to reduce the impact of psychological problems that arise after the completion of medical treatment at an early stage. In the long term the research may contribute to prevention of psychologiscal problems in breast cancer patients.

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

- Histologically proven malignancy of the breast.
- Breast cancer is treated with curative intent surgery and adjuvant chemotherapy, possibly in combination with radiotherapy.
- Patients with direct access to a computer with internet connection and some skill on the Internet.
- A good command of Dutch language.

Exclusion criteria

- Patients treated only with surgery.
- Patients with locally extensive breast carcinoma.
- Patients with metastatic breast carcinoma.
- Previous malignancy except adequately treated cervix carcinoma in situ and treated basal cell carcinoma of the skin.
- Psychiatric problems that interfere with adherence to the study.

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:	Recruiting
Start date (anticipated):	16-08-2010
Enrollment:	160
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	28-08-2009
Application type:	First submission
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	NL27951.091.09