The BREATH study: Online self-management to facilitate adjustment after curative breast cancer.

No registrations found.

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

Summary

ID

NL-OMON28971

Source
Nationaal Trial Register

Brief title
BREAst cancer e-healTH [BREATH]

Health condition

breast cancer, mamma carcinoma, borstkanker, Internet, web-based intervention, self-management

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre, Nijmegen, the Netherlands
Source(s) of monetary or material Support: Stichting Pink Ribbon, the Netherlands

Intervention

Outcome measures

Primary outcome

Psychological distress (SCL-90 ; Arrindell, 2003) and empowerment (Cancer Empowerment Questionnaire; Van den Berg, 2010).

1. Arrindell WA, Ettema JHM. SCL-90: Handleiding bij een multidimensionele psychopathologie-indicator [SCL-90: Manual for a multifaceted measure of psychopathology]. Lisse, Swets & Zeitlinger, 2003;

2. Van den Berg SW, Gielissen M, Prins JP. Validation of an empowerment questionnaire in breast cancer survivors. Meeting abstract 12th World Congress of Psycho-Oncology, May 2010.

Secondary outcome

1. Quality of life generally (EORTC QLQ C30) and specifically for breast cancer patients (BR23);

2. Anxiety and depression (HADS);

3. Remoralization (RS);

4. Perceived control (Mastery-scale);

5. Positive adjustment (PAQ);

6. Personality (BFI);

7. Coping (Cope);

8. Impact of events (IES);

9. Illness cognitions (ICQ);

10. Fear of cancer recurrence (CWS);

11. Openness to discuss cancer (ODHCF);

12. Self-efficacly (SE-28);

13. Fatigue (CIS-fatigue).

For patients in the experimental group, also medical disease-specific data are collected and technical data on the use of the web-based intervention, in addition to the standardized questionnaires.

Study description

Background summary

After completion of curative treatment, all breast cancer patients go through the transition from patient to survivor. During this re-entry phase, patients are faced with a broad range of re-entry topics, concerning physical and emotional recovery, returning to work and fear of recurrence. The universality of these topics motivated the BREATH study to develop an effective and easily accessible self-management intervention to facilitate adjustment for all breast cancer patients. Therefore, the BREATH study aims to develop and establish the effectiveness of a web-based self-management intervention to facilitate adjustment after completion of primary curative breast cancer treatment. The question is whether this intervention compared with usual care is effective in decreasing psychological distress and/or increasing patient empowerment. Secondary outcomes include psychological, physical, and social measures. Tackling universal re-entry topics shortly after completion of primary breast cancer treatment might facilitate the transition from patient to survivor. The BREATH intervention provides a non-traditional psychological self-management approach to support emotional, physical and social recovery after breast cancer. The intervention is offered to all patients, both distressed and non-distressed. Innovative is the use of patients own strengths as an explicit intervention target providing a buffer to prevent psychological distress in long-term survivorship. At this moment, the (cost) effectiveness of the BREATH intervention is evaluated in a multicenter randomized controlled trial involving 7 hospitals in the Netherlands.

Study objective

The purpose of this study is to develop a web-based 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 research question is whether this intervention compared with usual care is effective in reducing psychological distress and/or improving empowerment.

Study design

Baseline (3 months after completion of radio and/or chemotherapy) and 4, 6 and 10 months after baseline.

Intervention

The non-guided self-management BREATH intervention focuses on information and treatment of psychological problems (such as anxiety and depression), emotional processing issues, social problems (such as work resumption and reactions of the environment), and physical problems (such as pain, fatigue and sexuality), which can all be influenced by psychological factors. The intervention guides patients chronologically through universal re-entry topics. The protocol has a fixed structure that covers four months, representing four different phases

of recovery after breast cancer. Each month has a fixed week structure that targets consecutively psycho-education, problems in every day live, social environment, and empowerment. Working ingredients include Information (25 scripts), Assignment (48 tasks), Assessment (10 tests) and Video (39 clips extracted from the recorded interviews).

The control group receives care as usual.

Contacts

Public
POBox 9101
S.W. Berg, van den
Radboud University Nijmegen Medical Centre
Department of Medical Psychology
Internal Postal code 840
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3617022
Scientific
POBox 9101
S.W. Berg, van den
Radboud University Nijmegen Medical Centre
Department of Medical Psychology
Internal Postal code 840
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3617022

Eligibility criteria

Inclusion criteria

1. Histologically proven malignancy of the breast;

2. Breast cancer is treated with curative intent surgery and adjuvant chemotherapy and/or radiotherapy;

3. Patients with direct access to a computer with internet connection and some skill on the Internet;

4. A good command of Dutch language.

Exclusion criteria

1. Patients treated only with surgery;

2. Patients with metastatic breast carcinoma;

3. Previous malignancy except adequately treated cervix carcinoma in situ and treated basal cell carcinoma of the skin;

4. 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)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-08-2010
Enrollment:	170
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-06-2011
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	NL2795
NTR-old	NTR2935
Other	CMO Arnhem-Nijmegen / CCMO : 2009/144 / NL27951.091.09;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A