A randomized study of an internet-based cognitive behavioral therapy program for sexuality and intimacy problems in women treated for breast cancer.

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The proposed study will evaluate the efficacy of an internet-based cognitive behavioral intervention program designed to alleviate sexuality and intimacy problemens of women who have been treated for breast cancer.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON40346

Source
ToetsingOnline

Brief title
Internet-based CBT for sexuality and intimacy problems after breast cancer

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Sexual dysfunctions, disturbances and gender identity disorders

Synonym
problems with sexuality and intimacy, Sexual dysfunctions and intimacy problems

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF Kankerbestrijding en Stichting Pink Ribbon

Intervention

Keyword: Breast cancer, Cognitive Behavioral Therapy, Internet, Sexuality

Outcome measures

Primary outcome

The primary study outcomes are sexuality problems, as assessed with the Sexual Activity Questionnaire (SAQ), the Female Sexual Dysfunction Index (FSFI), and the Female Sexual Distress Scale (FSDS), and intimacy problems, as assessed with the PAIR Inventory.

Secondary outcome

The secondary study outcomes are body image (QLQ-BR23), menopausal symptoms (FACT-ES), marital functioning (MMQ), psychological distress (HADS), and health related quality of life (MOS SF-36).

Study description

Background summary

Approximately half of breast cancer survivors report sexual problems, and upwards 50% of these women express interest in receiving professional help. Nevertheless, despite the availability of effective treatment, very few women actually undergo formal, face-to-face counselling/therapy for their sexual complaints. There is evidence that many breast cancer survivors consider clinic-based, face-to-face therapy to be too confrontational. There is growing evidence that internet-based cognitive behavioral therapy (CBT) can effectively treat a range of psychosocial problems (e.g., anxiety, depression, PTSD, and more recently sexual dysfunction). There are a number of advantages to internet-based therapy, including relatively low cost, convenience,

accessibility, and privacy. The proposed study will evaluate the efficacy of an internet-based CBT program in alleviating sexuality and intimacy problems, and enhancing the HRQL of women with breast cancer. If demonstrated to be effective, the availability of internet-based cognitive behavioral therapy program will be a welcome addition to regular medical care offered to breast cancer patients with sexuality and intimacy problems.

Hypotheses:

1. Women who follow the internet-based intervention program will report significantly greater improvement from baseline to post-treatment and 3 months follow-up in sexual functioning, as assessed by the Sexual Activity Questionnaire (SAQ), the Female Sexual Function Index (FSFI), and the Female Sexual Distress Scale (FSDS), and in intimacy, as assessed by the PAIR Inventory, than women in the minimal intervention control group.

2. Women exposed to the intervention will report significantly more improvement in body image, menopausal symptoms, marital satisfaction, psychological distress, and generic health related quality of life than women in the minimal intervention control group.

Study objective

The proposed study will evaluate the efficacy of an internet-based cognitive behavioral intervention program designed to alleviate sexuality and intimacy problemens of women who have been treated for breast cancer.

Study design

For this multicentre trial patients will be recruited from 14 hospitals in the Amsterdam region. Participants will be randomly allocated to either the intervention condition or the control condition (N=80 per group). Upon completion of the study, the patients assigned to the control group will be given the opportunity to undergo the internet-based cognitive behavioral therapy program.

Women in the intervention group and control group will be asked to complete a battery of questionnaires prior to randomization (T0), at 10 weeks (T1), and at post-treament (intervention condition)/20 weeks (control condition). Women in the intervention condition will complete a final questionnaire at 3 months follow-up. Main outcome measures are sexuality and intimacy problems, body image, menopausal symptoms, marital/relational functioning, psychological distress, and health-related quality of life. Partners of women in the intervention condition are asked (on voluntary basis) to complete questionnaires about their experience of the relationship and sexuality. If they have agreed, the questionnaires are offered to the partners at the same

moments during the study as the women in the intervention condition.

Intervention

The intervention consists of an internet-based cognitive behavioral therapy program with a maximum duration of 20 weeks. Women will be motivated by the sexologist to involve their partner in the treatment. The CBT program comprises a maximum of 10 treatment modules that can be used in varying order. These include: 1) Put your problems into words, 2) How is my relationship doing?, 3) Sex and my body, 4) Focus my attention, 5) Explore my body, 6 & 7) Discovering my sexual arousal feelings (versions for the woman and for her partner), 8) Change my thoughts, 9) My sexual preferences, and 10) Relapse prevention. The choice of modules to be used by any given woman is based on the information obtained via the screening questionnaires and the intake evaluation by the therapist. Each module contains three interventions and a personal evaluation form to report on the intervention. Each intervention comprises the following elements: introduction, psycho-education about symptoms, *homework* assignments (e.g. relaxation techniques (pelvis); discuss intimacy with partner, sensate focus) and reporting back to the therapist and receiving feedback on homework assignments. The purpose of the internet-based therapy is to provide women with information, skills, and support to handle their sexuality and intimacy problems better or to let the problems decrease/disappear.

Study burden and risks

A potential disadvantage of participation in the study is the investment of time and the effort it takes to complete the therapy program.

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

The study sample will be composed of 160 women, between 18 and 65 years of age, with histologically confirmed breast cancer, who received treatment in one of the participating hospitals. All women will have completed treatment (with the exception of endocrine therapy), received their diagnosis between 6 months and 5 years prior to study entry, and will be disease-free at time of study entry. Potentially eligible women will be screened for the presence of sexuality and intimacy problems.

Exclusion criteria

Women will be excluded from the study if they: lack basic proficiency in Dutch; do not have access to the internet; exhibit serious cognitive or psychiatric problems (i.e. major depression, alcohol dependency, or psychotic disorders); report severe relationship problems for which the internet-based program is not designed (and which need to be addressed prior to undergoing sex therapy); are participating in a concurrent therapy program to alleviate their sexuality/intimacy problems; or have been treated for another type of cancer besides breast cancer (with the exception of cervical carcinoma in situ and basal cell carcinoma).

Study design

Design

Study phase:	3
Study type:	Interventional

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-10-2013
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	19-12-2013
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-02-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-02-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-03-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-11-2014

Application type:	Amendment
Review commission:	METC NedMec

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	NL44153.031.13