A randomized controlled trial of internet-based cognitive behavioral therapy for breast cancer patients with climacteric symptoms.

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

Summary

ID

NL-OMON42362

Source
ToetsingOnline

Brief title
Internet-based CBT for climacteric symptoms after breast cancer.

Condition

- Other condition

Synonym
Climacteric symptoms, menopausal symptoms

Health condition

Overgangsklachten

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Breast cancer, Climacteric, Cognitive behavioral intervention, Internet

Outcome measures

Primary outcome

The primary outcomes are menopausal complaints, as assessed with a menopausal complaints questionnaire called FACT-ES, and hot flushes and night sweats as assessed by the Hot Flushes Rating Scale (HFRS).

Secondary outcome

The secondary study outcomes are sexuality problems (SAQ); sleep quality (GSQS); psychological distress (HADS) and health related quality of life (MOS SF- 36).

Study description

Background summary

Breast cancer is the most common cancer among women in the Netherlands, with approximately 14.000 new cases reported in 2011. Nearly 30% of all women with breast cancer are premenopausal at the time of diagnosis. Premature menopause is a major concern of younger women undergoing (adjuvant/preventive) therapy for cancer. Menopausal symptoms include hot flushes, night sweats, decreased libido, insomnia due to night sweats, weight gain and psychological distress amongst others. Among menopausal symptoms, hot flushes are considered to be the most disruptive, with prevalence rates between 63% and 80% in breast cancer patients.

Currently, there are medical treatment for menopausal symptoms. However, these

might be contra indicated in breast cancer patients or have bothersome side effects. Effective and safe treatment options for these symptoms in breast cancer patients are needed. A CBT intervention has been found to be beneficial in the alleviation of menopausal symptoms in women with breast cancer, but compliance with face-to-face CBT programs can be problematic. A promising approach is to make this form of CBT more accessible and feasible for participants by having it available via the internet. Although the efficacy of CBT for this patient population has been demonstrated in the form of face-to-face group therapy, its efficacy has not been investigated in a randomized controlled trial when delivered via an internet platform in an individual setting. If demonstrated to be efficacious and cost-effective, the availability of such structured supportive intervention programs will be a welcome addition to standard medical treatment offered to cancer patients with treatment-induced menopause.

Hypotheses:
1. Women in the guided intervention group will report a significantly greater reduction from baseline to 10 week and 6 month follow-up in menopausal symptoms than patients in a usual care, waiting list control group, as assessed by the FACT-ES Scale and/or the Hot Flush Rating Scale.
2. Women in the self-management intervention group will report a significantly greater reduction from baseline to 10 week and 6 month follow-up in menopausal symptoms than patients in a usual care, waiting list control group, as assessed by the FACT-ES Scale and/or the Hot Flush Rating Scale.
3. Women in the guided intervention group will report significantly greater improvement in sexual functioning, sleep quality, hot flash frequency, psychological distress, and HRQOL than those in the control group.
4. Women in the self-management intervention group will report significantly greater improvement in sexual functioning, sleep quality, hot flash frequency, psychological distress, and HRQOL than those in the control group.

Study objective

The current study will evaluate systematically the efficacy and cost-effectiveness of two internet-based CBT/relaxation programs (one guided, the other self-managed) in reducing the severity of menopausal symptoms and improving copings skills with regard to hot flushes and night sweats as well as improving sexual functioning, improving quality of sleep, reducing emotional distress and improving quality of life in younger breast cancer patients who experience treatment-induced menopause.

Study design

For this trial patients will be recruited from several hospitals in the Amsterdam region. Participants will be randomly allocated to either the guided intervention group, the self-management group or the control group (N = 83 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 two intervention and control group will be asked to complete a battery of questionnaires prior to randomization (T0), at 10 weeks (T1) and at 6 months (T2). Main outcome measures are vasomotor symptoms, menopausal beliefs and behavior, sexual functioning, sleep quality, hot flash frequency, psychological distress, and health related quality of life.

Intervention

The CBT and relaxation training will consist of 6 weekly sessions that also include *homework* assignments (e.g., keeping a daily diary to monitor symptoms and their precipitants). It comprises the following elements: (1) information and advice about symptoms (e.g., hot flushes, night sweats and sexual functioning); (2) monitoring and modifying precipitants; (3) relaxation and stress reduction; (4) cognitive restructuring of unhelpful thoughts and (5) encouraging helpful behavioral strategies (e.g., pacing activities. The primary focus of the CBT is on hot flushes and night sweats, but other symptoms (e.g., vaginal dryness), sexuality, mood disturbance, and weight gain are also addressed. A relaxation/paced breathing mp3 file will be provided for practicing relaxation. The women allocated to the self-management intervention will work through the program independently. The women in the guided intervention will undergo a 30 minute phone interview with a trained therapist (medical social worker or psychologist) before the start of the program. The same therapist will provide support and weekly feedback by email during the course of the program. The therapist will have access to the participants* homework assignments and daily hot flush diary. Participants can also contact the social worker by email in case they have any questions.

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 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 248 women, younger than 50 years of age at time of breast cancer diagnoses or PBSO, with histologically confirmed primary breast cancer (stages: T1 - T4, N0 - N3 and M0). All women will have been premenopausal at the time of diagnosis, and will have experienced a treatment-induced menopause due to (neo)adjuvant chemotherapy, hormonal therapy or or oophorectomy. Women may currently be receiving adjuvant hormonal therapy. In case of treatment-induced menopause due to adjuvant chemotherapy (with the exception of herceptin), treatment should have been completed a minimum of 4 months and a maximum of 5 years prior to study entry. For women who receive neo-adjuvant chemo, we will use 4 month post-surgery or post-radiation therapy as the minimal time since treatment. Oophorectomy should have been completed no more than 5 years prior to study entry. All women should be disease-free at time of study entry. Potential eligible women will be screened for the presence of menopausal symptoms. Potentially eligible women will be screened for the presence of problematic hot flushes or night sweats during the past 2 months. Moreover, in the last week they should have experienced at least 10 hot flushes or night sweats during the past week and these hot flushes/night sweats should have been experienced as problematic (as indicated by an average score of two or higher on three items of the HFRS).

Exclusion criteria

Women will be excluded from the study if they lack basic proficiency in Dutch, if they have serious cognitive or psychiatric problems that would preclude them from following the intervention or completing the study questionnaires, or if they have no internet access. Patients participating in concurrent studies or rehabilitation programs to alleviate their menopausal problems will also be excluded.

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:	Recruitment stopped
Start date (anticipated):	01-08-2015
Enrollment:	248
Type:	Actual

Ethics review

Approved WMO

Date:	04-08-2015
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL53182.031.15