Cognitive behavioral therapy (CBT) and physical exercise for climacteric symptoms in breast cancer patients experiencing treatment-induced menopause: a multicenter randomized trial.

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

Summary

ID

NL-OMON32151

Source
ToetsingOnline

Brief title
Cognitive behavioral therapy, physical exercise and menopauze

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Menopause related conditions

Synonym
climacteric symptoms, menopausal symptoms

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognitive behavioral therapy, Menopause, Physical exercise

Outcome measures

Primary outcome

- Menopausal symptoms

- Vasomotor symptoms

Secondary outcome

- Urinary symptoms

- Sexuality

- Body image & self-image

- Psychological distress

- Generic health-related quality of life

Study description

Background summary

Premenopausal women with breast cancer treated with chemotherapy or hormonal therapy may experience a premature onset of the menopause. Estrogen deficiency following adjuvant treatments leads to primary endocrine symptoms, including vasomotor and urogenital problems. Secondary symptoms include insomnia due to night sweats, dyspareunia due to vaginal dryness, weight gain, and psychological distress. Healthy women who enter natural menopause are often prescribed hormone replacement therapy (HRT) to alleviate vasomotor and sexual symptoms. However, due to possible tumor-promoting effects, HRT is

contraindicated for patients with a history of breast cancer. In this study, the effectiveness of two supportive interventies will be assessed, i.e. cognitive behavioral therapy and physical exercise.

Study objective

The proposed study will evaluate the efficacy of a supportive intervention program in alleviating menopausal symptoms, improving sexual functioning and enhancing the quality of life of younger women (< 50 years) with breast cancer who have become prematurely menopausal as a result of their treatment. Specifically, the study will evaluate CBT including relaxation (A), physical exercise (B), and a combination of A and B.

Study design

For this multicentre trial, patients will be recruited from about 15 hospitals in the Amsterdam region, and they will be randomly allocated to group A, B, AB or the control group (N=81-82 per group) (2x2 factorial design). Upon completion of the study, the patients assigned to the control group will be given the opportunity to undergo either the A or B intervention program.

Women in the intervention groups and the control group will be asked to complete a battery of questionnaires prior to randomization (T0), at 12 weeks (T1) and at 6 months (T2) post-entry study. Main outcome measures are menopausal symptoms, vasomotor symptoms, urinary symptoms, sexuality, body image and self-image, psychological distress, generic health-related quality of life.

Intervention

The program will begin with a structured assessment of the target symptoms: hot flushes, night sweating and vaginal dryness. For group A, the intervention will consist of 6 weekly group CBT sessions of 1.5 hours, of 15 minutes of daily homework and a booster session at 3 months. The CBT will focus on understanding and self-control of menopausal symptoms. Relaxation techniques (paced respiration and muscle relaxation) will focus on the reduction of sympathetic nervous system activity, and are expected to have a positive impact on the frequency and intensity of hot flushes.

For group B, the intervention will be an individually tailored, 12 week home-based physical exercise program (of 2.5-3 hours a week), with instructions provided in-clinic on 2 occasions, and telephone support on 2 additional, interim occasions. The physical exercise program is intended to enhance fitness levels, in general, and to improve thermoregulation specifically related to hot flushes.

Group AB will receive both the CBT and exercise program elements.

Study burden and risks

Potential disadvantage is that participation in the study will be quite an effort.

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 325 women, younger than 50 years of age, with histologically confirmed primary breast cancer (stages: T1 - T4, N0 - N1 and M0). All women will have been premenopausal at the time of diagnosis, have completed adjuvant

chemotherapy or hormonal therapy a minimum of 4 months and a maximum of 5 years prior to study entry, and will currently be disease-free. Potentially eligible women will be screened for the presence of at least one of the following 3 menopausal symptoms during the previous 2-month period: hot flushes, sweating and/or vaginal dryness.

Exclusion criteria

Women will be excluded from the study if they lack basic proficiency in Dutch, if they have serious cognitive or psychiatric problems, or serious physical comorbidity that would preclude them from participating in a physical exercise program. Since physical exercise may be contraindicated as a treatment for hot flushes in obese women, patients with a BMI >= 30 will be excluded from the study. Patients participating in concurrent studies or rehabilitation programs containing psychosocial interventions 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:	Pending
Start date (anticipated):	01-12-2007
Enrollment:	325
Type:	Anticipated

Ethics review

Approved WMO

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	NL19935.031.07