The effects of a yoga-based stress reduction program on fatigue and quality of life in women with chemotherapy for breast cancer: a mono-centre, pragmatic, randomized clinical study

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To investigate whether an adjunctive YBSR program added to standard care compared to standard care alone, can reduce:1.fatigue symptoms (primary objective)2.psychological distressand improve:3.health-related quality of life4.sense of coherence5....

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

Summary

ID

NL-OMON43915

Source
ToetsingOnline

Brief title
The YBSR study

Condition

- Other condition
- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
breast cancer, mammacarcinoma

Health condition

moeheid

Research involving
Human

Sponsors and support

Primary sponsor: Louis Bolk Instituut
Source(s) of monetary or material Support: Stichting Pink Ribbon

Intervention

Keyword: adjuvant chemotherapy, breast cancer, fatigue, neoadjuvant chemotherapy, yoga

Outcome measures

Primary outcome

Mean fatigue symptoms: will be measured at baseline (T=0), 3 months (T=1) and 6 months (T=3) after the start of the intervention using the 20-item Multidimensional Fatigue Inventory (MFI), including questions on physical and mental fatigue and the 18-item Fatigue Quality List (FQL) assessing women*s* perception and appraisal of experienced fatigue

Secondary outcome

*Health-related quality of life: will be measured at baseline (T=0), 3 (T=1) and 6 months (T=3) after the start of the intervention using the 30-item European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire-C (EORTC-QLQ-C-30) together with the 23-item breast cancer specific module: EORTC QLQ-BR23.

*Psychological distress will be measured at baseline (T=0), 3 months (T=1) and 6 months (T=3) after the start of the intervention using the 14-item Hospital Anxiety Depression Scale (HADS) and the 22-item Impact of Events Scale (IES).

*Sense of Coherence: will be measured at baseline (T=0), 3 months (T=1) and 6 months (T=3) after the start of the intervention using the 13-item Sense of Coherence Questionnaire

*Participants expactations:will be measured at baseline (T=0) and 3 months (T=1)after the start of the intervention using the Participants Expectations Questionnaire

*Return to work:

by means of a semi-structured telephone interview by the research physician.

*Satisfaction with care:

by means of asemi-structured telephone interview by the research physician.

Adverse events: It will be noted 3 month after the start of the intervention (T=1) and at the end of the study (T=3) if participants have experienced any side effects from medication or therapies (by means of a telephone interview by the research physician). In addition, It will be noted every standard hospital visit during the study if participants have experienced any side effects from medication or therapies (by means of writing it down in the patient*s file by the oncology nurse or oncology surgeon).

Study description

Background summary

Breast cancer is the most common cancer diagnosed in women with an expected rise over the coming years. As survival increases, a better management of cancer related symptoms is important to reduce suffering in breast cancer survivors. Persistent fatigue and high levels of distress are the most frequently reported symptoms.Despite the high prevalence of cancer-related fatigue, few evidence-based interventions are currently available to manage this symptom. There is growing evidence that behavioural interventions such a physical exercise may have positive effects on fatigue. However, cancer survivors are often unable or unwilling to participate in standard exercise interventions in relation to their severe fatigue condition. Recent (pilot) studies have shown promising beneficial effects of yoga in breast cancer survivors, including reduction of persistent fatigue. However, results of yoga studies have not been entirely consistent, most likely due to methodological limitations Additional randomized controlled studies with yoga-based interventions are thus necessary to confirm its effectiveness.

Study objective

To investigate whether an adjunctive YBSR program added to standard care compared to standard care alone, can reduce:
1.fatigue symptoms (primary objective)
2.psychological distress

and improve:
3.health-related quality of life
4.sense of coherence
5.reintegration to work
6.satisfaction with care

Study design

A mono-centre pragmatic, randomized controlled prospective study with two parallel groups.

Intervention

Standard Care:
Standard care is provided according to the hospital guidelines. Women attend the breast cancer department *mamma poli*, which provides all necessary research to diagnose breast cancer in one day, with the biopsy result 2two days later. After the pathoanatomical diagnosis therapy options are discussed. Either neoadjuvant or adjuvant chemotherapy could be opted. In the case of neoadjuvant chemotherapy the start of chemotherapy will be planned within 5 weeks after diagnosis. In the case of primary sSurgery, surgery will be is

planned within 3 weeks after diagnosis. Pathology reports are delivered within 6-9 days after surgery and consultants see every case by videoconferencing to give an expert opinion as to the aftercare and adjuvant therapy (chemotherapy, radiotherapy and /or immunotherapy). Women will attend at certain times to an oncology nurse and a mamma-care nurse during these adjuvant therapies. In case of severe psychological problems a psychologist or psychiater is consulted. The oncology nurse is the first contact for care, explanation, support and appointments.

Standard Care + 12 week YBSR Program:
In addition to standard care the YBSR program will be followed once a week for a period of 12 weeks. The YBSR program is a behavioral intervention specifically designed and tailored to address womens* fatigue, pain and emotional distress. It is a comprehensive program provided by certified yoga teachers, that systematically integrates a broad spectrum of soft movements, breathing- and relaxation techniques. The physical exercises are designed to create body awareness and help women to improve flexibility in neck, shoulder, arms and back to regain trust in their body. The meditative breathing- and relaxation exercises are directed to reduce stress and fatigue and increase acceptance and emotional well-being.

Study burden and risks

The risk to participate with the YBSR program is judged as minimal. The extra time burden due to questionnaires, telephone interviews and the contacts with the oncology nurse will where desirable and possible integrated in the regular care.
Next tot this the lessons of the YBSR program itself will be combined if desirable with other hospital appointments. so the extra burden for the participating women will be minimal.

Further development and research after possibilities of stress reduction and exercise aprograms are justified. We expect that the benefits for the women will exceed the possible burdens . If the study confirms the efficacy of YBSR in the reduction of fatigue and improvement of quality of life in breast cancer survivors, the YBSR program will be taken up in the standard care program of the St. Jansdal hospital for adjuvant therapies of women after breast cancer surgery, specifically those who receive chemotherapy. This way, breast cancer survivors can be relieved with an intervention that is highly acces

Contacts

Public
Louis Bolk Instituut

Hoofdstraat 24
Driebergen 3972 LA
NL
Scientific
Louis Bolk Instituut

Hoofdstraat 24
Driebergen 3972 LA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

*Women with stage I-III breast cancer
*Scheduled to receive (neo)adjuvant chemotherapy
*Age 18-70 years
*Written informed consent
*Accessible by phone and internet /email

Exclusion criteria

*Previous treatment with cytostatics
*Presence of metastasis or other malignancies
*Deafness
*Serious psychiatric or cognitive problems
*Inability to understand and speak the Dutch language
*Participating in other yoga or stress-reduction programs at the time of the intervention
*inoperable tumor

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2012
Enrollment:	104
Type:	Actual

Ethics review

Approved WMO Date:	21-08-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	27-08-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-11-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-03-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26806
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL41230.028.12
OMON	NL-OMON26806