

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26806

### Source

NTR

### Brief title

YBSR study

### Health condition

breast cancer, surgery, adjuvant chemotherapy, fatigue, quality of life, stressreduction

## Sponsors and support

**Primary sponsor:** Performer: Louis Bolk Institute, Driebergen; Hospital St Jansdal, Harderwijk

**Source(s) of monetary or material Support:** Stichting Pink Ribbon, the Netherlands

## Intervention

## Outcome measures

### Primary outcome

Mean fatigue symptoms: Using the 20-item Multidimensional Fatigue Inventory (MFI) and the 28-item Fatigue Quality List (FQL).

### Secondary outcome

1. Health-related quality of life: using the 30-item European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire-C (EORTC-QLQ-C-30);
2. Psychological distress will be measured using the 14-item Hospital Anxiety Depression Scale (HADS) and the 22-item Impact of Events Scale (IES);
3. Return to work and treatment/ patient satisfaction will be measured during a semi-structured interview.

## Study description

### Background summary

N/A

### Study objective

The working hypothesis is that women undergoing chemotherapy for breast cancer, who receive a postoperative YBSR program added to the standard treatment will report a lower “fatigue symptom score”, lower psychological stress, higher quality of life, less days in return to work and more patient satisfaction than women who receive standard care alone.

### Study design

Contact 1 (screening):

In case of adjuvant chemotherapy: 6-9 days after surgery

In case of neoadjuvant chemotherapy: after PA diagnosis

A. Screening;

B. Verbal and written information.

2. Contact 2/ T=0 (intake-baseline):

In case of adjuvant chemotherapy: Within 3 weeks after surgery

In case of neoadjuvant chemotherapy: Within 3 weeks after PA diagnosis

A. Informed consent/ medical history/ demographic data/ stage of breast cancer/ type of surgery/ type of (neo)adjuvant chemotherapy/ other adjuvant therapies/ instruction for measurements and timelines during the study;  
B. Questionnaires (online): MFI, FQL, EORTC-QLQ-C30 + EORTC QLQ-BR23, HADS, IES, SOC, PE.

3. Intervention during 12 weeks: (Standard Care + YBSR-program or Standard Care only according to randomisation);

4. Contact 3, T=1 (3 months after start intervention):

A. Questionnaires (online): MFI, FQL, EORTC-QLQ-C30 + EORTC QLQ-BR23, HADS, IES, SOC, PE;

B. Telephone semi-structured interview: Compliance to the intervention, actual therapies, possible adverse events from intervention, return to work, satisfaction with the provided care.

5. Contact 4, T=2 (4 months after start intervention):

A. General well-being, evaluation treatment + actual medication / therapy, possible adverse events from medications and therapies.

6. Contact 5, T=3 (6 months after start intervention):

A. Questionnaires (online): MFI, FQL, EORTC-QLQ-C30 + EORTC QLQ-BR23, HADS, IES, SOC;

B. Telephone semi-structured interview: Actual therapies, possible adverse events from intervention, return to work, satisfaction with the provided care.

Standard Medical Treatment + 12 week Yoga-Based Stress Reduction (YBSR) Program: starts 1-2 weeks before the start of chemotherapy.

## **Intervention**

Standard Medical Treatment is provided according to the hospital guidelines.

Standard Medical Treatment + 12 week Yoga-Based Stress Reduction (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 an innovative behavioral intervention specifically designed and tailored to address patients' pain, fatigue, 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 patients 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.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

1. Women with stage I-III breast cancer;
2. Scheduled to receive (neo)adjuvant chemotherapy;
3. Scheduled to receive adjuvant chemotherapy;
4. Age 18-70 years;
5. Written informed consent;
6. Accessible by phone and internet.

### Exclusion criteria

1. Previous treatment with cytostatics;
2. Presence of metastasis or other malignancies;
3. Deafness;
4. Serious psychiatric or cognitive problems;

5. Inability to understand and speak the Dutch language;
6. Participating in other yoga or stress-reduction programs at the time of the intervention;
7. Inoperable tumor.

## 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):	05-11-2012
Enrollment:	86
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	13-11-2012
Application type:	First submission

## Study registrations

## Followed up by the following (possibly more current) registration

ID: 43915

Bron: ToetsingOnline

Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL3551
NTR-old	NTR3701
CCMO	NL41230.028.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON43915

## Study results

### Summary results

N/A