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.

Gepubliceerd: 13-11-2012 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26806

Bron
Nationaal Trial Register

Verkorte titel
YBSR study

Aandoening

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

Ondersteuning

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

Overige ondersteuning: Stichting Pink Ribbon, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Louis Bolk Institute
Hoofdstraat 24
I. Boers
Driebergen 3972 LA
The Netherlands
+31 (0)343 523860

Wetenschappelijk

Louis Bolk Institute
Hoofdstraat 24
I. Boers
Driebergen 3972 LA
The Netherlands
+31 (0)343 523860

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-11-2012
Aantal proefpersonen:	86
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-11-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43915
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A