The effect of yoga on endocrine therapy induced musculoskeletal symptoms in women with breast cancer

Published: 20-06-2024
Last updated: 07-03-2025

The objective of the proposed study is to assess the effectiveness of a 4-month yoga program compared to a waiting list control group on musculoskeletal complaints in women with hormone-positive stage I-III breast cancer receiving endocrine...

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

Summary

ID

NL-OMON56826

Source
ToetsingOnline

Brief title
COBRA study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: WCRF

Intervention

Keyword: Breast cancer, Endocrine therapy, Musculoskeletal compaints, Yoga

Outcome measures

Primary outcome

Musculoskeletal complaints (assessed by the modified version of the BPI) at 4 months, existing of 3 domains: worst pain, pain severity and pain interference. All three domain scores will be primary outcomes which will be tested sequentially to preserve an Alpha of 0.05.

Secondary outcome

Secondary endpoints (assessed at 4 months, unless otherwise stated)

• Lower extremity joint complaints (WOMAC)

• Upper extremity musculoskeletal complaints (DASH)

• Menopausal symptoms (FACT-ES)

• Fatigue (MFI)

• Sleep (PSQI)

• Quality of Life (EORTC-QLQ-C30;QLQ/BR45)

• Anxiety and depression (HADS)

• Cognitive problems (online cognitive test battery, at home: Amsterdam Cognition Scan) and self-reported (FACT-COG)

• Compliance with endocrine treatment

• Use of pain medication

- Pain response (composite measure of the BPI and use of pain medication)

• Physical fitness/strength (hand grip strength test/leg press/plank position holding test/steep ramp test)

- Balance (Short-Form Fullerton Advanced Balance (FAB) scale)

• Habitual physical activity (SQUASH)

• Blood markers (i.e., inflammatory markers)

• Vital signs and anthropometrics (blood pressure and anthropometrics)

• Safety : (serious) adverse events during the study

Study description

Background summary

Women with hormone-receptor positive breast cancer are usually prescribed endocrine therapy for a period of 5-10 years. This treatment reduces the risk of recurrence and improves overall survival in these women. Musculoskeletal complaints are a common (~50%) negative consequence of endocrine treatment, which affects daily functioning and quality of life. These symptoms frequently result in early treatment discontinuation, which is associated with shorter disease-free survival. Musculoskeletal complaints are often pharmacologically treated with limited effect and accompanied by side-effects. Therefore, interventions to counteract musculoskeletal complaints are urgently needed in this population. A potential non-pharmacological option is yoga. In patients with osteoarthritis, there is emerging evidence that yoga is effective to reduce pain and stiffness and improve function. Yoga as treatment for musculoskeletal complaints that are associated with endocrine treatment is rarely investigated and mainly in small studies.

Study objective

The objective of the proposed study is to assess the effectiveness of a 4-month yoga program compared to a waiting list control group on musculoskeletal complaints in women with hormone-positive stage I-III breast cancer receiving endocrine treatment who report musculoskeletal complaints.

Study design

The COBRA study is a randomized controlled trial with two study arms: a yoga- and a waiting list control group.

Intervention

The intervention consists of two hours/week supervised yoga and once a week

30-minute yoga exercises at home. The 4-month yoga program will be an active form of yoga, such as Easy Vinyasa yoga, which is characterized by continuous slow movements linked with breathing. The waiting list control patients will be offered an online yoga program after the 4-month study period.

Study burden and risks

Burden
- Burden of the study comprises time-investment, i.e., 2 visits to the study center for measurements and participation in supervised yoga program two hours per week for 4 months. Additionally, we ask the patients to perform yoga at home for 30 minutes once a week. Patients will be asked to perform an online cognitive test battery at home around baseline and end of study.

Risks
- As with any exercise, injuries can occur; to minimize the risk, the yoga program will be supervised by a qualified yoga trainer. To ensure safety and optimal execution of the different poses (asanas), health issues or physical limitations that may hinder adherence will be identified during the visit at the study center and communicated to the yoga teacher. In addition, a one-on-one intake session with the yoga teacher will take place.
- Following blood draws, a hematoma can occur.
- Incidental findings can arise during the different measurements (e.g., blood pressure measurement and assessment of depression), which will be reported to participants and their treating physician when potentially clinically relevant.

Benefit
We expect that the yoga program will have a beneficial effect on the participants* health status and may improve adherence of endocrine treatment.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

To be eligible to participate in this study, a woman must:
o Be diagnosed with oestrogen-receptor positive stage I-III breast cancer,
o Use of aromatase inhibitors or Tamoxifen (>4 months and will continue using it for at least six months),
o Have finished primary treatment (chemotherapy, radiotherapy, surgery) for at least twelve weeks,
o Experience musculoskeletal complaints (>3 months, which are at least mild in severity (i.e., score of >= 3 for worst pain item of a modified version of the Brief Pain Inventory [BPI], which started or exacerbated after initiation of endocrine treatment,
o Be stabilized on menopausal symptom medication or antidepressants for at least three months and three weeks, respectively, if applicable, and
o Be able to read, speak and understand Dutch or English.

Exclusion criteria

A woman who meets any of the following criteria will be excluded from participation in this study:
- Too physically active (i.e., >150 minutes/week of self-reported moderate-to-vigorous or leisure and sports activities)
- Following (during the last 6 months), or planned to follow yoga classes on a structural base
- Following, or planned to follow, a structured psychological intervention during the intervention period, i.e., cognitive behavioral therapy, or unstable on psychotropic medication
- Participated in the intervention group of an exercise study during breast cancer treatment

- Any circumstances that would impede ability to give informed consent or adherence to study requirements as determined by the study team
- More than 3 weeks not able to attend training sessions during the intervention period
- Body Mass Index (BMI) > 35 kg/m2

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-10-2024
Enrollment:	140
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	20-06-2024
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	26-09-2024
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	21-02-2025
Application type:	Amendment
Review commission:	METC NedMec

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
Other	Het protocol is nog niet geregistreerd, maar dat gaan we doen voor de eerste inclusie, bij het Dutch Trial Register.
CCMO	NL86325.041.24