The SHAPE study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22500

Source
NTR

Brief title
SHAPE: Sex Hormones and Physical Exercise

Sponsors and support

Source(s) of monetary or material Support: The Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

Endogenous hormone levels (sex steroid hormones, insulin).

Secondary outcome

1. Physical fitness, weight and the amount of total and intra-abdominal fat;

2. Lifestyle factors: habitual physical activity, diet, alcohol consumption and medication use.

Study description

Background summary

Purpose:

To examine the effects of an 1-year moderate-to-vigorous intensity exercise programme on endogenous hormone levels associated with breast cancer among sedentary postmenopausal women and whether a decrease in intra-abdominal fat is associated with a lowering of these hormone levels.

Background:

Physical activity has been associated with a decreased risk for breast cancer. The biological mechanismn(s) underlying the association between physical activity and breast cancer is not clear. Most prominent hypothesis is that physical activity may protect against breast cancer through reduced lifetime exposure to endogenous hormones. Another hypothesis is that physical activity prevents overweight and abdominal adiposity.

Methods:

In this intervention study, 180 sedentary postmenopausal women who are aged 50-69 years are randomly allocated to an intervention or a control group. The intervention consists of an 1-year moderate-to-vigorous intensity aerobic and strenght training exercise programme. Partcipants allocated to the control group are requested to retain their habitual exercise pattern. Primary study parameters measured at baseline, at four months and at 12 months are: serum concentrations of endogenous estrogens, endogenous androgens, sex hormone binding globuline and insuline. Other study parameters include: amount of total and abdominal fat, weight, BMI, body fat distribution, physical fitness, blood pressure and lifestyle factors.

Conclusions:

This study will contribute to the body of evidence relating physical activity and breast cancer risk and will provide insight into possible mechanisms through which physical activity might be associated with reduced risk of breast cancer in postmenopausal women.

Study objective

We hypothesise that exercise may reduce risk of breast cancer, either directly or indirectly

through a reduction in abdominal fat mass, by favouring the sex hormone profile and decreased insulin. Because the association between breast cancer and endogenous estrogens is rather convincing, we designed the Sex Hormones and Physical Exercise (SHAPE) study on the effects of physical activity on these hormones. Furthermore, since androgens and insulin are suspicious risk factors for breast cancer, the effects of physical activity on these hormone levels are also investigated. Since the intervention programme is aimed at maximising fat loss, we can also investigate whether a potential relation between physical activity and endogenous hormones is mediated by the amount of total body fat or abdominal fat. If change in exercise level has a beneficial effect on the sex hormone and metabolic profile of postmenopausal women, increasing exercise is a possible breast cancer protective intervention.

Study design

N/A

Intervention

1. Intervention group – participants in this group will participate in an 1-year moderate intensity exercise programme;

2. Control group – participants.

Contacts

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Eligibility criteria

Inclusion criteria

1. Women aged 50 –69 year;

2. > 12 months since last menses;

3. Non-smokers (at least 12 months);

4. Sedentary: < 2 hours per week of moderate sport activity (e.g. tennis, swimming, running, aerobics, fitness, volleyball) and not adherent to the international physical activity guideline. The international physical activity guideline states that every adult should accumulate 30 minutes or more of at least moderately intense physical activity for at least five days per week [83;84];

4. Knowledge of the Dutch language;

5. Agreement to be randomly assigned to either the exercise intervention or control group;

6. Informed consent to participate in all screening and study activities.

Exclusion criteria

1. Use of hormone replacement or oral contraceptives in past 6 months;

2. Morbidly obese (BMI > 40);

3. BMI < 22;

4. Currently on or planning to go on a strict diet;

5. Ever diagnosed with breast cancer;

6. Diagnosis of other types of cancer in the past 5 years;

7. Diabetes mellitus or other endocrine related diseases;

8. Disorders or diseases (locomotor, optical, neurological, mental) that might impede the participation in the exercise programme;

9. Alcohol or drug abuse;

10. Maintenance use of corticosteroids;

11. Use of beta blockers.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2005
Enrollment:	189
Type:	Actual

Ethics review

Positive opinion

Date:	03-07-2006
Application type:	First submission

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
NTR-new	NL713
NTR-old	NTR723
Other	: N/A
ISRCTN	ISRCTN11633173

Study results

Summary results
BMC Public Health. 2007 Sep 4;7:232.