

# The SHAPE study.

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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...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON22500

### Bron

Nationaal Trial Register

### Verkorte titel

SHAPE: Sex Hormones and Physical Exercise

### Ondersteuning

**Overige ondersteuning:** The Dutch Cancer Society

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

Endogenous hormone levels (sex steroid hormones, insulin).

## Toelichting onderzoek

### Achtergrond van het onderzoek

## 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 mechanism(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 strength training exercise programme. Participants 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 globulin and insulin. 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.

## **Doel van het onderzoek**

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.

## **Onderzoeksopzet**

N/A

## **Onderzoeksproduct en/of interventie**

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

## **Contactpersonen**

### **Publiek**

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### **Wetenschappelijk**

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## **Deelname eisen**

## **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

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.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

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;

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Actieve controle groep

### Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2005
Aantal proefpersonen:	189
Type:	Werkelijke startdatum

## Ethische beoordeling

Positief advies	
Datum:	03-07-2006
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL713
NTR-old	NTR723
Ander register	: N/A
ISRCTN	ISRCTN11633173

## Resultaten

### Samenvatting resultaten

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