

# The Sex Hormones And Physical Exercise study

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| <b>Submission date</b><br>26/09/2006   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>26/09/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>25/08/2009       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Acronym

SHAPE: Sex Hormones and Physical Exercise

## Study objectives

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.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the local medical ethics committee

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Prevention

## Participant information sheet

## Health condition(s) or problem(s) studied

Reducing the risk of breast cancer

## Interventions

1. Intervention group: participants in this group will participate in an one year moderate intensity exercise programme
2. Control group: participants in this group will receive care as usual

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Endogenous hormone levels (sex steroid hormones, insulin).

**Secondary outcome measures**

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

**Overall study start date**

01/01/2005

**Completion date**

01/09/2006

## Eligibility

**Key inclusion criteria**

1. Women aged 50 to 69 years
2. More than 12 months since last menses
3. Non-smokers (at least 12 months)
4. Sedentary: less than two 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
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

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Female

**Target number of participants**

189

**Key exclusion criteria**

1. Use of hormone replacement or oral contraceptives in past six months
2. Morbidly obese (Body Mass Index [BMI] more than 40)
3. BMI less than 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 five 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

**Date of first enrolment**

01/01/2005

**Date of final enrolment**

01/09/2006

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

University Medical Center Utrecht (UMCU)

Utrecht

Netherlands

3508 GA

## Sponsor information

**Organisation**

The National Cancer Fund (Koningin Wilhelmina Fonds [KWF]) (The Netherlands)

**Sponsor details**

P.O. Box 75508

Amsterdam

Netherlands

1070 AM

**Sponsor type**

Charity

ROR

## Funder(s)

### Funder type

Charity

### Funder Name

Dutch Cancer Society (Netherlands)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type                      | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol | 04/09/2007   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 20/09/2009   |            | Yes            | No              |