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The Sex Hormones And Physical Exercise study

Submission date	Recruitment status	[_] Prospectively registered
26/09/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/08/2009	Cancer	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 hypothesis
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

Condition
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

Overall study end date
01/09/2006

Eligibility

Participant 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

Participant 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

Recruitment start date
01/01/2005

Recruitment end date
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

https://ror.org/0368jnd28

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?
Protocol article	protocol	04/09/2007		Yes	No
Results article	results	20/09/2009		Yes	No