The effects of equivalent weight loss with or without exercise programme on breast cancer risk biomarkers in postmenopausal women: the SHAPE-2 study.

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Primary Objective: To examine the effects of equivalent weight loss with and without exercise on breast cancer biomarkers (endogenous sex hormones) in overweight, sedentary postmenopausal women.Secondary Objective(s): To examine the effects on body(...

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

Summary

ID

NL-OMON38377

Source
ToetsingOnline

Brief title
SHAPE-2 (Sex Hormones And Physical Exercise) study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: KWF kankerbestrijding;Pink Ribbon

Intervention

Keyword: breast cancer, exercise, sex hormones, weight loss

Outcome measures

Primary outcome

Sex-hormone levels: estradiol, estrone, testosterone, sex hormone binding

globulin (SHBG).

Secondary outcome

Physical fitness, anthropometrics, the amount of total body fat (DEXA scan) and

abdominal fat (MRI).

We also measure lifestyle factors: i.e. habitual physical activity, dietary

pattern, alcohol consumption and medication use.

Study description

Background summary

Postmenopausal women who are sedentary or overweight, have an increased breast cancer risk. In contrast to most other risk factors for postmenopausal breast cancer, physical inactivity and overweight offer a potential basis for primary prevention since they are amenable to intervention. However, these two factors are highly correlated and it is not clear which is most relevant to risk. It is suggested that physical inactivity and overweight mediate breast cancer risk mainly through sex hormone-related pathways. Intervention studies give insight into the interplay between physical activity and intended weight loss and the biological mechanisms by which behaviour influences breast cancer risk in postmenopausal women. We recently showed in a randomised study (the SHAPE-1 study) among postmenopausal women that physical activity influences hormone levels mainly when concordant loss of body fat was achieved. Of the two other randomised studies conducted, one shows similar results. The other study also

found an overall effect of exercise, but exercisers also lost (-1.8 kg) more body weight than controls.
So, it seems clear that weight loss (fat loss) reduces sex hormone levels, but the question is if there is an additional beneficial effect of reaching this by physical activity instead of nutritional interventions. We, therefore, propose to study the effect of equivalent weight loss with or without exercise on hormones known to be related to breast cancer risk.

Study objective

Primary Objective: To examine the effects of equivalent weight loss with and without exercise on breast cancer biomarkers (endogenous sex hormones) in overweight, sedentary postmenopausal women.

Secondary Objective(s): To examine the effects on body(fat) composition and whether this mediates potential changes in endogenous sex hormones

Study design

The SHAPE-2 study is designed as a single blind RCT with three study arms. The outcome assessors will be blinded for treatment assignment as much as possible. After a run-in period of 5 weeks, eligible women (n=250) will be randomised into (D) a diet-induced weight loss group (n=104), (E) an exercise- plus diet-induced weight loss group (n=104), or (C) a waiting list control group (n=42). This intervention period will take (a maximum of) 14 weeks. A weight maintenance period of 2-6 weeks will follow after. The total duration of the study is 21 weeks.

Block randomisation is used, with a block size of 5, stratified by centrum and municipality.

Intervention

During the run-in period, all women will follow a weight maintenance diet according to guidelines for healthy nutrition (50-60% carbohydrate, 15-20%protein and 20-35% fat) under supervision of a dietician.

Throughout the 14 week intervention period, the diet group will be offered a diet counselling intervention to reduce this isocaloric diet with 500 kcal/day. The diet intervention includes 2 individual and 5 group sessions with a dietician and 9 telephonic contacts.

The exercise- plus diet-induced weight loss group will follow an exercise programme with a mean energy expenditure of 350 kCal/day. The exercise intervention consists of 2 group sessions supervised by a physiotherapist and 2 hours of home exercise sessions. De dietprogramma consists of dietinstructions

by the dietician to reach a caloric deficit of 250 kCal/day. They will also have 9 telephonic contacts with a dietician.

Women in the control group will be asked to stick to the isocaloric diet from the run-in period and maintain their body weight. They will have telephonic contact with the dietician four times during the study period.

Study burden and risks

The study programma, especially the weight loss programmes are quite time consuming, which can be a burden for participants.
At first participants will visit the nearby hospital (either Utrecht or Enschede) for a 20 minutes screeningvisit to check eligibility. At baseline questionnaires will be filled out by all participants about their general health, medical history, reproductive history and exercise- and diet habits. They will all have a face-to-face instruction by a dietician about their isocaloric diet for the run-in period.
Furthermore, all participants need to visit the nearby hospital for measurements twice, including: physical examination, total body DEXA-scan, MRI-abdomen, maximal exercise capacity test, blood sampling, checking filled in questionnaires. During the study a dietary record should be filled in three times containing (in every record) information on food intake for 2 weekdays and 1 weekendday. And the actigraph, a non-invasive activity monitor, will be worn for 1 week two times.

During the intervention period of 14 weeks the diet weight loss group will follow a hypocaloric diet, which is supervised by a dietician by 2 individual one-hour contacts, 5 one-hour groupsessions and 9 telephone calls. The exercise- plus diet-induced weight loss group will follow a sportsprogram in which they'll practice 2 one-hour sessions of sports in a nearby physiotherapy clinic and 2 hours of individual nordic walking on a weekly basis. They will also get a hypocaloric diet, instructed by a dietician and monitored through 9 telephonic contacts by the dietician.

Participants have very low risk on (serious) adverse events or complications. Due to the exerciseprogramme injuries may occur. The risk is minimized by gradualy increasing the intensity of the exerciseprogram.
There is a risk on the normal complications of a vena puncture (e.g. hematoma/flebitis). Incidental findings can be done which will be reported to participants. During the maximal capacity exercise test (clinically occult) pre-existing heart problems can be exposed. To reduce the risk of complications due to ischemia the participant will be screened for ischemic heart disease by ECG monitoring during the exercise test. Emergency equipment and personnel trained to deliver appropriate emergency care will be available.

A benefit for the participants is that they will loose weight under supervision of a dietician and physiotherapist in a healthy way. This also applies to the

control group since they will be offered an adapted weight loss program at the end of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Female. 50-69 years of age. Postmenopausal (>12 months after last menses). BMI 25-35 kg/m2. Inactive (<2 hours per week of at least moderately intensive activities (>4 MET)). Willing to be randomly assigned to one of the three study arms.

Exclusion criteria

Use of sex hormones in the past 12 months. Suffering from breastcancer (in medical history) or other cancers in the last 5 years, except for non-melanoma skin cancers. Suffering from type II diabetes mellitus or other endocrine related diseases. Smoker.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2012
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	14-02-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-06-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL37240.041.11