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Hormonal and metabolic effects of diet and exercise programs in obese women with polycystic ovary syndrome (Hormonella och metabola effekter av diet- och motionsprogram hos överviktiga kvinnor med polycystiskt ovariesyndrom)

Submission date	Recruitment status	[ ] Prospectively registered
02/05/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/03/2014	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Hormonal and metabolic effects of diet and exercise programs in obese women with polycystic ovary syndrome : a prospective randomised controlled trial

Study objectives
Combined treatment with diet and exercise is superior than diet and exercise alone to improve reproductive function in women with polycystic ovary syndrome (PCOS)

Ethics approval required
Old ethics approval format

Ethics approval(s)
CI Research Ethics Committee at Karolinska Hospital North (KI forskningsetikkommitté Nord vid Karolinska sjukhuset), 29/08/2002, No 02-243

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Polycystic ovary syndrome (PCOS)

Interventions
The interventions lasted for four months, with monthly visits and follow-up was continued for more than one year after termination of the programs.

The diets were designed individually under the close supervision of a dietician. It was recommended that total daily caloric intake be reduced by at least 600 kcal/d in comparison to before the intervention, while maintaining a well-balanced diet containing 55-60% carbohydrates, 25-30% fat (10% saturated) and 10-15% proteins, according to Swedish nutritional recommendations (SNO) in 2005. A strict schedule of three main meals and two or three snacks was also introduced. Food intake was assessed by self-reporting once every 24 hours during the 4 days both immediately before and at the end of intervention.

The exercise program was supervised by a physiotherapist and was designed to enhance both the type and level of physical activity to a level conforming to each individual patient´s capacity, goals and interest at the beginning of this intervention. Physical activity was assessed utilising pedometers (Yamax SW-200 Tokyo, Japan) during the four days immediately before and at the end of the program.

During both types of intervention monthly follow-ups with the dietician and/or physiotherapist were scheduled for discussion of the goals achieved, as well as setting up new goals for the next month.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Immediately before this study, after four months of intervention and at the time of the long-term follow-up, each patient underwent a general health control involving determination of blood pressure, weight, height and waist/hip ratio (WHR).

1. All gynecological examinations including transvaginal ultrasound using Sonoline SI-250 equipment (Siemens Healthcare Diagnostics, Deerfield, IL, USA) were performed by the same investigator. The ovarian parameters evaluated were the maximal number of follicles in one plane and the volumes of the largest follicle and of the entire ovary. Menstrual bleedings were recorded and ovulation confirmed on the basis of an elevation in the serum level of progesterone during the luteal phase of the menstrual cycle.
2. For determination of body composition, the patients were examined by dual energy X-ray absorptiometry (DXA) employing a Lunar Prodigy Advance whole body scanner (GE medical systems, Fairfield, CT, USA).

Key secondary outcome(s))
Improved insulin sensitivity - In a resting and fasting state at 8:00 am a blood sample was collected from a peripheral vein and the serum separated by centrifugation and stored at 70 degree celsius, pending analysis for hormones, binding proteins and glucose.

Evaluated immediately before this study, after four months of intervention and at the time of the long-term follow-up

Completion date
31/12/2009

Eligibility

Key inclusion criteria
Women aged 18-40 years diagnosed with PCOS and having body mass index (BMI) > 27

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit

40 years

Sex
Female

Key exclusion criteria
1. The presence of other disease or a different endocrine disorder
2. An eating disorder
3. Smoking
4. Continuous medication including insulin sensitising drugs

Date of first enrolment
01/01/2003

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Women's and Children's Health
Stockholm
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SE-171 76

Sponsor information

Organisation
Karolinska Institute (Sweden)

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Research council

Funder Name

The Swedish Research Council (Sweden)

Results and Publications

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?
Results article	results	01/10/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes