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The role of exercise in treatment of women with Polycystic Ovary Syndrome (PCOS): mechanisms of action

Submission date	Recruitment status
22/12/2008	No longer recruiting
Registration date	**Overall study status**
23/01/2009	Completed
Last Edited	**Condition category**
28/08/2012	Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

A prospective cohort study examining the effect of 12 weeks of intensive endurance exercise on insulin sensitivity and muscle insulin signalling in overweight women with or without polycystic ovary syndrome (PCOS)

Acronym
PCOS

Study objectives
Women with polycystic ovary syndrome (PCOS) have both intrinsic insulin resistance and extrinsic obesity-related insulin resistance mediated via different mechanisms. Exercise is an effective intervention decreasing central adiposity reducing extrinsic insulin resistance and improving symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the Southern Health Human Ethics Committee in March 2005

Primary study design
Interventional

Study design
Prospective cohort non-randomised un-blinded controlled trial

Study type(s)
Treatment

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

Interventions
Both PCOS and non-PCOS women underwent the same study protocol. From baseline, participants in the two groups undertook a 12 week programme of supervised intensified endurance exercise (1 hr/day; 3 x per week). Two different exercise sessions alternated, performing 1 hour of moderate intensity treadmill walking to elicit work rates of 70% of maximal oxygen consumption (VO2max) or 75 - 85% of maximal heart rate (HRmax). These were adjusted as fitness improved. Alternate sessions involve high intensity exercise with intermittent walking up an incline with 6 - 8 repetitions (5 minutes walking, 2 minutes recoveries) targeting 90 - 100% VO2max or 95 - 100% HRmax. Participants progress to 8 repetitions by the 4th week, with 1 minute of recovery. After 12 weeks of exercise all baseline measurements were repeated.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Effects on insulin resistance, measured at baseline and after 12 weeks of exercise.

Key secondary outcome(s)
1. Clinical symptom improvement
2. Insulin signalling
3. Mitochondrial function

Measured at baseline and after 12 weeks of exercise.

Completion date
01/03/2008

Eligibility

Key inclusion criteria
1. Overweight women (body mass index [BMI] greater than 27 kg/m^2)
2. Aged 18 - 40 years with PCOS and without
3. Diagnosed from a history of perimenarchal onset of irregular cycles (less than 21 days or greater than 35 days)
4. Clinical manifestations of hyperandrogenism (hirsutism, acne) or biochemical hyperandrogenism with elevation of at least one circulating ovarian androgen (1990 National Institute of Health [NIH] criteria)

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. BMI less than 27 kg/m^2
2. Other concurrent medical conditions
3. Ongoing use of the oral contraceptive pill (OCP)
4. Pregnancy or desire for pregnancy
5. Secondary causes of amenorrhoea and hyperandrogenism

Date of first enrolment
01/03/2005

Date of final enrolment
01/03/2008

Locations

Countries of recruitment
Australia

Study participating centre
SHPM, Monash Institute of Health Services Research
Melbourne
Australia
3168

Sponsor information

Organisation
Southern Health (Australia)

Funder(s)

Funder type
University/education

Funder Name
Monash University (Australia) - New Investigator Award 2005

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	01/05/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes