

# Longterm lifestyle behaviour modification in overweighted women with polycystic ovary syndrome (PCOS).

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Primary: Evaluation of the effectivity of a multidisciplinary cognitive behavioural lifestyle program combined with a Short Message Service (SMS) maintenance treatment with infertile overweight and obese PCOS women.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON39189

### Source

ToetsingOnline

### Brief title

PCOS and overweight

### Condition

- Other condition
- Endocrine disorders of gonadal function
- Ovarian and fallopian tube disorders

### Synonym

obesity, Overweight, ovulation disorder, polycystic ovary syndrome

### Health condition

Overgewicht en obesitas

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cognitive behaviour therapy, lifestyle behaviour, overweight, polycystic ovary syndrome

## Outcome measures

### Primary outcome

Body Mass Index (BMI).

### Secondary outcome

Cycle duration, cycle regularity, anthropomorphometric outcomes, echoscopic outcomes, endocrine outcomes and psychological outcomes.

## Study description

### Background summary

Polycystic ovary syndrome (PCOS) is one of the most common endocrine disorders in women of reproductive age. 50-60% of the women with PCOS are overweight or obese. PCOS women are often insulin resistant, but especially the obese patients are at higher risk for developing type II Diabetes Mellitus. There is evidence that PCOS women have an increased risk of heart disease. When PCOS women are pregnant, they have more miscarriages than women without PCOS. Overweight and obese PCOS women are more at risk for the short- and long term consequences. Obesity and overweight influence the outcome of fertility treatments in a negative sense. Before overweight and obese PCOS women undergo a fertility treatment, there should be weight reduction to lower the health risks. At the moment, there are no special treatments in the Netherlands to reduce the overweight in PCOS women. Cognitive behavioural treatments are the most effective treatments to achieve weight reduction, especially when combined with an exercise program and advice from a dietician. Weight reduction of 5 percent can already lead to spontaneous ovulations and pregnancy in PCOS women, lowers the miscarriage percentage and leads to less complications during

pregnancy. On the long term, weight reduction decreases the risk for developing type II Diabetes Mellitus.

## **Study objective**

Primary: Evaluation of the effectivity of a multidisciplinary cognitive behavioural lifestyle program combined with a Short Message Service (SMS) maintenance treatment with infertile overweight and obese PCOS women.

## **Study design**

Randomized control trial with 3 groups. Patients are randomized according a 2:1 ratio in a treatment group (n=156) and in a control group (n=78). After six months of treatment, the treatment group will be randomized in 2 groups. One group receives the maintenance treatment through SMS, the other group doesn't receive the SMS maintenance treatment.

## **Intervention**

A lifestyle program (nine months) focussing on persisting lifestyle behaviour changes in infertile overweight and obese PCOS women and a Short Message Service (SMS) Maintenance treatment for support and lifestyle maintenance.

## **Study burden and risks**

The extent of burden that is associated with participation is 1 hour exercise program (physiotherapist), 2 hours cognitive behavioural group treatment (psychologist and dietician): The multidisciplinary program is the first three months weekly, the three months thereafter two times a month and the last three months monthly. The extent of burden is on five measurement moments one hour for measures and questionnaires (physican). The risks associated with participation is related to bloodsampling. There is a small chance for bruises and extravasation of blood. The location of bloodsampling can be sensitive afterwards. All physical examinations are harmless for the health of the participants.

## **Contacts**

### **Public**

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NL

## Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Polycystic ovary syndrome

Body Mass index higher dan 25 kg/m<sup>2</sup>

Wish to have children

Age between 18 and 40 years

### Exclusion criteria

Insufficient in the Dutch language

Patients with a psychiatric disorder

Obesity in the context of a somatic disease

Ovarial tumours leading to androgen excess

Adrenal diseases

Disorders genitalia interna

Pregnancy

## Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Prevention

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2009
Enrollment:	234
Type:	Actual

## Ethics review

Approved WMO	
Date:	04-12-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	01-10-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	09-12-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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
ClinicalTrials.gov	NCT2450
CCMO	NL24537.078.08