# 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.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | 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

oucomes, 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 excercise program and advice from a dietician. Weight reduction of 5 percent can already lead to spontanious 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 excercise 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

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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/m2
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

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

**Primary purpose:** Prevention

## Recruitment

NL

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

# Ethics review

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| Approved WMO Date: | 04-12-2008 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

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| Approved WMO Date: | 01-10-2009 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

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| 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 |