Long-term follow up of overweight and obese women with PCOS who participated in a randomized controlled three-component lifestyle study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine disorders of gonadal function
Study type	Observational invasive

Summary

ID

NL-OMON51254

Source
ToetsingOnline

Brief title
Follow up lifestyle PCOS and overweight

Condition

- Endocrine disorders of gonadal function
- Sexual function and fertility disorders

Synonym
PCOS, polycystic ovary syndrome

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: Lifestyle, Overweight, PCOS, Polycystic ovary syndrome

Outcome measures

Primary outcome

Anthropometric measurements approximately 5 years after participating in the

PCOS en overgewicht lifestyle study.

Secondary outcome

Transvaginal ultrasound, endocrine assessment and psychological outcomes

approximately 5 years after participating in the *PCOS en overgewicht*

lifestyle study.

Study description

Background summary

Overweight and obesity substantially increase the inherent health risks and phenotypical features in women with polycystic ovary syndrome (PCOS). It also has a negative impact on the chance to become pregnant and pregnancy outcome. Three-component lifestyle interventions are recommended as first line therapy in overweight and obese women with PCOS. However, evidence on long-term effects of three-component lifestyle interventions is still lacking.

Study objective

The aim is to evaluate long-term (+/- five years post-intervention) follow-up results of a previously completed study that investigated the effect of a three-component (diet, exercise, cognitive behavioural therapy (CBT)) lifestyle intervention with or without additional Short Message Service (SMS) support compared to a control group (care as usual e.g. an advise to lose weight) (MEC 2008-337). The main objective of the current study is to determine long-term

physical outcomes, other objectives include psychological outcomes, PCOS diagnosis and metabolic health.

Study design

Cross-sectional follow-up of a previously completed randomized controlled trial comparing three groups, 1) lifestyle intervention with SMS, 2) lifestyle intervention without SMS and 3) care as usual.

Study burden and risks

Women who participated previously in the *PCOS en overgewicht* lifestyle study will be invited once for a COLA-screening (Cycle OLigo- or Amenorrhea-screening) at our outpatient clinic which is part of our standard care for women with irregular menstrual cycles. During the COLA-screening women will have to complete questionnaires, a transvaginal ultrasound is performed as well as a physical examination (e.g. blood pressure, weight, waist and hip circumference). Eventually, venous blood sampling will be performed for endocrine assessment. This visit could comprise a burden for these women, however, the international PCOS guideline advises regular (health) check-ups for women with PCOS. Therefore, this visit could also count as a benefit for these women. The risk of participating in this study is related to the blood withdrawal, because there is a small chance of haemorrhage or sore feeling at the site of injection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Previous participation in the 'PCOS and overweight' study

Exclusion criteria

No previous participation in the 'PCOS and overweight' study

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2022
Enrollment:	209
Type:	Actual

Ethics review

Approved WMO Date:	25-06-2021
Application type:	First submission
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
CCMO	NL76910.078.21