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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25437

Source
NTR

Brief title
TBA

Health condition

PCOS, overweight, obesity, lifestyle intervention, three-component, cognitive behavioral therapy, diet, exercise.

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

The long-term affect of a three-component lifestyle intervention (with or without SMS support) on weight compared to care as usual.

Secondary outcome

The long-term affect of a three-component lifestyle intervention (with or without SMS support) on BMI, waist and hip circumference, emotional well-being, PCOS characteristics, PCOS phenotype, and metabolic health compared to care as usual.

Study description

Background summary

The aim is to evaluate the long term effects (+- five years post-intervention) of a previously performed one-year three-component randomized controlled trial (the 'PCOS and overweight' study; NTR2450). Outcome measures include weight, BMI, waist and hip circumference, PCOS characteristics and phenotype, emotional well-being, and metabolic health.

The 'PCOS and overweight' study was a one-year three-component (diet, exercise, cognitive behavioral therapy) lifestyle intervention, with or without SMS support, compared to control (care as usual e.g. an advice to lose weight autonomously). This study has been performed between 2010 and 2016.

Study objective

We hypothesize that women who received the one-year three-component lifestyle intervention will have more sustainable changes approximately 5 years after the study with regard to weight, PCOS characteristics, metabolic health, and emotional well-being when compared to care as usual.

Study design

1. Before the study (T0);

2. After 3 months (T1);

3. After 6 months (T2);

4. After 9 months (T3);

5. After 12 months (T4).

(the above 5 time points have already been completed in the 'PCOS and overweight' study)

New time point:

6. At least approximately 5 years after the 'PCOS and overweight' study (T5).

Intervention

N/A

Contacts

Public
Erasmus University Medical Centre
Alexandra Dietz de Loos

+31 (0)6 22666365
Scientific
Erasmus University Medical Centre
Alexandra Dietz de Loos

+31 (0)6 22666365

Eligibility criteria

Inclusion criteria

- Previous participation in the ‘PCOS and overweight’ study.
- Informed consent.

Exclusion criteria

- None.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2021
Enrollment:	209
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	28-05-2021
Application type:	First submission

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
NTR-new	NL9502
Other	METC Erasmus MC : MEC-2021-0197

Study results

Summary results
N/A