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

Gepubliceerd: 28-05-2021 Laatst bijgewerkt: 18-08-2022

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-...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25437

Bron
NTR

Verkorte titel
TBA

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- None.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2021
Aantal proefpersonen:	209
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	28-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9502
Ander register	METC Erasmus MC : MEC-2021-0197

Resultaten

Samenvatting resultaten
N/A