

Lifestyle changes in women with polycystic ovary syndrome (PCOS), overweight and a wish to become pregnant.

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1. Is a multidisciplinary cognitive behavioural lifestyle program more effective in losing weight and permanent weight loss for women with PCOS and obesity than regular care? 2. Is a multidisciplinary cognitive behavioural lifestyle program in...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21675

Bron

NTR

Aandoening

PCOS, overweight, children, high BMI, lifestyle, intervention, therapy, cognitive behavioural therapy, diet therapy, physical activity

Ondersteuning

Primaire sponsor: Erasmus MC

Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Purpose:

Evaluation of the effectiveness of a multidisciplinary cognitive-behavioral program combined with a lifestyle maintenance via Short Message Service (SMS) in infertile women with PCOS and overweight or obese.

Study design:

RCT with 3 groups. At the start of the study participants were randomized in a 2:1 ratio in a treatment group (n = 156) and a control group (n = 78). After three months the treatment group will be randomized into two groups. One group receives an SMS maintenance (n = 78) the other group will not.

Doel van het onderzoek

1. Is a multidisciplinary cognitive behavioural lifestyle program more effective in losing weight and permanent weight loss for women with PCOS and obesity then regular care?
2. Is a multidisciplinary cognitive behavioural lifestyle program in combination with SMS-interventions more effective in losing weight and permanent weight loss then a multidisciplinary cognitive behavioural lifestyle program without SMS-intervention?
3. Is a multidisciplinary cognitive behavioural lifestyle program in combination with SMS-intervention effective on the menstrual cycle, the anthropomorphic morphometric-, ultrasound-, endocrine- and psychological parameters, as well as physical activity?

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).

Onderzoeksproduct en/of interventie

A nine month during lifestyle change program focusing on sustainable eating and living habits, using SMS with the aim of sustainable weight loss. The team is consisting of a psychologist, a dietician, a physiotherapist and a gynecologist.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. PCOS;
2. Wish to have children;
3. Body Mass index above 25;
4. Age: from 18 to 38.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not able to speak and understand the Dutch language;
2. Psychiatric disorder;
3. Obesity with other somatic causes;
4. Ovarian tumors that result in androgen excess;
5. Adrenal diseases;
6. Other malformations of internal genitalia;
7. Pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	02-08-2010
Aantal proefpersonen:	234
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 02-08-2010

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	NL2344
NTR-old	NTR2450
Ander register	METC Erasmus MC : 2008-337
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A