

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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21675

Source

NTR

Health condition

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

Sponsors and support

Primary sponsor: Erasmus MC

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

Intervention

Outcome measures

Primary outcome

BMI.

Secondary outcome

1. Cycle duration;
2. Cycle regularity;
3. Anthropomorfometrische results (blood results);
4. Ultrasound findings;
5. Endocrine outcomes;
6. Physical activity (IPAQ);
7. Psychological outcomes (SF 36, PCOSQ, BDI, RSE, FNAES, EDE-Q).

Study description

Background summary

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.

Study objective

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?

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).

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2010
Enrollment:	234
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	02-08-2010
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	NL2344
NTR-old	NTR2450
Other	METC Erasmus MC : 2008-337
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A