# How 2 deal with PCOS

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To study if an online brief CBT intervention is effective for anxiety and depression compared to care as usual (CAU) in patients with PCOS

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Mood disorders and disturbances NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON56665

**Source**
ToetsingOnline

**Brief title**
H2deal-study

### Condition

- Mood disorders and disturbances NEC
- Menstrual cycle and uterine bleeding disorders

**Synonym**
Polycystic ovary syndrome (PCOS)

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Waterloo Foundation

### Intervention

**Keyword:** Anxiety, Depression, PCOS

## Outcome measures

### Primary outcome

The primary outcome measure of this study (depression and anxiety) will be measured with the Hospital Anxiety and Depression Scale (HADS).

### Secondary outcome

Secondary outcome measures are quality of life (QoL) measured with the validated Dutch version of the PCOSQOL. Body image with the BCS, Coping strategies will be measured with the Coping Inventory for Stressful Situations (CISS-21) and sleep quality with the Promis short form 4a.

# Study description

### Background summary

Polycystic ovary syndrome (PCOS) is a common endocrine disorder that affects 5-10% of women in their reproductive years . Women with PCOS report a major impact on their quality of life (QoL) due to PCOS symptoms and experience more depressive and anxiety complaints compared to women without PCOS. In the general population, the first-line treatment for depression is cognitive behavioural therapy (CBT). The effects of standardized brief CBT have not been tested in this group of women. Therefore, we want to investigate the effects of a brief psychological intervention in women with PCOS that could be easily implemented at any outpatient clinic.

### Study objective

To study if an online brief CBT intervention is effective for anxiety and depression compared to care as usual (CAU) in patients with PCOS

### Study design

Participants are randomized into one of three groups:
1) individual treatment (A)
2) group treatment (B) and
3) care as usal group (CAU)

Treatment A and B consists of a 3 month treatment:
Week 1: Session 1 +homework assignments
Week 3: Session 2 +homework assignments
Week 5: Session 3 +homework assignments
Week 8: Session 4 +homework assignments
Week 12: Session 5 +homework assignments

The care as usual group is referred to the general practitioner who makes an assessment for appropriate psychological support. It is up to the general practitioner to determine what care is necessary.

### Intervention

The online program consists of 5 modules and lasts for 3 months. In the online program, participants are given more information about PCOS, mood, depression and anxiety and perform exercises to cope with PCOS symptoms. There are also homework assignments associated with each module.
Every 2 weeks there is an appointment with a psychologist to discuss how things are going. The group with extra group sessions have an online session every 2 weeks through the Teams program with other women with PCOS.

### Study burden and risks

Participants will spend about 1 hour per week on the online program including homework assignments.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

women with a confirmed diagnosis of PCOS based on the Rotterdam criteria, body Mass Index (BMI) >=18.5*kg/m2, aged above 18 years.

## Exclusion criteria

pregnant, current treatment for clinical depression, anxiety disorders or eating disorders, suicidality (indicated by a score >2 on the Beck Depression Inventory II suicide item), having an endocrine disease (diabetes mellitus, thyroid function disorders, Cushing*s disease, adrenal tumors, and congenital adrenal hyperplasia) and inability to speak, read or write Dutch.

# Study design

## Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-04-2024 |
| Enrollment: | 222 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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|---|---|
| Date: | 29-03-2024 |
| 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 | NL83460.078.22 |