

# The effectiveness of group versus individual parent management training in preschool children with disruptive behaviors (ODD and ADHD)

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To compare the effectiveness of group versus individual parent management training (PMT) in preschool children with disruptive behavior problems and to identify predictors and moderators of treatment response.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Personality disorders and disturbances in behaviour
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33299

### Source

ToetsingOnline

### Brief title

PMT in preschool children

### Condition

- Personality disorders and disturbances in behaviour

### Synonym

Oppositional Defiant Disorder (ODD); behavior problems

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Accare

**Source(s) of monetary or material Support:** ZonMw

## **Intervention**

**Keyword:** behavior problems, parent management training, preschoolers

## **Outcome measures**

### **Primary outcome**

The primary outcome measure will be the mothers\* Eyberg Child Behavior Inventory (ECBI).

### **Secondary outcome**

To identify predictors and moderators of treatment response, which includes both parent (presence of psychiatric problems, socio-economic status, and parental stress associated with rearing) and children\*s characteristics (children's age, intelligence, range of co morbidities, and genetic polymorphisms).

## **Study description**

### **Background summary**

Disruptive behavior problems, i.e., attention-deficit/hyperactivity disorder (ADHD) and oppositional defiant disorder (ODD) at preschool age forms a major burden for parents, is associated with a wide range of functional impairments, and is a risk factor for child maltreatment. They are a well-established risk factor for future psychiatric problems, educational underachievement, social isolation, antisocial behavior and alcohol and drugs abuse.

### **Study objective**

To compare the effectiveness of group versus individual parent management training (PMT) in preschool children with disruptive behavior problems and to identify predictors and moderators of treatment response.

### **Study design**

Participating patients will be 150 referred treatment naïve preschool children with disruptive behavior (i.e., fulfilling criteria for ADHD and ODD) and will be randomly assigned to either group or individually delivered PMT.

## **Intervention**

Group or individually delivered PMT

## **Study burden and risks**

The treatments are routinely given in clinical practice and are as such not associated with particular risks or benefits. The extra burden for participating families is limited to completion of a number parent questionnaires.

## **Contacts**

### **Public**

Accare

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Children (2-11 years)

## Inclusion criteria

1. Treatment naïve.
2. Children of both sexes, of any ethnic and cultural background, ages 2.5 to 6 years.
3. A DSM-IV (American Psychiatric Association, 1994) consensus diagnosis of ADHD combined or predominantly hyperactive subtype.
4. A DSM-IV (American Psychiatric Association, 1994) consensus diagnosis of ODD.
5. An impairment scale score <55 on the Children's Global Assessment Scale (Shaffer et al., 1983).
6. Full Scale IQ equivalent of >70.
7. The same primary caretaker for at least 6 months before screening.
8. Parents have provided informed consent to participate in the study, in accordance with Dutch ethical regulations.

## Exclusion criteria

1. There is current evidence in the child of adjustment disorder, autistic disorder, psychosis, or other psychiatric disorder in addition to ADHD that requires treatment with additional medication.
2. The child has a major medical condition that would interfere with involvement in a long-term study
3. Inability of the parent to understand or follow study instructions.
4. History of bipolar disorder in both biological parents.
5. Patients whose families anticipate a move outside the geographic range of the investigative site or who plan extended travel inconsistent with the recommended visit interval

## Study design

### Design

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

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-09-2009  
Enrollment: 150  
Type: Anticipated

## Medical products/devices used

Registration: No

## Ethics review

Approved WMO  
Application type: First submission  
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL27754.042.09