# Randomized Controlled Trial (RCT) of Parent Management Training Oregon model (PMTO) for children with externalizing behavior problems in the Netherlands

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27309

**Source**
Nationaal Trial Register

**Brief title**
RCT PMTO

**Health condition**

child externalizing behavior problems; externaliserende gedragsproblemen; opoositioneel gedrag, agressie

### Sponsors and support

**Primary sponsor:** Maastricht University
**Source(s) of monetary or material Support:** - Fonds RVVZ
- Stichting Kinderpostzegels Nederland
- VSB Fonds
- ZonMw

## Intervention

## Outcome measures

### Primary outcome

Child externalizing behaviour problems

### Secondary outcome

- Parental stress level

- Psychopathology of parents

- Parenting skills

- Child internalizing behaviour problems

- Child prosocial behavior

- School performance of the children

# Study description

### Background summary

Rationale: As longitudinal research has demonstrated a high degree of stability and aggravation of conduct problems in childhood into criminal and violent behavior in adulthood, early interventions can result in great benefit. There is currently a high need for effective treatment programs for children 4-10 years with antisocial conduct problems in The Netherlands. The Ministry of Health decided in 2005 to fund the implementation of Parent Management Training Oregon model (PMTO), a theory-driven, evidence-based intervention for parents of children with externalizing behavior problems.

The following specific hypotheses will be tested in the current research project:

(1) PMTO, compared to CAU, will result in statistically significant benefits in terms of:
(a) parenting skills

(b) parenting stress

(c) child behavior problems (externalizing and internalizing)

(d) child prosocial behavior

(2) Benefits of PMTO will be observed at 6 months post baseline, and maintained in the ensuing follow-ups at 12 and 18 months.

(3) PMTO program integrity, as measured by means of the FIMP rating system, will have a significant positive correlation with PMTO effectiveness.

(4) PMTO, compared to CAU, will have higher treatment compliance and fewer dropouts.

Objective: The proposed RCT has as its goal to test the effectiveness of PMTO against Care As Usual (CAU).

Study design: The study will be conducted as Randomized Controlled Trial (RCT) with assessments at regular intervals, i.e. baseline (pretreatment), 6, 12 and 18 months. Four youth (mental health) care institutions in The Netherlands are committed to participate in the current project, and have guaranteed sufficient patient supply.

Study population: Parents with children in the age range of 4-10 years old with externalizing behaviour problems who are referred to the four participating youth care institutions by different sources, such as family physicians, paediatricians and Bureaus Jeugdzorg.

Intervention: One group receives PMTO once a week, the other group receives CAU.
Main study parameters/endpoints: The main study parameter is the change of behaviour problems of the children from baseline to endpoint.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Parents and children will participate in assessments at fixed time intervals. This will require some time and effort on their part. There are no risks involved; possible benefits are: increased parenting competence, decrease in child behaviour problems, overall stress reduction within the family.

**Study objective**

(1) PMTO, compared to Care As Usual (CAU), will result in statistically significant benefits in terms of:
(a) parenting skills
(b) parenting stress
(c) child behavior problems (externalizing and internalizing)
(d) child prosocial behavior
(2) Benefits of PMTO will be observed at 6 months post baseline, and maintained in the ensuing follow-ups at 12 and 18 months post baseline.
(3) PMTO program integrity, as measured by means of the FIMP rating system, will have a significant positive correlation with PMTO effectiveness.
(4) PMTO, compared to CAU, will have higher treatment compliance and fewer dropouts.

## Study design

intake (baseline, T0), after 6 months (T1), after 12 months (T2), and after 18 months (T3).

## Intervention

PMTO:

The theoretical model underpinning PMTO is Social Interaction Learning theory (SIL; Patterson, 2005), a model that specifies that parents mediate the effect of harsh family contextual factors, such as stress, poverty, parental psychopathology, on child adjustment. Because the SIL model emphasizes the importance of parental influence on child development, parents are the primary recipients of the intervention.
PMTO is built around 5 theoretically based effective parenting practices: skill encouragement, setting limits, monitoring, problem solving, and positive involvement. Essentially, a central role of the PMTO therapist is to coach parents in applying effective parenting strategies to diminish coercive tactics through these core practices. 'Skill encouragement' incorporates ways in which adults promote competencies using contingent positive reinforcement (e.g., establishing reasonable goals, breaking goals into achievable steps, promoting behavior, rewarding progress, use of praise, incentive charts). 'Setting limits or discipline' involves the establishment of appropriate rules with the application of mild contingent sanctions for rule violations. Parents are taught to be consistent in their use of short, relatively immediate negative consequences (e.g., time out, work chores, privilege removal) contingent upon the child's problematic behavior. 'Monitoring' (supervision) becomes especially critical as children spend more time away from home. This skill requires keeping track of children's activities, associates, whereabouts, and arranging for appropriate supervision. 'Problem solving' involves skills that help family members negotiate disagreements, establish rules, and specify consequences for following or violating rules. 'Positive involvement' reflects the many ways parents invest time and plan activities with their children (Forgatch and Knutson, 2002; Martinez and Forgatch, 2001). Other topics that are relevant to families with behaviorally disordered children are also part of the intervention, such as regulating emotion, communication skills, and promoting school success. Components may be added to enhance the program's effectiveness, depending on the family setting and context (e.g., issues specific to single mothers, stepfamilies; sibling conflict).

Care As Usual (CAU):
CAU for children with externalizing behavior problems varies depending on the institution/ region. CAU is thus operationalized as the existing mix of unproven treatments in The Netherlands, and as such representative of current clinical practice. We will describe the nature of CAU at the different sites in detail, to allow adequate interpretation of the results of the study. For now, we have a list of CAU-therapies for our target population at each site. CAU will be described in terms of a fixed set of parameters, including: targeted subject (parent, child or both), treatment format (individual, group, family, or combinations thereof), duration, frequency, theoretical model (e.g., behavioral, systems), skills and educational level of therapists.

# Contacts

**Public**
P.O. Box 616

Corine Ruiter de
Maastricht 6200 MD
The Netherlands
043-3884344
**Scientific**
P.O. Box 616

Corine Ruiter de
Maastricht 6200 MD
The Netherlands
043-3884344

# Eligibility criteria

## Inclusion criteria

1. Child Behavior Check List (CBCL) parent ratings of aggression, externalizing behavior and/or delinquency equal to or greater than 1.0 SD above the Dutch norm for the reference group;

2. Child lives with at least one biological/adoptive parent.

## Exclusion criteria

1. Parents with severe mental retardation/psychopathology (including substance abuse disorders);

2. Sexual abuse in the family;

3. Children with mental retardation (IQ < 70).

# Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2008 |
| Enrollment: | 260 |
| Type: | Anticipated |

## Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

## 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 | NL1175 |
| NTR-old | NTR1220 |

| Register | ID |
| --- | --- |
| Other | ZonMw : 80-82405-98-02001 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A