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

Published: 18-07-2008
Last updated: 11-05-2024

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

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON33600

Source
ToetsingOnline

Brief title
RCT-PMTO

Condition

- Personality disorders and disturbances in behaviour

Synonym
aggressive and oppositional behavior problems, externalising behavior problems

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZONMw,Stichting Kinderpostzegels Nederland;Fonds RVVZ;VSB-fonds

Intervention

Keyword: child behavioral problems, parent training, PMTO, RCT

Outcome measures

Primary outcome

The main study parameter is the change of behaviour problems of the children

from baseline to endpoint.

Secondary outcome

- Parental stress level

- Psychological problems in parents

- Parenting skills

- Child internalizing behaviour problems

- Child prosocial behavior

- School performance of the children

- Direct and indirect costs

Study description

Background summary

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 (cost)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
(e) costs related to the intervention

(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.

Study 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.

Intervention

The theoretical model underpinning PMTO is Social Interaction Learning (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).

Study burden and risks

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 to parents and children are: increased parenting competence, decrease in child behaviour problems, overall stress reduction within the family, prevention of future antisocial development.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Male or female child between 4 and 10 years old.
- 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
- Child lives with at least one biological/adoptive parent.

Exclusion criteria

- Parents with severe mental retardation/psychopathology (including substance abuse disorders);
- Sexual abuse in the family;
- Children with severe mental retardation (IQ < 70).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2008
Enrollment:	260
Type:	Actual

Ethics review

Approved WMO Date:	18-07-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-02-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-04-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL19855.068.07
Other	nog niet bekend