

Prevention of Child Maltreatment; A randomized controlled trial on the effectiveness of Parent-Child Interaction Therapy in the home situation (PCIT-Home)

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Research focusing on the prevention of child maltreatment is limited. Parent-Child Interaction Therapy (PCIT) has been identified as an evidence based treatment for families with young children who have experienced physical abuse and thereby...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Developmental disorders NEC
Study type	Interventional

Summary

ID

NL-OMON40865

Source

ToetsingOnline

Brief title

Effectiveness of in-home PCIT

Condition

- Developmental disorders NEC
- Family issues

Synonym

child behavior problems, Child maltreatment

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Stichting Kinderpostzegels

Intervention

Keyword: Child disruptive behavior problems, Child Maltreatment, Parent training interventions, PCIT

Outcome measures

Primary outcome

Primary outcome of the study is:

- * Decrease of the risk for child maltreatment

Secondary outcome

Secondary outcomes of the study are:

- * Decrease of child disruptive behavior problems
- * Decrease of parental stress
- * Improvement of the quality of parent-child interaction and relationship
- * Treatment satisfaction

Current study also focuses on the costeffectiveness of PCIT-Home and the influence of genes on the effectiveness.

Study description

Background summary

In the Netherlands child maltreatment is a national concern. The prevalence rate is high (3%). Many risk factors influence the occurrence of child maltreatment. Biological, social, cultural and environmental factors may lead to the inability of parents to provide their children a healthy and secure

developmental environment. The extent of maltreatment, its far-reaching individual health and social consequences and high economic costs emphasize the importance of the prevention of child maltreatment. Prevention is necessary to lessen the negative consequences. Preventive interventions which are accessible and provided on the home-situation of the family are able to strengthen the empowerment of parents and children. Therefore, prevention programs focusing on this empowerment and the enhancement of the parent-child relationship can contribute to the prevention of child maltreatment.

Study objective

Research focusing on the prevention of child maltreatment is limited. Parent-Child Interaction Therapy (PCIT) has been identified as an evidence based treatment for families with young children who have experienced physical abuse and thereby research provides evidence for the effectiveness of the prevention of child maltreatment. In the Netherlands, PCIT is provided since 2007 and a randomized controlled trial on the effectiveness of PCIT indicated important improvements in observations of positive parent*child interactions, reductions in child externalizing behavior and parent stress. However, premature termination of treatment has come up as a dominant problem during this study. International research supports the evidence of PCIT in the home situation. By providing PCIT in the home situation, attrition based on practical issues can be prevented. To make PCIT more accessible for families at risk for child maltreatment the primary purpose of the study is therefore to implement and study the effectiveness of PCIT in the home situation (PCIT-Home).

Study design

To study the (cost)effectiveness of Parent-Child Interaction Therapy in the home situation, several measures including questionnaires, interviews and video-observations are used for the pre-, post and follow-up assessments. The study is a randomized controlled trial using a waitlist control condition. Sixty families are included in the study. Thirty families start treatment directly after baseline assessment and thirty families start treatment after a waiting period of two months. For the families in the wait-list condition an extra assessment is included covering the end of the waiting period and the pre-treatment assessment.

Intervention

Parent-Child Interaction Therapy (PCIT) is a manualized intervention for parents and young children. In PCIT-Home parents are coached by the therapist using a bug-in-the-ear device. In two phases of treatment the therapist teaches parents communication skills that foster positive parent*child relationships and strategies of differential reinforcement. Also parents are taught to use an

effective and secure strategy to discipline their child. PCIT-Home is an adaptation of the original manual of PCIT. PCIT-Home is provided in the family's home situation and includes eight sessions of treatment.

Study burden and risks

No more risks are expected when participating in current study than receiving Parent-Child Interaction Therapy by the regular protocol. Participation in the study only requires some time from the parents and children. The research included three or four assessments (1 hour each). The researcher is visiting the parents and children at home to decrease to burden for the family.

Contacts

Public

Academisch Medisch Centrum

Schipholweg 73/75 73/75
Leiden 2316 ZL
NL

Scientific

Academisch Medisch Centrum

Schipholweg 73/75 73/75
Leiden 2316 ZL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Families with young children (2 to 7 years) with disruptive behavior at risk for child maltreatment.

Exclusion criteria

- a severe sensory or mental impairment of the child (e.g. deafness, mental retardation)
- a unsafe situation for the child at home, requiring out-of-home placement
- parents with mental retardation (IQ < 70)
- mental health problem for the parent or child which require individual treatment (e.g. suicidality, aggression regulation problems, and substance abuse)

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:	Recruitment stopped
Start date (anticipated):	14-10-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO	
Date:	17-12-2014

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL48795.018.14