Effectiveness of the Triple P program for parents of NICU graduates with emotional and/or behavioral problems

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The objective is to study the effectiveness of the Triple P program compared to a control group, for parents and their NICU-graduates with emotional and/or behavioral problems. Effectivenes concerns children's problems, parents' parenting...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35293

Source
ToetsingOnline

Brief title
Triple P for parents of NICU graduates

Condition

- Other condition
- Neonatal and perinatal conditions

Synonym
emotional problems; behavioral problems

Health condition

opvoedingsproblemen; emotionele en/of gedragsproblemen kind

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Child_behavior, Early_intervention, Neonatal_intensive_care, Parenting

Outcome measures

Primary outcome

Emotional and behavioral problems as indicated by the parents, measured with the Total Problems scale of the CBCL.

Secondary outcome

Internalising and externalising problems as indicated by the parents (CBCL), disruptive behavior (ECBI), parents' parenting experiences (NOSI), attitude of parents towards parenting (CRPR), vulnerability of the child as perceived by the parents (VCS), internalising and externalising problems as indicated by the teacher (TRF), observed parent-child interaction (DPICS-R) and number of families that need more (intensive) counselling after the intervention.

Study description

Background summary

At toddler age, NICU graduates show more emotional and behavioral problems than term born children without a medical condition. Having a child in neonatal intensive care burdens parenting, not only during the acute phase of illness but also in the years thereafter. Most interventions up till now take place during the NICU period or in the first year of life. These interventions usually aim at directly stimulating the motor and cognitive development of the child. The effects of early interventions are positive, but at school age the positive effects have usually disappeared. As of yet, there are no studies of interventions aimed at parenting support of parents of NICU graduates at

toddler age, while emotional and/or behavioral problems surface specifically at this age.

Study objective

The objective is to study the effectiveness of the Triple P program compared to a control group, for parents and their NICU-graduates with emotional and/or behavioral problems. Effectivenes concerns children's problems, parents' parenting experiences, and the interaction between parents and child.

Study design

After screening, a multicenter open randomized trial is performed.

Data will be collected using a developmental test for the child, structured behavioral observations of parent-child interactions, questionnaires for the parents, and a questionnaire for the teacher. The used developmental test is the BSID-II or the WPPSI-III, dependent on the child's age. The structured behavioral observation that will be conducted is the DPICS-R. Parents fill in the CBCL, ECBI, NOSI, NOSIK, CRPR, VCS, CSQ and the FBQ. The teacher fills in the TRF.

Intervention

The intervention is an evidence-based parenting program, Triple P (level 3) compared to a control group. It aims at improving the competences and the self-reliance of parents regarding their parenting behaviour. Triple P tries to establish a more competent parenting style in dealing with the child's emotional and/or behavioral problems, less use of cohersion and negative discipline, better communication about parenting between parents and between parent and child, and less parenting stress for the parents.
The duration of the intervention is four times 30 minutes.

Study burden and risks

Parents who participate have four therapy sessions of 30 minutes. They also fill out questionnaires at home. One of the parents and the child are invited to come to the treatment centre four times, so the researchers can conduct behavioral observations of family interactions.

The child is invited to come to the treatment centre with one of the parents four times. At the first measurement moment a developmental test of 45 minutes will be conducted. At all four measurement moments child and parent are given a play-assignment which is observed by the investigators and videotaped.
Parents who participate in the research have four therapy sessions of 30 minutes. Besides this they come to the treatment center to conduct a

play-assignment with their child. Finally, parents fill in questionnaires at five measurement moments.

Time for each measurement moment:
Screening:
parents: questionnaires, 40 min (home)

Week 1:
kind: developmental test, 45 min (treatment center)
kind en ouder: play-assignment, 30 min (treatment center)
parents: questionnaires, 55 min (home)
leerkracht: questionnaire, 20 min (home)

Week 2-5
parents: Triple P intervention, 4 times 30 min

Week 6:
kind en ouder: play-assignment, 30 min (treatment center)
parents: questionnaires, 10 min (home)

Maand 6 en 12:
kind en ouder: play-assignment, 30 min (treatment center)
parents: questionnaires, 1 hour, 15 min (home)
leerkracht: questionnaire, 20 min (home)

Contacts

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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

Parents and their NICU graduates whom are between 2 and 5 years of age.
Children are (1) born < 32 weeks and/or birthweight < 1500 grams or (2) children born between 37-42 weeks with perinatal asphyxia.

Exclusion criteria

Parents of children with motor- and/or intellectual disabilities.
Parents who do not sufficiently speak the Dutch language.
Parents of children who fit the inclusion criteria but already receive professional support for the emotional and/or behavioral problems of their child.

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:	Recruitment stopped
Start date (anticipated):	18-05-2009
Enrollment:	972
Type:	Actual

Ethics review

Approved WMO Date:	18-11-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-03-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-03-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27727
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL24922.041.08

Register	ID
OMON	NL-OMON27727