Randomised Controlled Trial of Triple P intervention for multi-problem families

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30566

Source
ToetsingOnline

Brief title
RCT Triple P

Condition

- Other condition

Synonym
Behavioural and emotional problems in children

Health condition

1) gedrags-en emotionele problemen bij kinderen; 2) opvoedingsvaardigheden bij ouders; 3) psychische en relatieproblemen bij ouders

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: multi-problem, parenting program, research, Triple P

Outcome measures

Primary outcome

The effectiveness of the Triple P family intervention for multi-problem

families will be evaluated on the different levels:

- child level: behavioural- and emotional problems of the child

- parent/family level: competences of the parents, psychological problems of

the parents (depression, stress) and relational problems.

Secondary outcome

Demographic family characteristics will be assessed with the Family Background

Questionnaire.

Satisfaction will be assessed with the Client Satisfaction Questionnaire.

Study description

Background summary

Behavioural and emotional problems are quite common in children and young people. This is around one in five pupils in primary and secondary school who has externalising problems and internalising problems. In Australia a muti-discipline program has been developed for children and youngsters with behaviour problems or emotional problems. The Triple P-Positive Parenting Program consists of five levels, ranging from brief and broad support to parents in dealing with a child who exhibits behavioural problems to an intensive family intervention (level 4/5).

Hypotheses are: The Triple P intervention is similar or superior to the Intensive Family Support in the comparing group in terms of clinical outcomes (decrease of behavioural and emotional problems in children, improvement of the parenting skills of parents, and decrease of the psychological complaints of parents). The hypotheses will be tested two-site.

Study objective

The objectives of this research is to asess the family-intervention Triple P on:
1) effectiveness in terms of (-) decrease of behavioural- and emotionel problems of the child (SDQ)
2) effectiveness in terms of (-) improvement of the competence of the parents in parenting (PS, PPC)
3) the effectiveness in terms of (-) decrease of the psychological complaints of the parents (RQI en DASS).

Study design

We conduct a randomised controlled trial with two parallel groups: the experimental conditition (family intervention of Triple P) and a 'care as usual' control group. It is a pragmatic, non-blinded, multi-site trial.

In the experimental condition the family-intervention Triple P will be offered. This is an indicated intervention for parents of children (4-13 years) with concurrent child behaviour problems and family dysfunction such as parental depression or stress or conflict between partners.

If during the Triple P intervention turns out that next to or after the Triple P family intervention other support is necessary, the Triple P intervention can be completed with other support (e.g. finding accomodation). This other support will be registrated by the therapist.

The 'care as usual' control group is the Intensive Ambulant Family intervention.'
This is different in each institute. The therapist will registrate what kind of support the families have had. It is not necessarily to standard this 'care as usual' in advance, because otherwise there will be a risk that the intervention will be adapted and no good comparison can be made with the 'care as usual'. It is essential for the research to assess the effects of the Triple P intervention by comparison with the present (and variable) therapy for multi-problem families.

Intervention

In the experimental condition the family-intervention Triple P will be offered. This is an indicated intervention for parents of children (4-13 years) with

concurrent child behaviour problems and family dysfunction such as parental depression or stress or conflict between partners.
This family intervention exists of several modules:
• The individual parenting support Triple aimed on severe behavioural problems in the child and dysfunction in the family. This module consists on 8-10 sessions (1 60- 90 minutes each) and 3 telephone sessions.
• Three modules for families with relational problems, psychological problems in one of the parents, stress. Parents can follow one of those modules or all three if they want. Each module consists of a maximum of three sessions of 60-90 minutes.

Study burden and risks

We expect no risks for the respondents, because:
- the respondents volunteer for support because of the problems with parenting or dysfuntion in the family (psychological problems, relational problems, stress). They will not be confrontated with new problems.
- the intervention is tailored to the requirements of parents and children.
Self regulation is a central skill. This involvs teaching parents skills that enable them to become indenpendent problem solvers. The program 'empowers' and not medicalizes.

The burden of participating is:
one introduction session (1 hour) + 8-10 sessions (1- 1 1/2 hour) + choice of 3 modules (1 - 1 1/2 hour) + homework (2 hours a week).
Total burden is between 40 and 100 hours, dependent on the choice of the extra modules, including 2 hours to fill in the questionnairs (3 moments of assessment).
The period of the intervention and research is 1 year (follow-up assessment 1 year after baseline-assessment)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

multi-problem gezinnen
hulpvraag betreft kinderen tussen 4-13 jaar

Exclusion criteria

In case of a crisis-situation

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:	Recruiting
Start date (anticipated):	01-10-2006
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	12-07-2006
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (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

No registrations found.

In other registers

Register	ID
CCMO	NL12806.097.06