Decreasing behavior problems: a randomised trial of the Utrecht Coping Power Program for youth with MID.

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

Summary

ID

NL-OMON32877

Source ToetsingOnline

Brief title Treatment of behavior problems in youth with MID

Condition

• Personality disorders and disturbances in behaviour

Synonym behavior problems, Disruptive behavior disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht Source(s) of monetary or material Support: Zon MW,VOBC LVG

1 - Decreasing behavior problems: a randomised trial of the Utrecht Coping Power Pro ... 25-05-2025

Intervention

Keyword: Disruptive behavior problems, Effect study, Parent-child intervention, Youngsters with MID

Outcome measures

Primary outcome

The primair outcome in this study is the behavior of the child.

Secondary outcome

Secondary outcomes are the social information processing and executive

functions of the child and the parenting factors. Besides, the influence of

several study parameters (moderators) is measured in the study.

Study description

Background summary

Youth with a mild intellectual disability (MID, IQ 50-85) have a higher risk of developing a behavior problems then their peers with a normal IQ. However, there is a possibility to intervene. A standardized child-parent intervention was developed to reduce the behavior problems in these youngsters. There are several causes and risk factors that explain the higher risk of developing behavioral problems in youngsters with MID. A distinction can be made between child factors, for example the social information processing en executive functions, and the environmental factors, most important the competence of parents to raise a child.

Despite the strong attention paid to behavioral problems in youngsters with an IQ above 85, the attention paid to the same problem behavior in youngsters with MID is relatively low.

Study objective

Aim of this study is to measure the effect of the child-parent intervention *Samen Stevig Staan* in decreasing the problem behavior of youngsters with MID. A secondary aim is to investigate the influence on this relation of several child- and parental factors.

Study design

A randomized controlled trial is executed on location level in the institute. Two rounds of intervention are carried out, desirable with 50 youngsters and their parents in each condition per round (200 total). Questionnaires are filled out by parents, children, teachers and group leaders five times; a pre-measure, a measurement during intervention, a post measure and two follow up measuring moments (six months and 1 year follow up). The children will fulfill several tasks to measure the social information processing and executive functions, all four measurement moments.

Intervention

The training *Samen Stevig Staan* exists of 2 parts; a child training and a parent training that are connected. Both the child training and the parent training are given in a group context (five youngsters and their parent(s). Children are mainly trained in communication skills, recognizing and handling emotions, and problem solving skills. Their parents learn how to set rules, to handle the behavior of their child, positive parenting, and problem solving skills.

Study burden and risks

It is expected that the pressure on the participants of this study is minimal. There is no risk of any harm to the participants as a result of participating in the study. It is important that this target group is used on behalf of the adapted version of the intervention to youngsters with MID, and the lack of evidence based treatment for these youngsters.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Children (2-11 years) Elderly (65 years and older)

Inclusion criteria

Participants have an IQ between 50 and 85. In day care they are treated for their behavior problems. The youngsters are living at home and are aged 10-16. Important condition to participate is that the parents are willing to join the parent training.

Exclusion criteria

Autistic Spectrum Disorders and manifest psychoses in either parent or child. Children or parents that do not speak dutch and children and parents that are deaf or blind are excluded from the study.

Study design

Design

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

4 - Decreasing behavior problems: a randomised trial of the Utrecht Coping Power Pro ... 25-05-2025

Primary purpose:

Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2009
Enrollment:	600
Туре:	Actual

Ethics review

Approved WMO	
Date:	20-01-2009
Application type:	First submission
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

No registrations found.

In other registers

Register CCMO **ID** NL24269.041.08