Study into the effectiveness of behavioral parent training for children with autism spectrum disorder and behavior problems

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We aim to determine the effects of a face to face and a blended parent training program (i.e., two formats of Behavioral Parent Training Groningen; BPTG) on behavior problems for children 4 through 12 years old with ASD and behavior problems....

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

Summary

ID

NL-OMON44994

Source
ToetsingOnline

Brief title
SPARTA

Condition

- Developmental disorders NEC

Synonym
autism spectdrum disorders, pervasive developmental disorders

Research involving
Human

Sponsors and support

Primary sponsor: Accare, Universitair Centrum Kinder- en Jeugdpsychiatrie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Autism spectrum disorders, Behavior problems, Parent training, Treatment effect

Outcome measures

Primary outcome

The amount of non-compliant behavior as measured with the Home Situation Questionnaire - Pervasive Developmental Disorders (HSQ-PDD, Barkley, Edwards, & Robin, 1999; adapted for ASD by Aman et al., 2009). The HSQ-PDD is a 25 item parent rated questionnaire.

Secondary outcome

All secundary outcome measures are parent rated.

1) Parental satisfaction with the content and effect of parent training, as measured with a parent satisfaction questionnaire (based on the Parent Satisfaction Questionnaire used in Bearss et al. 2013).

2) The Aberrant Behavior Checklist (ABC, Aman et al., 1985) is a measure of disruptive behavior.

3) List of Target Behaviors (slightly adapted version of Van den Hoofdakker et al. 2007) measures the occurrence and severity of specified problem behaviors in the last week.

4) The severity of parent chosen target behaviors and target situations and the competence parents feel in raising their childeren. These measures are rated regularly during parent training .

5) The Strengths and Difficulties Questionnaire (Goodman, 1997; Dutch translation by van Widenfelt, Goedhart, Treffers, & Goodman, 2003) measures

emotional problems, behavioral problems, hyperactivity / attention problems and social problems.

6) The Vineland Adaptive Behavior Scales II (Sparrow, Cicchetti & Balla, 2005) are used to assess adaptive behavior.

7) The Parenting Sense Of Competence scale (Gibaud-Wallston & Wandersman, 1978, as cited in Johnston & Mash, 1989) is a measure of parenting satisfaction and parenting efficacy.

8) The Parenting Stress Index - Short Form (Abidin, 1995) is a measure of stress associated with parenting.

9) The Parenting Scale (Arnold, O*Leary, Wolff, & Acker, 1993) is a measure of parenting style.

10) Forms of health care used during the study, among others medication and child treatment.

11) The number of face to face sessions.

12) The time spent on training by the therapists.

13) Belief of parents concerning the effectiveness of the training.

14) Use of skills learned during BPTG.

15) Use of training facilities after the end of BPTG, such as the book and online training program.

16) The Fragebögen zur Beurteilung der Behandlung (FBB, Mattejat & Remschmidt, 1993, 1995) is a measure of the evaluation of treatment as indicated by the BPTG therapist after treatment.

Study description

Background summary

Children with autism spectrum disorder (ASD) often show behavior problems (e.g., temper tantrums, disobedience, aggressive behaviors) that can severely influence their daily life and development. Parent counseling and parent training are commonly used treatments aimed at decreasing these behavior problems. While the clinical impression is that these are helpful, scientific evidence for the effectiveness of parent training in children with ASD is scarce and should be enlarged.
In the current study, a face to face and a blended (partially face to face and partially online) parent training program for children with ASD and behavior problems will be investigated, aimed at establishing the efficacy of each of the parent training formats.

Study objective

We aim to determine the effects of a face to face and a blended parent training program (i.e., two formats of Behavioral Parent Training Groningen; BPTG) on behavior problems for children 4 through 12 years old with ASD and behavior problems. Furthermore, we aim to investigate differences in parental satisfaction and amount of therapist time between the two formats. Finally, we aim to determine the effects of the training on a number of secondary outcome measures and to identify which child and parental factors may influence the effectiveness of treatment.

Study design

We will conduct a randomized controlled trial, including three conditions: 1) care as usual plus individual face to face BPTG (n=40), 2) care as usual plus individual blended BPTG (n=40), and 3) care as usual, in which participants have to wait twenty weeks before they receive parent training (n=38). In the latter condition, the participants will be randomized to face to face or blended BPTG after the waiting period. Assessments will take place before randomization, directly after completion of BPTG or twenty-weeks care as usual, and approximately three and six months after completion of BPTG.

Intervention

Face to face parent training consists of approximately fifteen manualized face to face contacts with homework to practice learned skills. In the blended parent training, parents participate in the training largely online, with an additional minimum of four face to face contacts. The duration of both treatments is approximately twenty weeks. In all three conditions participants

are allowed to receive other treatments (psychosocial and/or pharmacological), with the exception of behavior therapeutic interventions through parents directed at the behavior of their child.

Study burden and risks

Parents have to complete rating scales and an interview before randomization, immediately after the treatment or waiting period, and at follow-up. The estimated burden, measured in time, will be approximately ten hours for parents, with the first measurement point taking up the most time. Children who have not been administered an intelligence test or Autism Diagnostic Observation Schedule recently, will be subjected to these instruments before randomization. These instruments take about three hours of childrens time. Furthermore, and only with their consent, children*s and parental DNA will be collected by collecting saliva. None of these measures are expected to form a risk for the participants. The intervention and the care as usual condition are not expected to cause any harm.

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

1) The child has a clinical diagnosis of ASD.
2) The child is 4 through 12 years old.
3) The child has an IQ higher than 50.
4) At least one parent experiences behavioral problems at home and is able to select at least three problem behaviors on the List of Target Behaviors.
5) At least one parent is able to take part in the BPTG program.
6) The child is not taking any psychotropic medication or, when taking psychotropic medication, is on a stable dose for at least 6 weeks prior to the inclusion.
7) The referring clinician does not expect any changes in drug treatment policy during the study.
8) Parent(s) (and child, if 12 years) have given their informed consent for participation.
9) Parent(s) have a laptop or PC at their disposal.

Exclusion criteria

1) Parents participated in a behavioral parent training in the year prior to the current study. Parents who started the BPTG training without completing it will be excluded when the face to face training covered antecedent interventions or when the blended training covered chapter 4. Similar criteria will be used in the case of other behavioral parent training programs.
2) There are problems with the child and/or the family that require immediate intervention (e.g. crisis in the family).
3) The family is planning to move within 6 months to a region which is situated too far from one of the study locations.

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):	21-07-2014
Enrollment:	118
Type:	Actual

Ethics review

Approved WMO Date:	26-08-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-05-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-03-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL47931.042.14