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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22042

Source
Nationaal Trial Register

Brief title
SPARTA

Health condition

Autism spectrum disorders
Behavior problems

Dutch:
Autismespectrumstoornissen
Gedragsproblemen

Sponsors and support

Primary sponsor: Accare Universitair Centrum
Source(s) of monetary or material Support: Accare Universitair Centrum

Intervention

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

1) Parental satisfaction with the content and effect of parent training

2) Disruptive behavior (ABC)

3) The occurrence and severity of specified problem behaviors (List of Target Behaviors)

4) The severity of parent chosen target behaviors and target situations and the competence parents feel in raising their children

5) Emotional problems, behavioral problems, hyperactivity / attention problems and social problems (SDQ)

6) Adaptive behavior (VABS II)

7) Parenting satisfaction and parenting efficacy (PSOC)

8) Stress associated with parenting (PSI-SF)

9) Parenting style (PS)

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

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.

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.

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 plus waitlist for BPTG, 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. The study will include children 4 through 12 years old with a clinical diagnosis of ASD, an IQ higher than 50, and their parents. Parents can identify at least three behavior problems that regularly occur at home.

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 (e.g., psychosocial and/or pharmacological), with the exception of behavior therapeutic interventions through parents directed at the behavior of their child.

Our primary outcome is the amount of non-compliant behavior as measured with the Home Situation Questionnaire - Pervasive Developmental Disorders. Secondary outcome measures include parental satisfaction with the training, the amount of disruptive behavior, adaptive functioning, parental competence and stress, the amount of therapist time, and the consumption of mental health care. Parents have to complete rating scales and an interview before randomization, immediately after the treatment or waiting period, and at follow-up. Children who have not been administered an intelligence test or Autism Diagnostic Observation Schedule recently, will be subjected to these instruments before randomization. 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 either.

Study objective

The aims of the study are:

1) To investigate the effectiveness in diminishing behavior problems of Behavioral Parent Training Groningen (BPTG) for parents of children with an ASD and behavioral problems between 4 and 13 years of age in two formats: face to face and blended.

2) To investigate the difference in parental satisfaction between face to face and blended BPTG.

3) To investigate the difference in amount of therapist time between face to face and blended BPTG.

4) To investigate the effectiveness of face to face and blended BPTG on a number of secondary outcome measures, including disruptive behaviors, adaptive behaviors, and parental competence.

5) To identify child and parental factors that may moderate treatment effectiveness. Child factors include comorbidity, intelligence, severity of ASD and behavior problems at baseline, sex, age, and genetic polymorphisms. Parental factors include parental psychopathology, parental cognitions, socio-economic factors, and genetic polymorphisms.

Study design

There are four measurement points.

1) Baseline measurement before randomization.

2) Post-measurement after BPTG or 20-week care as usual plus waitlist period.

Measurement points 1 and 2 include the two treatment groups and the care as usual plus waitlist group. The care as usual plus waitlist group is excluded from follow-up measurement.

3) Three month follow-up measurement. This measurement takes place three months after the completion of BPTG and includes only certain outcome measures.

4) Six month follow-up measurement. This measurement takes place six months after the completion of BPTG and is a complete follow-up measurement.

Intervention

This study has three arms: face to face BPTG, blended BPTG and care as usual plus waitlist for BPTG.

- Face to face BPTG consists of approximately fifteen manualized face to face contacts with homework to practice learned skills.

- In the blended BPTG training, parents participate in the training largely online, with an additional minimum of four face to face contacts.

- Families in care as usual plus waitlist condition will have to wait twenty weeks before they receive treatment with BPTG. In this period their clinician will be free to provide treatment as appropriate. BPTG will not be offered during this period.

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 (BPTG in the two treatment arms excluded).

Contacts

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Eligibility criteria

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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2014
Enrollment:	118
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-10-2014
Application type:	First submission

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
NTR-new	NL4712
NTR-old	NTR4857
Other	CCMO : ABR: 47931.042.14

Study results