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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22042

Bron
Nationaal Trial Register

Verkorte titel
SPARTA

Aandoening

Autism spectrum disorders
Behavior problems

Dutch:
Autismespectrumstoornissen
Gedragsproblemen

Ondersteuning

Primaire sponsor: Accare Universitair Centrum
Overige ondersteuning: Accare Universitair Centrum

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

University of Groningen, University Medical Center Groningen, Department of Child and Adolescent Psychiatry, Accare Research
S. Breider
Groningen 9700 AR
The Netherlands
050-3681178

Wetenschappelijk

University of Groningen, University Medical Center Groningen, Department of Child and Adolescent Psychiatry, Accare Research
S. Breider
Groningen 9700 AR
The Netherlands
050-3681178

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	21-07-2014
Aantal proefpersonen:	118
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-10-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4712
NTR-old	NTR4857
Ander register	CCMO : ABR: 47931.042.14

Resultaten