DAVINCI - A study to the effectiveness of Pivotal Response Treatment in school-aged children with autism spectrum disorder

DAVINCI - Onderzoek naar het effect van Pivotal Response Treatment bij kinderen en jongeren met een autisme spectrum stoornis

No registrations found.

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

Summary

ID

NL-OMON23411

Source
Nationaal Trial Register

Brief title
DAVINCI

Health condition

autism spectrum disorder, ASD, autisme, autisme spectrum stoornis, ASS

Sponsors and support

Primary sponsor: Karakter, Expert Centre for Child and Adolescent Psychiatry (prof. J. K.

Buitelaar, MD PhD)
Source(s) of monetary or material Support: Stichting Karakter
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Intervention

Outcome measures

Primary outcome

-Significant response on the Social Responsiveness Scale (SRS-2): generalized improvment in child's social and communicative skills

Secondary outcome

-Clinically significant increase at the Clinical Global Impression (CGI) - Improvement scale

-Generalized social and communicative skills (SRS-2), percentage of clinical significant response

-child rearing pressure of parents (Dutch Opvoedingsbelating Vragenlijst, OBVL)

-Change in ASD symptoms (Autism Diagnostic Observation Scedule, ADOS-2)

-Child adaptive behaviour (Vineland Adaptive Behaviour Scales, VABS)

-Child internalizing and externalizing symptoms (Child Behaviour CheckList, CBCL)

Study description

Background summary

Rationale: Pivotal Response Treatment (PRT) is a promising intervention that focuses on the core symptoms of ASD. Research so far is limited due to methodological shortcomings and

there is insufficient scientific evidence that supports the use of PRT in school-aged children and adolescents. The current study aims to address these limitations by focussing on the effectiveness of PRT in children and adolescents with ASD aged 9 - 15, applying a randomized controlled trial.

Objective: The main objective of the current study is to investigate the effectiveness of PRT compared to care-as-usual (CAU) in improving child social and communicative skills and child global clinical functioning after treatment and at 2 month follow up. Secondary parameters are feelings of competence in parents, parent-child interaction, child behaviour problems and child adaptive behaviour.
Additionally, a secondary goal is to assess which child, parent and structural intervention factors influencing effectiveness of treatment.

Study design: A randomized controlled trail with partly blinded measures at end-point and follow-up.

Study objective

Pivotal Response Treamtent (PRT) is more effective compared to care-as-usual in:

-improving child social and communicative skills (primary)

-improving child clinical global functioning (secondary)

-improving feelings of competence in parents (secondary)

Study design

The duration of the treatment within this study is 12 weeks, with an extention of 8 weeks when there is no clinical significant improment on the CGI-I after 12 weeks of treatment. When treatment duration is 20 weeks, the 12-week measure will be an intermediate measure.

T1: week 0 (start of treatment)

T2: week 12 (end of treatment/intermediate measure)

T3: week 20 (follow-up/end of treatment)

T4: week 28 (follow-up/follow-up 2)

Intervention

-Pivotal Response Treatment (PRT): a 12-week intervention for social and communicative skills in children and adolescents with ASD and their caregivers

-care-as-usual: regular treatment of children and adolescents with ASD and their caregivers

Contacts

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Eligibility criteria

Inclusion criteria

-aged 9-15 years at inclusion in the study

-total intelligence quotiënt (TIQ) of > 80

-clinically diagnosed with autism spectrum disorder (DSM-IV-TR and DSM-5) or social communication disorder (DSM-5)

-at least one of the parents is able to understand and speak the Dutch language

Exclusion criteria

-Systemic problems that limit the possibility to engage in an intensive treatment, focused on training both the child/adolescent and parents

-presence of comorbid problems that require treatment first

-problems with accepting child's diagnosis of ASD by child and/or parent

-severe parental psychopathology

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2016
Enrollment:	42
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	10-06-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44124
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5476
NTR-old	NTR5893
CCMO	NL54706.091.15
OMON	NL-OMON44124

Study results