The effectiveness of Pivotal Response Treatment in children and adolescents with autism spectrum disorder: a randomized clinical trail

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Primary Objective: The main objective is to investigate the effectiveness of PRT compared to CAU in school-aged children and adolescents with ASD.The primary research question is:1) Directly after treatment and at follow-up, what is the...

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

Summary

ID

NL-OMON44124

Source
ToetsingOnline

Brief title
DAVINCI

Condition

- Psychiatric disorders NEC

Synonym
ASD, autism, autism spectrum disorder

Research involving
Human

Sponsors and support

Primary sponsor: Karakter Nijmegen

Source(s) of monetary or material Support: Fonds NutsOhra

Intervention

Keyword: autism, communication, intervention, pivotal response treatment

Outcome measures

Primary outcome

1) Significant response on the SRS (continuous measure): generalized

improvement in child's social and communicative skills

Secondary outcome

-Clinically significant increase at the CGI-I

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

response

-Child rearing pressur of parents (OBVL)

-Parent-child interaction (PCI)

-Change in ASD symptoms (ADOS-2)

-Child adaptive behaviour (VABS)

-Child internalizing and externalizing symptoms (CBCL)

Study description

Background summary

Autism spectrum disorder (ASD) is characterized by persistent deficits in social communication and social interaction and restricted, repetitive patterns of behaviour, interests, or activities (APA, 2013). Despite the large variety of treatment methods for ASD (Seida et al., 2009), sufficient scientific evidence for the effectiveness of the interventions in targeting the core symptoms of ASD (i.e. social communication and social interaction) is lacking. A promising intervention that targets the core symptoms of ASD is Pivotal Response Treatment (PRT) (Koegel & Koegel, 2006). Earlier studies have shown

that PRT, by targeting those pivotal areas, is effective in improving a variety of social and communicative skills in children with ASD, including joint attention (Vismara & Lyons, 2007), turn taking (Harper, Symon, & Frea, 2008), question asking (Koegel, Camarata, Valdez-Menchaca, & Koegel, 1998; Koegel, Koegel, Green-Hopkins, & Barnes, 2010) and spontaneous initiations (Kuhn, Bodkin, Devlin, & Doggett, 2008; Pierce & Schreibman, 1995). However, the majority of studies is conducted in children under the age of 6 (Verschuur, Didden, Lang, Sigafoos, & Huskens, 2014) and consequently, sufficient scientific evidence that supports the use of PRT in older children and adolescents is lacking.The current study aims to investigate the promising treatment option, PRT in a highly needed target population (i.e. school-aged children and adolescents with ASD). If PRT is effective in significantly reducing the core symptoms of ASD in this age group, PRT will be further implemented within Karakter and The Netherlands.

Study objective

Primary Objective:
The main objective is to investigate the effectiveness of PRT compared to CAU in school-aged children and adolescents with ASD.
The primary research question is:
1) Directly after treatment and at follow-up, what is the effectiveness of PRT compared to care-as-usual in improving:
-child social and communicative skills?

Secondary Objectives:
2) Which child, parent and structural intervention factors (predictors/moderators) have influence on effectiveness of treatment?
3) Compared to care-as-usual, what is the effectiveness of PRT in improving child clinical global functioning?
4) Compared to care-as-usual, what is the effectiveness of PRT in improving feelings of competence in parents?
5) Compared to care-as-usual, what is the effectiveness of PRT in improving parent-child interaction?

Study design

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

Intervention

Participants are randomized to one of the following conditions:
1) PRT condition: PRT on top of psycho-education
2) CAU condition: regular treatment of ASD (e.g. guidance of parents) on top of

psycho-education

Study burden and risks

Patients and their parents/caregivers in both treatment groups (PRT and CAU) are expected to highly benefit from their treatment. Both groups receive psycho-education on ASD prior to treatment and medical management is continued, when necessary. In both groups, trained clinicians focused on ASD provide high-quality care. Within both groups, gains are expected in both child-related factors (e.g. lower severity of symptoms) and parent-related factors (e.g. lower parenting stress).
The study is highly therapeutic and is expected to be highly beneficial for both subjects and their parents/caregivers. The risk of participating in the study are considered negligible and the burden associated with participation is estimated to be very low.

Contacts

Public
Selecteer

Reinier Postlaan 12
Nijmegen 6525CG
NL
Scientific
Selecteer

Reinier Postlaan 12
Nijmegen 6525CG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

• aged 9 - 15 years at inclusion in the study
• Total Intelligence Quotient (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 phase:	2
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):	13-06-2016
Enrollment:	42

Type:	Actual

Ethics review

Approved WMO Date:	01-03-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23411
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL54706.091.15
OMON	NL-OMON23411