A blended module for Pivotal Response Treatment

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25693

Source
NTR

Brief title
TBA

Health condition

Autism spectrum disorder

Sponsors and support

Primary sponsor: Karakter
Source(s) of monetary or material Support: Karakter

Intervention

Outcome measures

Primary outcome

Phase I: Experiences of parents, teachers and therapists with the current PRT intervention and digitalized care
Phase II: total score on the parent-rated Social Responsiveness Scale, 2nd version (SRS-2) at endpoint

Secondary outcome

Phase II:
-total score on the parent-rated SRS-2 at follow-up
-total score on the teacher-rated SRS-2 at endpoint and follow-up
-Improvement in global clinical functioning (endpoint and follow-up) and severity of the clinical global impression scale (CGI-I and CGI-S)
-child's adaptive behavior assessed by survey version of Vineland Adaptive Behavior Scales, 3rd version (VABS-3) at endpoint
-parent-rated quality of life of children at endpoint and follow-up, assessed by Pediatric Quality of Life Inventory (PedsQL)
-parenting stress at endpoint and follow-up, assessed by Opvoedingsbelastingvragenlijst (OBVL)
-percentage spontaneous self-initiations at endpoint

Study description

Background summary

Pivotal Response Treatment (PRT) is currently the most investigated evidence-based intervention for children with ASD. Unfortunately, whether a family can receive PRT depends highly on where they live in the Netherlands and therapists that are trained in PRT are scarce which contributes to long waiting lists. The objective of this study is improving accesiblity to PRT by developing an blended module and assessing its efficacy. The design of the first phase of the study (development) will is an exploratory interpretive study and the design of the second phase (efficacy testing) will be involve a one-group pre-test post-test design with follow-up. In phase I, the main study parameters will be the experiences of the current PRT intervention of therapists, parents and teachers, thereby looking at the different possibilities for increasing the accessibility when creating a blended PRT module. In phase II, the main outcome parameter will be the parent-reported Social Responsiveness Scale total score. The content of the protocol that will be studied in phase II is based on the outcomes in phase I.

Study objective

A blended module for PRT is efficient in improving social communication of children with ASD while increasing accesiblity to the intervention

Study design

Baseline, endpoint, 3 month follow-up

Intervention

Pivotal Response Treatment (PRT)

Contacts

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Eligibility criteria

Inclusion criteria

- (Caregivers or teachers of) children aged 2-12 years (all levels of expressive language) at the start of the intervention.
- (Caregivers or teachers of) children clinically diagnosed with ASD according to the Diagnostic and Statistical Manual of Mental Disorders (DSM), fifth edition (APA, 2013) or with a preliminary diagnosis of ASD for very young children.
- One of the caregivers must speak and understand the Dutch language
- Included therapists must be employed within Karakter at the time of the study and be licenced as PRT therapist on Level III.

Exclusion criteria

- Parents who participate(d) in an exclusively face to face intervention (Phase I)
- Systemic or family-related problems that interfere with implementation of PRT in natural situations (Phase I and II).
- Intervention on comorbid psychiatric symptoms is urgently required (although presence of comorbid psychiatric problems is not an exclusion criterion)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-04-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL9463
Other	CMO Arnhem Nijmegen : 2021-8328

Study results