Investigating the effectiveness of the PEERS program in adolescents with autism spectrum disorder using a randomized control trial design

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

Summary

ID

NL-OMON46998

Source
ToetsingOnline

Brief title
PEERS RCT

Condition

- Developmental disorders NEC

Synonym
Autism Spectrum Disorder; Pervasive Developmental Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W,Sipkema Foundation

Intervention

Keyword: adolescenten, autism spectrum disorder, PEERS, social skills training

Outcome measures

Primary outcome

The primary outcome is social competence as assessed using a blinded observation measure: the Contextual Assessment of Social Skills (CASS);

Secondary outcome

The secundary study parameters are the questionnaires filled out parents, teachers and the adolescent. These form the replication part of the study:

1. social skills questionnaire reported by the adolescents self, the parent and the teacher: Social Skills Improvement System-Rating Skills (SSIS-RS);

2. a questionnaire assessing autistic social impairment reported by parent and teacher: Social Responsive Scale (SRS).

In addition, we will assess hypothesized mediators of the effect on social competence:

1. social contacts of the participants assessed using the Quality of Socialization Questionnaire (QSQ);

2. social knowledge among adolescents assessed using the Test of Adolescents Social Skills Knowledge (TASSK);

3. social cognition of adolescents as assessed using the Test of Understanding of Social Conventions (TUSC);

4. fear of social rejection scored by participants using Brief Fear of Negative

Evaluation-II scale (BFNE-II);

5. parent*s satisfaction with parenting and self-efficacy in the parenting

role assessed using the Parenting Sense of Competence Scale (PSOC);

as well as potential moderators of the treatment effect:

1. severity of ASD, assessed using the Autism Diagnostic Observation Schedule

(ADOS) and 3Di;

2. IQ, from patient file or measured by the Wechsler Abbreviated Scale

of Intelligence (WASI);

3. emotional and behavioral problems, measured using the Child Behavior

Checklist (CBCL);

4. prior treatment with a social skills intervention or concurrent medicine

treatment.

Study description

Background summary

The core deficits of Autism Spectrum Disorder (ASD) are limited social-communication capacities. Consequences of these social communication deficits are a lack of social relationships, poor quality friendships and risk of anxiety or depression. Subsequently, this may lead to poor functioning in multiple domains/ contexts, such as a lack of independence, poor academic performance and underemployment. Given this impact on societal functioning, there is a strong need for treatments to improve social competence in this highly vulnerable population. The UCLA PEERS Program, parent-assisted social skills intervention, has been found to improve the parent-reported social competence in adolescents with Autism Spectrum Disorders in the USA and Korea relative to a waiting list comparison group. Although these results are promising, these previous studies mostly used parent-reported outcome measures and as parents were involved in the training, these may be biased. In addition, little is known about whether the specific elements of the training are

effective in producing the effect of improved social competence or whether this is the effect of general therapeutic factors, such as attention etc (i.e., doing something is better than doing nothing).

Study objective

We aim to evaluate the effectiveness of the Dutch translation and cultural adaptation of PEERS program in a randomized controlled trial (RCT) using an active treatment control group and a blinded observation of social competence as outcome measure. In addition, we aim to extend our knowledge of the possible mechanisms of effectiveness (mediators) of the PEERS program and participant characteristics (moderators) that influence the effectiveness.

Study design

The current study is a randomized controlled trial (RCT) where each participant is randomly assigned to either the PEERS social skills intervention (n = 75) or an active treatment control condition (n = 75). Both interventions will have similar duration and frequency (14 sessions held once a week). Assessments will be conducted prior to the randomization (baseline: T1), halfway during the intervention (week 7: T2), directly at the end of the 14-week intervention (week 14: T3), and a 14-week follow-up after the intervention (week 28: T4).

Intervention

The Program for Education and Enrichment of Relational Skills (PEERS) is a manualized social skills training program designed to learn cognitively able adolescents with ASD social skills to help them make and keep friends and deal with peer conflicts (Laugeson & Frankel, 2010; Laugeson et al., 2012; Laugeson et al., 2009). It is parent-assisted training that addresses elements of social functioning for adolescents such as two-way conversational skills, making friends, choosing appropriate humour, handling rejection, bullying or rumours (Laugeson & Frankel, 2010; see Table 3 for a detailed overview of topics that are covered each session)). The social skills are taught using psychoeducational and cognitive-behavioural treatment techniques (i.e. homework review, role play demonstrations, rehearsal exercises, homework assignments). The homework assignments require the adolescent to rehearse the newly learned skills with peers to enhance the generalization of the skills to other settings. The UCLA PEERS Program consists of 90-minutes sessions, delivered once a week for 14 weeks with parents and adolescents attending separate sessions.

The active treatment control condition (ATCC) is a manualized psycho-education program related to general issues in adolescents such as school, independence/responsibility, physical appearance and changes, dealing with emotions and boundaries. The ATCC will be based on an existing treatment on

psychosexual development for cognitively able adolescents with ASD (Tackling Teenage) and a program focused on frequent problems experienced by adolescents with ADHD in the home or school setting (PowerCoaching). The ATCC will be designed to have the same frequency and duration as the PEERS intervention. The emphasis of the ATCC will be less on skills and behavioral rehearsal but more on knowledge. The adolescents who will participate in ATCC will also undergo the same assessments as the PEERS group.

Study burden and risks

Adolescents with ASD who will participate in this study will receive several benefits. They will receive a training in a small group format that allow the discussion of the personal experiences of the adolescents and parents on topics that these families struggle with. Adolescents who will be randomized to the PEERS intervention are hypothesized to show improvements in social knowledge, social cognition and social competence. However, the adolescents who will receive the active treatment control condition are also expected to show some improvements (perhaps on other areas) due to some general therapeutic effects.

The risks associated with participation can be considered negligible. The burden will consist of the time that adolescents and parents need to invest in participating in the intervention and assessments. For adolescents this is about 4 hours in total for the assessments (1 hour per time point) and the parent and teacher about 2 hours (30 minutes per time point). The intervention consists of 14 sessions of 90 minutes for the adolescent and parent.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

(a) chronological age between 12 and 18 years old,
(b) in a secondary education,
(c) diagnosis of pervasive developmental disorder-not otherwise specific (PDD-NOS), Asperger's syndrome or autistic disorder by a reliable mental health professional established using the Autism Diagnostic Observation Schedule (ADOS-2) and 3Di;
(d) Dutch fluency for participants and parents and willing to participate in the treatment;
(e) IQ>70.

Exclusion criteria

(a) a history of major mental illness (e.g., schizophrenia, bipolar disorder, or other types of psychotic disorders, and
(b) any visual, hearing or physical impairments that prohibit participation in the intervention .

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2017
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	05-10-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-08-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-10-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL57472.078.16