

Tackling Teenage (Ik Puber).

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21408

Source

Nationaal Trial Register

Brief title

IP

Health condition

Autism/ ASD/ PDD-NOS/ Autism Spectrum Disorder

Autisme/ PDD-NOS/ pervasieve ontwikkelingsstoornis/ autisme spectrum problematiek

Sponsors and support

Primary sponsor: Stichting Yulius, Yulius Academie

Source(s) of monetary or material Support: Fund= ZonMw & Sponsor

Intervention

Outcome measures

Primary outcome

1. Knowledge of puberty, sexuality and related issues, measured by a knowledge test;
2. Psychosexual development, psychosexual problems and concerns of parents and youth, measured by the Teen Transition Inventory (TTI) for parents / caretakers and the adolescents;

3. Detection of sexually transgressive behavior, measured by 'het Vlaggensysteem';
4. Confidence / self-esteem, measured with the 'Nederlandse Persoonlijkheidsvragenlijst' (NPV-2);
5. Social skills in situations where intimacy and sexuality play a role as measured by the Social Responsiveness Scale (SRS) and TTI;

Number 6-8 are not outcome measures, but inclusion measures (WASI & SRS), instruments to measure the ASD severity (ADOS & 3Di) and other measures of interest (CBCL).

6. The degree of autism spectrum problems, measured by the Social Responsiveness Scale (SRS), the Autism Diagnostic Observation Schedule (ADOS) and Developmental, Dimensional and Diagnostic Interview (3Di);
7. Intelligence level, from file or measured by the Wechsler Abbreviated Scale of Intelligence (WASI);
8. Emotional and behavioral problems, measured by the Child Behavior Checklist (CBCL).

Secondary outcome

N/A

Study description

Background summary

This research tests the effects of a training to promote the psycho-sexual and pubertal development of twelve to eighteen year olds adolescence with problems on the autism spectrum. The objectives are firstly that the Tackling Teenage training increases knowledge, skills and confidence of young people with autism spectrum problems (ASP) , and that inappropriate sexual behavior decreases and secondly that the (sexual) vulnerability of these young people becomes smaller and their resistance increases.

The study design is an RCT with an experimental condition (training condition) and a control condition (waitinglist condition). The adolescents are randomly assigned to one of these conditions. Youngsters in the training condition receive the Tackling Teenage training over an average period of six months. Effects of training are investigated by comparing developments in the functioning of the youths in the two conditions, through questionnaires for the child and the parent/ caretaker of the child.

Study objective

The objectives are firstly that the Tackling Teenage training increases knowledge, skills and confidence of young people with autism spectrum problems (ASP) , and that inappropriate sexual behavior decreases and secondly that the (sexual) vulnerability of these young people becomes smaller and their resistance increases.

Study design

Until December 2011: Preparation of the research, PR activities;

January 2012 – April 2014: Inclusion, randomisation, Measurement 1, Tackling Teenage training, T2, collecting data;

October 2014 – April 2015: T3, data collection;

April 2014 – October 2015: Data-analyses; spreading results.

Intervention

The intervention tested in this research, the Tackling Teenage training, aims to educate, support and guide young people aged 12-18 years with ASP in their psychosexual development and puberty. The training consists of eighteen lessons with subsequent assignments in which the different topics belonging to the pubertal development and psychosexual treatment are being handled. These sessions will be received over an average period of six months.

The control group will be placed on a waitinglist.

Contacts

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Eligibility criteria

Inclusion criteria

1. Autism Spectrum Disorder;
2. an Total IQ of 85 and above.

Exclusion criteria

An IQ lower than 80.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 20-04-2011

Application type: First submission

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	NL2722
NTR-old	NTR2860
Other	ZonMw : 12427.0004
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A