

SOSTA net: Group-based social skills training in children and adolescents with high functioning autism spectrum disorder

Submission date 17/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/01/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 1: 01032010

Study information

Scientific Title

Randomised multicentre controlled trial of group-based social skills training in children and adolescents with high functioning autism spectrum disorder (SOSTA-Net)

Acronym

SOSTA net

Study objectives

To establish efficacy of group-based social skills training (SST) in children and adolescents with high functioning autism spectrum disorder (HFASD). It is hypothesised that add-on group-based SST using a manualised therapy-program will result in improved social responsiveness compared to treatment as usual (TAU), including no treatment (waiting list). In addition, a neurophysiological substudy in the Frankfurt subgroup (N = 60) will be performed pre- and post-treatment to explore changes in neuronal function induced by SST versus TAU. It is further expected that specific functional genetic variants will mediate treatment outcome. Functional genetic variants will be assessed in all participants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethikkommission des Fachbereichs Medizin der Johann Wolfgang Goethe-Universität Frankfurt am Main, 30/03/2010, ref: 57/10

Study design

Prospective randomised multicentre controlled parallel-group design

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Autism spectrum disorder (high functioning)

Interventions

1. Experimental intervention:

- 1.1. Weekly group-based manualised, social skills training of 12 sessions
- 1.2. 3 x parent training
- 1.3. Add-on therapy to treatment as usual (TAU)

2. Control intervention:

- 2.1. Treatment as usual (TAU), including waiting list, excluding group-based therapy
- 2.2. 3 x parent training

Follow-up per patient: three months

Duration of intervention per patient:

Experimental intervention: 12 x 90 minutes plus 3 x parent training

Control intervention: 3 x parent training; TAU without group therapy or waiting list

Intervention Type

Behavioural

Primary outcome measure

Change in total raw score of the Social Responsiveness Scale (SRS) as assessed by the primary caretaker (PC), measured:

1. Between baseline and end of intervention
2. Between baseline and 3 months after end of intervention

Secondary outcome measures

Measured 0 and 3 months after end of intervention:

1. Response to intervention: Individual symptom reduction of at least 16 raw points in SRS total score (PC and teacher [T] assessment)
2. Change in SRS total raw score (T)
3. Change in SRS subscale raw scores (PC, T)
4. Change in anxious-depressive symptoms (CBCL:PC)
5. Change in total psychopathology, pro-social behaviour, and peer related problems (SDQ: PC, T)
6. Change in depressive symptoms (DIKJ, self assessment)
7. Motivation and satisfaction with therapy (self assessment)
8. Change in neuronal function during cognitive and affective empathy tasks
9. Assessment of genetic variants and medication as possible mediating variables of therapeutic effect
10. Assessment of safety: serious adverse and adverse events will be documented

Overall study start date

07/05/2010

Completion date

07/03/2013

Eligibility

Key inclusion criteria

1. High-functioning autism (F84.0)
2. Asperger syndrome (F84.5)
3. Atypical autism (F84.1)
4. Aged 8 - 20 years, either sex

- 5. Informed consent
- 6. No or stable psychopharmacotherapy

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

N = 220

Key exclusion criteria

1. Intelligence quotient (IQ) less than 70
2. Schizophrenia
3. Social phobia
4. Obsessive-compulsive disorder
5. Major depressive episode with suicidal ideation
6. Aggressive behaviour interfering with group therapy
7. Any personality disorder
8. Neurological disorder (exception: well treated epilepsy)
9. Other medical disorder interfering with therapy
10. Group-based SST during last 6 months prior to study

Date of first enrolment

07/05/2010

Date of final enrolment

07/03/2013

Locations**Countries of recruitment**

Germany

Study participating centre

Klinik für Psychiatrie, Psychosomatik und Psychotherapie des Kindes- und Jugendalters der
Goethe-Universität
Frankfurt am Main
Germany
60528

Sponsor information

Organisation

German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

Sponsor details

Lebenswissenschaften 1
Geschäftsstelle
Kennedyallee 40
Bonn
Germany
53170

Sponsor type

Research council

Website

<http://www.dfg.de/>

ROR

<https://ror.org/018meiw64>

Funder(s)**Funder type**

Research council

Funder Name

Deutsche Forschungsgemeinschaft

Alternative Name(s)

German Research Association, German Research Foundation, DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/01/2013		Yes	No
Results article	results	01/05/2016		Yes	No