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

Submission date	Recruitment status
17/06/2010	No longer recruiting
Registration date	**Overall study status**
12/08/2010	Completed
Last Edited	**Condition category**
04/01/2016	Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Prospective randomised multicentre controlled parallel-group design

Study type(s)
Treatment

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

Intervention Type
Behavioural

Primary outcome(s)

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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
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Sponsor information

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

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research council

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)

German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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