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The Secret Agent Society Operation Regulation intervention

Submission date	Recruitment status	[_] Prospectively registered
12/09/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/10/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/05/2018	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Youth with high functioning autism spectrum disorders (HFASD) often struggle with anxiety, depression, or anger as a result of difficulty in regulating their emotions. There are a number of cognitive behavioral interventions that are designed to address factors related to anxiety in youth with HFASD, but few are designed to build emotion regulation skills more broadly. The Secret Agent Society: Operation Regulation adapts the pre-existing and widely available materials from the Secret Agent Society to help children with ASD build these skills. The Secret Agent Society is a cognitive behavioral social skills group intervention for children with ASD that has been shown to be effective in fostering social skills. A variety of activities and tools, like an emotion focused computer game, cue cards, in session games, and parent and teacher handouts, will be used to engage youth with HFASD in developing skills to help them cope with their emotions and to better handle the day-to-day stressors in their lives.

Who can participate?
Children (both male and female) between 8 and 12 years of age with a formal diagnosis of high functioning autism spectrum disorder or Asperger Syndrome. Children need to have at least average language skills, IQ scores of 85 or above, and be interested in working on emotions with a therapist.

What does the study involve?
All participants receive the same treatment (i.e. go through the intervention), but half of the participants are randomly allocated to receive the treatment immediately and the other half are put on a waiting list for 10 weeks before receiving the 10-week intervention. The intervention is provided individually to children.

What are the benefits and risks of participating?
Given that this therapy has been shown to improve social skills and appropriate control of emotional levels in children, participation in the program may result in a reduction of children's levels of negative emotions and improvement in social skills. Participants may also benefit from the attention and support provided by the graduate student therapist through the weekly one-on-one therapy sessions. The risk to parents may include fatigue related to the completion of questionnaires, as well as feelings of discomfort generated by the content of the questions

asked, in particular the questions relating to the child's experience of distressing feelings (e.g., anger, frustration, sadness). Many children with ASD have already completed the Secret Agent Society program, and it is well received by parents and youth. The spy watches may result in the temporary transfer of gray marks from the watch sensors to the child's skin surface, but the marks may be easily washed off with some soap and water. These watches have been found to be minimally invasive and rely on small electrical signals to measure the childs electrodermal activity - these electrical signals are not harmful and transmit less than 0.000001 of the power of a static charge one receives when touching a door knob in a dry room.

Where is the study run from?
York University (Canada)

When is the study starting and how long is it expected to run for?
October 2013 to September 2017

Who is funding the study?
The Spectrum of Hope Autism Foundation (Canada) will be funding this study. The principal investigator is support by a Chair in Autism Spectrum Disorders Treatment and Care Research.

Who is the main contact?
Paula Tablon
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
The Secret Agent Society Operation Regulation intervention: a randomized controlled trial

Acronym
SAS-OR

Study objectives
The hypothesis is that those in the treatment group will show significant improvements in emotional regulation skills compared to those in the waitlist control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Board (REB), 20/08/2013, ref: #e2013-229

Primary study design
Interventional

Study design
Two-year randomized waitlist controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autism Spectrum Disorders

Interventions
Half of the children will be assigned to the treatment condition immediately (provided with the emotion regulation training program immediately after the initial assessments), and the other half of the will be assigned to the waitlist control condition (asked to wait 10 weeks before receiving the intervention). Random number generated lists have been developed for males and females separately, given the higher ratio of males in the ASD population. Random assignment will occur after baseline assessment is complete.

The program involves 10 weekly 1-hour visits to the university where the parent and child will meet with a trained therapist for one-on-one therapy. During these sessions, the child will get to do an assortment of activities and play games computer games, problem solving tasks, role playing, and working with the therapist and parent. Post intervention assessments will be carried out following the 10th session of treatment. Ten weeks post intervention, children and parents will be invited back to the university for a follow-up assessment.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 01/02/2016:
Parent and child reports of emotion regulation skills, as measured by:
1. The parent reported:
1.1. Emotion Regulation Checklist (ERC; Shields & Cicchetti, 1997)
1.2. Emotion Regulation and Social Skills Questionnaire - Parent (ERSSQ-P; Beaumont & Sofronoff, 2008)
2. The child reported:
2.1. Emotion Regulation Questionnaire Child (ERQ-C; Gullone, Eleonora, & Taffe, 2011)
2.2. The Childrens Emotion Management Scales (CEM; Zeman, Shipman, & Penza-Clyve, 2001; Zeman, Cassano, Suveg, & Shipman, 2010),

All primary parent and child measures will be collected at the following time points for the treatment Immediate group: baseline (Time 1), post intervention (Time 2) and follow-up (10 weeks post intervention). For the waitlist control group, data will be collected at baseline (Time 1), 10 weeks later (Time 2), post intervention (Time 3) and 10-weeks post intervention (Time 4).

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2. The child reported:
2.1. Emotion Regulation Questionnaire Child (ERQ-C; Gullone, Eleonora, & Taffe, 2011)
2.2. The Childrens Emotion Management Scales (CEM; Zeman, Shipman, & Penza-Clyve, 2001; Zeman, Cassano, Suveg, & Shipman, 2010),
3. A parent-child Child Emotional Reactivity and Emotional Regulation Strategies Task (Melnick & Hinshaw, 2000).

All primary parent and child measures will be collected at the following time points: Baseline (Time 1), 10-weeks post Baseline (Time 2), 20-weeks post Baseline (Time 3)

Key secondary outcome(s)

Current secondary outcome measures as of 01/02/2016:
1. Parent reports of child psychopathology (BASC-2; Reynolds & Kamphaus, 2006) and social skills
2. Parenting competence and psychopathology
3. Direct testing of childrens cognitive flexibility (Emotional Stroop Task: Smith & Waterman, 2003; and CogState-Set Shifting Task)
4. Physiological arousal (electrodermal response)
5. Social-emotional awareness (CogState-Social Emotional Task)
6. Problem solving in social situations (James and the Math Test: Atwood, 2004; and Dylan is Being Teased: Atwood, 2004)

All secondary parent and child measures will be collected at the following time points for the treatment Immediate group: baseline (Time 1), post intervention (Time 2) and follow-up (10 weeks post intervention). For the Waitlist control group, data will be collected at baseline (Time 1), 10 weeks later (Time 2), post intervention (Time 3) and 10-weeks post intervention (Time 4).

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Completion date

17/02/2017

Eligibility

Key inclusion criteria
1. Age: 8-12 years
2. Diagnosis of High Functioning Autism Spectrum Disorder or Aspergers syndrome
3. Average language skills

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
All

Key exclusion criteria
Participants cannot be involved in another emotion regulation program

Date of first enrolment
01/10/2013

Date of final enrolment
14/04/2016

Locations

Countries of recruitment
Canada

Study participating centre
York University
4700 Keele Street
Toronto
Canada
M3J 1P3

Sponsor information

Organisation
York University (Canada)

ROR
https://ror.org/05fq50484

Funder(s)

Funder type
Government

Funder Name
Chair in Autism Spectrum Disorders Treatment and Care Research, funded by the Canadian Institutes of Health Research in partnership with Health Canada, Autism Speaks Canada, NeuroDevNet, the Sinneave Family Foundation, and the Canadian Autism Spectrum Disorders Alliance (#284208)

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2018		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes