

# The Secret Agent Society Operation Regulation intervention

<b>Submission date</b> 12/09/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/10/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/05/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## 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 child's 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 supported 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

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
N/A

## 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

**Study design**

Two-year randomized waitlist controlled trial

**Primary study design**

Interventional

**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).

Previous primary outcome measures:

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),
  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  
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## 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?
<a href="#">Results article</a>	results	01/11/2018		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes