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The Secret Agent Society: Operation Regulation intervention - transdiagnostic trial

Submission date	Recruitment status	[ ] Prospectively registered
26/05/2017	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/05/2017	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/10/2024	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Neurodevelopmental disorders (NDD) are impairments of the growth and development of the brain or central nervous system. Youth with NDD often struggle with anxiety, depression or anger as a result of difficulties controlling their emotions. There are a number of cognitive behavioural interventions that are designed to address factors related to anxiety in youth with NDD, 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 NDD build these skills. The Secret Agent Society is a cognitive behavioural 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, including emotion-focused computer games, code cards, in-session games, and parent and teacher handouts, are used to engage youth with NDD in developing skills to help cope with their emotions and better handle day-to-day stress.

Who can participate?

Children between 8 and 13 years of age with a neurodevelopmental disorder (autism spectrum disorder, fetal alcohol spectrum disorder, cerebral palsy, learning disability, or attention deficit hyperactivity disorder). Children need to have at least average language skills, an IQ of 80 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 12 weeks before receiving the 10-week intervention. The intervention is provided individually to the children.

What are the benefits and risks of participating?

Given that this therapy has been shown to improve social skills and emotion regulation 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 therapist through weekly one-on-one therapy sessions. Risks to participating 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 their child's experience of distressing feelings (e.g., anger, frustration, sadness). Many children with NDD have already completed this 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 study starting and how long is it expected to run for?
September 2016 to March 2023

Who is funding the study?
Canadian Institutes of Health Research (Canada)

Who is the main contact?
Paula Tablon
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Contact information

Type(s)
Scientific

Contact name
Ms Paula Tablon

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Additional identifiers

Study information

Scientific Title
Cognitive behaviour therapy for mental health problems in children with neurodevelopmental disorders: a transdiagnostic approach

Acronym
SAS:OR NDD

Study objectives
Treatment group participants 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)
Approved 01/09/2016, Research Ethics Board (York University, Toronto, M3J1P3, Canada; +1 (0) 4167362100; jonweiss@yorku.ca), ref: e2016-287

Study design
Five-year randomized waitlist controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neurodevelopmental disorders (autism spectrum disorders, fetal alcohol spectrum disorder, cerebral palsy, learning disability, or attention deficit hyperactivity disorder)

Interventions
Random assignment will occur after baseline assessment is complete. Once participants are deemed eligible for the study (following in-person screening) they are randomized to treatment immediately or waitlist control condition using a randomly generated list obtained from the following site: https://www.randomizer.org/

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 will be assigned to the waitlist control condition (asked to wait 12 weeks before receiving the intervention).

The program involves ten 1-hour weekly sessions, where the youth and a parent will meet with a therapist for one-on-one therapy. During these sessions, the youth will participate in an assortment of activities including computer games, problem solving tasks, role playing, and working with their parent and therapist. They also will get some brief homework tasks to help generalize what they are learning. The focus of all of these activities is to help build emotion regulation skills.

Intervention Type
Behavioural

Primary outcome(s)
1. Child mental health problems:
1.1. Emotional disorders, measured using the Anxiety Disorders Interview Schedule: Child and Parent Interview-4th Edition (ADIS-C/P-IV)
1.3. Child behaviour and emotions, measured using the Behavior Assessment System for

Children, Third Edition (BASC-3)
1.2. Child illness severity, global improvement/change and therapeutic response, measured using the Clinical Global Impression–Severity and –Improvement (CGI-Severity, CGI-Improvement)

All measures will be collected at the following time points for the treatment immediate group: baseline (Time 1), 12 weeks post baseline (Time 2) and follow-up (12-weeks post Time 2). For the waitlist control group, data will be collected at baseline (Time 1), 12 weeks later (Time 2), post intervention (Time 3) and 12-weeks post intervention (Time 4). With the exception of WRAT-4, which will only be completed at Time 1.

Key secondary outcome(s))

Current secondary outcome measures as of 23/07/2019:
Child Report Measures:
1. Child emotion regulation, measured using the Children's Emotion Management Scales (CEMS)
2. Child acceptance and mindfulness, measured using the Child & Adolescent Mindfulness Measure (CAMM)
3. Child social problem-solving, measured using James and the Math Test and Dylan is Being Teased
4. Child emotion regulation, measured using the Computerized Mirror Tracing Performance Task (2013)
5. Direct testing of children's cognitive flexibility using CogState (Set-Shifting Task) and the NIH Toolkit (Dimensional Change Card Sorting (DCCS) Task and the Flanker Test)
6. Child physiological arousal, measured using electrodermal response
7. Child therapeutic alliance, measured using Child Session Rating Scale (CSRS)
8. Child functioning, measured using Child Outcome Rating Scale (CORS)

Parent Report Measures:
1. Parents' expressed emotion, measured using the Five Minute Speech Sample (FMSS)
2. Child emotion regulation, measured using the Emotion Regulation Checklist (ERC)
3. Child emotion regulation and social skills, measured using the Emotion Regulation and Social Skills Questionnaire - Parent (ERSSQ-P)
4. Quality of the parent-child relationship, measured using the Positive Affect Index (PAI)
5. Child adjustment and psychopathology, measured using the Strength and Difficulties Questionnaire (SDQ)
6. Child health-related quality of life, measured using KIDSCREEN
7. Parent distress, measured using the Depression, Anxiety and Stress Scale (DASS-21)
8. Parent physiological arousal, measured using electrodermal response
9. Child emotion dysregulation, measured using the Emotion Dysregulation Inventory (EDI)
10. Child service assessment, measured using the Service Assessment of Children and Adolescents (SACA)
11. Parent functioning, measured using the Outcome Rating Scale (ORS)
12. Parent therapeutic alliance, measured using the Session Rating Scale (SRS)

Parent Child Dyad:
1. Parent and child emotion regulation and socialization, measured using the Emotion Discussion Task (EDT)

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Completion date
31/03/2023

Reason abandoned (if study stopped)
COVID-19 pandemic

Eligibility

Key inclusion criteria
1. Age 8-13 years
2. Diagnosis of a neurodevelopmental disorder (autism spectrum disorder, fetal alcohol spectrum disorder, cerebral palsy, learning disability, or attention deficit hyperactivity disorder)
3. FSIQ > 80 (WASI-II; Weschler, 2011)
4. At least one co-occurring anxiety or mood disorder

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
13 years

Sex
All

Key exclusion criteria
1. Participants cannot be involved in another emotion regulation program within a 12-month period of participating in SAS-OR
2. Presence of a psychotic disorder, or aggressive/self-injurious behaviours that pose a safety risk

Date of first enrolment
17/04/2017

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
Canada

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

Sponsor information

Organisation
York University

ROR
https://ror.org/05fq50484

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes