

Secret Agent Society (a virtual small group cognitive behaviour program for autistic children during the pandemic) proof of concept study

Submission date 07/09/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/09/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/05/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Emotion regulation, social challenges, and mental health problems are concerns that impact the wellbeing of children with autism. Outside of the COVID-19 pandemic, 40-70% are estimated to have significant emotional and behavioural problems, such as anxiety, depression, or anger (Simonoff et al., 2008). Supports can include using adapted behavioural interventions including The Secret Agent Society: Small Group Program (SAS:SG; Beaumont, 2016) in controlled settings. However, there is a limited understanding of how effective evidence-based programs focused on emotion regulation and social skills are under real world, ecologically valid conditions where autistic children and youth receive most of their services, especially within the context of a pandemic.

Who can participate in the study?

Autistic children between the ages of 8-12 years and their caregivers. Children should be verbally able and do not have a history of self-injurious behaviour. Children should have noted challenges in emotion regulation and social skills.

What does the study involve?

Children and their caregivers will be invited to participate in a 10-week socioemotional-focused program called the Secret Agent Society Small Group (SAS:SG) program. All families will be enrolled in the program and there are no control groups. The program will be led by SAS:SG therapist and delivery virtually. Children and caregivers will participate in separate groups (60-90 mins each) on a weekly basis. Parents will be asked to complete online questionnaires before and after the 10-week program program, and 3-months after finishing the program. Parents will also be asked to participate in focus groups to talk about their family's experience participating in the program.

What are the possible 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 your child's levels of negative emotions and improve in their social skills. Participants may also benefit from the support provided by the clinical team through the sessions. Risks to the participate may include fatigue related to the completion of questionnaires, as well as feelings of discomfort generated by the content of the questions asked, for instance, questions relating to their child's experience of distressing feelings (e.g., anger, worry, sadness).

Where is the study run from?

York University, Toronto, Ontario, Canada.

When is the study starting and how long is it expected to run for?

December 2019 to December 2021

Who is funding the study?

Kids Brain Health Network (Canada).

Who is the main contact?

Dr. Vivian Lee, vivian.lee4@carleton.ca

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Study information

Scientific Title

Utility of a virtual small group cognitive behaviour program for autistic children during the pandemic: evidence from a community-based implementation study

Acronym

CSAS

Study objectives

The study was conducted to explore the feasibility and clinical utility of implementing the Secret Agent Society: Small Group Program for autistic children as delivered by Canadian community-based autism services and programs during the pandemic.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 16/03/2020, York University Office of Research Ethics (4700 Keele Street. 309 York Lanes, Toronto, M3J1P3, Canada; +1 416-736-5914; ore@yorku.ca), ref: e2020-080

Study design

Multicentre interventional feasibility trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community, Internet/virtual

Study type(s)

Other, Treatment, Efficacy

Participant information sheet

Not applicable

Health condition(s) or problem(s) studied

Improving emotion regulation and social skills in children with autism

Interventions

Participants are recruited by community-based autism service providers. There is no randomization and all participants receive the intervention. All participants (children and their caregivers) are enrolled in a 10-week virtually delivered socioemotional behavioural intervention

called the Secret Agent Society Small Group (SAS:SG) program and receive a 3-month follow-up session. Child and parent groups meet separately once a week for 60-90 minutes on a virtual platform. All groups are led by trained SAS:SG therapists.

Intervention Type

Behavioural

Primary outcome measure

Child emotion regulation and social skills are measured using parent-report online questionnaires at baseline, post-intervention, and 3-months post-intervention.

Secondary outcome measures

1. Program satisfaction measured using parent-report online questionnaires post-intervention, and 3-months post-intervention
2. Intervention acceptability measured using parent-report online questionnaires post-intervention, and 3-months post-intervention.

Overall study start date

01/12/2019

Completion date

31/12/2021

Eligibility**Key inclusion criteria**

1. Official autism diagnosis by a healthcare professional
2. Between 8-12 years old
3. Verbally able to participate
4. Family had access to technology (e.g., high speed internet, technology) at home
5. Parent was available to participate in weekly parent groups

Participant type(s)

Patient, Carer

Age group

Child

Lower age limit

8 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

96

Total final enrolment

88

Key exclusion criteria

1. No intellectual disability
2. No history of self-harm behaviours

Date of first enrolment

01/09/2020

Date of final enrolment

09/01/2021

Locations**Countries of recruitment**

Canada

Study participating centre**Kerry's Place Autism Services**

34 Berczy St., Suite 130

Aurora

Canada

L4G 1W9

Study participating centre**Geneva Centre for Autism**

164 Merton St

Toronto

Canada

M4S 3A8

Study participating centre**Kinark Autism Services**

1521 Simcoe Street North

Oshawa

Canada

L1G 4X8

Study participating centre**Woodview Mental Health and Autism Services**

69 Flatt Rd

Burlington

Canada
L7P 0T3

Study participating centre
Ron Joyce Children's Health Centre
325 Wellington St N
Hamilton
Canada
L8L 0A4

Study participating centre
Lake Ridge Community Support Services
900 Hopkins St Unit 8
Whitby
Canada
L1N 6A9

Study participating centre
Surrey Place
2 Surrey Pl
Toronto
Canada
M5S 2C2

Sponsor information

Organisation
Kids Brain Health Network

Sponsor details
Simon Fraser University
Discovery 2 - Room 204
8900 Nelson Way
Burnaby
Canada
V5A 4W9
+1 778-782-7283
admin@kidsbrainhealth.ca

Sponsor type
Research organisation

Website

<https://kidsbrainhealth.ca/>

Funder(s)

Funder type

Research organisation

Funder Name

Kids Brain Health Network

Alternative Name(s)

Réseau pour la santé du cerveau des enfants, KBHN

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Canada

Results and Publications

Publication and dissemination plan

Planned publication in high-impact journal

Intention to publish date

01/11/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the stipulations outlined in or data sharing agreements with each of the community-based providers, and the fact that participants did not consent to having their de-identified data shared outside of the research team. Due to the potentially identifiable data the dataset will not be made available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/05/2024	31/05/2024	Yes	No