

Testing the impact of a social skill training versus waiting list control group for the reduction of disruptive behaviors and stress among preschool children in child care

Submission date 11/01/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/03/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/11/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Children from low-income backgrounds often show lower levels of school preparedness than their peers, causing them to be more likely to have school difficulties and to show aggressive behaviours. As school preparedness is a predictor of academic success, differences in families social and economic backgrounds are important. Child care centres (CCC) have been shown to promote children's school preparedness skills, by improving mental and social development, mostly helping children from low-income families. However, the quality of CCC can vary. Centres in disadvantaged neighbourhoods are usually lower in quality than those in more well-off areas. Studies have suggested that attending a CCC might be a stressful experience for young children. Children can experience stress at a CCC due to the quality of social interactions, which include frequent conflicts. CCC may be particularly stressful for children due to their stage of social development. The Minipally programme is a psychological (mental) and social skills training programme that was developed to help improve social behaviours in children attending CCCs. The primary aim of this study is to assess the effectiveness the programme in improving preschoolers' abilities to adjust socially to school settings and their school preparedness through the improvement of social and self-regulatory (ability to control and manage emotions) skills and to assess if the improvement in social skills can help regulate stress.

Who can participate?

Public child care centres with a minimum of 25% children from low-income families.

What does the study involve?

Participating child care centres are allocated to one of two groups. Those in the first group receive the "Minipally" programme which is based on 16 activities given by child care centre educators over eight months. The programme covers four topics, including introduction to social contact, problem solving process, emotional self-regulation, and how to express and recognize our own emotions and is delivered by trained child care centre educators. Those in the second group receive standard child care centre programming until the second year of the study in

which they receive the programme. Participating child care centres are tested at the beginning and the end of the programme to test the stress levels of the children (through a saliva sample), measure the frequency of conflicts and assess the behaviour of children.

What are the possible benefits and risks of participating?

Participating child care centres may benefit from the additional training potentially improving their educational practices. Children may benefit from an improvement in their social skills and stress regulation. There are no notable risks with participating, however children may be intimidated by the saliva test and parents may feel distressed due to the awareness of new emotions about their child.

Where is the study run from?

This study is run from the University of Montreal (Canada) and takes place in 19 public child care centres in Montreal (Canada)

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

January 2010 to June 2015

Who is funding the study?

1. Canadian Institutes of Health Research Grant
2. Fond Québécois de recherche Société et Culture grant
3. GazMétro's philanthropic donation at the Centre Hospitalier Universitaire Sainte-Justine

Who is the main contact?

Professor Sylvana Côté

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Testing the impact of a social skill training versus waiting list control group for the reduction of disruptive behaviors and stress among preschool children in child care: study protocol for a cluster randomised trial

Study objectives

The aim is to test the effectiveness of a social skill training intervention (hereafter referred to as 'Minipally' program) aiming at improving social behaviors among children aged 3 years old in child care centers of low-socio-economic status neighborhood.

Hypotheses:

1. Children in the Minipally intervention condition will have better social behaviors (higher levels of prosocial behaviors' lower levels of disruptive behaviors) as compared to children in the waiting list control group.
2. Children in the Minipally intervention will have better levels of stress regulation (i.e. better diurnal salivary cortisol patterns) than children in the waiting list group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

CHU Sainte-Justine Ethical Research Committee, 01/05/2013, ref: 2014-565, 3738

Study design

Multi-centre cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Social maladjustment and stress

Interventions

Centres are randomly assigned in a 1:1 ratio to either receiving the Minipally intervention in year one or to the waiting list control using a computer-generated randomisation sequence. In accordance with PROBE methodology, the team of investigators including Research Assistants (RAs) are blind to assignment during the study. The intervention is given over eight months. Those on the waiting list receive the standard child care centre programming and then receive the intervention in the second year of the study.

Educators working at the intervention child care centres are trained to implement the Minipally programme. The Minipally programme is a social skills training programme supporting the development of adaptive social behaviours among children aged two to five years old who are attending group-based child care services. It includes generic components of social skill training programs including: introduction to social contact (make with and accept contact from others, make requests), problem solving (identifying the problem, generating solutions), self-regulation (breathing to calm down, accepting frustration, learning to share, tolerating frustration), and emotional regulation (identifying and expressing emotions, listening to the other). The program is delivered through 16 playful sessions animated by child care educators over a period of eight months. The educators use a puppet named "Minipally" during sessions, who becomes a loyal and enthusiastic friend of the children, visits them every two weeks and takes advantage of the visits to model prosocial behaviours and promote social inclusion by discussing/playing with his friends (other puppets) and the children.

Participating centres are followed at baseline and after eight months to measure the children's behaviour, frequency of conflicts and stress level (measured through cortisol samples taken from the children who have agreed to participate).

Intervention Type

Behavioural

Primary outcome measure

1. Children's Behaviours are assessed using the Child Behavioural Questionnaire (CBQ) rated by educators at baseline and eight months
2. Frequency of conflicts and pro-social behaviors are assessed using an 8-item observational grid by research assistants during a 15-minute free play activity period at baseline and eight months
3. Levels of stress are measured using salivary cortisol samples collected by research assistants three times (30 minutes after the child's arrival at the CCC (between 7:30 and 9 am), before lunch (between 10:45 and 11:00) and one hour after waking from the afternoon nap (between 15:00 and 16:00)) during the child care visit at baseline and eight months

Secondary outcome measures

1. Educators' interactions with children are measured at baseline and eight months by:
 - 1.1. The Caregiver Interaction Scale used by research assistants
 - 1.2. A subset of the PACOTIS questionnaire used by educators
2. Treatment adherence is assessed by reviewing educator's logbooks at eight months

Overall study start date

08/01/2010

Completion date

30/06/2015

Eligibility

Key inclusion criteria

Public child care centres:

1. Containing a minimum of 25% of children from low-income families
2. From disadvantaged neighborhoods of the Greater Montreal area

Children:

1. Aged between 40 months and 65 months
2. Informed written consent from their parents

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

19 clusters of 8 participants

Total final enrolment

361

Key exclusion criteria

No exclusion criteria.

Date of first enrolment

01/05/2011

Date of final enrolment

01/05/2013

Locations

Countries of recruitment

Canada

Study participating centre

University of Montreal

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3050 Edouard Montpetit

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Sponsor information

Organisation

University of Montreal

Sponsor details

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Sponsor type

University/education

Website

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ROR

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Funder(s)

Funder type

Charity

Funder Name

GazMétro

Funder Name

Fond Québécois de Recherche Société et Culture grant

Funder Name

Canadian Institutes of Health Research

Alternative Name(s)

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR),
CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journals (the protocol and the results).

Intention to publish date

31/01/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due accordance with the ethical approval received from the Ethical Research Committee: CHU Saint-Justine for confidentiality reasons.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		06/03/2017	14/03/2017	No	Yes
Participant information sheet		06/03/2017	14/03/2017	No	Yes
Protocol article	protocol	07/08/2017	27/11/2020	Yes	No
Results article	results	23/04/2020	27/11/2020	Yes	No