

The I-CARE trial: support and education for children's adaptive social development

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
06/09/2019	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
26/09/2019	Ongoing	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
30/06/2025	Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Disruptive behaviour problems (DBPs) are behaviours that violate social norms and cause distress to others. Children with DBPs may be diagnosed with conduct disorder, oppositional defiant disorder or attention deficit hyperactivity disorder (DSM-5). DBPs begin in early childhood and generate high costs to society, with adult consequences including mental health problems, substance abuse, depression and suicide. DBPs are also associated with poor academic achievement, early parenthood, poor integration into the workforce and lifelong physical health problems, in both men and women. Children from low-income backgrounds are particularly vulnerable to continued DBPs, as they often grow up in conditions that interfere with their capacity for self-control, including family stress and conflict, harsh or abusive parenting, and poor-quality early childhood education. Early intervention is key to avoiding DBPs and their sequelae.

The aim of the I-CARE trial is to compare the efficacy of two intervention strategies to prevent DBPs in children of low-income families. The interventions evaluated are the Minipally+ educator's training program and the Incredible Years parenting training program. The principal research question is: What is the efficacy of an educator's training program delivered in daycare vs. parenting training program vs. the combined efficacy of both programs vs. a control group (i.e. usual daycare) in reducing DBPs in preschool children (ages 3–4 years) from low-income neighborhoods?

Who can participate?

Toddlers and their parents attending daycare centers located in low-income neighborhoods in selected urban areas of the province of Quebec that meet the inclusion criteria

What does the study involve?

Daycare centers will be randomly assigned to one of four conditions: 1) the Minipally+ social skills educator's training program; 2) the Incredible Years parenting group training; 3) the Minipally+ social skills educator's training program + Incredible Years parenting group training; and 4) daycare services as usual (waiting-list control group). Children's social behaviours will be evaluated throughout the trial.

What are the possible benefits and risks of participating?

Participating daycare centres may benefit from the additional training by potentially improving their educational practices. Parents in the intervention groups where a parenting program is offered may benefit from additional training that may improve their parenting practices.

Children may benefit from an improvement in their social skills and stress regulation. There are no notable risks related to study participation. However, children may be intimidated by the hair sampling and parents may feel uncomfortable when answering questions about some of their emotions or behaviours or that of their child (e.g. frequency of child oppositional behaviors; feelings of sadness).

Where is the study run from?

This study is run from the University of Montreal (Canada) and Centre Hospitalier Universitaire Sainte-Justine. The study will take place in 60 public daycare centres in Quebec.

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

October 2019 to June 2026

Who is funding the study?

The study is funded by the Canadian Institutes of Health Research (CIHR) and the Canadian Social Sciences and Humanities Research Council (SSHRC).

Who is the main contact?

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2. Marie-Kim Chabot (Research Coordinator), marie-kim.chabot.hsj@ssss.gouv.qc.ca

Contact information

Type(s)

Scientific

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Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

I-CARE: Efficacy of interventions in early daycare to prevent disruptive behaviours in children from low-income neighborhoods [Apprendre ensemble: Efficacité des interventions en garderie pour la prévention des comportements perturbateurs des enfants de quartiers défavorisés]

Acronym

I-CARE

Study objectives

Educator training and the parenting training will each have an impact on the reduction of disruptive behaviors

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 14/06/2019, CHU Sainte-Justine Ethical Research Committee (3175 Chemin de la Côte-Sainte-Catherine, Montréal, H3T 1C5, Canada; +1(514)345-4931 (#4342); genevieve.cardinal@recherche-ste-justine.qc.ca), ref: 2019-2218

Study design

Two-year cluster-randomized factorial controlled trial open-blinded with a 1:1 assignment ratio

Primary study design

Interventional

Study type(s)

Prevention, Efficacy

Health condition(s) or problem(s) studied

Disruptive behaviour problems

Interventions

Current intervention as of 14/03/2024:

Participants were randomly assigned to the following conditions:

1. Daycare-based social skills training for educators to use in class (16 sessions over 6 months)
2. Online parental training (14 sessions of 2 hours each)
3. Social skills training for educators plus parental training
4. Control group (daycare service as usual).

The randomization will be conducted by the Applied Clinical Research Unit of the Ste-Justine's Hospital Research center. Daycare centers will be randomized with a 1:1 ratio for every group. A pre-established numbered list of 999 randomization combinations will be publicly displayed in advance on the study website. Three randomization numbers will be drawn out of a bag to determine the assignment condition of any given daycare center. The research coordinator will then contact the daycare center directors to announce allocation.

Thus, the following two types of interventions will be implemented:

1. The daycare intervention:

The Minipally+ is a social skills training program to support the development of social and self-regulation skills among children aged 2 to 5 years. The program comprises a specific curriculum implemented over one school year and provides basic theoretical and practical knowledge in early childhood education practices. The main objective of the Minipally+ program is to promote positive social interactions between children, families and daycare professionals.

The Minipally+ curriculum is presented to every daycare educator during a 2-day training session led by a trained psycho-educator. The program is later delivered to children by each educator to his/her own group of children over 16 playful sessions. The sessions are animated by educators over a period of one school year using a puppet. The puppet presents itself as a loyal and enthusiastic friend who visits children in daycare services to model prosocial behaviors and social inclusion by discussing/playing with his friends (other puppets) and with the children. The intervention includes generic components of social skills training programs: introduction to social contact (make and accept contact from others, make requests); problem solving (identifying the problem, generating solutions); self-regulation (deep breathing to calm down, accepting frustration, learning to share, tolerating frustration); and emotional regulation (identifying and expressing emotions, listening to others). Daycare educators are encouraged to reinvest the content explored during each session in their day-to-day activities over the following two weeks (e.g., the Minipally+ puppet intervenes in a conflict between children, the educator recalls the problem-solving strategies presented by the Minipally+ puppet). Examples of reinvestment activities are presented in the curriculum.

As the daycare educators implement the Minipally+ curriculum, they will receive supervision by a trained psycho-educator specialized in early childhood education. Monthly meetings between psycho-educators and educators will insure adherence to the manualized intervention. The continuous training component aims to create a positive daycare environment, to promote children's prosocial behaviours while decreasing disruptive ones.

2. Parenting Intervention: Incredible Year Curriculum

The Incredible Years (IY) Parental Training is a comprehensive, multifaceted, and developmentally based curriculum for parents. The program is designed to promote children's

emotional and social competence and to help parents meet the social and emotional needs of young children and reduce conduct problems. The program includes generic components of parenting programs: parent-child relationship building, child-directed play, emotional and social coaching, how to congratulate and prize children, how to set rules and routines, and how to reduce children's disruptive behaviors. In order to facilitate parents' participation into the program, the IY curriculum will be offered online.

The program will be delivered via 12-14 weekly meetings led by two trained group leaders. Group leaders will come from a variety of helping professions such as social work, psychology, psycho-education and education. Each group will have two group leaders who will have been trained to the IY approach and the IY curriculum. The program includes a manualized curriculum where every session is organized around the presentation of parent-child interactions DVD vignettes, parent discussion, video modeling, role-play practices, and home assignments. Group leaders will use a collaborative, self-reflective style rather than a didactic expert leadership style. The IY parenting training encourages knowledge sharing and allows time for building parents' social network as well as sharing thoughts and emotions on educational practices and parenting.

3. Combination of the daycare and parenting interventions:

Children in the third interventional condition will receive both interventions over one school year.

4. Control group

Daycare service as usual and health education information provided to parents and educators (control group). Information about the importance of healthy lifestyle during childhood, including nutrition tips, bed time routines, physical activity, will be provided to all participating parents.

Previous intervention as of 25/07/2022:

We will compare the main and combined effect of two psychosocial interventions delivered to preschoolers in the daycare centers on children's social behaviours. We will perform a cluster-randomized control trial whereby 60 daycares in low-income neighborhoods will be randomly assigned to one of the following interventions:

1. Daycare-based social skills training for educators to use in class
2. Daycare-based parental training
3. Social skills training for educators plus parental training
4. Control group (daycare service as usual).

The randomization will be conducted by the Applied Clinical Research Unit of the Ste-Justine's Hospital Research center. Daycare centers will be randomized with a 1:1 ratio for every group. A pre-established numbered list of 999 randomization combinations will be publicly displayed in advance on the study website. Three randomization numbers will be drawn out of a bag to determine the assignment condition of any given daycare center. The research coordinator will then contact the daycare center directors to announce allocation.

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The Minipally+ curriculum is presented to every daycare educator during a 2-day training session led by a trained psycho-educator. The program is later delivered to children by each educator to his/her own group of children over 16 playful sessions. The sessions are animated by educators over a period of one school year using a puppet. The puppet presents itself as a loyal and enthusiastic friend who visits children in daycare services to model prosocial behaviors and social inclusion by discussing/playing with his friends (other puppets) and with the children. The intervention includes generic components of social skills training programs: introduction to social contact (make and accept contact from others, make requests); problem solving (identifying the problem, generating solutions); self-regulation (deep breathing to calm down, accepting frustration, learning to share, tolerating frustration); and emotional regulation (identifying and expressing emotions, listening to others). Daycare educators are encouraged to reinvest the content explored during each session in their day-to-day activities over the following two weeks (e.g., the Minipally+ puppet intervenes in a conflict between children, the educator recalls the problem-solving strategies presented by the Minipally+ puppet). Examples of reinvestment activities are presented in the curriculum.

As the daycare educators implement the Minipally+ curriculum, they will receive supervision by a trained psycho-educator specialized in early childhood education. Monthly meetings between psycho-educators and educators will insure adherence to the manualized intervention. The continuous training component aims to create a positive daycare environment, to promote children's prosocial behaviours while decreasing disruptive ones.

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The program will be delivered via 12-14 weekly meetings led by two trained group leaders. Group leaders will come from a variety of helping professions such as social work, psychology, psycho-education and education. Each group will have two group leaders who will have been trained to the IY approach and the IY curriculum. The program includes a manualized curriculum where every session is organized around the presentation of parent-child interactions DVD vignettes, parent discussion, video modeling, role-play practices, and home assignments. Group leaders will use a collaborative, self-reflective style rather than a didactic expert leadership style. The IY parenting training encourages knowledge sharing and allows time for building parents' social network as well as sharing thoughts and emotions on educational practices and parenting.

3. Combination of the daycare and parenting interventions:

Children in the third interventional condition will receive both interventions over one school year.

4. Control group

Daycare service as usual and health education information provided to parents and educators (control group). Information about the importance of healthy lifestyle during childhood, including nutrition tips, bed time routines, physical activity, will be provided to all participating parents.

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1. Daycare-based social skills training for educators to use in class
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3. Social skills training for educators plus parental training
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The randomization will be conducted by the Applied Research Unit of the Ste-Justine's Hospital Research center. Daycare centers will be randomized with a 1:1 ratio for every group. A pre-established numbered list of 999 randomization combinations will be publicly displayed in advance on the study website. Three randomization numbers will be drawn out of a bag to determine the assignment condition of any given daycare center. The research coordinator will then contact the daycare center directors to announce allocation.

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As the daycare educators implement the Minipally+ curriculum, they will receive supervision by a trained psycho-educator specialized in early childhood education. Monthly meetings between psycho-educators and educators will insure adherence to the manualized intervention. The continuous training component aims to create a positive daycare environment, to promote children's prosocial behaviours while decreasing disruptive ones.

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The program will be delivered via 12-14 weekly meetings led by two trained group leaders. Group leaders will come from a variety of helping professions such as social work, psychology, psycho-education and education. Each group will have two group leaders who will have been trained to the IY approach and the IY curriculum. The program includes a manualized curriculum where every session is organized around the presentation of parent-child interactions DVD vignettes, parent discussion, video modeling, role-play practices, and home assignments. Group leaders will use a collaborative, self-reflective style rather than a didactic expert leadership style. The IY parenting training encourages knowledge sharing and allows time for building parents' social network as well as sharing thoughts and emotions on educational practices and parenting.

3. Combination of the daycare and parenting interventions:

Children in the third interventional condition will receive both interventions over two years.

4. Control group

Daycare service as usual and health education information provided to parents and educators (control group). Information about the importance of healthy lifestyle during childhood, including nutrition tips, bed time routines, physical activity, will be provided to all participating parents.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measure as of 14/03/2024:

Child's social behaviors assessed by daycare educators assessed by the social behavior questionnaire (SBQ) at pre- and post-intervention assessments (T0, T1 and T2). (Items of the SBQ incorporates items from Preschool Behavior Questionnaire, Child Behavior Checklist, Strengths and Difficulties Questionnaire, the Infant-Toddler Social Emotional Assessment [ITSEA] and the NIH Toolbox. Note that educators performing T2 assessment will not have been involved in the intervention with the study children)

Previous primary outcome measure as of 25/07/2022:

Child's social behaviors assessed by daycare educators assessed by the social behavior questionnaire (SBQ) at pre- and post-intervention assessments (T0 and T2). (Items of the SBQ incorporates items from Preschool Behavior Questionnaire, Child Behavior Checklist, Strengths and Difficulties Questionnaire, the Infant-Toddler Social Emotional Assessment [ITSEA] and the NIH Toolbox. Note that educators performing T2 assessment will not have been involved in the intervention with the study children)

Previous primary outcome measure:

Child's social behaviors assess by daycare educators assessed by the social behavior questionnaire (SBQ) At pre- (T0), intermediate (T1) and post-intervention assessments (T2-T3) (Items of the SBQ incorporates items from Preschool Behavior Questionnaire, Child Behavior Checklist, Strengths and Difficulties Questionnaire, the Infant-Toddler Social Emotional Assessment [ITSEA] and the NIH Toolbox. Note that at educators performing T3 assessment will not have been involved in the intervention with the study children)

Key secondary outcome(s)

Current secondary outcome measures as of 25/07/2022:

Three types of secondary outcomes will be collected: child-related, educator-related and parent-related.

1. CHILD-RELATED OUTCOMES

1.1. Child's Social Behaviors assessed by parents using the Social Behavioral Questionnaire (SBQ) at pre-(T0) and post-intervention assessments (T1 and T2).

1.2. Children's level of stress will be assessed by collecting hair samples at two occasions to measure cortisol concentration. Samples will be collected at daycare by the educator prior to and after the interventions (T0 and T1).

1.3. Child's healthcare service use assessed by parents assessed using a questionnaire about their healthcare service use (i.e., medical and psychosocial services). Parents will complete this questionnaire at the first and last post-intervention assessments (T1-T2)

1.4. Child's temperament. Parents will fill the Children's Behaviour Questionnaire (CBQ) to assess their child's temperament at pre-intervention assessment (T0). The CBQ items involve statements describing emotions and behaviours that the child may or may not exhibit. The parents respond on a 7-point Likert scale ranging from extremely true to extremely untrue, indicating how closely the statements match the child's typical behaviour during the recent weeks. The three main domains of the questionnaire are negative affectivity, extraversion and effortful control.

1.5. Two measures of social cognition will be administered. The Empathy Questionnaire (EmQue), completed by the parent at T0, comprises 20 items divided into three scales measuring emotional contagion, attention to the emotions of others and prosocial responses to the emotions of others. The parent will also complete the Children's Social Understanding Scale (CSUS) at T1. This questionnaire has 18 items measuring theory of mind abilities in children aged 2 to 7 years.

2. EDUCATOR-RELATED OUTCOMES

2.1. Sociodemographic and professional information will be collected from the educators responsible for the children at pre-intervention and at the first post-intervention (T0-T1). Socio-

demographic information will include demographic characteristics, level of education, number of years of experience as an educator and other training received during the career. The professional information will cover the topics of job satisfaction, the level of perceived stress, and the management of disruptive behavior within the group. A short questionnaire on their general health status (General Health Questionnaire) will also be administered to them, as well as a short questionnaire on their group of children.

2.2. Implementation of the Minipally program. The educators who will be implementing the Minipally program will be asked to complete a questionnaire after each workshop. The educator will record in this questionnaire the number of children present and the activities carried out.

3. PARENT-RELATED OUTCOMES

3.1. Family sociodemographic characteristics. Information about parents' socio-demographics (education, occupation and income) will be assessed at pre-intervention. We will also collect information about children' daycare services attendance such as the number of hours children attend daycare services per week and the number of months the child attended a daycare

3.2. Parental practices. Parents will assess their own parenting practices using the Parenting Practices Interview (PPI) at the first post-intervention assessment (T1).

3.3. Mental health. Four short questionnaires relating to the mental health of the parent will be administered. The Center for Epidemiologic Studies Depression Scale Revised (CESD-R-10) measures the parent's depressive symptoms, the Adult ADHD Self-Report Scale (ASRS) measures their ADHD symptoms, the Alcohol Use Disorders Identification Test (AUDIT) concerns substance consumption (10 items = 2 minutes) and the Generalized Anxiety Scale (GAD-7) measures the symptoms of generalized anxiety. These questionnaires will be administered at T0 and T2.

3.4. Family dynamics. Two questionnaires will be administered to parents at T1 to measure the presence of conflict within the family. The Family Assessment Device and the Revised Marital Conflict Strategies Scale (CTS2).

Previous secondary outcome measures:

Three types of secondary outcomes will be collected: 1) child-related; 2) educator-related and 3) parent-related.

1. CHILD-RELATED OUTCOMES

1.1 Child's Social Behaviors assessed by parents using the Social Behavioral Questionnaire (SBQ) at pre-(T0), intermediate (T1) and post-intervention assessments (T2 and T4 only). Parents will not be asked to assess their child's behaviours at T3 because the length of time between T2 and T3 is too short to ask the same assessor to complete the questionnaire.

1.2 Children's level of stress will be assessed by collecting hair samples at three occasions to measure cortisol concentration. Samples will be collected at daycare by trained research assistants prior to and after the interventions (T0 and T2)

1.3 Child's verbal ability assessed by research assistant at the first post-intervention assessment (T2) during a day in daycare using the Peabody Picture Vocabulary Test-Revised (PPVT-R). Scores will be later adjusted for the child's age in months

1.4 Child's healthcare service use assessed by parents assessed using a questionnaire about their healthcare service use (i.e., medical and psychosocial services). Parents will complete this questionnaire at pre-intervention (T0), at the intermediary assessment (T1) and at the first and third post-intervention assessments (T2-T4)

1.5 Child's temperament. Parents will fill the Children's Behaviour Questionnaire (CBQ) to assess their child's temperament at the intermediate assessment time point (T1). The CBQ items involve statements describing emotions and behaviours that the child may or may not exhibit. The parents respond on a 7-point Likert scale ranging from extremely true to extremely untrue,

indicating how closely the statements match the child's typical behaviour during the recent weeks. The three main domains of the questionnaire are negative affectivity, extraversion and effortful control.

2 EDUCATOR-RELATED OUTCOMES

2.1 Educator-child interactions assessed by research assistants using the Caregiver Interaction Scale (CIS) at pre-intervention, at the intermediary and at the first post-intervention assessments (T0, T1 and T2)

3. PARENT-RELATED OUTCOMES

3.1 Family sociodemographic characteristics. Information about parents' socio-demographics (education, occupation and income) will be assessed at pre-intervention. We will also collect information about children' daycare services attendance such as the number of hours children attend daycare services per week and the number of months the child attended a daycare

3.2 Parental practices. Parents will assess their own parenting practices using the Parenting Practices Interview (PPI) at pre-intervention and at the first post-intervention assessment

Completion date

30/06/2026

Eligibility

Key inclusion criteria

Current inclusion criteria as of 25/07/2022:

1. Daycare centers:

- 1.1. Large enough to have preschoolers grouped by age, e.g. a classroom of 3-year-olds
- 1.2. Qualified early childhood educators on staff
- 1.3. Located in low-income neighborhoods in selected urban areas of the province of Quebec, as defined by official municipal or provincial criteria

2. Children:

- 2.1. Aged between 36 and 42 months in September of the ongoing school year
- 2.2. Informed written consent from their parents must be provided

3. Parents:

- 3.1. Parents must be able to fill in the evaluation questionnaires in French or in English

Previous inclusion criteria:

1. Daycare centers:

- 1.1 At least partially publicly funded
- 1.2 Large enough to have preschoolers grouped by age, e.g. a classroom of 2-year-olds
- 1.3 Qualified early childhood educators on staff
- 1.4 Located in low-income neighborhoods in selected urban areas of the province of Quebec, as defined by official municipal or provincial criteria

2. Children:

- 2.1 Aged between 18 and 30 months in September of the ongoing school year
- 2.2 Informed written consent from their parents must be provided

3. Parents:

3.1. Parents must be able to fill in the evaluation questionnaires in French or in English

Healthy volunteers allowed

No

Age group

Child

Sex

All

Total final enrolment

774

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/07/2021

Date of final enrolment

15/01/2023

Locations

Countries of recruitment

Canada

Study participating centre

Centre Hospitalier Universitaire Sainte-Justine

3175 Chemin de la Côte-Sainte-Catherine

Montreal

Canada

H3T 1C5

Sponsor information

Organisation

University of Montreal

ROR

<https://ror.org/0161xgx34>

Organisation

Centre Hospitalier Universitaire Sainte-Justine

ROR

<https://ror.org/01gv74p78>

Funder(s)**Funder type**

Government

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 - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Funder Name

Social Sciences and Humanities Research Council of Canada

Alternative Name(s)

Conseil de recherches en sciences humaines, Social Sciences and Humanities Research Council, sshrc_crsh, Conseil de recherches en sciences humaines du Canada, Social Sciences and Humanities Research Council - sshrc_crsh, Social Sciences and Humanities Research Council (SSHRC), Conseil de recherches en sciences humaines (CRSH), SSHRC, SSHRC-CRSH

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

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

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		12/09/2019	08/10/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 7		30/01/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes