



APPROUVÉ PAR LE COMITÉ D'ÉTHIQUE
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CHU SAINTE-JUSTINE



RESEARCH INFORMATION AND CONSENT FORM FOR PARENTS

Title: I-Care: evaluation of a program to support the development of children in childcare centre and in the family

Principal researchers:

Sylvana Côté, Ph.D., Université de Montréal and Benoît Mâsse, Ph.D., Université de Montréal

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WHY HAVE YOU BEEN INVITED TO PARTICIPATE IN THIS RESEARCH PROJECT?

This year, researchers from CHU Sainte-Justine Mother and Child University Hospital Centre will conduct a study in your childcare centre (CPE). The aim is to identify the best ways to enhance child development. We would like to seek your participation for this purpose. We invite you to read this information form to decide if you would be interested in participating in this research project. It is important to understand this form clearly. Do not hesitate to ask questions. Take all the time you need to decide.

In this consent form, “you” refers to you and your child.

1. Why are we conducting this research?

A period full of challenges starts around the age of two: children must learn to manage their behaviours, express their needs adequately and demonstrate pro-social behaviour in a group. These skills are necessary to function well when they start school. Children need help in fulfilling this task. Their parents and educators are therefore essential resources. This research will evaluate the different approaches to support parents and educators in this important role. Then, we will determine to what extent this aid makes children better prepared when starting school.

We have 60 childcare centres, including yours, participating in this study. Four approaches will be compared:

- 1) childcare centre educators receive training on best practices to encourage children's social development
- 2) parents receive training on best practices to encourage children's social development
- 3) a combination of the two first approaches is offered to educators and parents
- 4) parents receive information on best practices to promote healthy habits in their children

Lots will be drawn to determine which of the four approaches will be deployed in your childcare centre. **In the coming weeks, you will be informed about the result of this draw.**

2. What is involved in the approaches studied?

If your CPE is selected to evaluate the first approach, over the weeks, the **Brindami+** program will be integrated into the curriculum. Brindami+ aims to stimulate the development of social behaviour (for instance by sharing toys, making a request, managing emotions) to promote the well-being of children in their interactions with others. The program uses a special method to lead the workshop, that is, a puppet (Brindami), addressing children directly. It was implemented for the first time in 1997 and since then, more than 80,000 children have benefited from the visit of the happy and energetic little mouse to their childcare centre. Two studies suggest that it have beneficial effects.

If your childcare centre is selected to evaluate the second approach, you will be invited to take part in ***The Incredible Years*** program meetings along with other parents of two-year-olds from the childcare centre. The goal of this program is to help parents improve or develop concrete strategies to support them in their roles. In total, fourteen meetings will be offered from next January once a week for the first six first weeks, then every two weeks for the remaining meetings. The meetings will be held at your child's childcare centre after childcare hours. A free meal will be offered to all participating parents and their children attending the childcare centre. After the meal, the children will be invited to participate in activities led by an educator while parents attend the group meeting.

If your childcare centre is selected to evaluate the third approach, all the activities planned as part of the two first approaches will be offered.

If your childcare centre is selected to evaluate the fourth approach, an information kit on healthy habits for children will be given to you in winter 2020.

3. How will the project be executed?

a) Childcare centre visits

A research assistant **will visit your child's group three times** during the next two years, that is, over the next few weeks, in around nine months and in around 21 months. During these visits, he or she will observe how the child care centre works and how the children interact. He or she will also give the children a chance to participate in games to evaluate their social development. Children will be filmed during their participation in one of these games. The video recording will only be used to evaluate children's responses and will be destroyed at the end of the project.

He or she will then measure the children's stress levels. This will help us examine the relationship between stress and children's social development. To do this, the assistant will collect about thirty strands of hair near the nape of your child's neck.

Finally, he or she will take a sample of your child's saliva. The samples will be taken in a playful context. An attractive space reserved for the purpose will be set up in a corner of your child's premises. Your child will be invited there by the assistant, who will tell your child a story featuring a puppet and the objects used for measurements. Using special small sponges, the assistant will gently rub the interior of your child's cheeks. This method, which has been used for a long time with young children, is completely safe, painless and only takes a few minutes. Some children may, however, feel slight discomfort when the sponge is slipped into their mouth.

This sampling allows us to obtain the information necessary to better understand the role of genetic factors in the acquisition of social skills by children targeted by the program.

It is important to understand that the results will not focus on your child individually, but on a group of children. The results will be strictly confidential and will not be shared with the childcare centre or any other service.

b) Questionnaires to be completed (30 to 50 minutes)

You will be invited to answer a questionnaire comprising various components four times in the next three years (today, then in around nine months, 21 months and 33 months). The questionnaire can be completed online or on paper, according to your preference. The topics addressed will be the following: your child's characteristics, behaviours and health, recent family events, your health and parental practices.

We will also ask your child's educator to answer a questionnaire on his or her experience, childcare centre activities and your child's behaviour.

4. What are the disadvantages and risks?

Participation in the programs evaluated as part of the project does not involve any risk for the children and their parents.

The only disadvantage related to your participation in this project as a parent is the time spent on answering the questionnaire and in the case of parents of childcare centres where group meetings will take place, the time spent on meetings.

The questionnaire addresses personal topics such as symptoms of depression or anxiety that you may have experienced recently. If any of the questions should make you uncomfortable, you can simply refuse to answer it. If one of the topics addressed causes you concern or distress, we can refer you to the appropriate resources, if necessary. You can also contact Christine Doucet by telephone at 514-345-4931, ext. 7475 or by email at christine.doucet@recherche-ste-justine.qc.ca.

There is a slight chance that the analysis of your child's hair indicates high cortisol levels. If this is the case for more than one sample during the three-years of the study, we will contact you to inform you and obtain the contact details of your child's doctor to forward the results of the analysis.

5. What are the benefits of participating in this research project?

There is no benefit directly associated with answering the questionnaire used in this research except that you are contributing to increasing knowledge on child development.

On the other hand, you and/or your child may enjoy benefits associated with the program to which your childcare centre is assigned. Brindami+ may contribute to the development of better social skills in your child. *The Incredible Years* may encourage the development of more harmonious relations with your children, better problem solving and better communication in your family. Being better informed about healthy habits for children may help you boost your child's health and well-being.

6. Voluntary participation

Your participation, as well as your child's, in the evaluation of approaches studied is completely voluntary. So, you are free to accept or refuse participation in this project. You can decide to end your participation at any time and without any justification on your part. If you withdraw, data yet to be analyzed will be destroyed.

7. How do we guarantee confidentiality?

All the information, videos and biological samples collected for this study will be treated with strict confidentiality except with your permission or through a provision in the law to do otherwise. All the answers given in a questionnaire and samples and results obtained will be coded, which means that they will not be associated with your name or your child's name. Only authorized members of the research team will have access to the list linking the number assigned to your family, your name and your child's name. During the study, the data will be kept on the CHU Sainte-Justine's URCA Applied Clinical Research Unit's secure servers under the responsibility of the principal researchers.

To ensure that the research is properly managed, a research ethics board delegate or funding organization may consult the data collected.

Finally, the results of the study may be used in scientific publications or shared at a science conference, but no information that will allow you or your child to be identified will be revealed.

8. Database

The data collected during this study will be transferred to a new coded and digitized database which will be created by CHU Sainte-Justine's URCA. This will be hosted by URCA's secure server, under the responsibility of the principal researchers. Under no circumstances whatsoever will data enable participants to be identified be shared. This database will be kept for as long as the principal researchers have the necessary resources to administer it. Each data use request by research team members must be approved by the principal researchers and a competent ethics board.

9. Researchers' responsibility

By consenting to participate in this research, you will not be waiving any of your legal rights. You also do not absolve the researchers and promoter of their legal and professional responsibility for any situation that may be damaging to you.

10. Is there any compensation offered for the disadvantages related to participation?

A sum of \$15 will be given to you for each questionnaire that you fill out (a total of four in three years) to compensate for the time spent on answering the questionnaire.

11. Who do we contact if we have questions?

For questions related to the study or if you feel uncomfortable after completing the questionnaire, please contact Christine Doucet by phone at 514-345-4931, ext. 7475 or by email at christine.doucet@recherche-ste-justine.qc.ca.

For information about your rights, you can contact CHU Sainte-Justine's local service quality and complaints commission: 514-345-4749.

12. Research ethics board

The CHU Sainte-Justine research ethics board has approved this research and ensured its monitoring.

13. Consent

I have read and understood the information above and I have had the chance to ask questions, which were answered. After consideration, I, as well as my child, agree to participate in this research project.

Printed name of participant Participant signature Date

I have explained to the participant and/or his/her parent/guardian all relevant aspects of the study and I answered the questions they asked me. I told them that participation in the study is optional and voluntary and that they may end their participation at any time.

Name of the person who obtained (Signature) Date
the consent
(Block letters)

