This is a post-peer-review, pre-copyedit version of an article published in Psychoneuroendocrinology. The final authenticated version is available online at: https://doi.org/10.1016/j.psyneuen.2019.02.017

1	Impact of a social skills program on children's stress: A cluster randomized trial				
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## 1

#### Abstract

2 Background: Most preschool children in Western industrialized countries attend child care 3 during the day while parents work. Studies suggest that child care may be stressful to young 4 children, perhaps because they still lack the social skills to interact daily in a group setting away 5 from parents. This gap in social abilities may be greater for children in lower-income families, 6 who may face more adversity at home, with fewer resources and more social isolation. 7 Methods: We conducted a cluster-randomized controlled trial in 2013-2014 to test whether a 8 social skills intervention led by early childhood educators within the child care center could 9 reduce diurnal cortisol levels to more typical patterns expected of children this age. We 10 randomized 19 public child care centers (n = 361 children) in low-income neighborhoods of 11 Montreal, Canada, to either: 1) the Minipally program – intervention group (n = 10 centers; 186 12 children), or 2) waiting list – control group (n = 9 centers; 175 children). Saliva samples for cortisol levels were collected 3 times/day, pre- and post-implementation. The Minipally puppet 13 14 program consists of 2 workshops/month for 8 months for the development of social skills and 15 self-regulation in 2-5-year-olds, with reinforcement activities between workshops. Educators 16 received 2-days' training and 12 hours' supervision in Minipally. 17 **Results:** Linear mixed models for repeated measures revealed a significant interaction between 18 intervention status and time of day of cortisol sampling ( $\beta = -0.18$ , p = 0.04). The intervention 19 group showed patterns of decreasing diurnal cortisol secretion ( $\beta = -0.32$ , p < 0.01), whereas 20 the control group showed increasing slopes ( $\beta = 0.20, p < 0.01$ ). Moreover, family income was a 21 moderator; children in lower-income families benefited most from the intervention. 22 **Conclusion:** Results suggest that a social skills training program, when integrated into a 23 preschool education curriculum, can foster an environment more conducive to typical childhood 24 patterns of cortisol secretion. 25

26 Keywords: Child care, daycare, social skills training, cortisol, diurnal cortisol, low income

1 *Abbreviations:* HPA, Hypothalamic-pituitary-adrenal.

- 3 Trial registration number: ISRCTN84339956 (retrospectively registered in March 2017, no
- 4 amendment to initial protocol).
- 5

1

Impact of a social skills program on children's stress: A cluster randomized trial

## 2 **1. Introduction**

3 In most Western industrialized countries, the percentage of preschool children receiving child 4 care services has increased dramatically since the mid-1980s (OECD, 2014). In this context, we 5 will use the term "child care" to designate a daycare center; i.e. a preschool or regular group-6 based care of children prior to school entry by someone other than the parents, who are 7 generally at work. In the majority of countries belonging to the Organization for Economic Co-8 operation and Development (OECD), it is estimated that at least 80% of children receive full-9 time child care before they enter elementary school (OECD, 2014). Child care constitutes a 10 promising and supportive environment, especially for children from socioeconomically 11 disadvantaged neighborhoods, in at-risk families, or with early socioemotional maladjustment 12 (Côté et al., 2007; Herba et al., 2013).

13 For many children, child care represents the first social experience in a structured group 14 setting. Although child care is associated with a number of head start benefits for school 15 readiness (higher receptive vocabulary and reading skills), particularly for children from low 16 socioeconomic levels (Geoffroy et al., 2010), child care may also be a stressful experience, 17 especially for younger children or those attending lower-guality establishments (Ouellet-Morin et 18 al., 2010; Watamura et al., 2002). Two meta-analyses have reported that preschoolers (3-5 19 year-olds) tended to secrete higher diurnal levels of cortisol, the so-called "stress hormone", 20 when attending child care as compared to staying home (Geoffroy et al., 2006; Vermeer and 21 van lizendoorn, 2006). These flat or increasing patterns of cortisol secretion differ from the 22 gradually decreasing pattern biologically expected for children this age (Watamura et al., 2009). 23 1.1 Child Care Center as a Stressful Environment

24 The child care environment may be perceived by young children as unpredictable,

25 uncontrollable, and more threatening than their own home. Repeated and intense activation of

the hypothalamic-pituitary-adrenal (HPA) axis may lead to flattened or increasing diurnal cortisol secretion (Gunnar et al., 2009). Although there is no evidence of a direct link between stress in child care settings and poor health outcomes, chronic exposure to high levels of stress has been shown to negatively impact child health (Koss and Gunnar, 2017). Furthermore, tolerable and environmentally adaptive stress was shown to be associated to well-being (Gunnar and Quevedo, 2007), warranting interventions that target potential sources of stress in child care centers.

8 Two characteristics associated with the child care environment may induce stress and 9 activation of the HPA axis. First, developmentally, the age group in child care centers coincides 10 with peak levels of physically aggressive behaviors in response to conflict. This increases the 11 probability of victimization or of witnessing physical aggression (Côté et al., 2006). Indeed, 12 being either the perpetuator or the victim of physically aggressive behaviors may lead to high 13 levels of peer rejection, which in turn is also associated with rising cortisol patterns in children 14 attending child care (Gunnar and Donzella, 2002).

15 Second, preschoolers may not have reached sufficient levels of emotion regulation 16 (Gunnar and Donzella, 2002) to engage in prosocial behaviors. Emotion regulation has been 17 described as the ability to process emotions and emotional information, including inhibition of 18 emotional impulses, modulation of emotional behavior, and disengagement from distressing 19 elements (Grolnick & al., 2006). In children with poor emotion regulation skills, the risks of 20 disruptive behavior, poor social skills, and peer rejection are increased (Gunnar et al., 2003).

21 1.2 Targeted Interventions for Children Attending Child Care Centers

Results from relationship-focused interventions targeting children exposed to early life adversity,
such as foster care and neglect, suggest that improving the quality of the caregiver-child bond
may foster optimal HPA-axis activity (Bernard et al., 2015). To the best of our knowledge, only
one study tested the hypothesis that teacher-child relationships in child care could impact
cortisol levels (Hatfield and Williford, 2017). The objective of their 7-week program was to foster

sensitive teacher-child relationships and prosocial interactions among disruptive children (n =
 113). Lower cortisol levels in the morning were observed for children exposed to the intervention
 as compared to the control group. These results suggest that a psychosocial program within the
 child care environment can modify HPA-axis activity.

5 1.3 Targeted Interventions for Child Care Centers in Low-Income Neighborhoods 6 Low-income neighborhoods present a confluence of distal and proximal challenges thought to 7 influence biological, cognitive, and behavioral development in children (Koss and Gunnar, 8 2017). Specifically, child care centers in low-income neighborhoods tend to be fewer and of 9 lower quality than in higher-income neighborhoods (Cloney et al., 2016). Also, children from 10 disadvantaged socioeconomic backgrounds are more likely to have cognitive and 11 socioemotional deficits (Cloney et al., 2016; Goldfeld et al., 2015) which may lead to higher 12 levels of aggression in the child care setting. However, children from lower-income families also 13 stand to benefit the most from attending good quality child care, especially in terms of social 14 development (Côté et al. 2007). Interventions supporting the development of prosocial skills and 15 emotion regulation in low-income neighborhood child care centers may lower diurnal cortisol 16 secretion, by reducing the number of conflicts to which the children are exposed. Social skills 17 training might also buffer HPA-axis activation by lowering levels of peer exclusion, increasing 18 prosocial interactions with peers, and encouraging children to ask for help from a trusted 19 caregiver (Hostinar and Gunnar, 2015).

20 1.4 Study Aims and Hypothesis

We conducted a cluster randomized controlled trial of a training program for early childhood educators to implement in child care centers of low-income neighborhoods. The aim was to test whether preschoolers attending a child care center with a social skills intervention component, by educators with specific training, showed more normative patterns of diurnal cortisol secretion than children not exposed to such a program. Additionally, we tested whether the impact of the

- intervention varied as a function of family income, whereby children from lower-income families
   were hypothesized to benefit the most from social skills training.
- 3

### 4 **2. Methods**

#### 5 2.1 Participants

6 We conducted the study in low-income neighborhoods of Montreal, Quebec, Canada from 7 September 2013 to June 2014. Eligibility criteria were that at least 25% of the children attending 8 the child care come from low-income families, defined as those entitled to a special government 9 subsidy providing free child care access to families with an annual family income below 10 Can\$20,000. The income status of the neighborhood itself was defined according to both 11 provincial (Québec., 2013) and national criteria (Canada, 2011). Children were not clustered in 12 particular child care centers by familial income and the distribution of family income was not 13 uniform across child care centers, allowing us to investigate the moderating effect of family 14 income on intervention status and cortisol secretion. Of 38 child care centers manifesting an 15 interest, 19 were eligible. We determined that a sample of 19 centers would allow us to detect a 16 small-to-medium effect size, with 90% power at a two-sided significance level of 5% (Heo, 17 2008).

## 18 2.2 Study Design

19 Randomization was at the level of the child care center. Centers were randomized to receive the 20 Minipally social skills program in Year 1 (intervention group) or Year 2 (waiting list, control 21 group). Each child care center included 2-3 classes of 4-year-olds, with 8 children per class. 22 Altogether, 43 classes (n = 361 children) in 19 child care centers took part in the study (Figure 23 1). Cluster randomization ensured that children from the control (waiting list) group were not 24 exposed to the intervention. The intervention team provided Minipally training to the educators, 25 and the research team evaluated the impact of the intervention. Once data collection was 26 complete, all child care centers in the control group received the Minipally training. Consent to

1	participate in the study was obtained from parents and child care directors. The Sainte-Justine		
2	Hospital Research Ethics Board approved all procedures in May 2013. A detailed description of		
3	the study protocol has been published (Côté et al., 2017).		
4	Insert Figure 1 here		
5	2.3 Intervention		
6	The intervention was the Minipally program for the development of social skills and self-		
7	regulation in children aged 2 to 5 years. The Minipally curriculum is delivered via a puppet that		
8	presents itself as a loyal and enthusiastic friend visiting the child care to model prosocial		
9	behaviors and social inclusion. There are 16 play sessions (2/month for 8 months) where the		
10	educators and puppet discuss/play with friends (other puppets) and the children. The program		
11	includes generic components of social skills training for children: introduction to social contact		
12	(make and accept contact from others, make requests); problem-solving (identifying the		
13	problem, generating solutions); self-regulation (breathing to calm down, accepting frustration,		
14	learning to share, tolerating frustration); and emotion regulation (identifying and expressing		
15	emotions, listening to others).		
16	Child care educators at centers randomized to the intervention received 2 days of		
17	intensive training in the Minipally program plus 12 hours of classroom supervision (4 half-day		
18	sessions over the course of the program). After each Minipally session with the children,		
19	educators reinforced the principles with 2 weeks of activities based on the topic addressed (for		
20	instance, if the Minipally puppet intervened in a particular way in a conflict between two children,		
21	then over the next 2 weeks, the educator designed activities to recall the strategies presented		
22	by the puppet).		
23	3. Measures		
24	3.1 Saliva Collection		

Saliva samples were collected before and after the intervention by trained research assistants
blinded to the status of the child care center (intervention or control). Samples were collected at

3 time points: 1) 30 minutes after the child's arrival at child care (between 7:00 and 10:30 a.m.);
 2) before lunch (between 10:45 a.m. and 12:00 a.m.); and 3) one hour after waking from the
 afternoon nap (between 2:30 and 4 p.m.). Saliva was collected by placing a cotton sponge
 under the child's tongue for one minute (SalivaBio Children's Swab, Salimetrics).
 Samples were stored at -20°C until the laboratory assays. Cortisol concentration was
 obtained using a high-sensitivity enzyme immunoassay where the lowest limit of detection was

7 0.007µg/dL. All samples were assayed in duplicate. The intra- and inter-assay coefficients of

8 variation were 4.46% and 8.28%, respectively.

9 *3.2 Parent Questionnaires* 

Parents answered a short questionnaire upon arrival at the child care center, both before and after the intervention. Questionnaires included a wide range of variables potentially affecting cortisol secretion, such as children's habits and waking time, foods eaten for breakfast, current medication, sleep quality the night before, current mood (sad, excited), and state of health (cold, allergies).

Information on sociodemographic background (parent education and family income) was collected before the intervention. Annual family income ranged from "less than Can\$10,000" to "more than Can\$80,000." Because the income distribution was not uniform, and to ensure a similar number of children in each group, we split the sample into three: lower-income families entitled to government subsidy (income less than Can\$20,000), middle-income families (Can\$20,000 to Can\$80,000), and higher-income families (over Can\$80,000).

21

3.3 Children's Social Behaviors Assessed by Child Care Educators

Educators completed the social behavioral questionnaire (Tremblay et al., 1992) for each child in their group at pre- and post-intervention. Two dimensions of the validated and well-published questionnaire (Pingault et al., 2011) were used: a) disruptive behaviors including five items on opposition (e.g., has been defiant or has refused to comply with an adult request); four on impulsivity/hyperactivity questions (e.g., has had difficulty waiting for his/her turn in games); six

1	on physical aggression questions (three reactive, e.g., has reacted in an aggressively when
2	teased, and three non-reactive, e.g., has gotten into fights) (Cronbach alpha = 0.86); and b)
3	prosocial behaviors (e.g., has helped other children; 7 items) (Cronbach alpha = 0.79).
4	3.4 Child Care Educator Questionnaires
5	Every educator completed a sociodemographic questionnaire as well as a questionnaire
6	assessing their training in early childhood education and care. Educators in the intervention
7	group also completed a logbook in which they indicated when and which Minipally activities had
8	been conducted in their group.
9	4. Data Analysis
10	4.1 Preliminary analyses
11	We compared the intervention and control groups at baseline for 35 variables that might directly
12	or indirectly affect the impact of the intervention, including age, family income and number of
13	hours of child care per week. Less than 6% of the variables differed between groups,
14	suggesting that randomization was successful. Nonetheless, we verified whether those
15	variables were associated with diurnal cortisol secretion. None were, so we did not control for
16	them in subsequent models.
17	Second, we identified outlier values for which the cortisol concentration was above 3
18	standard deviations of the sample mean. At each saliva sample collection time, there were 2-5
19	outliers (for a total of 23); these were winsorized so as not to exert undue influence on the
20	results. We then performed a square root transformation of the cortisol distribution at each time
21	point to account for skewness. We used bivariate analyses (Spearman correlation coefficients
22	and ANOVA) to search for potential covariates associated with cortisol levels, such as exact
23	hour of sampling. For each cortisol sample, we modeled multiple variable linear regressions
24	using the following independent variables: exact hour of sampling, time of awakening, hours
25	since last saliva sample and all potential confounders related to cortisol secretion. We derived
26	the residuals from each linear regression (i.e. one regression for every cortisol sample) so that

the main analyses would be free from potential confounders. Raw cortisol concentration and
 residual concentration at each sample time according to intervention groups are presented in
 Table S3 in Supplementary material.

4 4.2 Main Analyses

5 To test the impact of the intervention on diurnal cortisol secretion (i.e. cortisol change during the 6 day), we used linear mixed models for repeated measures. This method allows the modeling of 7 multiple data points nested within individuals while also modeling between-subject differences. 8 Accounting for non-independence of repeated measures, linear mixed modeling allowed for the 9 possibility that cortisol samples taken on the same day in any given child might be more 10 correlated than samples in different children. Each child was assigned an individual intercept 11 and slope of diurnal cortisol secretion. Patterns were adjusted for missingness. The final model 12 represents the mean effect of every intercept and slope (i.e. diurnal cortisol secretion) according 13 to intervention status (intervention vs. control). We did not include an additional level for child 14 care as the intracluster correlation coefficient for child care was less than 5%. Analyses with and 15 without this level yielded similar results, so we reported the most parsimonious model 16 (Tabachnick and Fidell, 2007).

17 Linear mixed modeling was conducted pre-and post-intervention. At each time point, the 18 fixed effects were intervention status (intervention vs. control), time of saliva collection (morning 19 [0], just before lunch [1], and one hour after waking from the afternoon nap [2]), and interaction 20 (intervention status x time of saliva collection). At post-intervention, we also controlled for pre-21 intervention cortisol levels. We also examined whether the effects of the intervention varied 22 according to family income. More specifically, we tested a three-way interaction including 23 intervention status, time of saliva collection, and family income. All analyses were conducted 24 using IBM SPSS Statistics, version 24 (Armonk, NY, USA).

25

26 **5. Results** 

#### 1 5.1 Participants

2 There were 361 children, distributed among 19 child care centers. Table 1 summarizes 3 participant characteristics. In the course of the intervention, 20 children left child care, 4 representing a 6% attrition rate. These were replaced by 19 newcomers (10 in the control group 5 and 9 in the intervention group). With parental consent, the new children were included in the 6 post-intervention assessments. The intervention and control groups did not differ by sex, family 7 income, maternal education, or number of hours attending child care per week, but they did 8 differ in age and paternal education. We tested whether these variables were associated with 9 diurnal cortisol secretion. They were not and thus were not included in the main analyses. 10 5.2 Educator Demographics and Implementation 11 The educators involved in the trial were all women, of whom the majority had professional 12 training (college degree) in early childhood education and had worked in child care for more 13 than two years. All educators in institutions randomized to the intervention received the 14 appropriate Minipally training. According to educator logbooks, they provided at least 75% of the 15 proposed Minipally activities. 16 Insert Table 1 here 17 5.3 Impact of the Intervention on Diurnal Cortisol Secretion 18 The number of saliva samples collected did not differ between the intervention and control 19 groups. At baseline (pre-intervention), there was no effect for time of day ( $\beta = 0.06$ , p = 0.32), 20 suggesting that diurnal cortisol secretion was flat for children in child care. There was also no 21 difference in overall cortisol levels between groups ( $\beta = 0.08$ , p = 0.49). However, we did find a 22 marginally significant interaction between time of day and intervention status ( $\beta = -0.13$ , 23 p = 0.15), suggesting a marginally steeper cortisol decrease during the day for children in the 24 intervention group at baseline. To ensure that this initial difference did not bias the post-25 intervention analyses, we controlled for pre-intervention cortisol secretion levels in the post-26 intervention model.

1 At post-intervention, we included in the model the time of day ( $\beta = 0.07$ , p = 0.28), 2 intervention status ( $\beta = 0.03$ , p = 0.82), and cortisol levels at pre-intervention ( $\beta = 0.19$ , p < 0.193 0.01). The pre-intervention cortisol level was the most significant predictor, supporting our 4 decision to control for it on statistical analyses. At post-intervention, we found a significant 5 interaction between intervention status and time of day ( $\beta = -0.18$ ,  $\rho = 0.04$ ), suggesting distinct 6 patterns of diurnal cortisol secretion. Children in the intervention group showed decreasing 7 levels of cortisol secretion ( $\beta = -0.32$ , p < 0.01), whereas the control group showed increasing 8 levels ( $\beta = 0.20$ , p < 0.01) (Figure 2). No detectable effect for sex was found in the pre- and 9 post-intervention models. 10 Insert Figure 2 here 11 Controlling for pre-intervention levels of cortisol, we found a significant three-way 12 interaction between family income, intervention status, and time of day ( $\beta = 0.27$ , p = 0.03). The 13 interaction between time of day and intervention status remained significant ( $\beta = -0.79$ , 14 p = 0.01). This suggests that the strength of the association between intervention and cortisol 15 levels varied according to family income (Table 2). While no difference in diurnal cortisol 16 secretion patterns could be detected between intervention and control groups for children from 17 higher-income families ( $\beta = 0.02$ , p = 0.89), a more pronounced difference emerged for children 18 of lower-income families ( $\beta = -0.52$ , p = 0.03), and to some extent for middle-income families 19  $(\beta = -0.22, p = 0.09)$ , with significantly decreasing levels of cortisol during the day in the 20 intervention group as compared to increasing levels for controls (Figure 3 and Supplemental 21 Figure S4). 22 As shown in Supplementary Figure S4a and S4b, in the intervention group, differences in family income were reflected in the afternoon cortisol sample (F = 10.86, df = 94, p < 0.01) 23 24 where children from high-income families had the highest cortisol concentration, followed by 25 children from middle-income families and lastly by children from low-income families. In the 26 control group, the same moderating effect of family income was observed in the morning cortisol

- 1 sample (F = 27.34, df = 114, p < 0.01) where children from low and middle-income families had 2 their lowest level of diurnal cortisol concentration.
- 3

5.4 Supplementary analyses.

4 To explore the possibility that the impact of the intervention occurred via changes in child 5 behaviors, we tested whether disruptive and prosocial behaviors assessed by child care 6 educators in post-intervention mediated the effect of the intervention on cortisol secretion. 7 Specifically, we used two formulas for the calculation of overall diurnal cortisol secretion by 8 areas under the curve: 1) the "Area under the curve with respect to increase" (AUCI) and "Area 9 under the curve with respect to ground" (AUCG) (Pruessner et al., 2003). Using these 10 outcomes, intervention status was associated with AUCG ( $\beta$  = -1.62, p = 0.01), and not with 11 AUCI ( $\beta$  = -1.32, p = 0.07). The intervention was also associated with a significant decrease of 12 children's disruptive behaviors in post-intervention ( $\beta = -0.61$ , p = 0.02), but disruptive behaviors 13 were not associated with children's AUCG ( $\beta$  = -0.09, p = 0.52) or AUCI ( $\beta$  = 0.03, p = 0.85). 14 The intervention was not associated with an increase of children's prosocial behaviors in post-15 intervention ( $\beta = 0.38$ , p = 0.09), and prosocial behaviors were not associated with children's 16 AUCG ( $\beta = 0.01$ , p = 0.99) or AUCI ( $\beta = 0.01$ , p = 0.63). Thus, neither disruptive nor prosocial 17 behaviors in post-intervention were predictors of overall cortisol secretion. Finally, we 18 investigated if family income was also a moderator of the association between intervention 19 status and children's social behaviors in the mediation models between intervention status and 20 children's overall diurnal cortisol secretion. We did not find a significant moderation by familial 21 income for disruptive behaviors (p = 0.30) neither for prosocial behaviors (p = 0.65). 22 23 Insert Table 2 here

Insert Figure 3 here

25

#### 1 6. Discussion

2 Young children in child care have been reported to exhibit flat levels of diurnal cortisol secretion, 3 as opposed to the decreasing pattern expected for children that age (Vermeer and van 4 Ijzendoorn, 2006; Watamura et al., 2002). We conducted a cluster randomized controlled trial to 5 test whether a social skills training program, led by early childhood educators in child care 6 centers, would restore expected patterns. Whereas both the intervention and control groups in 7 participating child care centers exhibited flat diurnal cortisol secretion at baseline, we found that 8 children exposed to the intervention exhibited more typical, decreasing levels of cortisol 9 secretion throughout the day, as compared to controls. Further, children from lower-income 10 families seemed to benefit more from the intervention than those from middle- or higher-income 11 backgrounds. Interestingly, in the intervention group, children from higher-income families had 12 diurnal patterns characterized by early suppression of morning cortisol, whereas children from 13 middle- and low-income families had greater cortisol suppression in the afternoon, as compared 14 to controls.

15 A possible explanation for the sharper decline in the diurnal cortisol slope in children 16 from lower-income families is that they may be more sensitive than others to the intervention 17 and to the ensuing changes in the child care environment. Children from disadvantaged 18 backgrounds are more likely to be disruptive (Shaw and Shelleby, 2014) and to be victimized in 19 peer-play interactions (Barker et al., 2008). The social skills intervention might have enhanced 20 the dynamic of the group as a whole, thereby helping the children most at risk. Fewer social 21 challenges and confrontations in the intervention group might explain the observed cortisol 22 decreases. For the control group, the increasing cortisol levels observed for low- and middle-23 income children similarly point to the idea that these children were in need of an intervention 24 fostering a less stressful environment.

A complementary hypothesis is that children from higher-income families might be more sensitive to age-appropriate social challenges in the child care setting, as compared to children

1 from middle- or lower-income families, assuming that children from higher-income families faced 2 fewer challenges in their home environment (Ellis and Boyce, 2008). For children of higher-3 income families in both the intervention and control groups, the child care environment might 4 still be perceived as unpredictable and uncontrollable, two features associated with greater 5 cortisol response (Gunnar et al., 2009). The diurnal patterns observed in this study support the 6 idea that HPA-axis activation in child care is an adaptive reaction to the perception of challenge 7 and unpredictability in the environment. More generally, these findings support the concept that 8 children exposed to different levels of adversity will perceive threats differently and react to them 9 differently in daily life (Ellis and Del Giudice, 2014). 10 Finally, we note that our results are in line with those reported by Berry and colleagues 11 (Berry et al., 2016; Berry et al., 2014), where children in child care from lower socioeconomic 12 status exhibited lower levels of diurnal cortisol than their wealthier peers. However, despite 13 similarities between our results and those obtained in the Family Life Project (Berry et al., 2016; 14 Berry et al., 2014), the mechanisms underlying interactions between family income and diurnal 15 cortisol secretion remain largely unclear and there is some not-yet-understood complexity in the 16 present results. 17 To the best of our knowledge, there is no longitudinal study examining the impact of high 18 stress levels on later physical and mental health in children who regularly attend child care. We 19 are therefore limited in the discussion of potential long-term effects of our intervention on well-20 being and development. Future studies should investigate the consequences of flattened and 21 increasing diurnal cortisol secretion in children attending child care, as it is a developmental and 22 context-specific phenomenon that has been replicated several times in different welfare systems

23 (Geoffroy et al., 2006; Vermeer and van Ijzendoorn, 2006).

24 It is important to emphasize three features of the social skills program evaluated in this 25 study. First, the program is inclusive—all children are involved in the social skills training—not 26 only those exhibiting socioemotional or behavioral problems. This lowers the total cost of the

intervention and notably, reduces the risk of stigma in children. Second, the program can easily
be integrated into daily routine and educational activities, thus increasing adherence levels of
early childhood educators to the program. Third, the program can be disseminated with
relatively low implementation costs and educator training. Dividing the total expenses for
program implementation (educator training, supervision, and monetary compensation to child
care directors) by the number of children who received the intervention (n = 185), the total
cost/child works out to Can\$95.

8 It is noteworthy that we did not find an association between social behaviors (either 9 disruptive or prosocial) and diurnal cortisol secretion in supplementary analyses. Further 10 research will be needed to address the potential effect of social skills training on peer-peer 11 relationships, educator-child relationship, the degree of classroom chaos, and the social 12 behaviors of the group to identify the mechanisms involved in the interaction between the 13 intervention and HPA-axis activation.

14 6.1 Strengths and Limitations

15 The main strengths of this study are its cluster-randomized experimental design and the 16 measurement of diurnal cortisol levels three times per day to determine secretion patterns. 17 Further, cortisol samples were collected by our research assistants, ensuring that collection 18 procedures such as sampling time were uniform throughout. The study has high ecological 19 validity; it was conducted in community-based child care centers, with early childhood educators 20 whose qualifications were the two-year college program in early childhood and child care 21 education required by the Quebec government (as compared to fully licensed psychologists, 22 teachers, or social workers). Finally, our sample was sufficiently heterogeneous to justify testing 23 family income as a moderator between intervention status and diurnal cortisol secretion.

The study also had some limitations. First, 6% of the children left child care over the course of the study. While for the most part, the family sociodemographic characteristics of newcomers were no different from those who left, we could not statistically control for pre-

1 intervention cortisol secretion in children who joined the study later. Second, we do not know the 2 exact number of workshops animated by child care educators. We only know that 90% of the 3 educators performed 12 or more workshops out of 16 during the year of implementation. Future 4 studies should include comprehensive implementation evaluation. Third, as we did not collect 5 longer-term post-intervention cortisol samples, we did not test whether the reported differences 6 persisted over time. Similarly, we did not test whether the observed decline in cortisol secretion 7 was associated with a lower risk of behavioral difficulties later on. Such investigation would have 8 required additional time points to test this hypothesis according to a clear temporal sequence 9 where the HPA axis would be a mediator between the psychosocial intervention targeting 10 quality child care and disruptive behavior. Replication of this study with long-term follow-up, 11 larger sample size, and different models of child care (center-based vs. home-based) is needed 12 to advance knowledge on the mechanisms linking child care quality to diurnal patterns of 13 cortisol secretion and long-term social and emotional development.

14

## 15 **7. Conclusion**

Our findings suggest that a social skills training program, when integrated into a preschool education curriculum, can foster an environment more conducive to typical childhood patterns of cortisol secretion. Given that child care services cover a critical developmental period during which young children learn to interact in a group setting, this program may be a promising way to ensure and promote health and well-being from an early age.

21

## 22 Acknowledgements

The authors wish to thank Danielle Buch, medical writer, for critical revision and substantive editing of the manuscript. We are grateful to the participants who have given their time to take part in this study.

1	
2	Figure Legends
3	Figure 1. Trial Flow Diagram
4	
5	Figure 2. Post-intervention diurnal cortisol secretion, according to intervention status
6	Abbreviations: AM, morning; PM, afternoon.
7	Note: Post-intervention refers to 8 months after the start of the intervention.
8	
9	Figure 3. Post-intervention diurnal cortisol secretion, according to family income and
10	intervention status
11	Abbreviations: AM, morning; PM, afternoon.
12	Note 1. Post-intervention refers to 8 months after the start of the intervention.
13	Note 2. Cortisol concentration residuals were derived from the three-way interaction between
14	family income, intervention status, and time of day.
15	
16	Supplementary Material
17	Figure S4. Post-intervention diurnal cortisol secretion, according to intervention status and
18	family income
19	Abbreviations: AM, morning; PM, afternoon.
20	Note 1. Post-intervention refers to 8 months after the start of the intervention.
21	Note 2. Cortisol concentration residuals were derived from the three-way interaction between
22	family income, intervention status, and time of day.
23	

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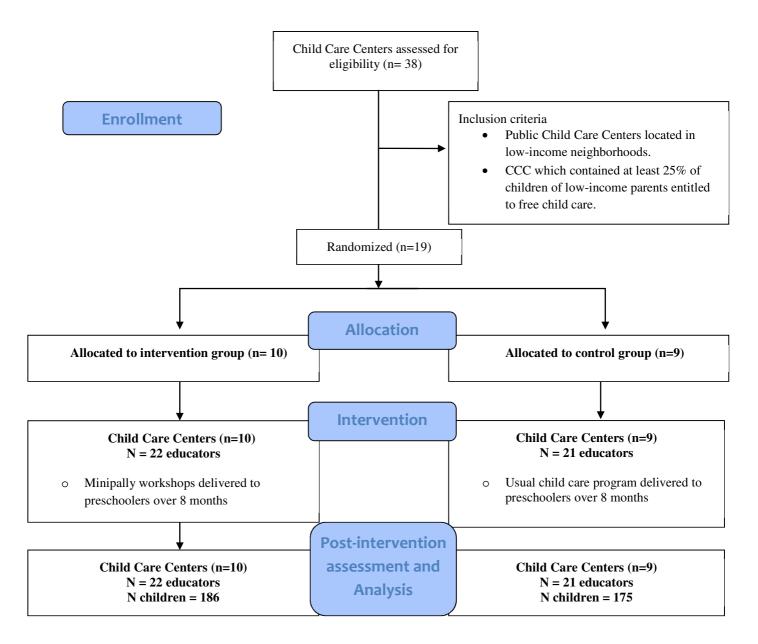
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- 12

# Figure 1. Trial Flow Diagram



	Control group (n = 175)	Intervention group (n = 186)	<i>P</i> value
Age, months <sup>a</sup>	52.8 (5.0)	54.5 (4.5)	< 0.01
0		. ,	
Sex ( <i>boy</i> ) <sup>b</sup>	86 (49.1%)	98 (52.7%)	0.57
	164	165	
Have siblings <sup>b</sup>	128 (78.5%)	143 (86.7%)	0.12
	163	165	
Child care hours/week <sup>b</sup>			
< 30 hours	24 (14.6%)	35 (21.2%)	0.26
30-40 hours	104 (63.4%)	95 (57.6%)	
> 40 hours	36 (22.0%)	35(21.2%)	
	164	165	
Family income <sup>b</sup>			
< Can\$19 999	34 (21.7%)	23 (14.7%)	0.26
Can\$20 000-80 000	69 (43.9%)	71 (45.5%)	
> Can\$80 000	54 (34.4%)	62 (39.7%)	
	157	156	
Highest maternal education <sup>b</sup>			
High school diploma	20 (12.7%)	21 (13.1%)	0.53
Vocational training	49 (31.0%)	48 (30.0%)	
Bachelor's degree	67 (42.4%)	60 (37.5%)	
Master's or PhD	22 (13.9%)	31 (19.4%)	
	158	160	

Table 1. Children's descriptive statistics at baseline

<sup>a</sup> Mean (SD). <sup>b</sup> n (%).

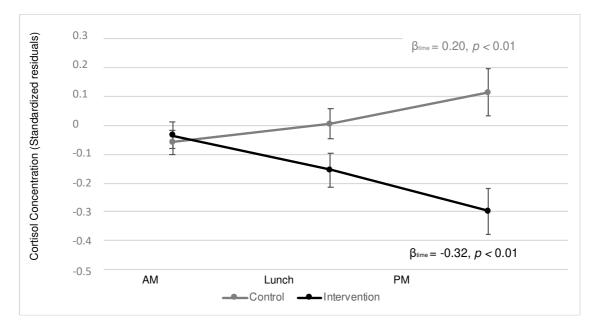


Figure 2. Post-intervention diurnal cortisol secretion, according to intervention status

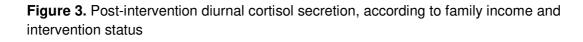
Abbreviations: AM, morning; PM, afternoon.

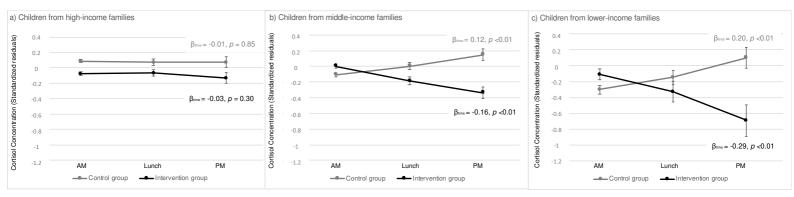
Note: Post-intervention refers to 8 months after the start of the intervention.

	β (95% CI)	P value
Intercept	-0.63 (-1.08, -0.17)	0.01
Pre-intervention cortisol levels	0.18 (0.11, 0.26)	< 0.01
Intervention	0.53 (-0.16, 1.23)	0.13
Time	0.38 (-0.01, 0.76)	0.05
Time x intervention	-0.79 (-1.36, -0.22)	0.01
Income	0.26 (0.06, 0.45)	0.01
Income x intervention	-0.23 (-0.53, 0.07)	0.13
Income x time	-0.14 (-0.30, 0.02)	0.09
Income x intervention x time	0.27 (0.02, 0.51)	0.03

**Table 2.** Post-intervention diurnal cortisol secretion, according to family income and intervention status

Abbreviation: CI, confidence interval.





Abbreviations: AM, morning; PM, afternoon.

Note 1. Post-intervention refers to 8 months after the start of the intervention.

Note 2. Cortisol concentration residuals were derived from the three-way interaction between family income, intervention status, and time of day.