Contact-based Intervention for Infants during Transition to Centre-based Care

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28625

Source
NTR

Brief title
NinO (Nieuw in Opvang)

Health condition

Participants are healthy infants entering centre-based childcare

Sponsors and support

Primary sponsor: Radboud universitair medisch centrum
Source(s) of monetary or material Support: Vici grant received by Prof. dr. Carolina de Weerth

Intervention

Outcome measures

Primary outcome

Infant outcomes
1.1 Infants' cortisol levels
Saliva will be collected at 10h and 16h on at least one day a week. From all infants present more than 1 day, saliva will be sampled twice a week.

1.2 Infants’ gut microbiota
Faecal samples will be taken from the infant’s diaper before the start of CBC, 4 weeks and 8 weeks after the start.

1.3. Infants’ mood, crying and sleeping behaviour at home in the night
Parents keep track of their infants’ sleep and crying at home with an adapted version of the “Parental diary of infant cry and fuss behaviour” (Barr et al., 1988), starting 2 weeks prior to centre-based care until 8 weeks after the start. Parents will fill in the diary daily from 18h until 8 hours the next morning. The diary also includes questions on the infant's mood, care arrangements, health, feeding type, and the use of an infant carrier.

Childcare professionals' outcomes
2.1. Childcare professionals’ cortisol levels
The childcare professional who works most hours a week with the infant will provide a salivary samples on the same days as the infant, at 10h in the morning and 16h in the afternoon.

2.2. Childcare professionals’ mood
All participating childcare professionals of the infant's group will fill in the adapted 3-item scale on affect after the 16h saliva sampling moments. (Vigor and affect scale; Monk, 1989). An additional question addresses the infant’s mood perceived by the childcare professional on that day.

2.2. Childcare professionals’ subjective experience
Qualitative questions on the childcare professionals’ experience with the study, the infant and work in the period of the last 4 weeks; filled in by all childcare professionals of the group after week 4 and week 8.

Parental outcomes
3.1.Parents’ subjective mood
Parents will fill in a shortened version of the “Global vigor and affect scale” (Monk, 1989) daily starting two weeks prior to the start of centre-based care until 8 weeks after the start.

Secondary outcome

Infant
- Demographics and health: Parents will fill in questionnaires on demographics of their infant such as infant age, number of siblings, and questions on the infant’s health.
- Temperament, assessed with the Infant Behaviour Questionnaire-Revised Short Form before the start of CBC and the Very Short Form after week 4 and week 8 of centre-based care (Putnam et al., 2014).
- The buddy will keep track of the infant's sleeping- and crying behaviour, as well as the amount of holding and bottles she provides, by filling in a logbook, based on the Parental cry- and fuss diary (Barr et al., 1988).

Centre-based care
- Group characteristics: In the Netherlands, the groups in childcare are either vertical or

horizontal. Vertical groups consist of children from the age of zero to four and in horizontal groups, children are divided by age, whereby infants go to “baby-groups”. In vertical groups, the care-taker child ratio is lower than in horizontal groups. Infants of both of the group styles can participate in the study. We will take this difference, as well as caretaker-child ratio, into account as moderators.
- Child care worker job stress inventory (translated; Curbow et al., 2000): The professionals of the infants' group will fill this in after week 4.
- Childcare professionals demographics (ie. education, work experience, number of own children)
- Childcare professionals' subjective experience with the infants' transition and the buddy intervention

Parental factors/Care in the first months
Parents fill in the following questionnaires at the beginning of the study:
“Parental Ethnotheories Scale” (Lamm and Keller, 2007), “Maternal Responsiveness Questionnaire” (Leerkes and Qu, 2016), Maternal Separation Anxiety Scale” (Hock et al., 1989), Questions on feeding type, sleeping arrangements (room-sharing/bed-sharing/own room), whether they use a baby carrier, care arrangements, noise of the home environment, demographics (ie. marital status, living arrangements, SES, work and profession), parents' subjective experience with the infants' transition and the buddy intervention

Blinding: At the end of the study, parents will be asked questions to assess whether the blinding was successful (ie. what they think in which group their infant was)

Study description

Background summary

Physical proximity and closeness are crucial for young infants and have been related to decreased cortisol concentrations. At centre-based care (CBC), Dutch childcare professionals have a ratio of 3:1 with infants, and cannot always provide them with optimal attention and closeness. Accordingly, a previous study found increased cortisol concentrations in 3-month-olds during the first weeks at CBC, suggesting that the transition can be stressful. In this project, we will investigate the effectiveness of a stress-reducing intervention during this transition. In a randomised controlled trial, infants are assigned to a care-as-usual (CAU) or an intervention condition. In the intervention condition, they receive additional closeness and attention by a “buddy” throughout the first four weeks at CBC. In both groups, we will monitor stress-related measures, such as cortisol, gut microbiota and behavioural reports. In both groups, behavioural data will be collected starting two weeks before the intervention, during the four weeks of intervention, and for another four weeks after the intervention. Cortisol and gut microbiota will be monitored from the first week at CBC until 8 weeks after the start. We will also assess the effects of the intervention on parents’ and childcare professionals’ subjective well-being and childcare professionals’ cortisol levels. Altogether, this study might lay foundations for a supportsystem that benefits both the infant and the

caregivers.

Study objective

1. Compared to the control group, 4 weeks and 8 weeks after the start of centre-based care infants in the intervention group will show:
- Lower morning and afternoon levels of salivary cortisol
- Less disruption of the gut microbiota and an improved diversity
- Decreased crying and fussing at night and a better mood at nights and in centre-based care
- Increased nightly sleep and less nightly awakenings

2. Childcare staff of the intervention group will show:
- Improved subjective well-being
- Decreased morning and afternoon levels of salivary cortisol
- Childcare staff in the intervention group will report less job related stress after the intervention.

3. Parents of infants in the intervention group will show improved subjective well-being, when compared to infants of the control group.

Potential underlying mechanisms:
Infant temperament, parental upbringing, care of the first months (noise of the home environment and prior care arrangements), and the amount of contact with the buddy mediates the relation of the intervention and infant outcomes.

Study design

Data collection will take place two weeks before the infants' entrance at centre-based care and last until 8 weeks after entrance.

Week -2: Two weeks before the start of centre-based care. Parents and childcare-staff will fill in questionnaires.
Week 1-4: At centre-based care. A buddy will be present for infants in the intervention group
Week 1-8: A faecal sample will be collected in week 1, 4 and 8. Saliva from infants and one childcare staff will be collected once/twice a week (depending on how many days the infant visits centre-based care) at centre-based care at 10 am and 16 pm. Parents fill in the nightly diary on crying and fussing. Parents and childcare staff regularly fill in a short screening on well-being.
Week 8: Childcare staff and parents will fill in questionnaires on their experiences with the project.

Intervention

Intervention
Trained researchers and assistants will be the buddy of infants in the intervention group. Throughout the first four weeks, the buddy will be present in the intervention group from

9.30 am to 16 pm, on every day the infant visits centre-based care. Every infant in the intervention group will have one buddy who is not exchanged throughout the study. Only on occasions when the infant's buddy is not available (e.g. sick), another researcher/assistant can replace the buddy.

Role of the Buddy
Buddies will assist the childcare professionals, providing the infants with closeness and attention during their adaptation to childcare. The buddy will support the infant and, for instance, hold the infant, gently rock the infant, talk and sing, and soothe the infant when needed. The buddy will hold the infant for at least 2 hours a day. In case the infant starts crying, the buddy will pick him/her up for soothing. In case the infant cries in the buddy's arm unsoothably for a longer time, the childcare professional will take over. When brought to bed, if the infant cries in the crib for longer than 2 minutes, or is fussy for longer than 10 minutes, the buddy will try to soothe the infant and pick him/her up if necessary. The buddy can also feed the infant. One bottle a day will always be fed by the childcare professional. The buddy will not take over other caregiving tasks, such as diaper changes. The childcare professional will still be responsible for monitoring the infants' needs and recognising when caregiving tasks are necessary. All buddies will acquire a "Verklaring omtrent gedrag" and be registered in the "personenregister kinderopvang". To ensure consistency across infants, all buddies will be female.

Contacts

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Eligibility criteria

Inclusion criteria

Infants participating in this study will be included if they:
o are between 1 and 5 months old at entrance to centre-based care.
o arrive at centre-based care no later than 10 am and stay there at least until 4 pm on at

least one day a week.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation:
o Infants of parents younger than 18 years old
o Infants of parents not fluent in Dutch (since many questionnaires are only available in Dutch)
o Infants with severe congenital anomalies
o Infants with severe health issues
o Infants born before gestational week 37

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-04-2021
Enrollment:	56
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9276
Other	CMO region Arnhem-Nijmegen : 2020-7230

Study results

Summary results
Planned