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

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Ethische beoordeling	Niet van toepassing
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28625

Bron
NTR

Verkorte titel
NinO (Nieuw in Opvang)

Aandoening

Participants are healthy infants entering centre-based childcare

Ondersteuning

Primaire sponsor: Radboud universitair medisch centrum
Overige ondersteuning: Vici grant received by Prof. dr. Carolina de Weerth

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Radboudumc
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Wetenschappelijk

Radboudumc

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	56
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

Planned