# Thuis in de opvang: Een fijne start voor baby's

No registrations found.

| Ethical review        | Positive opinion    |
|-----------------------|---------------------|
| Status                | Recruitment stopped |
| Health condition type | -                   |
| Study type            | Interventional      |

## **Summary**

## ID

NL-OMON20981

**Source** Nationaal Trial Register

Brief title TBA

#### **Health condition**

stress regulation of infant's and their parents during the transition to child care

## **Sponsors and support**

**Primary sponsor:** The Institute of Education and Child Studies of the Faculty of Social and Behavioral Sciences at Leiden University **Source(s) of monetary or material Support:** ZonMW (544001004)

### Intervention

### **Outcome measures**

#### **Primary outcome**

- Caregiver sensitivity towards the infant (observed)
- Caregiver attitudes towards sensitive caregiving (questionnaire)
- Attachment security to the caregiver (observed)
- (the change in) cortisol levels of the infant across the day

- Infant well-being (observation and questionnaire)

#### Secondary outcome

- Caregiver sensitivity in the group setting (observed)
- Separation anxiety of the primary parent (questionnaire)

- Quality of care provided by the caregiver at child care as perceived by the primary parent (questionnaire)

## **Study description**

### **Background summary**

The transition to child care is a major step for children and their parents. Children need to get used to a group environment and new people taking care of them, which can be emotionally challenging. This is reflected in elevated cortisol levels, indicating more stress, when children are at child care compared to home. Young children, and in particular infants, are not yet able to cope with stress and regulate emotions on their own. They need help from adults. Therefore, rises in children's cortisol levels may be buffered by caregiver sensitivity. Sensitivity refers to the ability to perceive infant signals, to interpret these signals correctly, and to respond to these signals promptly and appropriately. Highly sensitive caregivers are better able to co-regulate children's emotions and to help them deal with stress. In addition, research showed that caregiver sensitivity is the most important predictor of attachment security and that children with secure attachments to caregivers are more likely to exhibit the expected decline in cortisol levels across the child care day than insecurely attached children. In the current study, we test the effectiveness of a video training for professional caregivers, which aims to ease the transition to child care by enhancing caregiver sensitivity (both attitudes and behavior). The goal is to lower children's cortisol reactivity to child care, increase their level of well-being and promote attachment security to the caregiver. We will target professional caregivers who are the mentor of a firstborn infant starting child care in the first half year of life. Half of the caregivers will receive the video training shortly after the start of the target child in child care, whereas the other half will receive a 'dummy' intervention consisting of phone calls. Furthermore, we will investigate whether possible intervention effects are moderated by characteristics of the child (temperament, gender, age), caregiver (age, ethnicity, educational level, experience) or group (size, caregiver-child ratio) and the quality of care at home. We will also study the sensitivity of the professional caregiver towards the group as a whole, to test whether or not the intervention has a carryover effect. Although it is often argued that the start of child care is not only an emotionally arousing period for children but also for parents, research into the experiences of parents during this transition period is scarce. Therefore, a secondary aim of this study is to investigate (anticipated) parental separation anxiety associated with their child starting in child care. We will involve the primary parent in the first session of the (dummy) intervention and test if the intervention has a positive effect on parent's separation anxiety and on the perceived quality of care by the caregiver at child care.

#### **Study objective**

The intervention will result in:

- higher observed sensitivity and more positive attitudes towards sensitive caregiving in professional caregivers

- lower cortisol levels, higher wellbeing and more attachment security in infants
- less separation anxiety and a more positive perception of child care quality in parents

#### Study design

- T1: baseline assessment at home
- T2: pretest at the child care center
- T3: posttest at the child care center
- T4: follow-up at the child care center

#### Intervention

In the current study, we test the effectiveness of the Video-feedback Intervention to promote Positive Parenting – Transition to Infant Child Care (VIPP-TICC). This protocolized intervention is an adaptation of the evidence based Video-feedback Intervention to promote Positive Parenting and Sensitive Discipline (VIPP-SD; Juffer, Bakermans-Kranenburg, & Van IJzendoorn, 2016). The intervention consists of 6 visits of approximately 2 hours with the caregiver at the child care center. Each visit starts with a recording session of the interaction between the target child and his/her caregiver. After filming, the recordings of the previous visit are viewed and discussed with the caregiver by a trained intervener. We will work on the caregivers observational skills, their capacity to empathize with children, their knowledge about the upbringing and development of young children and their sensitive responsiveness in reaction to children's signals. Basic principles of the intervention are creating a positive atmosphere and emphasizing and reinforcing positive interactions between the caregiver and the infant. During the first visit we will invite the parent to the child care center to discuss a recording of themselves in interaction with the child at home together with the intervener and the caregiver. The aim of this discussion is to give the caregiver more information about the child and what he/she is used to with regard to care at home. This information might help caregivers to ease the transition from home to child care and to attune their caregiving to this specific child. Furthermore, caregivers are able to inform the parent about their experiences with the child at child care which may reassure the parent about the care provided to their baby. Caregivers in the 'dummy-intervention' group (= control group) will receive protocolized phone calls and will be asked guestions about the transition process and general development of the target child. The professional caregiver will be contacted six times, and the primary parent of the child once. This dummy-intervention will be administered to ensure that the same level of attention is given to caregivers in the intervention and control group. Caregivers in the control group do not receive any specific information or advice about child development or sensitive caregiving.

## Contacts

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## **Eligibility criteria**

## **Inclusion criteria**

Infants:

- less than 6 months old when they start center based child care
- attend child care at least one full day per week
- firstborn

Caregivers and primary parents:

- able to communicate in Dutch

## **Exclusion criteria**

Infants:

- born premature (< 37 weeks)
- birth weight less than 2500 grams

## Study design

## Design

Study type: Intervention model: Interventional Parallel

| Allocation: | Randomized controlled trial   |
|-------------|-------------------------------|
| Masking:    | Single blinded (masking used) |
| Control:    | Placebo                       |

### Recruitment

MI

| Recruitment status:       | Recruitment stopped |
|---------------------------|---------------------|
| Start date (anticipated): | 01-09-2018          |
| Enrollment:               | 100                 |
| Туре:                     | Actual              |
|                           |                     |

### **IPD** sharing statement

Plan to share IPD: No

## **Ethics review**

| Positive opinion  |                  |
|-------------------|------------------|
| Date:             | 08-04-2019       |
| Application type: | First submission |

## **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** NTR-new Other **ID** NL7647 ECPW : ECPW-2018/220

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## **Study results**