# A parenting support intervention on preventing parental distress.

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| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON24862

**Bron**
Nationaal Trial Register

**Verkorte titel**
A parenting support intervention on preventing parental distress

**Aandoening**

Parenting stress / Stress related to the parenting role

Ouderschapsstress / Stress gerelateerd aan de ouderrol

### Ondersteuning

**Primaire sponsor:** Vrije Universiteit Amsterdam
**Overige ondersteuning:** NWO

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The primary outcome of the study will be parenting stress.

# Toelichting onderzoek

### Achtergrond van het onderzoek

The first months after birth can be challenging for parents and affect well-being. This might lead to high parental stress and to other negative outcomes for the parents (e.g. to postpartum depressive symptoms). Parents with high levels of parental stress are also less able to respond adequately and sensitively to their infant. This might lead to less secure attachment bonds and to less than optimal infant (brain) development. Effective interventions to reduce parental stress are available but until now only used for high-risk groups. Furthermore, those interventions focus exclusively on the mother. This study focuses on a parenting support intervention consisting of psycho-education and practical tools. This intervention is aimed at reducing parental stress for both parents.

The primary objective is to assess the effect of the parenting support intervention on parental stress. Secondary objectives are the effect of the intervention on other parental outcomes (anxiety and depression, satisfaction with the parental role, self-efficacy in caring for their infant), caregiving outcomes (bonding, duration of breastfeeding and co-sleeping) and on infant well-being (indicated by their patterns of crying and sleeping behaviour and the infant’s health).

This study is a randomized controlled intervention study. Random allocation will take place at the individual level on a 1:1 ratio to either the intervention or a wait-list control group. Participants are randomized using random sequence block randomization (blocks of 2, 4 or 6), stratified by birth order of their child (first or second) and participation of the father (participate/not participate). Due to the nature and design of the study, blinding of the researchers or participants is not possible.

The study population will be pregnant women expecting their first or second child. Their partners will also be asked to participate. Women will be recruited through midwife practices and media. Women with a complicated pregnancy, current psychopathology, insufficient Dutch language proficiency and without access to the Internet will be excluded. Women need to be recruited before the 34th week of pregnancy.

The parenting support intervention is based on the work of Hiscock et al (2014) about infant sleeping and crying patterns which has proven to be effective on parents' and infants' health. We add information about how to respond to signals of distress which is essential for the bonding process. The intervention will be introduced prenatally, between the 34th and the 36th week of pregnancy. Parents will receive a booklet and access to an online video. During a subsequent prenatal home visit, parents will receive further explanation about the materials and how to implement the tools provided. Also, they are given the opportunity to ask questions. Parents will receive a phone call 4 weeks after birth, to ask how they are doing and to further support them with implementing the intervention.

**Doel van het onderzoek**

The primary objective is to assess the effect of the parenting support intervention on parental stress. Secondary objectives are the effect of the intervention on other parental outcomes (anxiety and depression, satisfaction with the parental role, self-efficacy in caring for their infant), caregiving outcomes (bonding, duration of breastfeeding and co-sleeping) and on infant well-being (indicated by their patterns of crying and sleeping behaviour and the infant's health).

We expect that the proposed intervention enhances parental well-being and reduces parental stress. By psychoeducating the parents during pregnancy, we expect parents to experience less distress and more self-efficacy in fulfilling this role and to experience less sleeping, crying and feeding problems of their infant. We expect that the quality of bonding will be higher, and breastfeeding and co-sleeping duration will be longer. In turn, we expect that the intervention has beneficial effects on infant's levels of distress, as indicated by less crying and better sleeping; less parent-reported problems with sleeping, crying and feeding; and less health complaints.

**Onderzoeksopzet**

- Baseline (t0; 26-34 weeks of pregnancy): parenting stress and satisfaction; parental self-efficacy; parent-child bonding; depression; anxiety; parental attachment style; marital satisfaction.

- Home visit (t1; 34-36 weeks of pregnancy): parenting stress and satisfaction; parental self-efficacy; anxiety; depression.

- 2 weeks after birth (t1): delivery characteristics

- 6 weeks after birth (t2): parenting stress and satisfaction; parental self-efficacy; anxiety; depression; quality and quantity of the parent's sleep; patterns of crying/feeding/sleeping; problematic crying/feeding/sleeping; health complaints.

- 10 weeks after birth (t4):
parenting stress and satisfaction; parental self-efficacy; parent-child bonding; depression; anxiety; marital satisfaction; problematic crying/feeding/sleeping; health complaints; number of weeks breastfeeding/co-sleeping; infant length and weight; adherence to/satisfaction with the intervention.

**Onderzoeksproduct en/of interventie**

The study consists of a randomized controlled trial with two conditions:

1)The intervention condition, in which parents receive psycho-education and guidance for practice with regard to infant sleeping, crying, feeding and parent-infant bonding prenatally, through a booklet and videos and through a home visit between 34 and 36 weeks of pregnancy and a phone call at 4 weeks postpartum. The booklet and the videos will contain practical information for parents which can be implemented postnatally.

2)A wait-list control condition, in which parents receive care as usual (information about bonding is given by midwifes and by specialized nurses). Participants of the control group will gain access to the intervention 10 weeks after the birth of their child (after the last assessment).

# Contactpersonen

## Publiek

De Boelelaan 1105

Marjolein Missler
Amsterdam 1081 HV
The Netherlands
+31 20 59 82589

### Wetenschappelijk

De Boelelaan 1105

Marjolein Missler
Amsterdam 1081 HV
The Netherlands
+31 20 59 82589

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Women expecting their first or second child

- Uncomplicated pregnancy

- Sufficient Dutch language proficiency (to understand the information in the booklet and on the website)

- Access to a computer and the internet

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Current psychopathology (defined as current treatment for psychopathology or treatment in the 6 months before
inclusion)

- Insufficient Dutch language proficiency

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |

| | |
|---|---|
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-10-2016 |
| Aantal proefpersonen: | 128 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 13-09-2016 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43052
Bron: ToetsingOnline
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL5782 |
| NTR-old | NTR6065 |
| CCMO | NL58528.028.16 |
| OMON | NL-OMON43052 |

# Resultaten

**Samenvatting resultaten**
nvt