

NL: Huid-op-huid contact tussen moeders en hun voldragen baby's

EN: Skin-to-skin contact in mothers and their full-term infants

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Compared to the control group, mother-infant dyads who practice at least one daily and continuous hour of skin-to-skin contact for the first five weeks after birth will show: Improved maternal outcomes 1. Mental health: 1.1 lower levels of...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22220

Bron

NTR

Verkorte titel

/

Aandoening

Mothers who just gave birth to their child.

Ondersteuning

Primaire sponsor: Radboud University and the Behavioural Science Institute

Overige ondersteuning: Radboud University and the Behavioural Science Institute

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Maternal outcomes

1. Mental health:

1.1 Depressive symptoms: Edinburgh Postnatal Depression Scale (EPDS) at week 2, week 5, week 12, and year 1

Toelichting onderzoek

Achtergrond van het onderzoek

Twenty-to-forty percent of women experience postpartum depressive symptoms, which can affect both the mother and infant. In preterm infants, daily skin-to-skin contact (SSC) between the mother and her infant has been shown to decrease maternal postpartum depressive symptoms. In full-term infants, only two studies investigated SSC effects on maternal depressive symptoms and found similar results. Furthermore, the studies in preterm infants also showed that SSC improves other mental and physical health outcomes of the mother as well as the infant, and improves the quality of mother-infant interactions. One may hypothesize that also in full-term infants, SSC may have additional positive effects for both the mother and infant. This randomized controlled trial will be the first to investigate the effects of a SSC intervention on postpartum maternal depressive symptoms and additional outcomes in mothers and their full-term infants. Additionally, two potential underlying mechanisms will be examined, namely maternal oxytocin concentrations and infant intestinal microbiota. This study provides important information for the development of a feasible, accessible, simple, and cost-effective prevention and (complementary) intervention method that may benefit both the mother and the full-term infant in the short-term and long-term.

Doel van het onderzoek

Compared to the control group, mother-infant dyads who practice at least one daily and continuous hour of skin-to-skin contact for the first five weeks after birth will show:

Improved maternal outcomes

1. Mental health:

1.1 lower levels of depressive symptoms (primary outcome);

1.2 lower levels of anxiety;

1.3 lower levels of stress;

- 1.4 lower levels of traumatic stress related to the delivery;
- 1.5 better sleep quality.

2. Physical health:

- 2.1 better physical recovery from to the delivery;
- 2.2 better health (less illnesses and health problems);
- 2.3 more frequent and a longer duration of breastfeeding;
- 2.4 lower levels of physiological stress.

3. Mother-infant relationship:

- 3.1 better bonding to the infant;
- 3.2 better quality of maternal caregiving behavior.

Improved infant outcomes

1. Behavior:

- 1.1 lower amounts of daily fussing and crying;
- 1.2 better sleep quality.

2. Physical health:

- 2.1 better growth and health (less illnesses and health problems);
- 2.2 lower levels of physiological stress.

3. General development:

- 3.1 better regulation capacities;
- 3.1 better social-emotional capacities;
- 3.3 better language, cognitive, and motor capacities.

Potential underlying mechanisms:

- 1.1 higher levels of maternal oxytocin concentrations. Maternal oxytocin concentrations will mediate the relationship between skin-to-skin contact and maternal outcomes.
- 1.2 better infant intestinal microbiota (i.e. faster developing, more diverse, and stable microbiota, fewer potentially pathogenic bacteria). Infant intestinal microbiota will mediate the relationship between skin-to-skin contact and infant outcomes.

Onderzoeksopzet

Prenatal phase:

T0: one day between week 34 and week 36 in pregnancy

Postnatal phase:

T1: 2 weeks after birth

T2: 5 weeks after birth

T3: 12 weeks after birth

T4: 1 year after birth

Skin-to-skin contact will be noted every day between the day of birth and week 5, and will be noted on a weekly basis from week 5 until week 12. Breastfeeding and sleep will be noted every week between the day of birth and week 12.

Onderzoeksproduct en/of interventie

Mothers in the skin-to-skin contact condition will be requested and encouraged to provide at least one daily and continuous hour of skin-to-skin contact to their infant for the first 5-weeks after birth. The control group will not be requested and encouraged to provide daily skin-to-skin contact to their infant. Both groups will fill out the same logbooks and questionnaires, will collect the same samples and will perform the same tasks.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Mothers who just gave birth to their child;
2. Aged ≥ 18 ;
3. Singleton pregnancy;
4. Infant born at ≥ 37 weeks of pregnancy;
5. Infant birth weight ≥ 2500 gram;
6. Infant ≥ 7 5-min Apgar score.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Drug use during pregnancy;
2. Severe maternal physical or mental health problems;
3. Insufficient understanding of Dutch;
4. Congenital anomalies.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2016
Aantal proefpersonen:	116
Type:	Verwachte startdatum

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	NL5591
NTR-old	NTR5697
Ander register Ethics Committee Social Sciences; Radboud University : ECSW2015-2311-358	

Resultaten

Samenvatting resultaten

Planned