

# The efficacy of swaddling in infants who cry excessively; a randomized controlled trial.

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We compared two interventions: behavioral modification of baby care through regularity and stimuli reduction, which has been shown effective in one controlled study, and the same approach supported with swaddling during all sleeping periods. Our...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON27533

### Bron

Nationaal Trial Register

### Verkorte titel

N/A

### Aandoening

Excessive crying infants.

## Ondersteuning

**Primaire sponsor:** prof. dr. W. Kuis

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**Overige ondersteuning:** The Netherlands Organization for Health Research and Development funded this trial, Frisocare provided hypoallergenic formula and Weleda Nederland NV provided the swaddling cloths.

# Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

During the first days of intervention the behavioral approach caused an increase in crying. <br>After several days this effect disappeared and crying decreased rapidly in all subgroups. Swaddling on the other hand, showed an immediate positive effect on crying. <br>After 7 days both groups did not differ until the end of intervention. Crying decreased in both groups after the first intervention week with 42%. Therefore, swaddling has no added benefit in reducing crying in the total group. <br>However, when stratified by age different strategies had significantly different effect. <br>- Young infants (aged 1-7 weeks at randomization) benefit significantly more from swaddling as shown by a larger decrease of crying and larger increase in sleep time. <br>- Older infants (8-13 weeks at randomization) showed a significantly greater decrease in crying when not swaddled, but only offered stimuli reduction and regulation in baby care.

## Toelichting onderzoek

### Achtergrond van het onderzoek

Excessive crying occurs in 5-15% of Dutch infants. Recent research showed that more than 5% of parents of young infants are driven to seriously dangerous behavior such as shaking by the excessive crying of their infant.

Many interventions can be launched to reduce crying, but in the Netherlands no unambiguous strategy is used. Swaddling could be an effective method to reduce excessive crying, but it has never been systematically investigated.

One controlled study showed effect of a behavioral intervention consisting of stimuli reduction and regularity in babycare.

We conducted a randomized trial using a standardized approach of regularity and stimulus reduction compared to a group receiving the same, supplemented with swaddling.

### Doel van het onderzoek

We compared two interventions: behavioral modification of baby care through regularity and stimuli reduction, which has been shown effective in one controlled study, and the same approach supported with swaddling during all sleeping periods. Our conclusion will be based on if there is any added effect of swaddling.

### Onderzoeksopzet

N/A

## Onderzoeksproduct en/of interventie

A standardized approach which consists of offering regularity and stimulus reduction was compared with an experimental group which received the same approach, supplemented with swaddling.

Specially trained health care nurses guided the parent-infant couples for a period of three months.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

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

Clinically healthy infants in the age of 0-12 weeks and 6 days who cry excessively, who have no (increased) risk for developmental hip dysplasia.

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

Clinically non-healthy infants or infants with a physical explanation for the excessive crying, infants older than 12 weeks and 6 days, infants born before 32 weeks of gestational age, infants with a(n) (increased) risk for developmental hip dysplasia.

## Onderzoeksopzet

### Opzet

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

### Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2001
Aantal proefpersonen:	398
Type:	Werkelijke startdatum

## Ethische beoordeling

Positief advies	
Datum:	08-09-2005
Soort:	Eerste indiening

## 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	NL241
NTR-old	NTR279
Ander register	: ZonMW registration number 2100.0061
ISRCTN	ISRCTN18400679

## Resultaten

### Samenvatting resultaten

J Pediatr. 2006 Oct;149(4):512-7.