

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27533

### Source

NTR

### Brief title

N/A

### Health condition

Excessive crying infants.

## Sponsors and support

**Primary sponsor:** prof. dr. W. Kuis  
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**Source(s) of monetary or material Support:** The Netherlands Organization for Health Research and Development funded this trial, Frisocare provided hypoallergenic formula and Weleda Nederland NV provided the swaddling cloths.

## Intervention

## Outcome measures

### Primary outcome

During the first days of intervention the behavioral approach caused an increase in crying. 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. 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. However, when stratified by age different strategies had significantly different effect.

- 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.
- 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.

### Secondary outcome

N/A

## Study description

### Background summary

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 baby care.

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

### Study objective

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.

### Study design

N/A

## **Intervention**

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.

## **Contacts**

### **Public**

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## **Eligibility criteria**

### **Inclusion criteria**

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.

### **Exclusion criteria**

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.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2001
Enrollment:	398
Type:	Actual

## Ethics review

Positive opinion	
Date:	08-09-2005
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	ID
NTR-new	NL241
NTR-old	NTR279
Other	: ZonMW registration number 2100.0061
ISRCTN	ISRCTN18400679

## Study results

### Summary results

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