

The efficacy of swaddling in infants who cry excessively: a randomised controlled trial

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/11/2008	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZonMW: 2100.0061; NTR279

Study information

Scientific Title

Study objectives

We compared two interventions: behavioural 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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre, randomised, single-blind, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Excessive crying, infants

Interventions

A standardised 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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

During the first days of intervention the behavioural 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 randomisation) 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 randomisation) showed a significantly greater decrease in crying when not swaddled, but only offered stimuli reduction and regulation in baby care.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/02/2001

Completion date

01/08/2004

Eligibility

Key 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.

Participant type(s)

Patient

Age group

Child

Upper age limit

12 Weeks

Sex

Both

Target number of participants

398

Key exclusion criteria

1. Clinically non-healthy infants or infants with a physical explanation for the excessive crying
2. Infants older than 12 weeks and 6 days
3. Infants born before 32 weeks of gestational age
4. Infants with an increased risk for developmental hip dysplasia

Date of first enrolment

01/02/2001

Date of final enrolment

01/08/2004

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Utrecht

Utrecht

Netherlands

3508 AN

Sponsor information

Organisation

Sponsor not defined (The Netherlands)

Sponsor details

-

-

Netherlands

-

Sponsor type

Not defined

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration