

COMPARISON OF BEHAVIOR MODIFICATION WITH AND WITHOUT SWADDLING AS INTERVENTIONS FOR EXCESSIVE CRYING

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Objective To test the hypothesis that swaddling is an effective method to reduce crying, we compared a standardized approach of regularity and stimulus reduction with the same approach supplemented with swaddling.

Study design Healthcare nurses coached 398 excessively crying infants up to 12 weeks of age for 3 months. Outcome measurements were crying as measured by Barr's 24-hour diary and parental perception of crying.

Results Crying decreased by 42% in both groups after the first intervention week. Swaddling had no added benefit in the total group. Young infants (1-7 weeks of age at randomization) benefited significantly more from swaddling as shown by a larger decrease of crying over the total intervention period. Older infants (8-13 weeks of age at randomization) showed a significantly greater decrease in crying when offered the standardized approach without swaddling. The actual difference in crying time was 10 minutes.

Conclusion For older babies, swaddling did not bring any benefit when added to regularity and stimuli reduction in baby care, although swaddling was a beneficial supplementation in excessively crying infants <8 weeks of age. (*J Pediatr* 2006;149:512-7)

Excessive crying, defined as crying for more than 3 hours a day for at least one day in the preceding week, occurred in 13% and 8.6% respectively in two large Dutch prevalence studies in 1999¹ and 2003 (unpublished data). Wessel et al's definition² of excessive crying, namely more than 3 hours on at least 3 days of the 3 previous weeks, occurred in 2% and 2.5% of the cases. In the Netherlands 22% of parents consult a well-baby clinic doctor for excessive crying.¹ Excessive crying elicits risky behavior in caregivers: In the Netherlands half of the 7% of parents who place their infant prone to sleep do so because their infant cries excessively or sleeps restlessly. Other consequences of excessive crying may be breast-feeding failure, attachment problems, marital stress, and postpartum depression.³ In a recent Dutch study, 5.6% of parents of infants 6 months of age reported having smothered, slapped, or shaken their baby at least once because of its crying.⁴ In 80% of the cases of child battering, excessive crying precedes the beating and inconsolable crying is a trigger event for shaking.^{5,6}

Most parents, as a reaction to the crying of their infant, start carrying it, thus adding stimuli. In a randomized controlled trial such carrying has been shown to be ineffective.⁷ Instead of placing the tired infant in bed while awake, the infant falls asleep in the arms of the parent. Thus parents get more and more entangled in the sleeping practices of their child, while the child does not learn to fall asleep by itself.⁸ Through lack of evidence-based interventions, primary healthcare workers offer various coping strategies to parents. Swaddling has rapidly become perceived as effective, not only by parents but also by primary healthcare workers. The introduction of yet another new intervention without scientific proof of efficacy led to this study.

We compared two interventions: behavioral modification of baby care supporting regularity and stimuli reduction, which has been shown to be effective in one controlled study,⁹ and the same behavioral modification supplemented with swaddling during all sleeping periods.⁸

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R	Regularity	(t ₀)	One of two interventions
RS	Regularity and swaddling		

METHODS

Design

Targeted for ascertainment were parents of 400 excessively crying infants. The intervention considered as potentially effective, namely advice concerning stimuli reduction and regularity in infant care, was offered to 200 parent-infant couples (regularity, R), whereas 200 parent-infant couples received the same advice, but their infant was also swaddled during all sleeping periods (regularity and swaddling, RS).⁸⁻¹⁰

A standardized case definition with the most commonly used modified Wessel et al's criteria of excessive crying (ie, crying for more than 3 hours/24 hours for at least 3 days a week) was used for recruitment.² The perception of the parents and/or doctors about the amount of crying was decisive for participation. The actual frequency and duration of crying was established later in a 24-hour diary.¹¹

In a baseline week, all infants received a hypoallergenic diet, either hypoallergenic formula or a hypoallergenic diet for breast-feeding mothers, to exclude infants with a possible cow's milk allergy.

After this baseline week, blinded randomization by telephone through an independent computerized center divided the participants into one of the two groups; all parents received instruction about regularity and stimuli reduction and half of the parents were also taught to swaddle their infants during sleep. Stratification occurred on (1) area (Utrecht, The Hague, Arnhem, and Raalte/Zwolle); (2) age (older or younger than 7 weeks); and (3) amount of crying as assessed by the parents (more or less than 5 hours/24 hours). Before randomization, the parents were asked for their intervention preference to assess the influence of preference on outcome. The Medical Ethical Committee of the University Medical Center Utrecht approved the study. All parents gave informed consent.

Selection

Infants were referred from February 2001 to March 2003 by well-baby clinics, general practitioners, children's hospitals, or self-referral. Inclusion criteria were healthy infants with a maximum age of 12 weeks and 6 days and a minimal gestational age of 32 weeks who cried excessively according to their parents, doctor, or healthcare worker. Children with a risk for developmental dysplasia of the hip by familial predisposition or breech position during the last month of pregnancy were excluded. Attending physicians of all participating infants filled out a form declaring normal hip function at physical examination.

Intervention

All infant-parent couples visited a specially trained healthcare nurse at one of the four locations. The consultation process, frequencies, and content as well as the method of swaddling used in this research are described by Blom et al.⁸ Parents were given a written outline of the study and filled

out a questionnaire. The nurse instructed the parents to use a 24-hour diary for 7 days, starting that day.¹¹ All infants were put on a hypoallergenic diet (hypoallergenic formula or, in case of breast-feeding, a maternal diet free of milk, egg, wheat, and nut products). The project manager had a 15-minute supervision call at day 3 to verify the proper use of the 24-hour diary and the hypoallergenic diet and to check that all concomitant interventions had been stopped.

After the baseline week the parents made their second visit. If the crying had been reduced to <2 hours/24 hours from day 3/4 of the baseline week onward and/or the parents perceived no more excessive crying, the infants were excluded. For all other infants the hypoallergenic diet was stopped, and the infant was randomly assigned to start of intervention (t_0).³

The behavioral intervention applied to both groups is based on earlier work,⁸⁻¹⁰ and consists of a recurrent pattern of baby care, which provides structure and regularity without being rigid or inflexible. Parents applied a sequence of (1) sleeping; (2) feeding; (3) positive interaction with baby; and (4) awake time of baby alone in a playpen. Parents were instructed to watch for signs of tiredness of the baby while in the playpen. When tired, the baby was put to bed and tucked in tightly with sheet and blankets, after which a new cycle started. Essential is the repetitiveness of the elements, feeding the infant directly after waking (with an assumption that a well-rested baby is able to drink effectively) and not feeding to stop crying, and after playing alone putting the child to bed sleepy but awake. The detailed instructions were also given to parents in writing. The RS-group was given identical instructions but additionally was taught to swaddle their infant during each sleeping period. The RS-group was given the same written instructions augmented with details on how and when to swaddle the child.⁸ The infant was swaddled by wrapping it in two rectangular cloths. Shoulders and arms are wrapped tightly; from the hip down the wrapping was less tight, allowing for leg flexion and abduction.

Parents had to continue with the 24-hour diary on t_0 for a second run of 7 days.¹¹ On day 2 and 5 after randomization the nurse made a 15-minute supportive call. One week after randomization the parents had their third visit. In a 30-minute appointment the nurse asked about the progress the parents had made and answered questions. After the first intervention week parents filled out the 24-hour diary on one fixed day a week. The project manager had a 30-minute supervision-call at week 5 and week 13 after inclusion, and the nurse had a 30-minute supportive call at week 9. In the call at week 5, in case of lack of effect perceived by the project manager and the parents, parents were offered the possibility to switch to the other intervention group. Before this supervision call parents were not informed about the possibility to change intervention.

Measurements Obtained during the First Visit

Parents recorded infant behavior continuously in a 24-hour diary.¹¹ Maternal perception of infant crying and quality of the cry were recorded three times during the 12 weeks of

the trial in the Cry Perception Scale¹²; twice during the baseline week, to assess reliability, and once at week 12.

Furthermore, medical and psychological measures were obtained to assess their influence, as their effect on infant crying needs further explanation.¹³⁻¹⁹

Statistical Analysis

All data were entered and analyzed in the Statistical Package for the Social Sciences for Windows 12.0 (SPSS Inc., Chicago, Ill.), Statistical Package of Social Science 2.0 (The R Foundation for Statistical Computing, Vienna University of Technology, Vienna, Austria), and MIXOR 2.0 (Discerning Systems Inc., Burnaby, Canada). T-tests, Pearson's χ^2 tests, repeated measures analyses, Mann-Whitney *U* tests, and Analysis of Variance were used to analyze the demographic data and the Cry Perception Scale. Linear mixed models were used to account for dependencies within subjects in time, where response is adjusted by the covariate baseline. In case of non-normal distributed errors, logarithmic transformation was applied to achieve better fit. The analysis was split: We first investigated whether the odds of crying was different for the treatments using the binary logistic model for longitudinal data, and then, given that a child cried, the amount of crying was modeled in time (MIXOR 2.0, Discerning Systems Inc., Burnaby, Canada).

Following the principle of intention to treat, the children who changed treatment after week 5 were analyzed in the group to which they were assigned at t_0 .

Cry Features

From the diary we calculated the total and mean duration of crying, fussing, sleeping, being awake alone and content, playing with the baby, feeding, caring and crying/fussing (minutes/24 hours [SD]). Excessive crying was defined as crying ≥ 180 minutes/24 hours in the baseline week. In a linear mixed-effects model, the differences in the group slopes of the two curves of crying, fussing, and crying/fussing were analyzed. For the baseline as well as the first week of intervention the mean of the daily diaries was used; for the long-term effect the data from the fixed day of the week were used. At first, the effect of age (groups), intervention (groups), and time on crying were analyzed. These analyses were repeated with covariates.

Cry Perception Features

With repeated measurement analyses differences in scores between the baseline week and week 12 as well as differences in scores of the swaddling and regularity group were obtained from the Cry Perception Scale.¹²

RESULTS

Response

In the study 504 infants were ascertained of whom 496 were included (Figure 1; available at www.jpeds.com). After

the baseline week with the hypoallergenic diet 47 infants (9.5%) were excluded because the parents or nurse observed that the crying was not perceived as excessive or respectively was < 2 hours/24 hours from day 3/4 of the baseline week onward (average crying at day 3-7: 89.48 minutes/24 hours). Fifty-one parents (10.3%) decided to stop participation. Finally, 398 infants (80.2%) were included. After randomization another 16 parents (4%) quit and after 4 intervention weeks two parents in the swaddled group stopped swaddling and 16 in the regularity group started swaddling.

Demographic Characteristics

Demographic factors were determined from questionnaires (Table I; available at www.jpeds.com). First-born infants were overrepresented (56% vs 45.8% in the Dutch population).²⁰ There were no differences in demographic factors except for paternal age ($P = .006$). Compared with the Dutch population, mothers lived together with partner and infant(s) more often (96% vs 82.8%) and smoked less at time of inclusion (16.6% vs 29.3%).^{7,20}

Cry Measurements

The mean duration of crying and fussing as calculated from the diaries in the baseline week was 4.37 hours/24 hours (SD 1.79), crying was 2.47 hours/24 hours (SD 1.38), and fussing was 1.90 hours/24 hours (SD 1.14). At t_0 parents reported a mean duration of crying of 5.76 hours/24 hours (SD 3.31). Of all infants whose parents reported that their infant cried more than 3 hours a day, 32.3% actually did so according to the diary. At t_0 there was no significant difference in crying, fussing, crying/fussing, and sleeping between the two intervention groups.

The reduction in crying in the total group after the first intervention week was 62.1 minutes/24 hours (41.9%) and after 2 weeks 70.7 minutes/24 hours (49.5%). At week 8, stabilizing up to the end of the intervention period, the infants cried 36.4 minutes/24 hours, which is a 75% reduction compared with the amount of crying during the baseline.

During the first week of intervention the amount of crying differed between both study groups. In the R-group, the amount of crying increased by 20 to 25 minutes on the first day, and then, on the following days decreased by about 11 minutes. In contrast, in the RS-group on the first day the amount of crying decreased by 30 to 40 minutes (Figure 2). After 7 days there was no significant difference (Mann-Whitney *U* test).

In the whole study group, there was no significant difference in decrease of crying between the R- and the RS-group in the total intervention period (Table II). However, the success of the two interventions differed with age: Infants 1 to 7 weeks of age at randomization benefited significantly more from being swaddled, whereas infants 8 to 13 weeks of age at randomization benefited significantly more from regularity instructions without swaddling (OR 0.065; 95% CI 0.023;0.107) (Figure 3). The group differences within

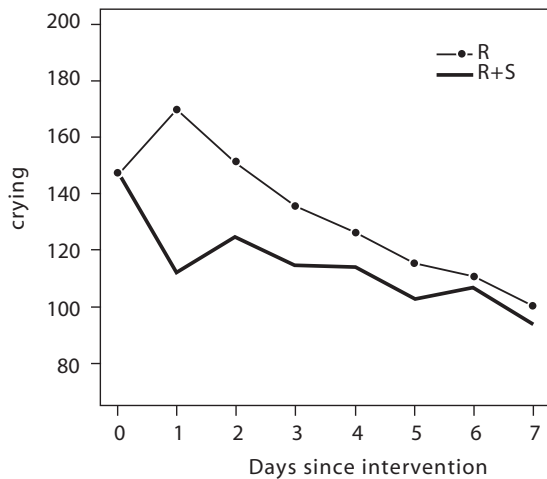


Figure 2. Average amount of crying (minutes/24 hours) during the first intervention week.

each age category were approximately 10 minutes. Subgroup analyses between excessive (>3 hours/24 hours for at least 3 days a week) and non-excessive crying did not show a significant difference between the R- and RS-group in the total intervention period. Furthermore, in all (sub) groups R and RS did not differ in amount of fussing (data not shown).

Cry Perception Scale

Comparing the baseline week and week 12, in the parent's perception the crying was less worrisome ($P = .000$). No differences were found between the R- and the RS-group. Subgroup analyses between excessive and non-excessive crying and between younger and older infants showed similar results.

DISCUSSION

Excessive infant crying occurs often and can lead to serious sequelae.³⁻⁶ Therefore a randomized trial was designed in which two strategies were compared that could both be easily incorporated in the working practices of well-baby clinics, thus offering possibilities for secondary prevention. As it is the parental perception of the crying that leads to frus-

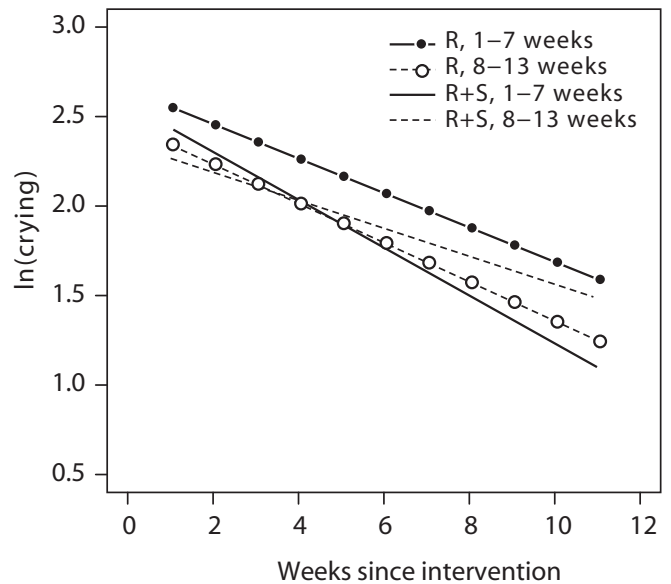


Figure 3. Decrease in amount of crying (minutes/24 hours) during the total intervention period for both age groups (logarithmic transformation).

tration and undesirable reactions, parental estimate of the amount of crying was used as the most important inclusion criterion.

An unambiguous intervention for excessive crying has not yet been described, although some (non-) effective strategies have.²¹⁻²³ Barr et al demonstrated in a randomized controlled trial that one aspect of behavior modification, carrying the baby, is ineffective.⁷ Three systematic reviews show insufficient evidence for simethicone, dicyclomine, methyl scopolamine, lactase enzymes, soy-based formula, casein hydrolysate milk, low lactose milk, sucrose solution, herbal tea, and behavioral modification.²¹⁻²³ The use of whey hydrolysate milk does seem effective for subgroups and in primary care settings.¹⁷ In 2% to 5%, excessive crying can be explained by cow's milk protein intolerance.^{24,25} Behavior modification studies differ widely in methods and results and are of course not double-blinded. One study indicates that regularity and stimulus reduction is an effective strategy.⁹ Wolke et al compared empathic

Table II. Parameter estimates linear mixed model for crying (minutes/24hours), in which response is adjusted by the covariate baseline (logarithmic transformation)

	Corrected for age baby (wk)		Corrected for other variables*	
	Value	95% CI	Value	95% CI
Intercept	2.44	2.043;2.85‡	3.67	2.76;4.58‡
Week	-0.0105	-0.12;-0.09‡	-0.087	-0.121;-0.052‡
Group - RS	-0.0104	-0.242;0.0338	-0.091	-0.232;0.049
Crying	0.4251	0.344;0.5062‡	0.378	0.291;0.465‡
Week:Group-RS	0.0051	-0.016;0.026	0.006	-0.015;0.027

*Corrected for age of the baby (wk), intervention area, birth weight (g), sex, age mother at first live birth (y), age mother at time of interview (y), age father at time of interview (y), type of feeding, health perception of mother, birth by suction, smoking during pregnancy, current smoking behavior, General Health Questionnaire total score.

‡ $P < .05$.

‡ $P < .001$.

telephone calls with a behavioral modification similar to ours and a third control group.⁹ Although the study was quite small (n = 92) and the included infants were older (1-5 months of age), the empathy group showed a decrease in crying and fussing of 37.5% after 3 months compared with the behavioral group, 51.2%, and the control group, 35.2%. These data and several advice items concerning prevention of excessive crying by Hofacker et al¹⁰ and Blom⁸ were used to construct our intervention of regularity and stimulus reduction.

Possible Limitations of the Study

In the study we chose not to include a "care as usual" intervention group as there is no standardized care in the Netherlands for excessively crying infants. Participating in a study with 24-hour diaries and telephone calls is already incompatible with "care as usual" as the effect of extra attention and empathy cannot be controlled for adequately. Therefore our research question was whether or not swaddling has added benefit to offering a form of behavior modification of regularity in baby care and stimulus reduction.

Another unavoidable drawback is that double-blinding was not possible in a behavioral intervention study.

Strengths

Both interventions were well accepted by the parents, and healthcare workers were positive about the ease of implementation in a well-baby setting. Eleven of 16 parents who switched from the R- to the RS-group after week 5 had a preference for swaddling before randomization and one parent had no preference. One of the 2 parents who switched from RS- to the R-group expressed doubts about swaddling before randomization.

The sharp increase in crying on the first day after starting the intervention in the R-group can be interpreted as a token of protest of the infants. After only a few days the parent-infant couples seem to adjust to the new routine. Parents should be informed about this initial increase in crying by the infant, to prevent needless distress.

Swaddling

Swaddling is an ancient technique by which movements of children are limited, by tightly winding cloths around them.²⁶ Research in experimental settings demonstrates that the arousal function is influenced by swaddling, which promotes sleep.^{27,28} There is evidence, that swaddling influences arousal and could be a preventive measure for cot death.^{27,29}

However, swaddling is not uncontroversial, especially in relation to developmental dysplasia of the hip.³⁰ Participating infants were screened for hip dysplasia, and the method of swaddling used allowed normal leg flexion and abduction. The method also allowed normal chest excursion necessary for unimpeded respiration. Instructions were given to temporarily stop swaddling in case of fever.^{31,32} A swaddled infant who is able to turn to prone has an increased risk of cot death.³³ Swaddling

should therefore be only applied in infants unable to turn when swaddled and no older than 6 months of age.

The young infants (1-7 weeks of age at randomization) showed a significantly greater decrease in crying during the 11 weeks of intervention if they were swaddled (approximately 12 minutes/24 hours). The older infants (8-13 weeks of age at randomization) showed a significantly greater decrease in crying in the regularity group without swaddling (approximately 9 minutes/24 hours). Swaddling decreases the infants' level of reactivity through motor restraint. Perhaps this is a more important factor in the younger group. It would therefore be worthwhile to extend this research to the group of premature and small-for-gestational-age infants who are known for their jitteriness.

The natural course of excessive crying is favorable. However, considering the anxiety it causes and the serious sequelae especially in relation to child abuse, it is appropriate to offer parental support. Both interventions offered were well accepted by parents and healthcare workers, and easily implemented in a well-baby clinic setting. Overall, no significant difference was found in the decrease of crying in both intervention groups. Although at the first day of intervention a regular pattern of baby care increases crying, whereas crying was reduced when the infants were additionally swaddled, this difference disappeared after one week. Swaddling may be tried as a supplementary intervention for excessive crying in infants <8 weeks of age, but the effect is modest.

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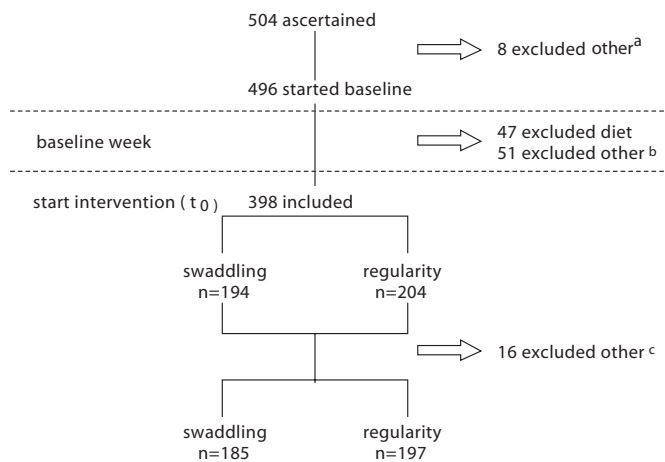


Figure 1. Included and excluded cases ^aSix not meeting inclusion criteria, 1 admitted to hospital, 1 metabolic disorder. ^bTwo not meeting inclusion criteria, 15 sudden unexplained reduction of crying, 6 admitted to hospital, 2 started swaddling, 7 could not identify one-self with the given advises, 4 visited alternative healthcare, 2 treatment of thrush, 3 treatment of reflux, 1 treatment with lactulose, 7 reduction of crying because of malnutrition, 2 transport problem. ^cOne not meeting inclusion criteria, 1 admitted to hospital, 1 started swaddling, 12 could not identify one-self with the given advises, 1 visited alternative healthcare.

Table I. Demographic factors

	regularity (n = 197)	swaddling (n = 185)	exclusion diet (n = 47)	exclusion other (n = 75)
<i>Parental features</i>				
Age of mother at first live birth (years) [#]	29.9 ± 4.42	29.7 ± 4.55	26.5 ± 3.87	28.2 ± 5.01
Age of mother (years) [#]	31.9 ± 4.29	32.2 ± 4.63	29.8 ± 4.95	30.3 ± 5.23
Age partner (years) [#]	34.1 ± 5.11	35.6 ± 5.45	31.2 ± 8.00	32.7 ± 5.20
Maternal education [¶]				
- no education/primary school	3 (1.5)	2 (1.1)	2 (4.3)	11 (15.5)
- lbo/mavo*	40 (20.3)	44 (23.8)	10 (21.3)	17 (23.9)
- havo/vwo/mbo†	69 (35.0)	73 (39.5)	26 (56.5)	25 (35.2)
- hbo/university‡	85 (43.1)	66 (35.7)	8 (17.4)	18 (25.4)
Paternal education [¶]				
- no education/primary school	4 (2.1)	1 (0.6)	1 (2.2)	3 (4.5)
- lbo/mavo*	44 (22.9)	45 (25.0)	17 (37.8)	14 (21.2)
- havo/vwo/mbo†	82 (42.7)	61 (33.9)	18 (40.0)	23 (34.8)
- hbo/university‡	62 (32.3)	73 (40.6)	9 (20.0)	26 (39.4)
Marital status [¶]				
- living together with partner and infant(s)	188 (95.9)	175 (95.1)	44 (95.7)	65 (95.6)
Maternal smoking indoors at time of interview [¶]				
- yes	29 (14.7)	30 (16.2)	13 (28.3)	11 (16.9)
Maternal smoking indoors at time of interview [¶]				
- 1–10 cigarettes/day	6 (50.0)	9 (81.8)	4 (50.0)	3 (50.0)
Maternal smoking during pregnancy [¶]				
- yes	32 (16.2)	29 (15.8)	11 (23.4)	12 (18.5)
Maternal smoking during pregnancy [¶]				
- 1–10 cigarettes/day	23 (76.7)	24 (82.8)	5 (55.6)	8 (72.7)
Paternal smoking indoors at time of interview [¶]				
- yes	17 (8.9)	14 (7.8)	10 (21.3)	4 (6.3)
<i>Child features</i>				
Sex [¶] - boy	100 (50.8)	101 (54.6)	25 (53.2)	44 (62.0)
Birth order [¶] - first born	117 (59.4)	91 (49.2)	26 (55.3)	46 (64.8)
Parity [¶] - singleton	184 (93.4)	178 (96.2)	45 (95.7)	66 (93.0)
Age of infant at enrollment (wk) [#]	7.9 ± 2.52	8.0 ± 2.53	8.5 ± 2.43	7.9 ± 2.97
Birth weight (g) [#]	3338.0 ± 602.34	3430.6 ± 552.17	3422.4 ± 612.29	3405.2 ± 543.92
Birth length (cm) [#]	50.2 ± 2.63	50.6 ± 2.71	50.4 ± 3.68	50.7 ± 2.55
Pregnancy duration (wk) [#]	39.4 ± 2.03	39.6 ± 1.63	39.6 ± 1.84	39.4 ± 1.81
Delivery duration (h) [#]	11.9 ± 12 (64)	12.1 ± 12.60	7.8 ± 7.73	13.7 ± 15.08
Contraction of labour (min) [#]	42.5 ± 51 (93)	39.8 ± 40.59	31.0 ± 31.02	53.0 ± 75.96
Crying/24 as indicated by parents (h) [#]	5.5 ± 2 (89)	6.0 ± 3.72	6.22 ± 2.70	6.71 ± 4.23

*Lower technical and vocational training and lower general secondary education.

†Intermediate vocational training and advanced secondary education.

‡Higher vocational education (college education) and university.

§Significant difference between regularity and swaddling.

||Significant difference between inclusion and exclusion diet.

¶Counts (percentages).

#Mean ± SD.