INFANTS WITH COLIC

Parents’ experiences in short and long perspectives and the effect of acupuncture treatment on crying, feeding, stooling and sleep

Kajsa Landgren
Put up in a place where it's easy to see
the cryptic admonishment T.T.T.

When you feel how depressingly slowly you climb,
it's well to remember that Things Take Time.

*Piet Hein*

If you do not change direction, you may end up where you are heading.

*Lao Tzu*
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ABSTRACT

Infantile colic, involving an otherwise healthy infant crying and fussing more than three hours per day and more than three days per week, is a common problem in Western countries. Both the infant and the parents suffer during the months of persistent crying and there is a risk that the establishing of the early relationship might be disturbed. Safe and effective treatment that provides relief in infantile colic is lacking.

The aim of this thesis was to elucidate parents’ experiences of having, and having had, a baby with infantile colic and to evaluate the effect of acupuncture treatment on crying, feeding, stooling and sleep patterns in infants with colic. Individual interviews were conducted with 23 parents (12 mothers and 11 fathers) of infants with colic. The narratives were analysed using a phenomenological, hermeneutic method. The parents expressed that the colic overshadowed everything. Both fathers and mothers experienced they were living in an inferno and yearned for the scenario that they had dreamed of. They used various strategies to ease their child’s pain and thereby help them all get through the months of almost constant crying. The parents were disappointed when nothing they tried worked and when they did not receive help from the professionals. It was important for them to be able to share their burden. Four years later 17 of the parents were interviewed again, 13 of them individually and four in a focus group. These interviews were analysed with content analysis. The results showed that the parents vividly recalled the emotional and practical chaos they had lived in during the colic period and how relationships within the family had been strained. They had tried many recommended treatments but were frustrated when almost nothing helped. The lack of responsiveness from professionals and the experience that no one understood their situation was the worst part of the colic period. When the colic symptoms faded out relations healed and parents could enjoy the new family member. Parents’ confidence in the Child Health services was decreased and they suggested changes in treatment.

To evaluate the effect of minimal acupuncture treatment on crying, feeding, stooling and sleep patterns in infants with colic, a blinded, randomised, controlled trial comprising 81 infants aged 2–8 weeks and fulfilling the criteria for infantile colic was conducted. The infants went through a structured programme comprising six visits to an acupuncture clinic, twice a week, where parents could ask questions as well as receive verbal support from a nurse. Subsequently the infants were carried to a separate room; here, another nurse handled all the infants in a similar way with the exception for the infants who were allocated to receive acupuncture being given minimal, standardised acupuncture for two seconds in the acupuncture point, LI4 on the hand. Parents registered their infants’ fussing, crying, feeding and stooling in a diary on a daily basis. The results indicated that minimal acupuncture shortened the duration and reduced the intensity of crying in infants with colic. There was a difference (p=0.034), favouring the acupuncture group, in the time that passed from inclusion until the infant no longer met the criteria for colic. The duration of fussing in the first and second week (p=0.029 and 0.047) and of colicky crying in the second
intervention week (p=0.046) was lower in the acupuncture group. The total duration of fussing, crying and colicky crying (TC) was lower in the acupuncture group during the first (p=0.025) and the second intervention week (p=0.016). The relative difference from baseline throughout the intervention weeks showed differences between groups for fussing in the first week (p=0.028), for colicky crying in the second week (p=0.041) and for TC in the second week (p=0.024), demonstrating favour towards the acupuncture group. During the third week there were no statistical differences in crying.

The infants had a higher stooling frequency than reported in healthy infants in previous reports. Minimal acupuncture showed no effect on feeding and only minor effect on stooling frequency. Parents in the acupuncture group more often described their infant to have normalised stooling, better sleep and improvement of colic compared to the control group.

The results indicate that infantile colic affects most aspects of family life. Mothers and fathers alike felt powerless and were overwhelmed by strong feelings when they could not ease their child’s pain. Acupuncture may constitute a valuable treatment for reducing the duration and intensity of crying in infants with colic and thereby preventing disturbances in families. To improve acupuncture treatment, research into different acupuncture points, needle techniques and intervals between treatments is required. In order to be able to support parents and infants when a child has infantile colic individualised but structured guidelines are needed.
### ABBREVIATIONS AND DEFINITIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>CHC</td>
<td>Child Health Centre</td>
</tr>
<tr>
<td>CNS</td>
<td>Central Nervous System</td>
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<td>EA</td>
<td>Electro Acupuncture, acupuncture with electric stimulation</td>
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<td>LI4</td>
<td>The 4th acupuncture point on the Large Intestine meridian</td>
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<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<td>SBS</td>
<td>Shaken Baby Syndrome</td>
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<td>SP6</td>
<td>The 6th point on the Spleen meridian</td>
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<tr>
<td>ST36</td>
<td>The 36th point on the Stomach meridian</td>
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<tr>
<td>TCM</td>
<td>Traditional Chinese Medicine</td>
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<td>TC</td>
<td>Total duration of fussing, crying and colicky crying</td>
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Colic     | In this thesis defined as “crying and fussing for more than three hours per day and more than three days during the same week”

Fussing   | In this thesis defined as “showing dissatisfaction and whimpering even while being carried”

Crying    | In this thesis defined as “screaming loudly”

Colicky crying | In this thesis defined as “crying hysterically and being impossible to comfort”
ORIGINAL PAPERS

This thesis for the doctoral degree is based on the following papers referred to in the text by their Roman numerals:


INTRODUCTION

Infantile colic, involving the infant crying and fussing for more than three hours per day, is a common problem in the Western world.\(^1\) Even if the prognosis for infantile colic is good and the child often recovers spontaneously by the age of 3–4 months\(^2\) both the infant and the parents suffer during the months of persistent crying. Colic disturbs both mother-infant, father-infant and other family relationships\(^3-5\) and there is a risk that the establishment of the essential relationship might be delayed.\(^6-7\) Furthermore, children who cry a lot are more likely to be exposed to child abuse and physical violence.\(^8-10\) Studies describing parents’ experiences of having a baby with colic\(^3,\) \(^5,\) \(^7,\) \(^11-12,\) validate each others’ findings. Negative emotions such as anger, frustration, worry and guilt were frequently expressed by both mothers and fathers, and they felt helpless, hopeless, depressed and isolated. There is no known treatment for infantile colic that provides relief and is safe and effective. Health service staff have an important task in guiding parents through the period of colic in order to facilitate attachment and thus provide a secure base for the child.\(^13\)

Feeding and stooling habits are important topics for many new parents. A description of these patterns in infants with colic is lacking but could be a valuable tool in everyday clinical practice.

Acupuncture is a treatment method with ancient roots in Asia. In Western countries, acupuncture is most often used for somatic pain. Acupuncture might also affect visceral pain, the autonomous nervous system,\(^14\) anxiety and sleep.\(^15\) Few acupuncture studies are conducted with children. In spite of weak evidence, parents often seek complementary methods such as acupuncture to relieve infantile colic.

This thesis fills a gap in the research by elucidating mothers’ and fathers’ experiences of having a baby with infantile colic when they are in the midst of the colic period, and their recalling of the colic period four years later as well as the impact the colic had on the family relations. Furthermore it describes the feeding and stooling patterns of infants with colic and evaluates the effect of acupuncture treatment on fussing, crying, feeding, stooling and sleep in infantile colic.
BACKGROUND

Healthy infants’ crying

An infant is not supposed to be quiet even when it is completely healthy. Crying is one of the few ways in which an infant can express his or her emotions and the first language of the new dyadic relationship. The crying and fussing do not necessarily mean that the infant is in pain but can be a sign of being tired, hungry, wet or of merely needing contact. The mean duration of crying for Western infants during their first two months is 1.6–2.8 hours per day, usually concentrated to the evenings. The crying reaches a peak at six weeks of age. Preterm infants follow the same crying curve after adjustment for the age of conception.

Infantile colic: definition and incidence

Infantile colic has been defined in different ways. The classic definition of infantile colic is: “a seriously fussy or colicky infant who is otherwise healthy and well fed, but has paroxysms of irritability and fussing or crying, more than three hours per day, more than three days per week for more than three weeks – or symptoms so severe that medication is indicated”. The modified Wessel criterion “an otherwise healthy and well fed infant who is crying and/or fussing for more than three hours per day, more than three days per week” where the words “for more than three weeks” have been excluded for practical reasons to allow treatment to start earlier is used in this thesis. As definitions of colic differ, it is difficult to compare data from different studies.

“Otherwise healthy” means that organic causes of excessive crying have been excluded, like damage in the central nervous system, constipation, anal fissures, gastroesophageal reflux, otitis media, urinary tract infections, meningitis or other infections, cow’s milk protein allergy or rashes. Likewise feeding problems and trauma should be outruled.

Wessel described colic in accordance solely with the amount of crying. Others add criteria such as the crying having to have a paroxysmal onset, be high-pitched or in some other way indicating that the infant is in pain. Mothers of infants with colic perceived their infants’ cries as more urgent, arousing, piercing and distressing than mothers of infants without colic. In acoustic analyses, the crying of colicky infants differs from that of other infants in pitch, pitch variability and turbulence or disphonation, and objectively has particularly aversive acoustic features. Helseth suggests three categories of crying. The first is intense crying that is hysterical, inconsolable and considered to be related to pain and digestion. The second is non-specific fussing that is consolable and not related to pain and suggested as being part of the normal developmental process. The third category is feeding-related crying that is considered to be a problem related to breastfeeding.
The occurrence rate for infantile colic varies between countries. While there are almost no reports of colic from non-Western countries, Western countries report colic as being a common problem. This phenomenon might reflect that infantile colic is not perceived as a problem in non-Western countries, that fewer studies on infant’s crying are conducted there, or that the perception and interpretation of “negative emotionality” may depend on the cultural context. It might also mirror the different care-giving practices: in cultures where infants are carried in direct body contact most of the time, infantile colic is seldom reported as a problem. In Western studies, the occurrence rate varies depending on how colic is defined. In a review, the occurrence rates of infantile colic in prospective studies varied from 3% to 28% and in retrospective studies from 8% to 40%. The largest population study ever conducted included 76,747 infants in the UK and identified a colic rate of 18.9%. With Wessel’s modified definition of colic, five Scandinavian studies involving 376, 959, 1628, 432, and 1955 infants respectively found the incidence of infantile colic to be 7.9%–11.7%. A prospective Iranian study with 321 mother-infant dyads found an incidence of 20% and a prospective American study with >800 dyads found that 24% of the infants had colic at 6 weeks of age.

Infant’s feeding, stooling and sleep
Parents are encouraged to feed their healthy newborn baby whenever and for as long as the baby desires in order to adjust the natural control of appetite, maternal milk production or amount of formula. Six to eight meals per day is the postulated standard. In a study with 2587 breastfeeding mothers in the USA, breastfeeding was reported to be eight times per every 24 hours in the first two months and 11 times per day in an Australian study. Infant crying has been linked to feeding problems. There is no correlation between specific types of feeding and infantile colic.

Age is the factor that influences stooling frequency the most. Healthy infants have bowel movements approximately four times per day during their first 1-2 weeks. At the age of one month infants are registered as having 2.2 stoolings per day, approximately three stoolings per day, and in one study six stoolings per day. Following the first weeks there is a radical decrease in stooling frequency up until the age of two months when stooling frequency was reported to be one per day and 2.2 times per day. At three months the mean frequency had decreased to one per day, 1.25/day and approximately 1.7 per day. Formula feeding has been reported to decrease the frequency of stooling. Two trials measured the difference between the bowel movements of colicky and non-colicky infants: one reported that infants with symptoms of colic during the first two months had less frequent bowel movements, the other that there was no difference. In a Swedish case report study including 913 infants with colic, mean age 5.4 weeks, 64% reported a stooling frequency of 5-8 stoolings per day. In a qualitative study parents of infants with colic correlated crying to stomach aches and a disturbed gut function. They remarked that their infants had bowel movements more than ten times per day or hardly at all and that the stools were green, explosive and foul-smelling.
Two-month-old infants with colic slept two hours less compared to infants without colic but in another study six-week-old infants with and without colic slept almost the same amount of time. However, in excessively crying infants, the proportion of rapid eye movement sleep was higher during the 3-hour period from the beginning of the first long sleep in the evening and lower during the preceding 3-hour period compared to the control group. Parents of the control infants are more likely to overestimate the amount of infant’s sleep and, therefore, report more sleep than the parents of the crying infants. Although no differences in the total amount of sleep or proportions of sleep stages were observed, excessively crying infants may be characterized by a disturbance that affects the proportion between the rapid eye movement and the non-rapid eye movement sleep stage proportion during the evening hours.

**Aetiology**

The aetiology of infantile colic is still unknown. Several hypotheses have been suggested and probably the aetiology is multifactorial. The word “colic” comes from the Greek word for colon, and one of the main hypotheses is that colic is a gut issue. Most parents refer to their infant’s symptoms as pain originating from the intestines, as the infants’ crying is often combined with disturbed gut function. Optimal digestion is dependent on the equilibrium of the two parts of the autonomic system. As the parasympathetic system is responsible for salivation, digestion and defecation and increases peristalsis and secretion from glands, and parasympathetic action is inhibited by sympathetic action, a less than optimal balance between the sympathetic and the parasympathetic system might be a state of colic. Parents often relate their infant’s pain to intestines filled with gas. Viscera have fewer nociceptors than somatic tissues. The intestines, for instance, are not sensitive to a knife cut, but react to distension, ischemia and inflammation. If the bowel is distended past a certain limit, which might be the case in colic, it causes intense pain.

Allergy to cow’s milk protein is thought to be a possible cause of infantile colic as exclusion of cow’s milk protein helps 5–25% of colicky infants. When the children are one year old, they often tolerate cow’s milk again. Hypersensitivity to other food like eggs, peanuts, tree nuts, wheat, soy and fish has been suggested as a cause of colic.

One hypothesis is that colic is a symptom of abdominal cramps and hyperperistalsis. Lothe et al found a raised level of motilin, promoting intestinal peristalsis, from the first day of life in infants who develop infantile colic, indicating gastrointestinal involvement even before any symptoms of colic appear. Another trial found no association between umbilical cord plasma motilin levels and the development of infantile colic. Cholecystokinin, inducing gallbladder contractions and satiety and having a calming effect on infants, was lower in infants with colic. Another suggestion of an organic disease being the reason for colic is gastroesophageal
reflux. Yet another hypothesis is that infantile colic is linked to the gut microflora and that infants with colic have an inadequate level of lactobacillus.

Besides the hypothesis that infantile colic is a gut issue, there is an idea that infantile colic can be a behavioral condition, resulting from less than optimal parent-infant interaction. Other hypotheses are that the symptoms of colic are due to feeding problems or that the cause is neurodevelopmental. The latter hypothesis is supported by the fact that most infants outgrow colic by four months. It has also been suggested that colic mirrors a temperament that is more emotional and reactive than in other infants.

**Related factors**

Neither the gender of infants nor obstetric factors such as vaginal delivery, Caesarea, vacuum extraction or epidural analgesia are found to be related to the risk of suffering from colic. No difference in the occurrence of infantile colic in breastfed or bottlefed infants is found. No seasonal variation has been found.

During pregnancy, maternal smoking and a caffeine intake of over 400 mg/day increased the risk of colic. Women who during pregnancy believed that there was a risk of spoiling young infants with too much physical contact had a higher incidence of colicky infants, even if they had as many hours of physical contact with the infant as mothers who did not believe that physical contact increased the risk of spoiling the infant.

A birth weight of <2500gr or a cranial circumference of <35cm are in one study associated with a higher risk of developing infantile colic. Some studies showed a higher risk of firstborns getting infantile colic while another study showed no increased risk. Having a family history of gastrointestinal diseases and atopic diseases and/or having a sibling who had had colic was found to imply an increased risk.

Several studies demonstrate inconclusive findings. Maternal age has in different studies either no correlation with the risk of having an infant with colic or correlates with an increased tendency for mothers younger than 25 or older than 35 to have a greater risk. Canivet found on one hand a tendency of higher risk for highly educated mothers but, on the other hand, a high level of education seemed to protect from the influence of high trait anxiety.

Some research shows a link between psychological factors such as maternal and/or paternal anxiety, stress and depression during and after pregnancy and the development of colic while two prospective trials found no such relation. A European study including 1015 mothers found an association between maternal depression and infantile colic when the child was two months old and also four months later. Maternal stress and depression might either be predisposing factors or be a result of colic. Colic has been linked to a mothers’ inability to respond in an
appropriate manner to the baby’s crying ⁸⁸-⁸⁹, while some studies found mothers of colicky infants to be no different from others in their sensitivity to infant cues.⁸⁵, ⁹⁰

**Treatment for infantile colic**

Unclear aetiology, diffuse criteria for defining normal crying and the non-existence of known relief-giving, safe and effective treatment make it difficult for health staff meeting parents who are seeking help for infantile colic. Because of the many possible causes, several interventions with different levels of evidence have been suggested. In Table 1 the effect of different interventions according to reviews, or to RCT’s if no review is available, are described.
Table 1. The effect of interventions on infantile colic according to reviews, and to RCTs if no review is available.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Reviews show effect:</th>
<th>RCT’s show effect:</th>
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<tbody>
<tr>
<td></td>
<td>No, Hall et al (2011)</td>
<td></td>
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<tr>
<td>Lactase</td>
<td>No, Hall et al (2011)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maybe, Hall et al (2011)</td>
<td></td>
</tr>
<tr>
<td>Cimetropium bromide</td>
<td>Yes, Hall et al (2011)</td>
<td></td>
</tr>
<tr>
<td>Proton pump inhibitors</td>
<td>No, van der Pol et al (2011)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes, Shergill-Bonner (2010)</td>
<td></td>
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<tr>
<td>Chiropractic</td>
<td>No, Posadzki (2011)</td>
<td>Yes, Alecantara (2011)</td>
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<td></td>
<td>No, Perry (2011)</td>
<td></td>
</tr>
<tr>
<td>Cranial osteopathy</td>
<td>Yes, Hayden (2006)</td>
<td></td>
</tr>
<tr>
<td>Reflexology</td>
<td>Yes, Bennedbaek 2001</td>
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</table>
**Changed feeding**

Several trials suggest that eliminating cow’s milk from infants’ food, either by changing from a standard cow's milk formula to a hydrolyzed protein formula if the infant is bottle-fed, or by eliminating cow’s milk from the mother’s diet if the infant is breast-fed, may shorten the duration of crying.\(^{58-64}\) Allergy, or intolerance to cow’s milk protein, is often confused with lactose intolerance. It is important to point out that, in infantile colic, it is the protein and not the lactose that causes problems, so low-lactose products are of no use.\(^{58}\) For a fair opportunity to evaluate whether the infant improves with this diet intervention, 100% parent compliance is necessary. On the other hand, if it is cow’s milk that is causing the infant’s pain then eliminating cow’s milk will give a distinct decrease in crying within five days. If the infant is better after five days, parents are recommended to introduce cow’s milk again, to see whether symptoms reoccur. If they do reoccur, parents are recommended not to give the infant cow’s milk again until the age of 18 months. This treatment is recommended as a first intervention for children with colic.\(^{62}\)

Likewise a soy-based formula reduces the symptoms in infants with colic\(^ {60}\) but is not recommended due to the risk of developing an allergy to soy. Fibre-supplemented formulae and lactase enzyme-treated formulae had no effect.\(^ {60, 64}\) A low-allergen maternal diet where not only cow’s milk but also eggs, peanuts, tree nuts, wheat, soy, and fish were excluded has been compared to a diet including this food in mothers to breastfed infants. Crying was reduced in the former group.\(^ {65}\)

For bottlefed infants a special bottle (Dr. Brown's Natural Flow Baby Bottles) reduced the time of crying in infants with colic.\(^ {91}\)

**Medical treatment**

Existing medication is either ineffective or has serious or frequent side effects.\(^ {58}\) Simethicone (Minifom®) is a surface-active substance intended to break down bubbles of gas in the intestines. Simethicone has, according to three reviews\(^ {58-59, 92}\) and one report from the Norwegian Knowledge Centre for the Health Services,\(^ {62}\) no effect other than placebo in infantile colic, and conflicting evidence in a recent review.\(^ {64}\) Simethicone can be bought over the counter and, in spite of evidence of its non-effectiveness, it is still widely used as a treatment. It has been considered to be a safe drug but contains parabens as preservatives and is therefore not recommended for infants by the authorities of some countries, for example in Norway (Statens legemiddelverk, 12.04.2007). Dicyclomine or dicycloverine is a spasmylytic anticholinergic drug, reducing peristalsis in the intestines. Dicyclomine reduces crying in infants with colic but has the disadvantage of having rare but serious side effects such as respiratory difficulties, seizures, asphyxia, coma and death\(^ {58-59, 64}\) and frequently, less serious, relatively speaking, side effects such as sedation.\(^ {92}\) Dicyclomine must be prescribed by a doctor and the manufacturer has since 2009 contraindicated it for use in infants under the age of 6 months. Another anticholinergic drug, Cimetropium bromide, is widely used in Italy to treat infants with colic but is not available in, for example, the United States. Cimetropium bromide showed positive effects on crying but side effects like increased sleepiness were noted.\(^ {93}\) The use of
proton-pump inhibitors for the treatment of gastroesophageal reflux disease in children has increased enormously but, according to a systematic review, has no effect in reducing symptoms in infants.

**Complementary methods**

Some complementary methods are used in infantile colic although they are not evidence-based. *Chiropractic treatment* is used on the assumption that the infant has subluxation of columna vertebralis caused during delivery. A recent survey among all chiropractors in Denmark found that babies were the most common paediatric patients, with about one third being between the ages of 0 and 4 months. Infantile colic was the most common complaint representing this age group. However, three reviews found no evidence for the effectiveness of chiropractic treatment in infantile colic while another review found that chiropractic care is a viable alternative for the care of infantile colic and is congruent with evidence-based practice. A Cochrane meta-analysis of nine RCTs found some evidence that *infant massage* reduced crying while a recent review did not find sufficient evidence for the effectiveness of massage. In the only RCTs published on the subject cranial osteopathic manipulation reduced crying and improved sleep compared to no treatment in a trial with 28 infants and both specific and non-specific reflexology was found to be effective compared to no reflexology.

*Herbal treatment* is common in infantile colic. An Israeli study tested a herbal tea containing mixtures of chamomile, vervain, licorice, fennel and lemon balm, an Italian study tested an extract of chamomile, fennel and lemon balm, in Russia fennel seed oil was tested and a herbal tea was tested in Turkey all of these had favourable results and no negative side effects. An exception from this lack of negative side effects is Chinese star anise (*Illicium verum* Hook f.), often used as a treatment for infantile colic, which can have neurotoxic effects in infants and should not be used due to this possible side effect. Gripe water is often used in colic. It is an over-the-counter product which may contain a variety of ingredients like bicarbonate, ginger, cinnamon, dill, fennel, licorice and chamomile. It may also contain sugar and alcohol and is not recommended. A longitudinal study including 2653 children found that as many as nine percent of children were given dietary botanical supplements or teas in their first year of life, including infants as young as one month old. However, the authors of a review do not recommend herbal treatment to infants due to the multiplicity of herbal products and the lack of standardisation of strength and dosage.

*Oral sugar solution* is used in many cultures to soothe infants. The infant is served a teaspoon of the sugar solution when crying. Oral sucrose solution, 12% or 30%, was tested with good results and the Norwegian Knowledge Centre for the Health Services recommend this oral sugar solution for the relief of symptoms in infantile colic.

*Probiotics*, classified as functional foods, are sold over the counter and, for the last few years, have been used for infantile colic. In one randomized trial with 83 infants (*Lactobacillus reuteri* (Semper Magdroppar®)) was shown to decrease the time of crying
compared to simethicone and in another trial with 46 infants lactobacillus reuteri decreased the time of crying compared to placebo.\textsuperscript{111} Savino et al also tried a formula with probiotics with positive results.\textsuperscript{112} However, in another study including more than 1000 children\textsuperscript{113} where half of the infants got probiotics and half of them were given placebo infants in both groups had the same amount of crying.

To conclude, many complementary methods are tested in infantile colic. However, a recent systematic review on complementary methods of treating infantile colic found methodological problems in most studies but, at the same time, found encouraging results for fennel extract, mixed herbal tea and sugar solutions but no evidence for probiotic supplements or manual therapies like chiropractics or massage.\textsuperscript{97}

The effect of \textit{acupuncture} on infantile colic has not been evaluated in the reviews mentioned above. Liu\textsuperscript{114} reported 13 cases of infants with “night crying” being successfully treated with acupuncture, and Zhao\textsuperscript{115} reported treatment of 100 infants prone to night crying in an uncontrolled trial. In the only controlled study yet published on acupuncture in infantile colic,\textsuperscript{116} acupuncture reduced the duration and intensity of crying. Twenty of the 40 infants included were given acupuncture. Some of the infants were older than eight weeks where spontaneous remission could be suspected. Parents were blinded but not the investigator, as she also administered the acupuncture. In a historical review,\textsuperscript{52} parents of 67 out of 68 infants stated that their infants no longer had colic after a mean of four acupuncture treatments. A Norwegian trial with acupuncture in infants with colic is ongoing\textsuperscript{117} (www.spedbarnskolikk.no). In a recent case study with 913 infants with colic, parents rated their infants as having an inflated stomach less often, as drooling, belching and regurgitating more often and as having a reduced frequency of stooling and colicky crying after a mean of six acupuncture treatments.\textsuperscript{51}

\textbf{Support and guidance}

For several decades, Sweden has had a health care system that offers children follow-up visits from the neonatal period until 6 years of age at a Child Health Center (CHC). This structured programme is followed by 99\% of the families. The programme includes check-ups, screenings and immunisation to promote the children’s health, and is free of charge.\textsuperscript{118} The National Board of Health and Welfare recommends families with infants to visit the CHC about ten times during the first three months. This close contact with parents of infants with persistent crying can be demanding for health staff\textsuperscript{27, 119-120}. During this first period, the CHC-nurse has the important function of promoting the early interaction and empowering of parents. The nurse can help the parents by being there for them, by understanding, and by frequently giving them support and guidance through the colicky period.\textsuperscript{121} Counselling may result in a reduction of infants’ crying\textsuperscript{88-89, 122} and the parents’ way of coping can influence the duration and intensity of infant crying.\textsuperscript{120} In an early three-armed trial all groups were reassured that colic is a common condition and that it is self-limiting. The first group was also given advice about responding to the crying baby within 90 seconds, about using gentle, soothing movements, avoiding overstimulation, and about using a pacifier and a carrier. These words of advice had no real effect other than that of
reassurance, or reassurance plus a crib vibrator. Yet behavioural interventions such as reassuring parents that colic is self limiting and not a disease, and teaching parents to respond more appropriately to the infant by, for example, reducing sensorial stimulation to infants younger than 12 weeks might lessen colicky symptoms. A home-based nursing intervention reduced parental stress. Nurses who focus on the parents’ needs of encouragement help them to better cope with their situation, which results in the parents being more satisfied with the help they get from the nurses.

Parent’s strategies for care-giving

Just as infants vary in their ability to communicate through crying, parents also vary in how they interpret the crying and in the parental behaviour they exhibit. All infants cry but inconsolable crying can be extremely stressful and disruptive to everyday life and parents search for help. Not only the amount of infant crying, but also to what extent the mothers perceive the cries as being cries of pain are decisive factors for whether or not they seek help.

Wade et al found that mothers tried various activities to stop or diminish their infant’s irritability and searched desperately and creatively for effective activities to pacify the child. Coping mechanisms could be aimed towards the infant or towards themselves. Mothers tried to establish why the child was crying and tried to comfort it by feeding, changing nappies, rocking, singing and walking the child outdoors. If the interventions did not help, the mother acted by, for instance, putting on headphones, turning on the radio or walking out of the room and going out to have a cigarette. Mothers and fathers of colicky infants react cognitively by searching for tips in books or on the Internet and by seeking social support. If a mother does not have enough social support from family and friends, support can be non-traditional such as from a sponsor at Alcoholics Anonymous, a neighbour or a church member.

Influence on parents and family dynamics

Having an infant with colic certainly causes a variety of parental feelings and emotions, with anger, guilt, self doubt, worry, frustration, fear of losing control, hopelessness, fatigue and disappointment being described by mothers of infants with colic. The few studies in which fathers were asked found similar experiences. Allowing the infant to cry aggravated negative feelings. Parents can react with crying, depression and resentment. This phenomenon has been described as “parental colic”.

Siblings, other relatives, friends and health staff can also be included in the family system. When one person in the system has symptoms, the others will be affected, and the way in which they react will, in turn, affect how the rest of the system perceives the situation. An infant with erratic, disorganised behaviour affects the interactional synchronicity of the mother-infant dyad. Obviously the mother and the infant are closely related in a dyad, but the father and the siblings are also connected to this system and therefore the father-child relation can also be disturbed.
Räihä et al compared the interaction between parents and baby in 32 families who had an infant with colic and 30 control families. They found that both parents of colicky infants had less than optimal parent-child interaction; this was most pronounced between the fathers and the infants in the severe colic group. These fathers’ voices were less expressive when they spoke to their infant, they had less visual contact, expressed fewer positive feelings towards the baby and were less responsive and sensitive in reading the infant’s cues. The colicky infants were less competent in communication with their mothers. In addition, interaction was more often dysfunctional between the parents in this group. Communication between parents was less efficient and less clear and the expression of feelings was more restricted in the colic group.

Self-efficacy refers to parents’ belief in their ability to effectively manage the varied tasks and situations of parenthood. When attempts to soothe an infant are met with failure, feelings of incompetence are likely to develop. Mothers of infants with colic rated themselves as significantly less competent as mothers than other mothers did. Parents described a delay in the development of “good” feelings for the baby, and were concerned about their lack of joy in the situation. It was difficult for them to establish contact with the crying infant, and some felt rejected by the infant or that they had perceived a loss of the baby. Stifter and Bono state that infants with colic are no more likely to develop insecure attachments, but if the mother’s self-efficacy is low, attachment may be affected. Yet the majority of the colicky infants developed secure attachments.

Colic can result in tense relations and affect nearly every aspect of family life. It is considered to cause a crisis involving chaos and disruption in the families’ lives for its duration. Colic may affect mothers and families even after the colic has been resolved. Some studies show long-term problems with parental interaction in families with an infant that cries excessively. Four and six months after delivery, mothers of colicky infants scored significantly higher on a parental stress index and felt they received no positive feedback from interaction with their infants, compared to mothers of non-colicky infants. Another prospective study found no residual effects on maternal distress once the colic had resolved. In a study elucidating fathers’ experiences the themes describe how fathers experienced colic as a feeling of first falling into a crying abyss, then hitting the bottom and weaving strands together in order to make a rope from the support they could find and finally, climbing out of the abyss together as a family. In this study the fathers experienced that their relationship with their partner became deeper and better as they saw each others’ handling of the colicky situation.

Maternal perception of temperament showed colicky infants being rated as intense, negatively reactive, and difficult to manage later in infancy and childhood, suggesting that colicky infants may continue to cause stress in the relationship well after the colic has ended. In families with an infant with severe colic, family problems persisted one year later, but had been normalised after three and four years respectively. When the children were three years old families who had had colicky infants still had...
more distress compared to families who had had infants without colic. In this study, including 1200 families, the parents who had had infants with colic were less satisfied with the arrangements of daily family responsibilities and with the amount of leisure time and shared activities. There was no difference in the frequency of divorces between the groups but the children who had had colic three years earlier had significantly fewer younger siblings.

Increased risk of child abuse

In periods of heightened tension, colic can result in a fear of losing control and of non-accidentally injuring the infant. Persistent crying is a major challenge that places caregivers, especially those with limited resources and support systems, at risk with regard to child abuse and neglect. Children who cry a lot are more likely to be exposed to child abuse and physical violence. There is a correlation between infants being admitted to hospital for Shaken Baby Syndrom (SBS) and the crying curve, although a time lag exists. In one investigation 26 children under the age of one were identified with SBS in Estonia during a period of seven years. Prior to admission to the hospital with SBS or death, parents to 23 of the 26 children had contacted their doctor because of excessive crying.

Prognosis

Infantile colic often starts during the first three weeks of life. The prognosis is good. Most infants with colic have recovered spontaneously by 3–4 months of age. However, a prospective study with 547 dyads found 35 infants (24%) with colic when the infants were six weeks old. At three months 18 infants who had had colic when they were six weeks old (14% of the infants who had had colic at 6 weeks) still fulfilled the colic criteria while 86% had remitted. Yet another 17 infants who did not have colic when they were six weeks old fulfilled the colic criteria at three months, indicating two types of colic: “persistent” and “latent”.

Some differences have been found in follow-up studies that compare infants with and without colic. Kalliomäki et al found that fussing and colic-type crying preceded atopic disease in 116 high risk infants. Likewise Savino et al found an association between infantile colic and allergic disorders (allergic rhinitis, conjunctivitis, asthmatic bronchitis, pollenosis, atopic eczema and food allergy) in a study with 96 children at 10 years of age while Rautava et al found no difference in verified or suspected allergies or in special diets when comparing three year old children who had or had not had colic when they were infants. One prospective study that followed children from infancy up to 11 years of age found no association between infantile colic and asthma, atopy or allergic rhinitis and no differences in children’s weight and height at 11 years of age.

Stifter and Braungart found no difference in behaviour between former colicky infants and controls at five and ten months of age. Children who had had colic as infants complained more often about stomach aches when they were four years old and ten
years old as compared to control groups, and were also less likely to enjoy meals and to enjoy eating. They also refused certain foods more often. Children who had colic as infants had more frequently sleeping problems when they were three, four and ten years old. Children who had had colic as infants were in five follow-up studies perceived by their mothers to be more emotional and to have temper tantrums more often. This phenomenon was not found in two other studies. One metaanalysis found an association between infant regulatory problems like excessive crying and later behavioural problems like attention-deficit/hyperactivity disorder (ADHD) problems in 1935 children, particularly in multi-problem families.

Acupuncture

Acupuncture can be described from two different perspectives. The first is as a part of an ancient, complex medical tradition, often called Traditional Chinese Medicine (TCM). From this first perspective, acupuncture is called traditional acupuncture or classical acupuncture. From the second perspective, a modern Western medical view, acupuncture is described as a sensory stimulation of the nervous system.

Acupuncture according to TCM

Acupuncture as a part of TCM has been used for the treatment of a huge variety of diseases in Asia for thousands of years. TCM does not only consist of acupuncture and herbal medicine, although this is the part of TCM that is most frequently used. Other parts are moxibustion (moxa is a herb that is burned close to the skin), cupping, Tui Na (a meridian massage), Tai Ji and Qi Gong. Dietary advice and lifestyle advice are also included in the treatment.

TCM is considered to be holistic, meaning that the acupuncturist regards the body, mind and emotions as a whole and diagnoses the patients on the basis of all of their symptoms. However, TCM is not a homogenous theory. Over the centuries, great numbers of acupuncturists in many different countries have developed the theories of Chinese Medicine. Thus, TCM comprises many traditions and styles. The foundations of TCM are the concepts of qi, and of yin and yang. Qi is a concept without an equivalent in Western languages, but “life force” or “life energy” are relatively close matches. Qi is supposed to move in the body, to flow in the fourteen meridians, these being channels for energy that are distributed symmetrically throughout the body. Yin and yang are two polarities, each other’s opposites. All phenomena in the universe, including symptoms and diseases, can be defined according to yin and yang. Good health presupposes a free flow of qi and a balance of yin and yang and, consequently, all treatments are aimed at restoring the free flow of qi and balancing yin and yang. Patients are diagnosed, often with the help of pulse and tongue diagnosis, according to their status of qi, yin and yang, and the function of the inner organs. The organs are considered in TCM to have functions differing from those in Western medicine. The spleen, for example, is responsible for the major part of the digestive system. People who present the same symptom can receive different diagnoses and thus different
treatment if the acupuncturist assumes that the symptom has different roots. Conversely, people with different symptoms can receive the same treatment if the acupuncturist assumes that these symptoms have the same energetic origin.¹⁴⁰

The 364 acupuncture points are in TCM seen as “openings” on the meridians, where it is easier to get in touch with and influence the qi and the balance of yin and yang. According to TCM, it is not only the choice of acupuncture points that is important, but also the way in which the points, and thereby the qi, are stimulated. The word “acupuncture” means “penetrating with a needle” but is sometimes used for other techniques than needling. The points and meridians can be stimulated by massage, acupressure, heat from moxa, cupping or by needling. Different needling techniques are said to have different effects: a TCM-acupuncturist can choose to needle deeply or superficially, with mild or strong manual stimulation that can be “reinforcing” or “sedating” and sometimes bleeding technique is used. When manual acupuncture is chosen, the needle is often stimulated to “de qi”. This is a needle sensation that can be described as a “heaviness” or “numbness” but not as pain.¹⁴⁰ In other traditions, such as Japanese acupuncture, the needle is hardly stimulated at all.¹⁴¹ Electro-acupuncture (EA), where an electrode is attached to the needle and a current stimulates the point, can also be used. Acupuncture points in TCM are chosen individually to match the patient’s actual status of qi, yin and yang, and the choice of points and the stimulation technique are reconsidered on every treatment occasion.¹⁴⁰

Infantile colic according to TCM
From a TCM perspective, infantile colic can be differentiated into three syndromes.¹⁴² The first syndrome, “accumulation disorder”, means roughly that the infant has eaten more food than the spleen can “transport and transform”. A baby’s digestion works so close to its maximum capacity that it is easily disturbed. The overload can be due to a large intake of food, or a weak spleen not strong enough to transform even a moderate intake of food. The symptoms are intense: the infant cries loudly, often with a sudden onset, the belly is distended, and stooling is explosive and foul-smelling. The acupuncture point chosen is often SiFeng, described as being “for all infantile indigestion of an excessive nature”.¹⁴² The second syndrome for infants with colic is “weak spleen”. Infants with this syndrome can cry for as many hours per day as an infant with “accumulation disorder”, but with a lesser intensity. The child tends to be paler, the body more floppy and the appetite is often poor. Points to choose between are the 4th point on the Large Intestine meridian, LI4, and the 6th point on the Spleen meridian, SP6, with the addition of the 36th point on the Stomach meridian, ST36, if the bowel movement is slow. The third syndrome is “cold”. Symptoms are similar to “weak spleen”, but the onset of pain is sudden and the pain more intense, the child is paler, with cold hands and feet, and can be comforted with warmth. Points are the same as for “weak spleen” but a TCM-acupuncturist would consider using moxa if “cold” is predominant and SiFeng if symptoms are intense.¹⁴² When treating young children, fewer acupuncture points are used, needle technique is considered to be important, and needle retention is not recommended.¹⁴²-¹⁴³
Acupuncture from a modern medical point of view

From a modern, Western medical point of view, the effect of acupuncture is described in other terms. An inserted needle causes a tiny lesion and the cascade of reactions that ensues can be interpreted in neurophysiological terms. Acupuncture points, according to modern Western theories, are chosen on the basis of their segmental position and local points are often used. It is common to use electric stimulation of the needles, with the same points and stimulation method often being used throughout the treatment period.

Evidence of acupuncture research

For decades, the major focus in acupuncture research has been the analgesic effect on somatic pain, the gate control theory and the role of stress hormones/endorphins. More recent research has revealed many other mechanisms triggered by acupuncture, and new knowledge about these neurological pathways is added to the databases every week, not least from research using newer methods like fMRI. When the receptors are stimulated by acupuncture to levels over a certain threshold, an action potential is generated that will pass the synapse to the next neuron in thin A-delta-fibres and C-fibres, which transport the signal via sensory nerves to the central nervous system (CNS). Several neurotransmitters and hormones are released on different levels of the nervous system. Peripheral mechanisms include a local reaction at the needling site and local pain relief through axon reflexes. Central mechanisms trigger descending, pain-inhibiting, non-segmental pathways mediated by beta-endorphins and met-enkephalin, serotonin (5-HT) or noradrenalin, with effects on the sympathetic nervous system. When acupuncture needles are inserted within the segment of pain, the spinal gate control mechanism operates through a circuit involving inhibitory enkephalin and dynorphin in the spinal cord. Afferent signals result in a postsynaptic blockage of the transmission of the pain signal to the motor neurons and the sympathetic neurons in the spinal cord, but this system is only active during stimulation of the needle.

Acupuncture can affect the HPA-axis with increased levels of β-endorphins and cortisone in the blood, at least if administered under painful and stressful conditions. These systems are supposed to produce widespread, extra-segmental, non-selective analgesia but only have an effect for up to 8 hours after stimulation. If acupuncture is administered with painful stimuli, yet another opioidergic mechanism, Diffuse Noxious Inhibitory Control (DNIC), can result in even shorter pain reduction. The release of stress hormones, such as endorphins, cortisone, adrenalin and noradrenalin, is related to the strength of the stimulus. Another substance that is released if acupuncture is administered in a non-painful way is oxytocin. Oxytocin can give rise to a long term beneficial effect on stress, pain and anxiety.

Besides having a pain-reducing effect, acupuncture has also been shown to have an effect on the autonomic nervous system. Studies of the effect on the sympathetic nervous system have shown a diversity of results. The point used in the present study, LI4, in the first dorsal interossei muscle of the hand, is one of the acupuncture points that is studied the most. LI4 is innervated by the ulnar nerve by sensory and...
autonomic, mainly sympathetic, fibres. Ernst and Lee\textsuperscript{151} found that manual acupuncture in LI4 produced reduced sympathetic activity and proposed a central mechanism. Liao et al found increased sympathetic activity and inhibition of parasympathetic activity in anesthetised rats after electroacupuncture in LI4\textsuperscript{152} while, in another study, acupuncture applied into LI4 induced changes in both the sympathetic and parasympathetic nervous systems in healthy subjects.\textsuperscript{153} The latter authors suggest that this explains the relaxation, calmness and reduced feelings of distress commonly experienced by patients. Sato et al show that low-intensity stimulation leads to a reduced sympathetic outflow, while strong stimulation leads to increased activity.\textsuperscript{154} Prospective, randomized studies have shown acupuncture to reduce pain in cases, for example, of migraine, low back pain, dental pain and knee arthrosis, as well as to reduce nausea in adults.\textsuperscript{144-145, 155} Experimental animal research indicates that acupuncture increased or decreased motility of the intestinal tract depending on which points were needled.\textsuperscript{154, 156-159} Only a few studies evaluate intestinal symptoms in humans. Yim et al\textsuperscript{160} claim no effect on gastric motility in healthy humans. Ouyang & Chen\textsuperscript{161} conclude in a review that acupuncture inhibited gastric acid secretion and affected gastric emptying in patients with motility disorders. Using acupuncture on children is controversial and few acupuncture trials are performed on children. A review analysing 23 RCTs and 8 metaanalyses/reviews on paediatric acupuncture concludes that acupuncture reduces nausea and pain in children and may also reduce nocturnal enuresis, seasonal allergic rhinitis, infantile diarrhoea, constipation and ulcerous colitis.\textsuperscript{143} Acupuncture has, in spite of weak evidence, been used to treat a variety of symptoms in children.\textsuperscript{162-163} One survey\textsuperscript{164} showed that 33\% of paediatric pain clinics in the USA used acupuncture. Serious adverse effects of acupuncture are rare\textsuperscript{165-167} and the acceptability in children aged 6–18 years is good.\textsuperscript{162} In the only controlled study yet to be published on acupuncture in infantile colic,\textsuperscript{116} acupuncture reduced the duration and intensity of crying. Possible explanations could be a reduction of pain as shown in adults,\textsuperscript{168} a beneficial effect on other visceral symptoms such as nausea which has been reduced by acupuncture in adults\textsuperscript{169-170} and in children,\textsuperscript{171} an altered gastric motility,\textsuperscript{172} or changed gastric emptying as shown in adult patients with motility disorders.\textsuperscript{173} Furthermore, acupuncture affected constipation in children\textsuperscript{174} even though gastric motility in healthy adult humans was not altered.\textsuperscript{160} Finally a sedative effect of acupuncture could explain the reduction of colic as it has been demonstrated to promote sleep in adults.\textsuperscript{15}

**Methodological problems in acupuncture research**

Insufficiency with regard to study design is a major problem in quantitative acupuncture studies.\textsuperscript{144-145} The major methodological problems are the inability to blind patient and practitioner, and to find an inert control.\textsuperscript{175} A true placebo procedure does not exist.\textsuperscript{176} Double-blind design is not an option as it is impossible to blind the practitioner in acupuncture studies. Likewise, it is hard to find a control where the patient is blinded. Many studies have compared needling in acupuncture points with needling outside such points.\textsuperscript{176} As several mechanisms are triggered when a needle penetrates the skin, this method does not compare acupuncture with non-acupuncture but rather two types of acupuncture.\textsuperscript{176} Studies have often used minimal acupuncture, which is shallow needling or needling with mild stimuli as control. This might be
inappropriate, as such needle stimulation is used as a treatment in, for example, Japan. The only study yet published on acupuncture and infantile colic used minimal acupuncture as a treatment. Many studies from recent years have used a “placebo-needle” as control. This “needle” does not penetrate the skin. The needle disappears into the shaft but the blunt tip of the needle stimulates the skin during the intervention. In several controlled studies, both acupuncture and the chosen type of sham acupuncture mentioned above had effect. Typically, they produce a difference in effect that favours true acupuncture, with this difference not being significant between the acupuncture groups but between the acupuncture groups and a non-treatment group. Besides the effect that might be a treatment effect of the sham devices, placebo effects result in statistically and clinically significant improvements. Placebo effects can be induced by counselling and reassurance. so, as in other research, it can be difficult to evaluate the true effect of the intervention.

Another problem in acupuncture research is the difficulty in comparing the results of different acupuncture studies. This is due to the acupuncture concept comprising many types of stimulation such as body or auricular acupuncture, deep or superficial needling, mild or strong or electric or manual stimulation of the needles. Some researchers have not even used needles, but “acupuncture-like stimulation” in the form of laser, electrodes, acupressure or seeds taped to an acupuncture point. Many acupuncture trials are conducted with animals in experimental situations. The animals, either awake and stressed or anesthetised, have been given electric and probably painful stimulation via needles that were relatively much thicker than those used in human acupuncture. This implies that results from an experimental study cannot always be transferred to clinical acupuncture.

Most acupuncture research focuses on evaluating the effect of needling in one single, or a few different, acupuncture points in an RCT. Very few studies are conducted in clinical settings, including all parts of TCM treatment, and even fewer trials use TCM diagnoses and individually chosen treatment protocols. Conducting an RCT on the effect of acupuncture assumes that the components of the TCM treatment (acupuncture, herbs, therapist/patient relationship, dietary changes, lifestyle advice, moxa, cupping) are separable and do not interact.

**Acupuncture in Sweden**
The first Swedish thesis on acupuncture was written in 1829 by Gustav Landgren, but acupuncture was only sparsely used in Sweden up until the 1950s. Acupuncture has been used in the Swedish National Health Service since the 1980s. Swedish acupuncturists comply with different legislation depending on their medical background. Registered health professionals, for example nurses, midwives, physiotherapists and doctors, can use acupuncture on indications where there is evidence that acupuncture has effect (Socialstyrelsens Meddelandeblad 11/93, 1993). Acupuncturists not belonging to a medical profession comply with different legislation (The Health and Medical Service Act, section 4). They are allowed to use acupuncture on wider indications as they are not limited to evidence-based treatment but, on the
other hand, they have other restrictions. For instance, they are not allowed to treat children under the age of eight years.
AIMS

The aim of this thesis was to elucidate parents’ experiences of having, and having had, a baby with infantile colic and to evaluate the effect of acupuncture treatment on infantile colic. Specific aims were formulated as follows:

- To illuminate the meaning of being a parent of a baby with infantile colic.
- To elucidate parent’s experience of having had an infant with colic and how the colic and the care influenced the family in a long-term perspective.
- To investigate whether acupuncture reduces the duration and intensity of crying in infants with colic.
- To describe the feeding and stooling patterns of infants with colic and to evaluate the influence of minimal acupuncture on feeding, stooling and sleep patterns in infants with colic.
METHODS

Design

This thesis includes two qualitative studies with an inductive design (Study A and B) and one prospective clinical blinded randomized controlled trial (Study C) resulting in four papers. An overview of the samples and the methodology can be seen in Table 2.

Table 2. Sample and methodology

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Methodology</th>
<th>Paper</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>23 parents (12 mothers and 11 fathers)</td>
<td>Individual interviews Phenomenological hermeneutic analysis</td>
<td>I</td>
</tr>
<tr>
<td>B</td>
<td>17 parents (10 mothers and 7 fathers)</td>
<td>Individual and focus group interviews Content analyses</td>
<td>II</td>
</tr>
<tr>
<td>C</td>
<td>90 infants with colic (46 in acupuncture group and 44 in control group)</td>
<td>RCT Statistical analysis and content analyses</td>
<td>III, IV</td>
</tr>
</tbody>
</table>

In Study A and B parents were interviewed about a certain phenomenon, namely: having, and having had, a baby with infantile colic. Two qualitative methods, phenomenological hermeneutic analysis and content analysis, were used to analyse data collected in individual interviews and in one focus group interview. Qualitative methods are well suited for describing a phenomenon and for elucidating the essential meaning of the lived experience of the parents. Narratives touch us and move us, and through a narrative we can participate in another person’s life world without concluding or judging whether it is right or wrong.\(^\text{188}\) Focus groups are an academic research tool used to provide qualitative data in a focused discussion and thereby gain insight into complicated topics. They are used when the aim is to understand how people who have something in common feel or think about an issue and when one is trying to understand differences in perspective.\(^\text{189}\) A randomized controlled study (RCT) is the golden standard to detect differences between groups. The qualitative studies were, in this thesis, combined with the statistical analysis of data collected in RCTs conducted to describe feeding and stooling patterns and evaluate the effect of acupuncture in infantile colic (Study C). In Paper IV quantitative and qualitative methods were combined.\(^\text{190}\)

The context of the studies

The studies were conducted in Helsingborg, a city of 110,000 inhabitants in southern Sweden. Families living in towns and rural communities up to 100 km from Helsingborg participated. 90 nurses at CHCs, four private paediatric doctors, the paediatric clinic at the hospital and the acupuncture clinic where Study B was
conducted were involved in recruiting participants. The acupuncture clinic has three treatment rooms and a small waiting room where music is played through loudspeakers. All infants continued the regular programme at their ordinary CHC for the duration of the study.

**Study population**

Twenty-five parents of otherwise healthy babies, seeking help for infantile colic at a CHC in Helsingborg and having verified in a diary the infants’ crying as lasting more than three hours per day and for more than three days in the same week, were asked to participate in Study A. Parents were selected to ensure variation in age and gender and whether they were first-time parents. Of those selected, two fathers declined immediately due to time pressure. The remaining 23 parents (twelve mothers and eleven fathers), all married or cohabiting, represented 14 families. In nine families both parents were interviewed, and in five families one of the parents was interviewed. Two families had newborn twins and in both of these families one of the infants had colic and one did not. At the time when the parents were interviewed, the infants varied in age between 4 and 20 weeks (mean 9.6 weeks). All the infants had colic symptoms at the time of the interview although, for some, the symptoms had improved from their lowest point. For background variables see Table 3. None of the parents had an infant participating in Study C.

In Study B all the parents who had participated in Study A four years earlier were invited to a second interview. Of the 23 parents taking part in Study A, one father declined to participate due to a lack of time, and one could not be found. One mother who lived far away and one father who had moved abroad wanted to take part but interviews could not be arranged with these parents for practical reasons. One couple scheduled for the focus group interview did not show up. The remaining 17 parents (10 mothers and 7 fathers) representing 12 families were interviewed. For background variables see Table 3.
### Table 3 Sociodemographic characteristics of the participants.

<table>
<thead>
<tr>
<th></th>
<th>Study A</th>
<th></th>
<th>Study B</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>Mothers</td>
<td>Fathers</td>
<td>Mothers</td>
<td>Fathers</td>
</tr>
<tr>
<td>n</td>
<td>12</td>
<td>11</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>age, min – max (mean)</td>
<td>22 – 39 (30)</td>
<td>23 – 51 (32)</td>
<td>26 – 44 (35)</td>
<td>28 – 56 (39)</td>
</tr>
<tr>
<td>Married/cohabiting</td>
<td>12</td>
<td>11</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>University degree</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Immigrant n (mean years in Sweden)</td>
<td>1 (2)</td>
<td>2 (7)</td>
<td>1 (6)</td>
<td>0</td>
</tr>
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<td>Having only one child</td>
<td>7</td>
<td>9</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Number of children</td>
<td>1-4</td>
<td>1-4</td>
<td>1-4</td>
<td>1-4</td>
</tr>
<tr>
<td>Had experience of children with colic before the first interview</td>
<td>4</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Having had a new baby since the first interview</td>
<td>-</td>
<td>-</td>
<td>6</td>
<td>4</td>
</tr>
</tbody>
</table>

In Study C, sample size was calculated based on a power analysis, showing that to have a 90% chance of detecting a difference in remission rate of 50% in the control group (estimated spontaneous remission) and 75% in the treatment group as significant at a 5% level, 40 patients per group were needed. Criteria for inclusion were that the infants should be healthy, 2–8 weeks old, be born after gestational week 36, not be medicated with dicyclomine, and fulfil the modified Wessel criterion for colic: “crying/fussing at least three hours a day, three days or more in the same week”. Parents seeking help for infantile colic at either of the CHCs in the town, the hospital’s paediatric clinic or the acupuncture clinic where the study was conducted were preselected consecutively from November 2005 to February 2007 by the professionals who were informed of the inclusion criteria. Parents of 210 eligible infants willing to participate recorded the amount and degree of their infant’s crying and fussing in a diary for at least three days. The 90 infants who fulfilled the colic criterion were randomized (44 to the control group and 46 to the acupuncture group). We used stratified randomization to ensure that 2–5 week old infants and 6–8 week old infants were equally distributed between groups. To prevent infants recovering due to non-exposure to cow’s milk during the study period, all parents who had not already tried a five-day period without exposing their infant to cow’s milk protein were urged to try this intervention during the baseline week. Thus, infants who recovered due to this intervention were not included. Eighty-one infants continued through the three intervention weeks (see the flowchart in Figure 1). For baseline data see Table 4.
Eligible infants whose parents reported their crying in a diary (n=210)

Not meeting the criterion for infantile colic (n=120)

Randomization (n=90)

Allocated to acupuncture group (n=46)

Allocated to control group (n=44)

Excluded (n=3): were included by mistake in spite of not having met the inclusion criterion. Drop out (n=1): parents went to an acupuncturist where the infant was guaranteed acupuncture

Started the structured programme with six visits to the clinic, including acupuncture (n=46)

Started the structured programme with six visits to the clinic, without acupuncture (n=40)

Lost to follow-up (n=3): started with dicyclomine

Lost to follow up (n=2): one of them got dicyclomine, one dropped out when parents went to an acupuncturist where the infant was guaranteed acupuncture

Included in the analysis (n=43)

Included in the analysis (n=38)

Figure 1. Flow of infants through trial
Table 4. Baseline data for infants

<table>
<thead>
<tr>
<th>Background characteristics</th>
<th>Infants completing 3 weeks (N=81)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acupuncture group (n= 43)</td>
</tr>
<tr>
<td>Firstborn, n (%)</td>
<td>21 (48)</td>
</tr>
<tr>
<td>Gender, female, n (%)</td>
<td>21 (50)</td>
</tr>
<tr>
<td>Gestational age, weeks. Mean (SD)</td>
<td>39.3 (1.4)</td>
</tr>
<tr>
<td>Age when colic started, weeks. Mean (SD)</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>Age at inclusion, weeks. Mean (SD)</td>
<td>5.1 (1.9)</td>
</tr>
<tr>
<td>Solely breastfed, n (%)</td>
<td>32 (74)</td>
</tr>
<tr>
<td>Having a parent and/or sibling with food intolerance/allergy, n (%)</td>
<td>15 (35)</td>
</tr>
<tr>
<td>Having a parent and/or sibling who had had infantile colic, n (%)</td>
<td>25 (58)</td>
</tr>
</tbody>
</table>

Control and acupuncture groups

In Study C, infants in both the control and acupuncture group went through a structured programme consisting of six visits to the acupuncture clinic, twice weekly. The first visit lasted 30 minutes during which the parents met nurse B (KL, who was blinded to the group allocation) who repeated all the information relating to the study and collected baseline demographic data. During the following five visits, parents met this nurse B for a 15-minute appointment that included standardised questions concerning the degree of crying, standardised oral support, and a time for questions. Thereafter nurse B carried the infant to a treatment room, left the infant with nurse A, a registered nurse with extensive acupuncture skills and who was hired specifically to perform the randomization and administer the intervention. The initial handling of the infants in the treatment room was identical. Nurse A held the infant’s hand and talked to it in a calm voice, repeating the same sentences to all infants. After this procedure the infants who were allocated to the acupuncture group were given minimal, standardised acupuncture with a sterilised, disposable acupuncture needle, Vinco Micro Clean, 0.20 x 13 mm. The needle was inserted unilaterally and left in place for two seconds at a depth of approximately two millimetres in the acupuncture point LI4 of the first dorsal interossal muscle of the hand, innervated by the ulnar nerve by sensory and autonomic, mainly sympathetic, fibres. Left and right hands were used alternately. After a total of five minutes in the treatment room, nurse B entered and carried the infant back to the parents.
Instruments

Interview
In Studies A and B parents were asked to narrate their experiences of having, respectively having had, a baby with colic. All interviews in Study A were individual and commenced as follows: “Tell me about your experience of having an infant with colic”. In Study B, which covers both an individual and a focus group interview, the interviews started with the question “Please, tell me/us about your spontaneous memory of having a baby with colic four years ago”. Further questions in both Studies A and B were asked aiming at encouraging further narration, like: “How did you feel then?” or “What do you mean?” After the interview, the interviewer gave a summary of what she had heard, and if the parent wanted to add or correct something, the tape recorder was started again. If parents in Study B did not touch on any of the interview areas, they were asked more specific and focused key questions like “How did the colic influence family relations?” and “Which words of advice were you given?” “Which kinds of treatment did you try?” and “Did the treatment work?”

Diary
To measure infants’ crying, a diary (see Appendix A) was used in Study A and in Study C to see whether infants fulfilled the modified Wessel’s criterion for infantile colic. The same diary was also used daily in Study C during the three intervention weeks. The diary was first presented by Barr et al, further developed by St James-Roberts et al and slightly further modified by Canivet et al. In the diary, crying and fussing were recorded in detail. The diary had boxes for every 5-minutes period during a 24-hour period, from 06.00 to 06.00 the next day. Parents also noted times and length of feeding, and the infant’s stooling, marked with “S” for stooling or “s” for a “stain in the diaper”. Parents were informed both verbally and in writing (see Appendix B) about how to use the diary. Examples of how to record were given and parents could phone for information if they were unsure.

Questionnaires
In Study A, socio-demographic data such as age, education, infant’s age, siblings, and any previous experience of having a baby with infantile colic were obtained via a questionnaire prior to the interviews. In Study C, two questionnaires were used. One for obtaining baseline demographic data about the infants and their parents, including questions about education, smoking, the pregnancy, delivery, medication, parental and sibling allergies, age when the colic started, and the infant’s feeding. A second questionnaire, used by Reinthal, included questions about perceived changes in the infant’s feeding pattern, stooling, sleep and progress of the colic, and whether or not any side effects had been noticed. A record of the infant’s visits to the treatment room was kept, documenting the infant’s study number, allocation, intervention given, whether the infant was crying and the time of the crying, and bleeding or any other adverse events.
Data collection

Individual interviews with parents (Study A) were conducted by KL between March 2006 and April 2007. Date, place and length of the interview was decided by the parent. Four parents chose to be interviewed at the interviewer’s workplace and 19 parents were interviewed in their homes. Interviews lasted between 17 and 55 minutes (median 35 minutes). Time was reserved so that parents could relax and take their time. If their infant needed attention during the interview, the interview was interrupted until the parent could focus on the interview again. All interviews were tape-recorded and transcribed verbatim by KL.

For Study B the first 10 individual interviews with parents were conducted by two pediatric nurses. Three individual interviews were conducted by the second author, AL. The focus group interview with four parents was conducted by the second and the third authors of Paper IV, AL and IH. Interviews were conducted between December 2010 and May 2011. Date, place and length of the interview was decided by the parent. All parents who were individually interviewed chose to be interviewed in their homes. The focus group interview took place in a conference room. Individual interviews lasted between 30 and 60 minutes. The focus group lasted 95 minutes. All interviews were tape-recorded. The first ten interviews were transcribed verbatim by the interviewers, the remaining interviews were transcribed verbatim by KL.

Collection of data for Study C started in November 2005 and continued until February 2007. Parents registered their infant’s crying and fussing in the diary, three to seven days during baseline. Parents of infants who were crying/fussing for more than three hours per day, more than three days per week and thereby fulfilled the modified Wessel criteria for colic were included and they continued to register the infant’s crying, fussing, stooling and sleeping in the diary on a daily basis during the three intervention weeks. During the first visit to the acupuncture clinic, baseline demographic data were collected. At the next five visits, parents were asked to complete the questionnaire concerning perceived changes and side effects, as well as the infant’s sleep and the progress of colic. Nurse A was responsible for documentation of data relating to visits to the treatment room.
ANALYSIS

Phenomenological hermeneutic analysis

Phenomenology is a method used to describe a phenomenon and hermeneutics is a method of interpretation. A combination of these two – a phenomenological hermeneutic method inspired by Ricour, described by Lindseth and Norberg – was used in Study A. The purpose of the phenomenological hermeneutic method is to describe a phenomenon and to elucidate the essential meaning of the lived experience that is expressed in the text.

The phenomenological hermeneutic analysis included three methodological steps. In the first step, both authors read the interviews several times – naïve reading to grasp the general meaning – and a naïve understanding was formulated. The naïve understanding was later validated or invalidated in the structural analysis performed by KL, with this forming the second step. In the structural analysis, the text was divided into meaning units and then condensed, i.e. the essential meaning of each meaning unit was expressed in everyday words. The text was then abstracted to form sub-themes, themes and a main theme (Table 3). The text was reread and the structural analysis was discussed in a dialectic movement between understanding and explanation. The themes were checked and discussed and reflected on in relation to the naïve understanding until the themes matched the naïve understanding and the authors reached an agreement. In the third step, the authors used their imagination and associations with relevant literature in order to revise, widen and deepen their understanding of the text and the parents’ lived experience, formulating a comprehensive understanding.
### Content analyses

In Study B, the narratives were analysed with content analysis, another method well aimed to illuminate participants’ experiences of a certain phenomenon. First the interviews were listened to and read through several times to obtain a sense of the whole. Then the text was divided into meaning units which were condensed. The next step was to abstract the text into codes. The codes were compared based on differences and similarities and sorted into sub-categories and categories (Table 4). The tentative categories lead to a process to find the underlying meaning including discussion and reflection among all three authors until consensus was reached and the underlying meaning was formulated into themes and sub-themes. The interviews were read again to confirm that all text that was relevant the purpose had been included. Finally an overall theme was formulated, i.e. a thread of the underlying meaning of all themes and sub-themes.
Table 4. Examples of meaning units, condensation, subcategories and categories forming the theme “Remembering the chaos - but life went on and the wound healed”.

<table>
<thead>
<tr>
<th>Meaning units</th>
<th>Condensation</th>
<th>Subcategory</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never felt like… I didn’t think… I mean she wasn’t a burden in my life or in our relationship.</td>
<td>She wasn’t a burden in my life or in our relationship.</td>
<td>Distance and closeness to the suffering infant</td>
<td>Relations were strained but healed.</td>
</tr>
<tr>
<td>So I didn’t think that she’d come and destroyed anything. She made it tough for us but I never felt… mostly I felt sorry for her.</td>
<td>She didn’t destroy anything. I felt sorry for her.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>But, meanwhile I thought that if baby number two would get colic, I would still be a bit safer because now I know that colic heals and that there’s an end to it. But yet I was afraid it would happen again.</td>
<td>I felt safer with baby no. 2 because I knew that colic heals.</td>
<td>Feeling confident in parental role</td>
<td></td>
</tr>
<tr>
<td>But I felt the time was tough. When my daughter asks today “How was I when I was little?”, the first thing I think (laughter) is “Yes, you cried, you cried all nights and all days when you were little and you never slept, but otherwise you were good”.</td>
<td>When my daughter asks I tell her that she cried day and night but otherwise she was good.</td>
<td>Missing the golden baby-period</td>
<td>Isolation ended while the colic resumed</td>
</tr>
<tr>
<td>But still, somehow, you forget it quickly. Like that.</td>
<td>You forget it quickly</td>
<td>The memory fades</td>
<td>Overwhelming emotions turned into relief.</td>
</tr>
</tbody>
</table>

In Study C, parts of the data were analysed with content analyses. Answers concerning changed stooling and possible side effects, collected in questionnaires, were summarised and analysed with content analysis at a manifest level meaning that the visible content in the text was coded. Similar remarks were grouped together into one code, codes with similar content were grouped into categories and the amount of remarks was registered. The coding was done by the first author (KL) and subsequently checked by the third author (IH) to ensure intercoder reliability.

**Pre-understanding**

In a qualitative study, the authors’ preunderstanding is part of the interpretative process as well as being a guiding tool. Over the years I have met several hundreds of families with babies with infantile colic, initially as a nurse at a paediatric emergency unit and for the last ten years at an acupuncture clinic. Being specialised in psychiatry, I am trained to be aware of patients’ emotions and of the importance of
strengthening their resources when they are fragile. I am trained in both TCM and medical acupuncture theories and have worked as an acupuncturist for twenty-four years. The second and third authors (IH and AL) have extensive experience involving work and research with children and parents. Hence our pre-understanding was discussed, reflected upon and bracketed throughout the process in order not to judge or influence the interpretation in a biased way. When analysing the data collected in Study B, we (KL and IH) were aware that our pre-understanding was influenced by the analyses of the interviews in Study A.

**Statistical analysis**

Results were calculated with a statistical analysis in Study C. The power calculation was based on assumptions of how acupuncture would affect the primary outcome of crying. If 50% of the infants would go into spontaneous remission without treatment and 75% with acupuncture, 40 patients per group were needed in order to have a 90% chance of detecting a significant difference in remission rate at a two-sided 5% level. The statistical software SPSS™ version 17 (SPSS Inc., Chicago, IL) was used for calculations. As some variables in Study C were not normally distributed all data were analysed with non-parametric statistics. Kaplan Meier analysis was performed to assess the time it took for each infant’s crying to fall below 180 minutes, indicating that the infant no longer fulfilled the criteria for colic. The Mann-Whitney U test was used to analyse differences in crying, feeding and stooling between groups at each time point. The relative difference in crying and fussing between the baseline and the intervention weeks were measured in percent. Changes in feeding and stooling within the groups over baseline and the three intervention weeks were analysed with the Friedman test. P-values of < 0.05 were considered statistically significant.
ETHICAL CONSIDERATIONS

Ethical approval was obtained from the University’s Research Ethics Committee (Reference no. 583/2005). In this thesis the most salient ethical issues were found to be those regarding the involvement of children in research, informed consent and the researcher-participant relationship.

Involving children in research

Children should not be involved in research if the desired information can be found by other means. On the other hand it is extremely important that methods of treatment used in paediatric care are evidence-based as children cannot choose treatment themselves. It is also important that treatment used for children is evaluated on the basis of children.

Acupuncture is an invasive method and, as such, controversial particularly in paediatrics. Therefore, the associated risks were questioned rigorously before the study started. When treating children with acupuncture, the need for needle stimulation strong enough to achieve an effect balances the fear of overstimulation. Use of stimulation that is too mild becomes an obvious risk, with infants perhaps being treated with an invasive method with no chance of achieving effect. In such cases, there is also a risk that acupuncture could be considered ineffective, although it was in fact just the stimulation technique that was too mild. In one review, acupuncture was considered to be a safe modality for paediatric patients, but the authors stated the advisability of applying only a few needles or delaying treatment in the case of children who have overeaten or are very weak. In Study C we used acupuncture with light stimulation to avoid the risk of overstimulation.

Separating an infant from its parents is a sensitive issue. Therefore steps were taken to minimise the disadvantages. To minimise unease for the infant and the parents in Study C, the nurse asked pleasantly whether she could take the infant for a few minutes prior to carrying the infant to the treatment room, with the separation taking place when the parents felt ready. The period in the treatment room was short and the infant was not woken if it was sleeping. We were aware of adverse events, and both the nurse who administered the acupuncture and the parents reported possible side effects. Record was made of whether the infant cried during treatment and, if so, for how long.

For the duration of the study, all infants continued their regular programme at their ordinary Child Health Centre so that any illness that could explain the infant’s crying had the same chance of being detected as if the infant had not participated in the study.

If acupuncture can be shown to be effective, it can be of benefit for children in the future with infantile colic.
Informed consent and confidentiality

Informed consent means that a person has evaluated the potential drawbacks and benefits of participating in a study. As infants cannot give informed consent, this was obtained from their parents \(^{199, 200}\) (SFS, 2003:460, Swedish Statute 2003:460 about the Ethical Review of Research involving Humans) for Study C, with both parents giving their informed consent for each infant. Parents received repeated oral and written information, including the freedom to discontinue their (Study A and B) or their infant’s (Study C) participation at any time without further explanation. All parents were informed about and were guaranteed confidentiality. The participants’ names were protected in code-lists and changed in the transcribed interviews. Code-lists were kept separate from the data and all data were stored securely.

Researcher-participant relationship

Doctors and nurses informed parents about the studies when parents sought help for their persistently crying infant, either at a CHC, the hospital’s paediatric clinic or a private acupuncture clinic in Helsingborg. In Study A, parents whose infants were starting treatment at the acupuncture clinic were asked by the acupuncturist, KL, to participate. As she was going to treat their infant, there was a risk of parents finding themselves in a relationship of dependency with the investigator. The acupuncturist/interviewer was aware of this, and made efforts to minimise the event of parents feeling obliged to participate. This could be done by pointing out that participation was voluntary; that participation or non-participation would not influence the treatment of the infant, and that they could decline whenever they wanted. During the days between signing the informed consent and the interview, they had time to reflect and consider carefully whether they wanted to participate. Before the interview started, the interviewer repeated the information about their right to decline. The atmosphere during the interviews was friendly and relaxed, and the interviewer made every effort to show respect and be non-judgemental. Clarification in order to eliminate misunderstandings was sought in as neutral a manner as possible. Several of the parents that were interviewed, spontaneously expressed relief and positive feelings after having told their story. In Study B the interviews were conducted by interviewers who had not met the parents before.
RESULTS

Parents’ experience of having and of having had an infant with colic (Study A and Study B)

The phenomena of living with a baby with infantile colic formed the main theme “Colic overshadows everything” with the sub-themes “Living in an inferno”, “Missing the situation dreamt of” and “Surviving infantile colic” (see Table 2 in Paper I). The naive understanding is expressed as a metaphor: parents were compared to passengers on a ship in stormy seas. They had started out with high expectations, but had not expected the journey to be so exhausting. They had lost control, were living at the limit of their capacity, and were tired and afraid of drowning. The crew could not help. Suffering with the baby, parents searched for strategies to enable the family to survive. They tried every trick to make the trip easier for themselves and for the baby, and clung to each other for help. Their main goal was to dock safely. When the waves calmed occasionally, they could see the sun and feel hope for the future.

Parents could not, when they were in the midst of the colic period, believe that a baby could cry that much without having a serious medical disease. The child’s colic was described as a strain for everyone in the family and their relationships were challenged. Parents were convinced that their child was in great pain and they found it unbearable to hear the heartbreaking, hysterical, inconsolable cries. Parents felt powerless when neither their endless efforts nor the medicine helped. Mothers had no time to fulfill even their most basic needs such as eating or taking a shower. Fathers were stressed about having to perform well both at work and at home. Both parents had a guilty conscience for not being able to help the infant’s siblings with school work or other activities while the baby was crying.

Parents felt shame as they thought they were not good enough as parents. They felt guilty because they were not only happy and grateful. Parents tried to control themselves but did not manage to act as they wished. They got close to handling their children roughly when they were exhausted or very frustrated. Parents described how they sometimes had cried, hit things or screamed in despair when they lost their temper. Sometimes they just gave up and had to take a break to prevent themselves from going over the top. The seeing of relatives and friends was minimised as parents never knew when their child would be crying. They felt “locked in”. To get through the colic period, parents used various strategies such as trying different drops and herbal teas, milk-free diets and massages, baby slings and baby carriers. They rocked and sang and danced with the baby in their arms, trying different sounds and baby formulas and specially designed bottles to make their baby cry less, and they sought information in many different ways. Sharing the burden was of the utmost importance and helped parents to gather new strength. Some parents shared their burden with professionals, taking the baby to the hospital or to the CHC. Parents felt that professionals could not imagine what the situation was like and they often felt ignored.
Once they had accepted that the inferno was quite simply their reality, parents rolled up their sleeves and started dealing with “project colic” using their existing inner resources. They concentrated on being patient, counting down the time until this three-month period was over. Parents felt relief, for both themselves and for the baby, when they discovered what to do so that the baby would not cry as much. The more knowledge and experience they gained, the more proud and confident they became. Even in the middle of the colic period, the child was the parents’ greatest joy and they could feel intense pleasure when the child had moments of contentedness.

Four years after the colic period parents recalled this time vividly. The main theme was “Remembering the chaos but life went on and the wound healed” (see Table 2, Paper II). They described how parenting and everyday life was a struggle when the colic was at its peak, and how this perceived emotional and practical chaos, characterized by strong feelings and frustration, had turned into relief once the colic disappeared. The colic scream was remembered as unbearable, deafening and traumatizing and impossible to ignore, and hearing colic screams still evoked negative feelings.

Parents experienced that the relationships within the family were strained and family life became disrupted during the colic period. On the one hand parents described a delayed attachment to the infant; on the other hand a close tie to the suffering child and now, four years later, all parents had developed a good relationship with the child. Likewise, the relationship with their partner was either described as very strained or as stronger than ever as they shared the burden of the chaotic everyday life. When the colic declined, relationships between parents could normalise. Fighting the colic together had even strengthened their relationship. They now knew how capable they were, and they were proud that they had endured that difficult period.

The worst part for parents was not being believed. They felt that nobody understood their situation and that the nurse at the CHC lacked knowledge about colic. They were disappointed that the advice they were given had not helped. Most parents were positive about the acupuncture treatment the infant had received, and thought that this helped soothe the symptoms.

Finally, parents’ experience was primarily that once the colic had healed then the family relationships also began to heal. They were still disappointed that they had not had “the golden baby-period”. Some thought that their four-year-old children were more sensitive than other children and some thought that their children were tougher and more resistant to pain than others. Parents themselves were now more sensitive to others’ infants if they cried excessively and many wanted to help parents with colicky infants. They felt there was a need for CHCs where nurses were responsive and had knowledge about colic, and most of all they wished for a cure for colic.
The effect of acupuncture on infantile colic (Study C)

Of the 210 infants believed by the parents to suffer from colic, only 90 infants fulfilled the criteria, according to the registering of symptoms in the diary, and were randomized to acupuncture or no acupuncture. There were no significant differences between groups regarding demographic data, crying and fussing (See Table 2 in Paper III) nor with regards to feeding or stooling (See Table 2 in Paper IV) during the baseline registration week.

Crying
Acupuncture for two seconds in LI4, twice a week for three weeks, shortened the duration and reduced the intensity of crying in infants with colic. There was a difference (p=0.034) between groups regarding time passed from inclusion until the infant had a mean value for TC under 180 minutes/day for the first time, indicating that the infant no longer met the criteria for colic. Figure 2 in Paper III demonstrates this difference by showing the proportion of infants with a mean TC that was less than 180 minutes a day for each of the six treatment periods consisting of three or four days depending on whether treatment was given on a Monday or a Thursday. Median time until criteria for colic were no longer fulfilled was 7 days in both groups. The duration of fussing was shorter in the acupuncture group during the first (p=0.029) and second (p=0.047) intervention weeks. The duration of colicky crying was shorter (p=0.046) in the acupuncture group during the second intervention week. However, TC was lower in the acupuncture group than in the control group as early as the first intervention week (p= 0.025) and in the following intervention week (p=0.016) (Table 3 in Paper III). A sub-analysis showed TC to be lower (p=0.005) in the acupuncture group already after the first treatment. The relative difference between groups, measured in percentage of decreased crying and fussing from baseline to intervention weeks 1, 2 and 3 shows differences between groups for fussing the first week (p=0.028), for colicky crying the second week (p=0.041) and for TC the second week (p=0.024) (Table 4 in Paper III).

Feeding
During baseline and the three intervention weeks infants in both groups were fed approximately eight times a day with a variation between 5.3 and 14.2 times a day (Table 2 in Paper IV), placing this group in the upper level of the previously reported norm of 6-8 times a day. At inclusion the appetite of the infant was described as “gluttonous” by 56% of the parents, as “good” by 42% and as “bad” by 2% with no difference between the groups. The duration of feeding in the present study was approximately 148 minutes a day, with considerable variations (min 49, max 458). Minimal acupuncture had no major effect on feeding.

Stooling
Infants with colic in the present study had a higher frequency of stooling than reported internationally in healthy infants. At baseline when the infants in the present study had a mean age of five weeks they had bowel movements 4.1 times a day (acupuncture
Frequency of stooling varied widely between infants in the present study, from the mean of 0.1 to the mean of 12.4 times per day (Table 2 in Paper IV). There were no significant differences between groups in the mean frequency of stooling (Table 2 in Paper IV) and there was an expected decline in both groups during the intervention weeks (p=0.001 in the acupuncture group and p<0.001 in the control group). The frequency in the third intervention week, mean age eight weeks, was 2.1 times/day in the acupuncture group and 3.1 in the control group. Thus the frequency in the control group remained higher than average whereas infants in the acupuncture group reached a frequency reported in earlier studies of healthy infants. The mean value of large bowel movements decreased linearly in the control group (p=0.011) but not in the acupuncture group (p=0.787).

**Changed stooling patterns and possible side effects**

In the acupuncture group parents commented on changes in stooling habits of their infants 56 times as compared to 25 times in the control group. Comments on changes in the stooling frequency and possible side effects consisted of a total of 271 remarks (168 from the acupuncture group, 103 from the control group). The amount of remarks reported from each group, codes and categories are presented in Table 3, Paper IV. Close to twice as many parents in the control group remarked that the infants’ stools were “more watery” (22 to 12). In contrast almost three times as many parents in the acupuncture group (16 to 6) remarked that the infant’s stools were “more firm.” The word “normalised” or a similar word was mentioned 22 times in the acupuncture group and 8 times in the control group. Parents in the acupuncture group gave 16 comments coded into “Can defecate/break wind easier/without help” compared to none in the control group.

**Sleeping and progression of colic from the parents’ perspective**

Infant’s sleep was rated as “better” or “much better” (see Table 4, Paper IV) more frequently in the acupuncture group than in the control group. During the second week parents in the acupuncture group reported “better” or “much better” 26 times (constituting 30% of the answers) compared to six times in the control group (8% of the answers). During the study period significantly more parents in the acupuncture group (28% compared to 15% in the control group, p=0.006) evaluated the infant’s sleep as “better” or “much better.” More parents in the acupuncture group experienced an improvement in colic during the study time at the last visit (Table 4, Paper IV).

**Side effects**

Slight bleeding (one drop) was detected after needling in one of the 256 acupuncture treatments administered. 32 infants (74%) in the acupuncture group cried for more than 10 seconds during one to four interventions in the treatment room compared to 14 infants (37%) in the control group (p = 0.009) (Table 5 in Paper III). Crying lasted for more than a minute in 37 out of 256 needling occasions (16 %). No infant cried for more than two minutes. No other adverse events were reported.
METHODOLOGICAL DISCUSSION

Methodological considerations

Qualitative and quantitative methods may complement each other in nursing research as they have different strengths and limitations [200]. In Study A and study B, qualitative methods were chosen in order to gain a deeper understanding of the phenomenon and the lived experience of having, and having had, an infant with infantile colic, since qualitative methods are aimed to illuminate participants’ experiences of a certain phenomenon. In qualitative studies, the aim is not to produce results that we can explain or control. Thus, we have not studied whether or not parents’ stories are true, if all of the parents have the same experiences or how often a phenomenon has appeared, and methods used for validation in quantitative studies cannot be used. In Study B, the thirteen individual interviews were combined with one focus group interview to further explore parents’ experiences. A focus group is an academic research tool that yields qualitative data in a focused discussion and, thereby, provides insight into complicated topics and understanding of differences in perspectives.

In Study C, quantitative and qualitative methods were combined in order to be able to detect even subtle changes that are not so easily captured, such as characteristics of bowel movements other than the two variables of frequency and size.

For the qualitative analyses the concepts of credibility, dependability, transferability and confirmability, all of them parts of the concept of trustworthiness and used in qualitative studies, are discussed.

In Study C, we conducted an RCT to measure the effect of acupuncture in infantile colic. RCTs are recommended (Medical Research Council, 2008) for the evaluation of differences between groups and to achieve results that can be generalised to a larger population. Study C was registered at ClinicalTrials.com, a registry and web-site linked to the US National Institutes of Health, to provide anyone with easy access to information about the ongoing study. The concepts of internal validity, construct validity, statistical validity and external validity are discussed.

Trustworthiness

Credibility refers to how confident the reader can be about the truthfulness of the results and conclusions. It comprises how the data were collected, how data are covered in the emerging themes, and whether relevant data have been left out. In Study A and Study B the data were collected during interviews with parents who had the ability and the willingness to openly share their experiences. This provided data rich in depth as well as in breadth. The 23 parents in Study A were interviewed when the infants still had colic symptoms, although for some the symptoms had improved from their lowest point. The 17 parents in Study B, who all participated in Study A, were
interviewed four years later. To ensure truthfulness, the interviewer’s understanding of the information was checked with follow-up questions during the interviews. To establish credibility during the analysis process, the emerging themes were discussed between the authors until they reached agreement. The authors’ pre-understandings were discussed, reflected upon and bracketed throughout the process in order not to judge or influence the interpretation in a biased way. To add depth and insight to interpretation, the preliminary results were also discussed at research seminars with paediatric nurses and midwives.

Credibility presumes a selection of participants with differing experiences. Purposive sampling was therefore used in Study A to get a broad variation regarding age, gender, education, living conditions and family situation, whether they were first-time parents and whether they had earlier experience of having a colicky infant. Mothers as well as fathers were asked to participate, and everyone who was asked to participate in the interview study agreed, with the exception of two fathers who both said they had no time to take part. Interviews were conducted individually so that the partner’s presence could not exert any influence. Parents with different socio-demographic backgrounds took part, but no single parent was available during the period of data collection, which would have been preferable. 17 of the 23 parents from Study A were interviewed in Study B which must be considered a reasonable number for a follow-up as four years had passed, and all families except one from Study A are represented by at least one parent in Study B.

Study B consists of 13 individual interviews and one focus group interview including one couple and one single father and one single mother. In the focus group a response from one participant triggered memories and thoughts in other participants. The parents might have influenced each other, which on one hand is a risk but on the other hand is one of the reasons for using focus groups. The talking flowed freely and intimate facts and feelings were shared in this interview like in the individual interviews.

**Dependability** relates to the extent to which data change over time and under different conditions. Dependability is difficult to achieve in qualitative research as experiences change over time. The world that everyone sees is not “the” world but “a” world; their personal perception of that world. Change occurs in humans, triggered by interactions. Parents are triggered by interactions between family members or with the environment in which the family exists. No one way of experiencing the world is more right or wrong than any other.

Parent’s recall of what it had been like having an infant with colic four years previously might or might not be accurate. Parents’ experiences of the colicky period could have been altered or distorted over time, or by them having repeated the memory in conversations, or due to their having been interviewed about the topic. The aim of Study B was not to investigate how accurate and consistent long-term memories of the colicky period are but a comparison can nonetheless be made with the ability of women to recall other key events in life, linked with giving birth. Most studies of
women’s memory of labour and birth have concluded that there is a substantial agreement between maternal recall and birth records even decades after the delivery \(^{205-207}\) and maternal recall was valid with regards to the initiation and duration of breastfeeding three years after giving birth. \(^{208}\) Women’s memories of labour pains can often be vivid but not always entirely accurate \(^{209}\) and the experiences of labour pains and overall experience of the birth changes over time. In women with a negative overall experience of childbirth, the memory of the labour pains tends to increase through the years. \(^{210-211}\) Simkin \(^{212}\) investigated women’s memories not only about what had happened in childbirth, but also what had been said or done to them, and how they had felt, 15-20 years later. Some details were lost over the years, but many details were remembered and described by the women years later in almost the same way as they were originally. In the case of the death of a child the accuracy with which mothers remember their child’s symptoms seems to vary with the severity of the disease. Mothers reported most of the signs and symptoms their child had had before it died with a high degree of accuracy 6 months after the death. \(^{213}\) When mothers were asked to recall their children’s diarrhea on a weekly basis, they underestimated the frequency with 20 – 44\% \(^{214}\) and maternal reporting of symptoms of their children with pneumonia was non-specific after 2 and 4 weeks. \(^{215}\)

Dependability also relates to a logical, clearly described and traceable research process. Therefore, the research process in Study A and Study B is described as clearly as possible so others can follow how themes and sub-themes emerged from the narratives. Quotations are used as examples and the interpretations are grounded in the text.

**Transferability** concerns whether the results can be transferred or be relevant in other settings. \(^{200-201}\) In qualitative research the aim is not to find a result that can be repeated, but rather to gain understanding of others’ life worlds. There is always more than one way of understanding a text, \(^{216}\) and this limits the transferability of findings in qualitative studies. On the other hand, Dahlberg \(^{193}\) suggests that phenomenological results can be transferred to similar groups within the same context. The present studies were performed in Sweden, with Swedish-speaking, cohabiting parents, which might influence transferability to non-Swedish and single parents.

**Confirmability** refers to the neutrality and objectivity of the data. \(^{200-201}\) To achieve confirmability, both authors read the transcribed interviews separately before starting the analysis, and reached a naive understanding of the text. One interview was analysed twice by the same author (KL). To confirm the result further, quotes from the interviews were used to verify that the findings were retrieved from the data. \(^{195}\)

**Validity**

**Internal validity**

Systematic bias (or errors) can influence the result. Such bias includes selection bias (errors made when identifying a study population), information bias (whether exposure or effect are misclassified) and confounding factors as they can lead to an incorrect conclusion of causality, for example regarding the association between exposure and
Internal validity refers to avoiding such bias and, in Study C, internal validity refers to the question of whether or not we can trust that it is the acupuncture treatment that caused the differences in crying and the linear decrease of stooling between the groups, and that it did not cause any other changes of stooling frequencies or feeding.

As data were collected prospectively, the risk of selection bias was minimised. However, we do not know how many parents who sought help were not informed about the study, and we do not know how many parents were informed but were not interested in participating, or whether these families differ from the participating families. Only families in which at least one parent spoke Swedish were informed about the study and asked to participate. However, families with one parent from a different country and culture were included.

Study C included a strictly concealed randomization and a double blinding because of the infant’s limited communication skills. Not only the parents (and infants) but also the nurses they met were successfully blinded to the infant’s allocation. The intensity of the provider contact was thus the same in both groups, as the nurse gave the same support, confirmation and advice to all participating families. Study C includes only a few drop outs, and all infants remained in the same allocation throughout the study. A placebo effect in the present study is unlikely, as the infants probably did not expect any pain relief from meeting nurse B nor from receiving acupuncture. The present study avoided the risk of using an active control by blinding the parents who assessed the infants’ crying, and by not using any type of needles or needling in the control group.

Confounding factors are variables that influence the result. In Study C these could, for instance, be factors like the infant’s age, breastfeeding, parents who smoked, and medication such as antibiotics. These factors were equally distributed between the groups. To prevent the risk of spontaneous healing during the study period, the infants were included before the 8th week of age. Another confounding factor is exposure to cow’s milk. As all parents were recommended to eliminate cow’s milk protein for at least five days during baseline, we avoided the inclusion of infants whose crying was due to exposure to cow’s milk.

Dicyclomine was an exclusion criterion as it has a proven effect on infantile colic and four infants were excluded as they started treatment with dicyclomine during the intervention period. As three meta-analyses show that dimethicone has no effect other than placebo in infantile colic this was not an exclusion criterion. We nevertheless asked at the intake interview about consumption of dimeticone. Seventy-six parents, evenly distributed between groups, reported at inclusion that dimethicone had been tested or was still used. Lactobacillus reuteri was introduced on the Swedish market (under the brand “Semper Magdroppar”) when the first 63 infants were recruited. Among the last 27 infants recruited, 12 (six in each group) had tried lactobacillus reuteri before and during the baseline period prior to inclusion in the study. As these infants still fulfilled the colic criteria, they were included.
Evaluation of infants’ response to treatment is more difficult than in patients with a more developed communicative ability. The results in Paper III and Paper IV are based on parents’ recordings of their infants’ crying and fussing, feeding and stooling in a diary. The use of a diary validated in several studies by tape recordings of the infant’s crying' increased the precision of the data. One study showed a good correlation between parents’ diary records and tape recordings, and another that parents of infants with colic underestimated the crying by 33 minutes per day. However, registration of stooling did not include measurement of weight or description of colour. Parents in Study C were informed both verbally and in writing about how to use the diary and could ask questions during the study. The patients complied well with regards to filling in and returning the diaries. No infant was lost to the follow-up due to a loss of data, which can be seen as a validation both of the result and of the usability of the instrument.

**External validity**

External validity refers to the extent to which data can be generalised/applied to other populations, measures, times and settings. Study C was an RCT, which increases the possibility of generalising the results to other populations. The families were recruited in an area surrounding Helsingborg, a city in Southern Sweden, with different social categories being included. Colic is defined as persistent crying in otherwise healthy infants, but two infants with eczema (one in each group), one with a rash from a von Rosen splint, one who had fever for some days (both the latter in the acupuncture group) and one (control group) who was burned on the hand by boiling water were included. Likewise, we did include infants whose mothers had a high level of anxiety or were depressed. In this aspect, the participants corresponded to clinical reality. Only infants with parents who were positive about letting them try acupuncture and who were able to fill in the diary 24 hours a day for four weeks participated. Premature infants, who often cry more than full-term infants, were excluded. Consequently, the results of this study can only be generalised to full-term infants. Families in which neither parent spoke Swedish were not included in the study, but parents from other countries and cultures were included, implying that the results may be generalised to a broad range of families having an infant with colic.

The point LI4 was chosen in Study C because of its suggested effect on the intestines and its pain-reducing effect. Our results cannot be deemed valid for other points or methods of stimulation. Since the same point was used in the only randomized article published so far on acupuncture in infantile colic, this allows for a comparison of results.

**Statistical validity**

Statistical validity refers to the use of statistical methods in a study that allows for the detection of causal relations or differences between groups and between time points to be evaluated. A power calculation was performed to ensure that the sample was the size necessary in order to establish differences in crying. As the Kolmogorov-Smirnov test showed non-normal distribution for core variables, all data were analysed with
non-parametric statistics. In Paper III Kaplan Meier analysis was performed to assess the time it took for each infant’s crying to fall below the line of 180 minutes, indicating that the infant no longer fulfilled the criteria for colic. To evaluate differences between intervention and control groups the log rank test was performed. Mann-Whitney U test was used for analysing crying and fussing times and the relative difference in crying and fussing between the baseline and the intervention weeks was measured in percentages. In Paper IV the Mann-Whitney U test was used to analyse differences between groups at each time point. Changes within the groups over baseline and the three intervention weeks were analysed with the Friedman test. A power calculation performed to find differences in variables other than crying could have influenced the results in Paper IV.

Three infants, all allocated to the control group, were mistakenly included and randomized (they cried 15 minutes less than the criteria or fulfilled the criteria only two days during baseline) and were therefore excluded. To avoid allocation of more infants not fulfilling the colic criteria the procedure for analysis of the diaries prior to randomization was changed.
GENERAL DISCUSSION OF RESULTS

Infantile colic is a condition with spontaneous remission. It has been concluded that the one proven treatment is time\textsuperscript{219} and one could thus argue that it should not be a major problem. Yet there is an urgency about finding a treatment that could provide relief and be safe since the colic is a great burden to the family. Study C indicates that minimal acupuncture reduces time and intensity of the crying without adverse effects.

The parental mission is to be a secure base for the child and to form an attachment to their newborn child. Bonding can be delayed when positive communication between parents and child is missing, and the parents cannot fulfil the baby’s basic needs.\textsuperscript{220} In the interviews in Studies A and B, parents described feelings of hopelessness and despair when they could not comfort their infant. When parents found a way to console their baby, this provided comfort and well-being for the baby, the parents and the siblings. It was a transforming experience for the parents to find a way of comforting the child, to see the baby calm down and suffer less pain and distress. The parents then felt proud and pleased and appreciated their own value. Their self-efficacy increased, which is important as this can help attachment.\textsuperscript{6} Important validation of our findings is also that they are comparable with how parents experienced living with an infant with colic in three other qualitative studies conducted in the US\textsuperscript{3, 5, 7, 11} and in the UK.\textsuperscript{12} The findings regarding disrupted family life, strong emotions and feelings, were similar.

Interviews with parents showed that they lived in a complex life world and were influenced not only by the child’s colic but also by the support they received and how they were treated by professionals. Both mothers and fathers shared the colicky infant’s pain and frustration and felt that nurses and doctors did not understand the parental life world or take their situation seriously. Not all the parents were emotionally stable, nor had strong inner resources or good networks. Among the parents in Study A, as in that of Long & Johnson,\textsuperscript{12} sharing the burden was of the utmost importance. It was crucial for these parents, mostly mothers, to have another close contact to rely upon. Some parents said that their child’s colic strengthened their relationship while others described a challenged relationship, with some parents feeling both hopelessness and hope. An important finding was that, in the midst of the distress, parents perceived the child as the light of their lives.

Parents’ memories four years after the colic period were strikingly similar to their experiences described when they were in the midst of that period. Parents could recall exact details, and some told their story in the same words as four years earlier. However, parts of the memory had faded out, the wound had healed and the families had been repaired. A delay in the development of “good” feelings for the baby was experienced but the good news is that all parents had close relations to their four-year-old children. What is apparent is that parents had lost their confidence in the CHC, which is an alarming find, and that they had formulated suggestions for changes. Most of all, parents expressed the need for an effective treatment of colic, and also for the
presence of professionals with a sensitive and keen ear to families with colicky babies and who would pay attention to the child’s and the parents’ suffering.

Parents experienced that they had needed to be guided through the colic period. They searched actively for information on colic and got lots of tips of a diverse quality. When the professionals could not heal the child immediately, the parents in the present study wished that the professionals had at least given clear advice and that the advice had been followed up. Parents suggested a manual, a week-by-week structured set of directions, where treatments would be systematically tried and evaluated. To allow for this systematical guidance, parents wanted a more frequent contact with the nurse, as suggested by Long & Johnson.\textsuperscript{12}

Parents experienced that nobody understood how much their baby cried. A clear diagnosis, an examination to exclude the incidence of disease and reassurance that colic heals, although it takes time, had been better than not being believed, also expressed in Levitzky & Cooper.\textsuperscript{221} Parents appreciated the diary as a tool to reach an understanding of their situation. For professionals, the use of a diary could help to identify those children who actually do cry excessively.\textsuperscript{30, 120} Professionals could thereby discern when to intervene with medical examinations so as to exclude the incidence of disease and thus spare the parents from unnecessary anxiety and the baby from unnecessary treatments. Of the 210 infants in Study C, believed by the parents to suffer from colic, only 90 fulfilled the criteria according to the recordings of their symptoms in the diary. This indicates that parents have a tendency to overestimate (or to under-record) the crying.

The experience of the colicky period is for some influenced by variables such as depression or substance abuse. In these respects, they represent the clinical reality.\textsuperscript{7, 120} Professionals, who screen mothers showing signs of depression, stress, and substance abuse can identify families at risk for delayed attachment, and so be better equipped to help parents endure the period of colic and provide a secure base for their baby.

An effective treatment to shorten the period of colic is desired. A positive effect is supported by our Study C and the few other articles published on the topic.\textsuperscript{51-52, 116} Although acupuncture is a promising treatment for infantile colic most clinicians request stronger evidence before introducing a new treatment and further research is needed. Since no negative side effects are reported and there is to date no other known safe and effective treatment, acupuncture can be considered an appropriate treatment.

The birth of a child, especially a first child, represents a landmark event in a person’s life and people who have recently become parents are often extremely vulnerable.\textsuperscript{211} Parents in the present study want to give their eagerly awaited child everything. Not being able to comfort the baby challenge their self-esteem as they perceived a loss of competence as parents, like in Megel et al.\textsuperscript{7} Infant crying and parental response is the first language of the new dyadic relationship. Misunderstanding can compromise infant care and parental effectiveness, and can undermine the budding relationship.\textsuperscript{16} However, parents in the present study experienced that having managed a family
through the colic period strengthened their self-esteem. Supportive care may protect parents from a long-lasting negative experience. In the period of infantile colic, the way parents are treated by the professionals may determine their long-term feeling about the experience. Professionals can support parents by helping them remember the baby period with joy and pride by helping them feel a sense of accomplishment. By focusing on solutions and parents’ strengths, and by commending parents and telling them that they are doing a great job, nurses could minimise the risk of parents being stuck in feelings of helplessness and failure. Praising the child also makes parents feel proud. This could change their behaviour towards the child, as well as each other. Active listening, compassion, and empathy are nurturing forms of behaviour associated with raising parents’ self-efficacy beliefs, thereby influencing parents’ performance.

In Study C, all infants went through a structured programme with six visits to a clinic where parents got support and guidance from a nurse who was blinded to the allocation of infants to the treatment and control groups. All infants were treated in the same way excepting for minimal acupuncture stimulation for infants randomized to the acupuncture group. Acupuncture reduced the intensity and duration of crying. This supports the results in Reinthal et al’s study.

Feeding and stooling patterns vary widely in infants and no data about frequencies in infants with colic has been available. Study C provides data for normal habits of infants with colic that can be used clinically to reassure parents that their infants’ stooling habits are normal.

Infantile colic has been linked to feeding problems. In Study C the length of feeding was approximatly 148 minutes per day, with variations between 49 and 458 minutes per day and there were no statistical differences between groups, neither with regard to frequency or length of feeding nor for the quartile values. However, fewer infants were fed extremely long meals in the acupuncture group, which might reflect the lower amount of crying in this group. If looking at minimum and maximum times for feeding, instead of quartile values, differences are found. Although the maximum time for feeding per day was higher in the acupuncture group at baseline, maximum times for feeding were 107, 184 and 105 minutes a day longer in the control group the first, second and third intervention week, which is interesting but not statistically significant.

The diaries showed no significant differences between groups, neither in mean frequency of stooling nor for the quartile values. However, the mean value of large bowel movements decreased linearly in the control group (p=0.011) but not in the acupuncture group (p=0.787), indicating a faster reduction of stooling frequency in the acupuncture group. The largest reduction of both crying and stooling frequency was measured after the first acupuncture treatment. A limitation of this article is that no correlation analysis was done to see if each infant’s crying was correlated to its stooling patterns, if the parents’ experience of normalized stooling was correlated to her/his infant’s reduced crying or if the parents’ experience of improvement of the
colic was mirrored in the actual crying of their infant. Results in Paper IV are presented with quartile values. Examining minimum and maximum values reveals that the extreme values decreased more in the acupuncture group. The maximum frequency of stooling was double or close to double in the control group both for large bowel movements and for the total of large and small bowel movements during the first two intervention weeks. For example the maximum value for stooling frequency was 5.9 in the acupuncture group compared to 11.4 in the control group the first week, and 5.4 compared to 10.9 the second week. These non-significant differences of the maximum rate of defecation, and the fact that infants in the acupuncture group reached normal levels more often and faster than controls, might explain some of the differences between groups in parents’ comments. Parents of infants in the acupuncture group more often mentioned the word “normalised” when describing the infant’s stooling, and they gave 16 comments coded into “Can defecate/break wind easier/without help” compared to zero times in the control group (see Table 3 in Paper IV). This supports the findings in Reinthal et al\textsuperscript{51} showing that gastrointestinal symptoms were reduced during acupuncture.

The power analysis for Study C was estimated for the variable crying. In a larger group significant differences between maximum values for frequency of stooling and feeding might have been detected.

We chose to use a standardised form of acupuncture, which means that all the infants in the acupuncture group were needled in the same point, LI4. Thus we have only evaluated the effect of this particular point in infantile colic. It has been shown that different acupuncture points have different effects\textsuperscript{154, 157-158, 159} and we might have had other results with other points. As an example, Zhao\textsuperscript{115} used the point PC9 with bleeding technique, Liu\textsuperscript{114} used the points SiFeng and PC7 and an ongoing study evaluates the effect of the point ST36\textsuperscript{117} when treating infants with excessive crying. Some studies found best pain relief effect when points in the same segment were used.\textsuperscript{225} As some points increase the frequency of stooling, while others decrease it,\textsuperscript{158} points could have been chosen in accordance with the infants’ stooling pattern. Evaluation of stimulation of ear points could be interesting, especially in infants with less frequent stooling, as ear acupuncture can increase parasympathetic activity.\textsuperscript{153}

The mechanism behind the effect of acupuncture in infants with colic is not clear and was not studied in Study C. In fact, the exact mechanism of infantile colic is not even known. It is assumed that the infant feels pain, originating from the intestines, since the infant’s crying is often combined with disturbed gut function. The parasympathetic system is responsible for salivation, digestion and defecation as it increases peristalsis and secretion from glands. The vagus nerve innervates the upper part of the digestive system with both afferent and efferent neurons, while the distal part of the intestinal system, including the anal sphincter, is innervated by the pelvic splanchnic nerves. Sympathetic innervation, containing visceral afferent fibres, comes from the sacral splanchnic nerves and inhibits parasympathetic action. Viscera have fewer nociceptors than somatic tissues. The intestines, for instance, are not sensitive to a knife cut, but do react to distension, ischemia and inflammation. If the bowel is distended over a certain
limit, which is probably the case in colic together with an activation of the autonomic nervous system, this causes intense pain.\textsuperscript{57, 226} Pain from viscera is transmitted mainly via sympathetic nerves. The afferent parasympathetic sensations from the intestines are mostly unconscious visceral motor reflex sensations, but some visceral nociceptions might also be mediated via the parasympathetic nerves nervus vagus and plexus hypogastrica inferior.\textsuperscript{227} Optimal digestion is dependent on equilibrium between the two parts of the autonomic system.

As it has been demonstrated that acupuncture has an effect on visceral symptoms such as nausea, that it inhibits gastric acid secretion, decreases visceral pain, alters gastric motility and affects gastric emptying in adults\textsuperscript{161, 173} and in children\textsuperscript{143} it is plausible that acupuncture can affect infantile colic. Needling may have a modulator effect on the sympathetic and the parasympathetic systems via neural, neurochemical and humeral mechanisms. Thus, it is plausible that light needling at LI4 as performed in Study C by activating either or both mechanisms can influence pain and gut motility and thereby alleviate infantile colic. Acupuncture inhibits pain on the peripheral, segmental\textsuperscript{225} and central levels.\textsuperscript{228-230} The spinal gate control mechanism is only active during stimulation with the needle\textsuperscript{148} and can thus probably not be responsible for the infant’s pain relief in Study C. Gentle stimulation of the acupuncture needle, as in the present study, reduces the level of stress hormones while noxious and intense stimulation increases their release. In the case of visceral pain, mechanisms other than those present in somatic pain must be considered. As the effect of morphine on intestinal pain is limited there may be other mechanisms than the release of endorphins that reduce the colicky pain in infants. Oxytocin is released if acupuncture is given as a non-noxious sensory stimulation, giving rise to a long-term beneficial effect on stress, pain and anxiety\textsuperscript{148, 150}. In Study C, release of oxytocin might have affected the infant’s pain and stress, and acupuncture might have affected autonomic functions as well.\textsuperscript{147} Another suggested mechanism is that acupuncture affects secretion of melatonin and serotonin and thereby the circadian rhythmicity which may relieve infantile colic symptoms.\textsuperscript{231} Acupuncture also works on cortical, psychological, “placebo” mechanisms from counselling, reassurance and anxiety reduction.\textsuperscript{145} In Study C it is less likely that infants themselves were influenced by placebo mechanisms, and we do not know whether parents’ registering of infants’ crying was influenced by placebo.

**Light needling as control in RCTs**

We used one single acupuncture point, with the needle being inserted to a depth of two millimetres for only two seconds. We thus probably did not elicit de qi sensations which in many studies are considered vital for optimising acupuncture results. Yet we found a significant reduction in the crying and fussing symptoms. This supports the idea that even minimal acupuncture can be active, which has previously been demonstrated.\textsuperscript{116, 153, 179-181} It also indicates that the use of short stimulation, mild stimulation or shallow insertion, often used as control in RCTs, might not be an inert control.\textsuperscript{177, 232}
Conclusions and clinical implications
Parents’ experience of living with a child with colic was that it overshadowed everything else in their lives while it lasted. However the wound healed and family relations were repaired. A standardised, light form of acupuncture performed twice a week for three weeks on infants with colic reduced the time and the intensity of the crying significantly as compared to an untreated control group. Acupuncture had no effect on the frequency of feeding and only a minor effect on stooling even though parents described decreased gastrointestinal symptoms in their infants. No serious side effects were reported.

Parents of colicky infants have a need for frequent support and guidance and nurses at CHCs have a demanding task when parents seek help for their crying infants. By listening to the parents’ stories, they can better understand their situation and offer support and guidance, thereby empowering parents and helping them to endure the colic period. When professionals’ understanding of a phenomenon changes, their behaviour and treatment might change too, resulting in an improvement in the quality of care. Creating a partnership with the parent/family might lessen their feelings of isolation and increase their self-efficacy, self-worth and self-esteem. Parents can then better endure the period of colic and continue to provide a secure base for their child. The nurse should observe the family’s needs, plan the care together with the parents, help them to find solutions by pointing out evidence-based alternatives and choices, and systematically evaluate the effect of the interventions. In order to protect the infant, the nurse also needs to identify parents who run the risk of harming their baby. A diary in which the parents report their infants’ crying is a valuable diagnostic tool that can spare infants with normal crying patterns from unnecessary medical treatment.

An important part of nursing is to emphasise the healthy aspects and, in families with children with infantile colic, this means focusing on the periods of hope and joy. Helping parents to regain control by promoting interaction and family dynamics is a way of empowering the parents. Merely identifying strengths can be a potent intervention, and the mere recognition of existing resources can maximise family coping.

In the case of colic, the aim of the treatment is to reduce the infant’s pain and help the family to function normally. Our study indicates that acupuncture gives a faster reduction in crying and this can be assumed to be a difference that is not only statistically significant but also clinically relevant. As no serious side effects were found, light acupuncture stimulation can be considered in otherwise healthy, full-term infants by health staff trained in acupuncture. However, more research is needed.
FUTURE PERSPECTIVES

Further studies dealing with family dynamics during and after the colic period are needed in order to gain better support for parents and infants. To improve the care of and provide relief for infants with colic, it would be interesting to develop and evaluate a programme in which a diary is used to measure the infant’s crying, with structured counselling being given together with evidence-based interventions.

To improve acupuncture treatment further, more research is needed into the use of individually chosen acupuncture points related to symptoms other than crying that the infants present and into finding the optimal number of treatments, intervals between treatments and methods of stimulation when treating infantile colic with acupuncture. Studies about how oxytocin levels change when infants receive acupuncture are also needed.

As in an earlier study, it was found in Study C that many (24% and 30% respectively) of the infants had been exposed to antibiotics, either administered to them directly or via breast milk. We do not know whether this is a higher rate of exposure to antibiotics than in the ordinary population of newborns. If it is, it may indicate that antibiotics are a risk factor in infantile colic, and that further research is needed.
Spädbarn med kolik – föräldrars upplevelse i ett kortare och ett längre perspektiv samt effekten av akupunktur på barnets skrik, ätande, avföringsmönster och sömn.


För att utvärdera effekten av akupunktur vid spädbarnskolik utfördes en randomiserad kontrollerad studie med 81 spädbarn med kolik, 2-8 veckor gamla, som lottades till akupunktur- eller kontrollgrupp. Åtioett barn (43 i akupunkturgruppen och 38 i kontrollgruppen) genomförde ett strukturerat program som utgjordes av sex besök på en akupunkturmottagning. Vid besöken träffade föräldrarna en sjuksköterska som lyssnade på dem, svarade på frågor och gav standardiserade råd. Därefter bar sjuksköterskan, som inte visste vilken grupp barnet ingick i, barnet till ett annat rum där en akupunkturtutbildad sjuksköterska behandlade alla barnen lika förutom att...
barnen i akupunkturgruppen dessutom fick akupunktur i form av en nål som stacks ca två mm djupt in i akupunkturpunkten LI4 på den ena handen under två sekunder. I en dagbok registrerade föräldrarna under de tre interventionsveckorna när barnet gnällde, skrek, hade en kolikattack, åt och bajsade. Dessutom fick föräldrarna svara på frågor om barnets sömn och hade möjlighet att beskriva förändringar i barnets beteende. Resultaten visar att akupunktur minskade tid och intensitet på skriket. Det var en skillnad (p=0.034) till akupunkturgruppens fördel, på tiden från inklusion tills barnet inte längre uppfyllde kriteriet för kolik. Mängden gnäll första och andra interventionsveckan (p=0.029 and 0.047) och av skrik under andra veckan (p=0.046) var lägre i akupunkturgruppen. Den totala mängden av gnäll, skrik och kolikskrik (TC) var lägre i akupunkturgruppen under den första (p=0.025) och den andra interventionsveckan (p=0.016). Den relativa skillnaden mellan baseline genom interventionsveckorna visade skillnader mellan grupperna den första veckan (p=0.028), för kolikskrik den andra veckan (p=0.041) och för TC under den andra veckan (p=0.024), allt till akupunkturgruppens fördel. Under den tredje interventionsveckan fanns inga skillnader mellan hur grupperna skrek.

Barnen hade en högre avföringsfrekvens än vad som tidigare rapporterats bland friska spådbarn. Akupunktur gav ingen förändring i barnets matmönster och bara en mindre effekt på avföringsfrekvensen. Föräldrarna till barn i akupunkturgruppen beskrev ofta att deras barn fått en normaliserad avföring, att barnen sov bättre och att koliken förbättrats jämfört med föräldrar i kontrollgruppen.

Sammanfattningsvis visar resultaten att kolik påverkar de flesta aspekter av familjelivet, att föräldrar känner sig maktlösa när de inte kan lindra sitt barns smärta men också att familjerelationerna läcker och att minnet av kolikperioden bleknar. Fortsatt forskning behövs för att öka förståelsen för föräldrarnas situation så att bästa möjliga stöd och råd kan ges. Akupunktur minskade spådbarnens skrik och föräldrarna upplevde att barnens tarmfunktion normaliserades. Inga negativa effekter uppvisades. Akupunktur kan vara en behandling för att minska barns lidande och påfrestningar i familjelivet. Dock behövs det fortsatt forskning för att undersöka effekten av olika akupunkturpunkters effekt vid kolik och vilka behandlingsintervall som är optimala.
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Parents’ experience of living with a baby with infantile colic – a phenomenological hermeneutic study

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Parents’ experience of living with a baby with infantile colic – a phenomenological hermeneutic study

Background: About 10% of newborn babies have infantile colic which means that they cry more than 3 hours per day. The baby’s crying risks disturbing the early parent–child interaction.

Objective: This study aimed to illuminate the meaning of being a parent of a baby with infantile colic.

Design: An inductive qualitative interview study.

Participants and settings: Twenty-three parents (12 mothers and 11 fathers) seeking help for infantile colic at a Child Health Clinic in south Sweden, having verified in a diary their babies’ crying to more than 3 hours/day, were individually interviewed between March 2006 and April 2007. Parents were selected to ensure variation in age and gender and if they were first-time parents.

Method: Parent’s narratives were analysed using a phenomenological hermeneutic method.

Findings: The main theme found was ‘Colic overshadows everything’. Tired and worried parents experienced living in an inferno. Both fathers and mothers suffered with their babies, felt powerless and overwhelmed by strong feelings and neglected their other needs. To get through this period, parents used various strategies to ease their baby’s pain. Parents forced themselves not to lose control, to keep a stiff upper lip and generally to bear up. Sharing the burden was important. In spite of the suffering, they also felt hope, happiness and gratitude that they had a healthy baby. The results were reflected upon in relation to systems theory, attachment theory and a theory of interpersonal aspects of nursing.

Conclusion: It is an important task for professionals to empower parents and help them to endure the colic period and to gain higher self-esteem as parents. By listening to the parents’ stories they can better understand their situation, offer support and increase self-efficacy.

Keywords: crying, infantile colic, interviews, parents’ experiences, phenomenological hermeneutic.

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Introduction

Infantile colic is a common problem in the Western world. Both the baby and the parents suffer, and there is a risk that the early interaction and establishment of the essential relationship is disturbed (1, 2). Not much is known about parents’ experience of living with a baby with colic and even less is known about the father’s experience. To be able to help the parents through the stressful period, it is of utmost importance that professionals understand what the parents are dealing with.

Background

The most used definition for infantile colic nowadays is the modified Wessel criteria: an otherwise healthy baby who is fussing or crying more than three hours per day, more than 3 days per week (3). Occurrence rates in nine studies varied between 3 and 40% depending on the criteria for diagnosis (4). In two different Swedish cohorts, Canivet found the rate to be 9.3 and 12.1% (5). Infantile colic often starts during the first 3 weeks of life. The prognosis is good, and the baby recovers spontaneously by 3–4 months of age (6). Painful gut contractions are suggested, but the aetiology is unclear (7). The exclusion of exposure to cow’s milk protein is found to relieve the symptoms in 5–25% of the cases. Simethicone is often recommended, although three meta analyses have concluded that it is not effective. Dicyclomine has effect but also rare but serious side effects such as...
seizures, asphyxia and death (7–9) and has been contradicted to use in babies under 6 months age. In one trial (10), lactobacillus was shown to decrease the symptoms, but not in another (11). Acupuncture treatment proved effective in the only study yet published on acupuncture in infantile colic (12).

Some authors link maternal anxiety, depression or stress during pregnancy and postpartum to the development of colic (13–15) while others do not (16, 17). It is not known whether the baby’s crying increases maternal stress or vice versa. Colic was shown to disturb mother–child and family relations (18–20), create chaos and disrupt family life (21). Parents described a difficulty in establishing contact with, as well as a delay in the development of ‘good’ feelings for the baby (1). Some authors state that colic may affect parental interaction even long after the colic has been resolved (13, 22), while others suggest that maternal behaviour may be stressed when colic is at its peak but returns to normal levels when the colic is resolved (14). Stifter and Bono (23) state that the majority of the colicky babies develop secure attachments, but if the mother’s self-efficacy is low, attachment may be affected.

In periods of heightened tension, colic can result in fear of losing control and in nonaccidental injury of the baby (1, 21). Persistent crying is a major challenge that places caregivers, especially those with limited resources and support systems, at risk for child abuse and neglect (20). Babies who cry a lot are more likely to be exposed to physical violence (24, 25).

The ability to respond to the baby’s needs is the basis for maternal self-efficacy, i.e. mothers’ belief in their ability to manage motherhood (23). When attempts to soothe the baby are met with failure, feelings of incompetence are likely to develop. Mothers of babies with colic rated themselves as significantly less competent (23), maybe because mothers of persistently crying babies did not experience the baby as a source of positive reinforcement (16). Mothers tried various activities to diminish their baby’s irritability and searched desperately even long after the colic has been resolved (13, 22), while others suggest that maternal behaviour may be stressed when colic is at its peak but returns to normal levels when the colic is resolved (14). Stifter and Bono (23) state that the majority of the colicky babies develop secure attachments, but if the mother’s self-efficacy is low, attachment may be affected.

A deeper understanding of parents’ experiences during their stressful time can help professionals provide better support.

Aim
This study aimed to illuminate the meaning of being a parent of a baby with infantile colic.

Method

Design
This was an inductive qualitative study where mothers and fathers were interviewed about their experience of having a baby with infantile colic. We used a phenomenological hermeneutic method, inspired by Ricour and described by Lindseth and Norberg (28), both for interviewing and analysis to elucidate the essential meaning of the parent’s lived experience expressed in a text.

Participants. Twenty-five parents of otherwise healthy babies, seeking help for infantile colic at a Child Health Centre (CHC) in south Sweden, having verified in a diary the babies’ crying to more than 3 hours/day, were asked to participate. Two fathers declined because of pressure of time. The remaining 23 parents (12 mothers and 11 fathers) represented 14 families. Parents were selected to ensure variation in age, gender and whether they were first-time parents.

Data collection. Individual interviews were conducted between March 2006 and April 2007 by the first author (KL). Dates, places and length of interview were decided by the parent.

Interviews lasted between 17 and 55 minutes (median 35 minutes). Parents were asked to narrate their experiences of having a baby with colic. All interviews commenced: ‘Tell me about your experience of having a baby with colic.’ Further questions were asked, aiming at encouraging further narration, such as: ‘How did you feel then?’ or ‘What do you mean?’ All interviews were performed in Swedish, tape-recorded and transcribed verbatim (on 220 pages) by the first author. During the last four interviews, no new information was obtained.

Ethical considerations
The study was carried out in accordance with the Declaration of Helsinki (29). All parents gave written, informed consent and were informed about guaranteed confidentiality and the right to discontinue the interview at any time. All participants agreed to the interviews being tape-recorded. Ethical approval was obtained from the University’s Research Ethics Committee (Dnr 583/2005).

Data analysis
A phenomenological hermeneutic analysis including three methodological steps (28) was used. First, both authors did a naïve reading to grasp the meaning as a whole and formulated a naïve understanding (30). Second, in a structural analysis, the first author divided the text into meaning units, including important words or sentences...
which were condensed and abstracted to form preliminary sub-themes, themes and a main theme which were compared with the naïve understanding for validation. The text was reread, and the structural analysis was discussed in a dialectic movement between understanding and explanation until the authors agreed. Finally, the authors used their imagination and associations with relevant literature to revise, widen and deepen the understanding of the text, and the parents’ lived experience.

In a qualitative study, the authors’ preunderstanding is part of the interpretative process and a guiding tool. Hence, their preunderstanding was discussed, reflected upon and bracketed throughout the process not to influence the interpretation in a biased way. The first author has met parents of babies with infantile colic, initially as a nurse at a paediatric emergency unit and for 10 years at an acupuncture clinic. The second author has extensive experience involving work and research with children and parents.

**Trustworthiness.** Heterogeneity among the interviewed parents in terms of gender, age, living conditions and family situation supports the credibility of the study. However, as no single parents were available during the period of data collection, the present results only reflect experiences of individuals living within couples. Single parents’ experiences require further investigation. Interviews were conducted individually to ensure that the partner’s presence could not influence the interviewee. All parents spoke openly, and interviews contained narrative life-world material, rich in depth as well as in breadth. The interviewers’ understanding was checked during the interviews with follow-up questions. The findings were discussed at research seminars with paediatric nurses and midwives to add depth and insight into the interpretation. To further confirm the result, quotes from the interviews, freely translated, are used to verify that the findings were retrieved from the data (28). In the third step of the analysis, the findings were validated with the existing literature.

**Findings**

All 23 parents were married or cohabiting. Two families with newborn twins had one baby with colic and one without. At the time of the interviews, the babies’ age varied between 4 and 20 weeks (mean 9.6 weeks), and all of them presented with colic symptoms, although for some the symptoms had improved from their low point. For them presented with colic symptoms, although for some the symptoms varied between 4 and 20 weeks (mean 9.6 weeks), and all of them presented with colic symptoms. However, as no single parents were available during the period of data collection, the present results only reflect experiences of individuals living within couples. Single parents’ experiences require further investigation. Interviews were conducted individually to ensure that the partner’s presence could not influence the interviewee. All parents spoke openly, and interviews contained narrative life-world material, rich in depth as well as in breadth. The interviewers’ understanding was checked during the interviews with follow-up questions. The findings were discussed at research seminars with paediatric nurses and midwives to add depth and insight into the interpretation. Further analysis of educational research data is recommended. The findings were discussed until the authors agreed. Finally, the authors used their imagination and associations with relevant literature to revise, widen and deepen the understanding of the text, and the parents’ lived experience.

**Naïve reading.** The naïve understanding is expressed as a metaphor; parents were like passengers on a ship in stormy seas. They had started out with high expectations but had not expected the journey to be so exhausting. They had lost control, were living at the edge of their capacity and were tired and afraid of drowning. The crew could not help. Suffering with their baby, parents searched for strategies to enable the family to survive. They tried everything to make the trip easier for themselves and for the baby and clung to each other for help. Their main task was to dock safely. Other needs were neglected as their attention was on their crying baby. When the waves sometimes calmed down, they saw the sun and they felt hope for the future.

**Living in an inferno**

Being constantly tired and worried. Parents felt exhausted and worn out. As parents did not know when the colic would stop, it felt like a dark tunnel with every minute seeming an eternity. Never getting undisturbed or sufficient sleep was torture and limited their patience.

Tiredness. In your head. So much tiredness... When my husband came home yesterday I sat with her in my arms, just crying. I had been crying since she stopped crying... I’m totally drained. (Mother 22)

Parents were constantly worried, and they could not believe that a baby could cry that much without having a serious medical disease. When the baby actually was quiet, they worried about when the crying would start again. Not knowing when the next bout would start, and when the colic would be gone, was perturbing. They worried about how they themselves or their partner would withstand the chaos without losing their minds.

Each day would have been easier if he hadn’t colic. Then I wouldn’t have to worry if he would sleep ... and when he swallows air he gets more pain... and when the next bout is coming. Plus, I wouldn’t have to worry that he would start crying when we get on the bus. (Mother 13)
The baby’s colic was described as a strain for everyone in the family, and their relations were challenged. Irritation rose as things accumulated when both parents were exhausted and worried.

Without sleep the brain doesn’t function. You don’t say many words during the day. (Mother 11)

Suffering with the baby. Babies’ crying and behaviour convinced parents that they were in great pain. Parents could stand the babies crying for food, but it was unbearable to hear the heartbreaking, hysterical and inconsolable cries of pain. Parents suffered when they saw tears, the baby’s little body cramping and when they could not get eye contact or distract the baby from pain and panic.

When he has pain, I have pain too, in my body and my soul. If it was possible I would gladly have taken his pain and put it into my body. So he did not have to suffer. (Mother 13)

Feeling helpless and overwhelmed. Parents felt helpless, despondent, insecure and inadequate as they could not stop the hysterical cries. Not being able to satisfy the baby’s basic needs was extremely frustrating. They could not interpret the baby’s signals and felt frustrated when they heard the sick-sounding cry and saw the vicious circle of pain, exhaustion and hunger. They felt powerless when neither their endless strains nor medicine helped.

Both anger and frustration and also, partly, sadness came. So, yes, a combination of helplessness, sadness and pure rage and... yes, madness. I am constantly furious. (Father 23)

Neglecting everything else. Mothers had no time to fulfil even the most basic needs like eating, going to the toilet or taking a shower. When the fathers came home from work, their partners needed to eat and rest. Fathers were stressed about having to perform well both at work and home and be ‘on duty’ both night and day. It was frustrating not being able to sit down and have dinner together or to help the siblings with school work or other activities when the baby was crying. When the baby was asleep parents did not dare to turn on the light, put on the TV or even open the fridge. They could remain seated with the sleeping baby in their arms for long periods afraid of waking it up.

On bad days, there was no chance of eating, no chance. I lost weight, many many many kilos in the beginning, not only because of breastfeeding, but also because I didn’t eat, and when she finally slept I tiptoed around so that she would not waken... (Mother 22)

Feeling shame and guilt. Parents felt ashamed feeling that they were not good enough parents, neither to the baby nor to the siblings. If having more than one child, parents thought it was unfair to give so much attention to only one of the children. Parents suspected that their own irritation and behaviour made the baby’s situation worse. They described how they had forbidden feelings and thoughts like anger, anxiety and an impulse to throw the baby out of the window or leave it alone. Parents felt guilty because they were not solely happy and grateful. They believed that others thought that they were bad parents.

When I sit on the balcony I try to think, ‘Take it easy, don’t panic, he won’t die because you sit here and smoke a cigarette.’ We need to be separated for a while so that I can calm down, because he senses when I am so wound up. … But it worries me sick that he is alone in his pram when he is in such pain. (Mother 13)

Losing control. Parents tried to control themselves but did not manage to act as they wished. This situation was new, sometimes the first in their life that they could not control. They lost their grip and foothold and that scared them. They got close to handling their babies roughly or giving up when they were exhausted or very frustrated. Parents were afraid of losing their minds and described how they sometimes had cried, hit things or screamed in despair when they lost their temper. Sometimes they just gave up, surrendered, when they had to take a break to prevent themselves from going over the top.
But sometimes, you have to just lay her down and leave her screaming there, let her yell herself to exhaustion. You have tried everything and she is still screaming. I have to shut down for a while and go away. (Mother 2)

Longing for relaxed closeness with friends and family. Taking care of their longed-for and beloved baby was considered to be the primary task in the parents’ life. They had dreamt about romantic situations and felt sorrow because a period of time that could have been happy and fun was lost, like strolling with the pram, enjoying and getting to know their newborn baby with their partner and introducing the baby at family parties. Seeing relatives and friends was minimised as parents never knew when the baby would be crying. They did not want to invite anyone to the inferno they felt. They felt locked in.

And you couldn’t call anyone because he was screaming. And you couldn’t have contact with friends or family. You had to be on your own with him all the time. It was really tough, and I was alone at home. (Mother 19)

Surviving infantile colic

Sharing the burden. It was essential to have someone to hand the baby over to, and to share the frustration with, when all strength and patience had gone. Sharing the burden helped parents to gather new strength. It was easiest to accept help from their partner, whom they trusted most. The partner was the only one who could fully understand how frustrating the situation was, and with whom they could share their inner feelings about the frustration.

It would not have worked without my husband. If he had not been close by I would have moved to my parents or checked in at the emergency ward when night was coming. I could absolutely not have managed myself. (Mother 16)

Parents struggled to be good and willingly took an active role in trying to comfort the baby and to take care of the siblings. The parents were concerned about each other’s health. They had alternate responsibility and, when one took over, he or she loyally let the other go away for rest. They could take care of the baby all night long to let their partner sleep so that he/she would get strength to go on the next day. Parents believed that by having shared this experience, their relation would be stronger when they had solved the problem and helped each other through a difficult period.

It is not a heavy responsibility to be the stronger one! It would have been worse to be the one who was breastfeeding and worry about that, whether there was enough milk. It is positive to be the strongest! (Father 15)

Help from grandparents and other relatives was often accepted with gratitude, as it would simply not have worked without them. Burdens could also be shared with an older sibling or even with the family dog. Some parents shared their burden with professionals, taking the baby to the hospital or to the CHC. It was a relief to be reassured that the baby was not severely ill. However, the frustration and confusion increased when nurses and doctors did not listen or gave ineffective or contradictory advice. Parents felt that professionals could not imagine what the situation was like. They often felt ignored.

I have often felt that I know more than them, at CHC. They say the same things that they have said for years. I have found new information on the internet, new since my first child had colic six years ago. (Mother 1)

In some families, parents did not share the burden. For parents who had hardly anyone to share the burden with, this loneliness was the worst part of their situation.

I said I needed a rest. My boy friend ignored me and took a bath. When he returned I was sitting on the floor, crying hysterically, and the baby was crying, too, in the cradle. But he just ignored us and went out for a cigarette. (Mother 13)

Trying every trick. Parents tried various strategies to make their baby cry less. They held and carried the child in different ways and used different types of baby sling. They tried swinging and massaging, hushing, hugging and singing, driving around in the car, walking outdoors at night through rain and wind or pulling the stroller indoors, for hours and hours. They tried different kinds of food, feeding techniques and medication. To gain control and find a way to stop the crying, parents sought information in many ways, such as reading books and searching the internet.

You test, you try every trick to find something that helps. For example, she liked a pouring faucet. If you place her beside the flooding water she kind of likes it and it helps for about ten seconds. Then she starts to scream again. … I have searched the internet for different kinds of sound that I can use in a loudspeaker or something. But most of them don’t work. (Father 6)

Getting confidence from knowledge and experience. Parents felt relief, for both themselves and for the baby, when they found out how to make the baby suffers less, and as time passed they learned to understand the baby’s cries. Crying, which the parent knew that they could stop by feeding the baby or changing diapers, did not evoke panic in the same way as cries of pain. When parents knew which tricks could ease the pain best, they were proud and, the more knowledge and experience they got, the more confident they became.

When I can comfort her and she becomes content I get a feeling of blessing. First, I become calm because she
is calm and I feel good because I have succeeded with something. I feel that I can do something. (Father 6)

Keeping a stiff upper lip and bearing up. Parents perceived it as work to take care of the crying baby, the siblings, the partner and for working family members, their own employment as well. Just getting on with it they tried, hour after hour, to comfort the baby and to be good parents. When they accepted that this inferno simply was their life they rolled their sleeves up and started dealing with ‘project colic’. When evening came and the colic increased, they steeled themselves to endure the demanding night shift ahead, keeping up as long as possible. They produced, from their existing inner resources, a barrier to any serious reactions or dangerous behaviour, controlled themselves, concentrated on being patient and counted down the time until this 3-month period was over. Parents knew that other parents had totally lost control and hurt their babies, but said that they themselves had been able to control themselves so far.

If you’re supposed to do it for eight hours you have to get ready for it, like thinking, ‘OK, I can take these eight hours but then I have to sleep’. After such a work shift I really have to sleep, I have to rest, otherwise I can’t do it, ... It is a strategy for survival to think ‘go on, survive this, when the colic is over we can move on’. (Father 20)

Feeling hope, happiness and gratitude. The baby was the parents’ greatest joy, even in the middle of the colic period. They knew that this was a transitional period and that the colic would end sometime and they could see light at the end of the tunnel. They focused on the times when the baby did not cry and gathered energy when it was happy and laughing. Parents forgot the panic and could feel intense joy when the baby had content moments. A night of crying could be accepted after a good afternoon. They expressed great love towards their babies and admired their courage. Parents were rational and thought that it could have been even worse; the baby, after all, was healthy and alive, and parents thought they should be grateful for that.

I have two wonderful daughters and a husband. It couldn’t be better! Two healthy babies! And a little smile is enough, then she can cry another hour and it doesn’t matter! That’s how it is. (Mother 9)

Comprehensive understanding and reflection

The text revealed possible meanings of being a parent to a baby with colic, naively understood as in the metaphor: a journey on a stormy sea. To reach a comprehensive understanding of these meanings, the authors’ preunderstanding, the naïve understanding, the themes and the sub-themes were reflected upon in relation to theories of systems, attachment and interpersonal aspects of nursing.

In the families who shared their experience in this study, not only the baby was suffering. The colic overshadowed everything in the families’ lives, and the parents suffered with their baby. The baby’s pain and frustration influenced all family members, whose feedback then influenced the baby right back. The relations between all family members were affected. All members of a family are mutually dependent on each other in a complex system (31, 32) so when a baby is crying constantly in spite of the parents’ attempts of consolation, the balance within the family is disturbed. Parents in this study were influenced not only by the baby and each other but also by the support they got and how they were treated by professionals. Both mothers and fathers found that the professionals did not understand their parental lifeworld nor take their experience seriously.

Parents in our study described a lifeworld filled with loneliness, powerlessness and frustration. Not all the parents were stable, with capacity and good networks. In our study, as in the study of Long and Johnson (23), sharing the burden was a theme of utmost importance. Often the partner was considered to be the only person who could fully understand the situation. Some parents (all mothers) expressed the fact that they could not share the burden with their partner. Not having someone to share with was felt to be the worst part for these women, and they felt locked up and totally isolated. It was crucial for these mothers to have another close contact to rely on. A nurse who interacts with the family, communicates and shows empathy (33) can build a relationship with the family characterised by a therapeutic alliance (34) which can be valuable. Communication is necessary to understand others’ lifeworlds (33). When communicating with parents and sharing their experiences, professionals gain understanding and the seed of a therapeutic relationship can be sown and grow in respectful interaction. If professionals’ understanding of a phenomenon changes, their behaviour and treatment might change and lead to an improvement in the quality of care (35). Creating a partnership with the parent/family might lessen the feeling of isolation that parents described and increase their self-efficacy, self-worth and self-esteem by building confidence that they are doing a good job (1, 2, 36). Parents can then better endure the period of colic and provide a secure base for their baby.

Being able to comfort the baby teaches the parent to interact with and handle the new family member (37). The parental mission is to be a secure base for, and to form an attachment to, their new-born baby. Bonding can be delayed when positive parent-child communication is missing, and the parents cannot supply the baby’s basic needs (38). Providing comfort and well-being for the baby and its siblings was perceived as a main task. It was rewarding and encouraging for the parents in this study when they found a tool to comfort the baby. The parents then felt proud and satisfied and perceived themselves as

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valuable. They gained power to ease the baby’s suffering, and they could relax together. When self-efficacy increases, attachment is facilitated (2).

Implications for nursing practice

Nurses at the CHC have a demanding task when parents come to them with their crying babies (27) but also a chance to give encouraging and systematic guidance. Early counselling can help parents to cope, and this may influence the duration and intensity of baby crying (19, 27, 39). When parents seek help at the CHC, the health staff is connected to their family system (35). As a part of it, nurses can strengthen the family system, thus helping the family to function better, and attachment between parents and baby is facilitated.

In families with colicky infants, the nurse is supposed to observe the family’s needs and plan the care together with the parents (33). Hope emanates from a favourable ratio of trust to mistrust (33). To gain trust, nurses should give evidence-based recommendations, like recommending systematic exclusion of cow’s milk protein for 5 days as this intervention relieves the symptoms in 5–25% of babies with colic (7). By guiding parents how to find food for the breastfeeding mother, and formulas free from cow’s milk for the bottle-fed baby, the nurse can make this intervention manageable. It is also important to find alternative methods, if the first method chosen does not work and to systematically evaluate the effect of each intervention (33). On the other hand, parents in this study lost trust in the health staff when they recommended medications with negative evidence, like simethicone.

It is nurses’ responsibility to facilitate a context for change in the family’s experience of health and illness and to inform and educate them (35). Nurses, by creating a therapeutic alliance, can help parents with colicky babies to withstand and cope with the situation. One important task is assisting people, including parents with babies with colic, to maintain hope to cope with the stress of illness and suffering (33). Hopelessness can affect attachment (38), so it is vital that the nurse reassures parents that the colic will not harm the baby but will disappear.

Family-focused and strength-orientated care (35, 36) relies on parents’ stories. Narrating one’s history can give relief and be a treatment in itself (40). We recommend giving the parents enough time to tell their story both as a method of facilitating nurses’ understanding and to enable nurses to make an inventory of the parent’s resources. Family’s strengths can be used by mirroring, providing feedback and offering commendations (41). Merely identifying strengths can be a potent intervention, and the mere recognition of existing resources can maximise the ability of a family to cope (36). Further research is needed to find evidence-based treatments for infantile colic and methods for documentation and evaluation. From a nursing perspective, this study fills a gap by elucidating both mothers and fathers experience of having a baby with infantile colic. Nurses with a deep understanding of the parents experience may be an important part of the reliable crew during the journey on the stormy sea. By encouraging parents, nurses may help parents to control the waves by reassuring and commending them and help them to regain hope and high self-esteem, thus helping them to dock safely.

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Author contributions

Both authors have contributed to the design of the study, analysis of data, writing the article and finally approved to the manuscript. No one else is entitled to authorship. There are no conflicts of interests.

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References


REMEMBERING THE CHAOS - BUT LIFE WENT ON AND THE WOUND HEALED. A FOUR YEAR FOLLOW UP WITH PARENTS HAVING HAD A BABY WITH INFANTILE COLIC

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ABSTRACT

Objective: To elucidate parent’s experience of having had a baby with colic four years previously and of how the colic and care influenced the family in a long-term perspective.

Methodology and participants: A qualitative inductive follow-up study with 13 individual and one focus group interview including four parents. Altogether ten mothers and seven fathers, representing 12 families, with a child diagnosed with colic four years ago were interviewed between December 2010 and May 2011. Parents’ narratives were analysed using content analysis.

Results: Parent’s memories of the exhausting colic period were vivid, but when the colic had healed the family relationships also healed. Although it had taken longer time for some parents to attach to their child they now experienced a close relationship with their four year old child and felt confident in their role as parent. The colic scream was still unbearable and evoked negative feelings in the parents. Parents had decreased confidence in Child Health services and made suggestions for improvements in the health care approach. Most of all they wished for an effective treatment of infantile colic.

Conclusion: The family relationships were healed and the colic left only few residual symptoms but parents still had decreased confidence in the Child Health Center. Consequently, there is a need to raise awareness to parents’ situation when having a child with infantile colic.

Keywords: Baby, Content analysis, Crying, Infantile Colic, Interviews, Long term effects, Parents’ experiences.

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INTRODUCTION

Infantile colic, which starts within the first few weeks after birth and is defined as “crying or fussing more than three hours/day more than three days/week”, strikes about 10% of newborn babies in Western countries [1]. By definition, infants with colic have excessive and inconsolable crying. In addition, they may have a more distressed and intense cry that is more draining for parents than normal crying [2]. Retrospectively, mothers who have had a baby with colic experienced a variety of thoughts and emotions such as anger, guilt, self-doubt, anxiety, frustration, fear of losing control, hopelessness, fatigue, and disappointment [3], [4], [5]. The studies involving fathers found similar experiences relating to both parents [6], [7], [8], [9]. When a baby cries constantly in spite of the parents’ attempts at consolation, the balance within the family is disturbed as all of the members of a family are mutually dependent in a complex system [10]. Colic disturbs mother-child [4], [5], and father-child relationships [8], [11], creates chaos and disrupts family life [3], [9]. In a previous study, parents were interviewed in the midst of the colicky period [9], showing that the colic overshadowed everything in the families’ lives. Both mothers and fathers felt powerless and frustrated, and searched desperately and creatively for treatments to soothe their baby’s crying. They became very frustrated when they found that no intervention seemed to help. Parents experienced a lack of understanding about their life situation and a lack of support from healthcare professionals [9].

The prognosis for colic is good: 85% of infants’ with colic have remitted when they are 3 months [12]. Nonetheless, besides the baby’s presumed suffering, the early interaction and establishment of the essential relationship might be disturbed [6]. Furthermore, infants with persistent crying are more likely to be exposed to physical violence [13]. Having a child with infantile colic is a common reason for parents to ask for advice at a Child Health Centre (CHC). Guiding these parents is a demanding task for nurses [6], but it also provides them with an opportunity to connect with the family system [14]. This connection, in turn, allows nurses to give encouraging and systematic guidance and to help increase parents’ sense of self-efficacy [15].

Treatments

There is no known safe and effective cure for infantile colic, but several treatments are available. Symptoms are relieved in 5-20% of infants with colic after the systematic exclusion of cow’s milk protein for five days [16]. Among medications simethicone is the one most commonly most used in Sweden. Simethicone is sold over the counter and often recommended by nurses and doctors at CHC, although it has no greater effect on colic than placebo [17]. Dicyclominechlorid has a beneficial effect but also causes severe side effects [17] and has been withdrawn in Sweden since 2010. Lactobacillus reuteri is a popular treatment and has shown promising effects but a recent systematic review found no evidence [18] for the effectiveness of probiotic supplements. Acupuncture has been proven to reduce crying and fussing in two randomized trials [19], [20] and to soothe gastrointestinal symptoms in one case study with >900 infants [21]. Counseling parents has been shown to reduce the infants’ crying. Specific instructions about modification of the parent/infant interaction have shown good
Long term effects of colic

Although colic heals spontaneously, it might disturb family relationships and delay attachment [11]. Some studies reporting on the long-term effects of colic on family relationships show that colic may affect interaction between the infant and the parent for a long time after the colic is over [25], [26], [27], [28]. Other researchers suggest that maternal behaviour may become disturbed when colic is at its peak but returns to normal once the colic has disappeared [29]. Stifter and Bono [30] found that the majority of babies with colic develop secure attachments, but if maternal self-efficacy is low, attachment may be affected. No lasting effects to maternal health were found in a trial with 547 dyads [12].

However, few trials have studied how parents recall the colic period years after it has disappeared. There is also a lack of knowledge about how parents experienced the treatment from professionals and the effect of the care. The aim of this study was to elucidate parents’ experiences of having had a baby with colic four years previously and of how the colic and the treatment influenced the family in a long term perspective.

MATERIALS AND METHODOLOGY

An inductive qualitative study including individual and focus group interviews with parents was performed.

Participants

Twenty-three parents with a child diagnosed with colic four years previously were invited to participate. The inclusion criteria were as follows: an otherwise healthy infant who cries for more than three hours per day, more than three days in the same week. Before the first interview, parents used a diary to verify that the babies had colic [9]. The babies took part of the ordinary programme at the CHC, which included a visit every week or every second week. In addition to this programme, all parents chose to let their baby try acupuncture, which was available at a private acupuncture clinic.

Of the 23 parents taking part in the previous study [9], one father declined to participate due to a lack of time, and one could not be found. One mother who lived far away and one father who had moved abroad agreed to take part, but interviews could not be arranged for practical reasons. One couple scheduled for the focus group interview did not turn up. Consequently, 17 parents (10 mothers and 7 fathers, in the results presented as M1-10 and F1-7) representing 12 families were interviewed. Background variables for the interviewed parents are presented in Table 1. Individual
interviews were conducted with five fathers and eight mothers, representing nine families. Four parents (two mothers and two fathers representing three families) took part in the focus group interview (FG).

Table 1 Background variables of the participants.

<table>
<thead>
<tr>
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<th>Mothers</th>
<th>Fathers</th>
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<tr>
<td>n</td>
<td>10</td>
<td>7</td>
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<tr>
<td>Age, min – max (mean)</td>
<td>26 – 44 (35)</td>
<td>28 – 56 (39)</td>
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<tr>
<td>Married/cohabiting</td>
<td>10</td>
<td>7</td>
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<tr>
<td>University degree</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Immigrant n (mean years in Sweden)</td>
<td>1 (6)</td>
<td>0</td>
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<tr>
<td>Having only one child</td>
<td>2</td>
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<tr>
<td>Number of children</td>
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Data collection

Interviews were conducted between December 2010 and May 2011. Parents who consented to participate in individual interviews were interviewed in the family’s home, if they so wished. Ten interviews were conducted by two external interviewers (paediatric nurses) and three by the second author (AL). The focus-group interview was conducted in a room at a conference centre in the nearest town by the second and third authors (AL, IH).

Before all interviews, a presentation and an informal introduction were arranged to create a relaxed atmosphere and to facilitate talking about emotions and experiences [31]. To encourage parents’ narration about their experiences, the interviews started with an open question: “Please tell us about your spontaneous memories of having a baby with colic four years ago,” followed by follow-up questions if necessary. The interview areas included: spontaneous recollections from the colic period, the colic’s influence on family relationships both four years previously and at the time of the interview, impact of the treatment on the family and the support the family received as well as thoughts about future treatment and care. The individual interviews lasted from 30-60 minutes and the focus-group interview 95 minutes. Interviews were tape-recorded and transcribed verbatim. The first ten interviews were transcribed by the interviewers. The remaining interviews were transcribed by the first author (KL).

Ethical considerations

The study was carried out in accordance with the Declaration of Helsinki [32]. At the first interview four years ago, parents were informed that follow-up interviews were planned. At the second interview, they gave written, informed consent and were informed about the guaranteed confidentiality and the right to discontinue the
interviews at any time. All of the participants agreed to have the interviews recorded. Ethical approval was obtained from the University’s Research Ethics Committee (Dnr 583/2005).

Data analysis
The narratives were analysed with content analysis [33]. First the interviews were listened to and read through several times to obtain a sense of the whole. Then the text was divided into meaning units which were condensed. The next step was to abstract the text into codes. The codes were compared based on differences and similarities and sorted into subcategories and categories. The tentative categories lead to a process to find the underlying meaning including discussion and reflection among all three authors until consensus was reached and the underlying meaning was formulated into themes and sub-themes. The interviews were read again to confirm that all text that was relevant for the purpose was included. Finally an overall theme was formulated, i.e a thread of the underlying meaning of all themes and sub-themes.

In qualitative studies the preunderstanding of the authors is used as a guiding tool in the interpretative process. In order not to influence the interpretation in a biased way we discussed and reflected upon our pre-understanding throughout the process [34]. The first author had met babies with infantile colic and their parents, initially as a nurse at a paediatric emergency unit and for eleven years at an acupuncture clinic. The second and third authors had extensive experience of work and research with children and parents. The first and the third author conducted the previous study [9].

RESULTS
The overall theme was formulated as “Remembering the chaos but life went on and the wound healed”. Themes and sub-themes are shown in Table 2.
Remembering the chaos… but life went on and the wound healed

Table 2 Overall theme, themes and sub-themes.

**Remembering the chaos…**

Parental struggle and tiredness…

*Isolation…*

*The colic scream was unbearable…*

Relationships were strained…

*Distance and closeness to the suffering baby…*

*Feelings of inadequacy…*

Not getting the support needed…

*Not being understood…*

*Almost nothing helped…*

*But parental struggle and tiredness turned into relief with only a few residual symptoms turned to relief with only a few residual symptoms ended once social life resumed and still evokes negative feelings*

*But relationships were strained…*

*But distance and closeness to the suffering baby turned into feelings of confidence in the parental role but healed*

*Not getting the support needed…*

*Resulted in low confidence in child health services and a call for changes but healed*

**Remembering the chaos but life went on and the wound healed**

The interviews revealed how parents still remembered the colicky period and how the experience of the colic had influenced the family. The analysis revealed a process where the chaotic colicky period faded away and the wound healed without leaving any deep traces in the long run.

**Parental struggle and tiredness turned into relief with only a few residual symptoms**

Parents remembered how they had experienced losing control during the colicky period. Everyday life had turned into emotional and practical chaos. Parenting became a matter of struggling to fulfill the family’s basic needs. Parents could recall, very vividly, a variety of overwhelming emotions, such as anxiety, frustration, compassion, guilt, shame, and a sense of failure.

*I thought that he was dying or something. (M8)*

*There were moments when, both me and my husband… when she was apoplectic and howling so much that I almost got this thought, ‘now I’ll take a pillow and put over her face just until she quietens down, until the screaming stops’. (M1)*

The haze of overwhelming exhaustion cleared up. Four years later, the colicky period was still considered to be one of the worst times in life, but in spite of the intensity of the experience, the parents felt that the colic had not seriously influenced the family in the long run. When colic healed, life returned, the wound healed and the memory faded.
With four years of perspective, parents noted that it was extremely difficult while it lasted, but that it was still a relatively short time in a life span.

You were ready to throw yourself in front of a train or something. Because it was completely horrible. It’s hard to imagine that now when it’s over, but it really was like that. (M7)

**Isolation ended once social life resumed**

During the colic period parents could very rarely leave the house or talk on the phone, friends stopped coming to visit as well and it was an ordeal to go out with a baby who screamed all the time. Isolation in the home was the option available.

I went to a parenting class, and all the other mothers massaged their baby’s tummy. But my baby screamed the whole time, so I couldn’t participate. And everyone was singing together, but I had to run out of the room, because they said the screaming was contagious... . I tried to go there two or three times, but every time was the same. (M8)

It was a huge relief when the colic passed, and parents could bring the child with them or invite friends to their home again. Parents’ social lives became normalized.

Those who have not had a colicky baby can’t understand. You can’t explain a delivery, and you can’t explain how it is to have colic. (M2)

The colic had passed without leaving any long-term effects on the child, or was it the case that the baby still had feeding or stomach problems, were particularly rough and rowdy, less sensitive to pain and the parents linked the now four year old child’s temper tantrums to the colic.

It got worse when we tried new food later on. ... He very often got tummy aches. (FG, M10)

The colic had passed without long-term effects on most parents but one of the fathers who lost 12 kilograms had a maintaining weight loss and one mother still has pain in her knees after months of jumping up and down with the baby in her arms. In eight of the twelve families the child who had colic four years previously had got a younger sibling.

It took five years before we even thought of having another child. Our family would not have survived if we had had another colicky baby. (F5)

While it lasted, the colic distorted the parent’s preconceptions regarding life as a parent. The first year did not give as many positive memories as the parents had wished. They had not been able to cuddle the baby, and they were always happy when the baby slept. Four years later, they still envy other parents whose contented babies
just sleep and eat, as well as the bond they believe that other mothers have with their new-born babies.

Well, the golden period with a new-born baby – we never had that. We did not! We knew it was super fantastic that we finally got a baby, we wanted it as much as one possibly could. But there is nothing glamorous about the memory of that time, not at all. (FG:F6)

The colicky scream was unbearable and still evokes negative feelings

The colicky scream had a special tone and could not be ignored. Colicky crying was experienced as deafening, traumatizing, and extremely draining. The scream inflicted physical pain from hearing it.

It was like, when she was crying, your ears hurt, even if you were in the basement and the baby was upstairs. And, that’s not normal. The crying could penetrate four walls. (M7)

Parents still feared colic and had a hyper-sensitivity to children’s crying. Even now, when their own child cried, the memory of the baby’s heartbreaking crying night and day was evoked, and parents could still experience physical sensations from hearing other baby’s cry.

When we started to suspect that my second daughter also had colic, I panicked. I thought ‘Shit, that cry was a colicky cry!’ I froze. ... I handed her over to my husband and said ‘You take her. I don’t want her.’ ... I just cried and cried, thinking, ‘Not another colicky child. I can’t take another one.’” (FG:M10)

Parents’ experiences had given them a new understanding and increased responsivenes towards other parents with colicky babies. They were willing to support them and were proud that they now can reassure them by telling them they understand their situation and that the colic will pass.

You can hear it now and then, for example, at the [shopping mall], and you know... (takes a deep breath) ... ‘THAT was not an ordinary cry!’ ... I want to help. Even if I don’t know them, I approach them and give my phone number and tell them “Just call me if you need to sleep an hour.” (M7)

Relationships were strained but healed

Relationships within the whole family were strained during the colicky period due to stress, anxiety and tiredness but healed when the colic was over. The feeling of togetherness that the family had longed for eventually came, and parents and siblings were able to fully embrace the baby. It just took a bit longer.
**Distance and closeness to the suffering baby and closeness to the four year old child**

It was difficult for some parents to become attached to the colicky baby, and for some parents it was difficult to feel real happiness with the child until it was over a year old, due to the very limited response from the baby and to being so worn out. Even after the crying had stopped it took several months before becoming a mother because of difficulties to have the crying child close. Other parents did not want to put down the screaming child and kept the baby close at all times. These children received plenty of attention, and parents were more emotionally tied to the child.

> But every little peep or cry made me put her down or give her to my husband. I felt like I didn’t want her. That she wasn’t mine. She shouldn’t scream like that. It was really: “I don’t want to hear your crying anymore, let someone else take you.” (M6)

Four years later, all parents had developed a good relationship to the child and sometimes had even formed a closer bond to the formerly colicky baby. They had pitied the baby so much and had given it extra love and attention.

> In some way, it made me stronger, and made my relationship with my son stronger (pause). Actually (pause). Because I felt that he had no one else but me. ‘If I can’t manage, no one can.’ So I had to cope. (FG:M10)

**Feelings of inadequacy turned into feelings of confidence in the parental role**

During the colicky period parents tried hard to get the family to function but had a constant feeling of inadequacy. They felt that others thought that they were bad parents and they worried night and day, as they did not understand why the baby was crying or how to stop it. Four years later, they had experienced the healing of the colic and seen that they could endure, which strengthened their self-esteem. They were now more confident as parents.

> When our next child also got colic, we went for acupuncture directly, as it worked so well for the first child. We didn’t try anything else. Acupuncture was the only alternative, actually. (F2)

Colic drained not only the baby/parent-relationship but also other intra-family relationships as well as the parents’ romantic relationship. Parents were more like co-workers than couples, and they saw themselves as double losers: first, for splitting up, so that not everyone suffered the screaming attacks; second, for staying apart, so that one parent at a time could recover. Siblings did not get the attention they needed, and their schoolwork and sleep were disrupted. Families with many children or twins had even more difficulties satisfying everyone’s needs.

> And I remember, when she cried so damn much we went into the closet, where we had placed a chair among the tons of clothes. Because the clothes
muffled the sound! All the clothing sucked up so much noise that you could sit and try to calm her down there. And it didn’t echo inside your head as much. This way the other person who was outside could get some rest. (FG, F7) (The others laugh) ... This could be a tip for parents with colicky babies, “Sit in the closet!” (FG, M9)

When the colic declined, relationships between parents could become normalized. Fighting the colic together had even strengthened the parents’ relationship. They now knew how capable they were, and they were proud that they had endured that difficult period, though they were surprised at their fast recovery.

Maybe we should show how proud and happy we are that we made it and say, ‘We made it!’ (FG, F6) (all talking at the same time) ‘We have had a colicky baby!’ It is a qualification! (M9) You can put that in your CV! ‘Have had a colicky baby!’ (F7) (all laugh). You could get a certificate when it’s over! (F6)

In two families, the parents had split up.

I think many people have a child in an effort to save a relationship. But, if the child gets colic, you split up anyway. That’s my experience. I’m divorced now, not only because of the colic, but the colic didn’t make it any easier. (M2)

Not getting the support needed resulted in a call for changes and a low confidence in Child Health services

Parents strongly suggested that professionals learn more about colic. For example, parents were irritated when they had made efforts to exclude cow’s milk protein for several weeks without any effect, and later learned that five days is sufficient for determining whether milk is causing the colicky symptoms. And, parents who were informed that colic ends after three months and had relied on this felt despair and hopelessness when it did not correspond with their reality.

”The nurses are educated, aren’t they?” (FG, M10)

Parents were desperate and looked for solutions both at the CHC and outside of the public health system and felt frustration and disappointment when all of their efforts yielded no results, or only helped temporarily.

... the drops [dicykloverinchloride] that they first didn’t want to prescribe, due to the strong side effects ... She went incredibly limp and lethargic and tired when we tried them, and she screamed anyway. (M4)

Four years later parents were still critical towards the treatment and had no confidence left in CHC. This was reflected in that they did not visit the CHC at all any-more, or only brought their children there for weight control and vaccinations but thought it was
no idea to ask for advice as they did not trust the advice they got from the CHC any longer. Today the parents have more demands on health care.

*No, I would not consider turning to the CHC if I had a new baby who had problems (pause). No, I would really not (pause). No, I don’t think very highly of CHC. No. (F5)*

Among this disappointment and frustration regarding the professionals there were also some parents who experienced trust in the nurses at the CHC. They were loyal to the nurse, appreciated her and her listening and they considered her to be kind and supportive, and good in handling other issues than the colic.

Lack of sleep resulted in desperation. Some got help from their own parents periodically and were sure that they would not have managed without it. Those who could not get outside help or even help from their partner felt very lonely. Others did not want to expose anyone else to the extremely annoying scream. They also thought it was hard to hear the baby crying in someone else’s arms.

*Probably we didn’t ask for help. No one else would like to have her while she was crying when not even I wanted to have her. (M6)*

**Not being understood was still considered to having been the worst part**

The biggest disappointment was that they had not been believed and that they did not get reassurance and confirmation. It was frustrating when the professionals or friends and family questioned the existence of colic or belittled the symptoms. There was great disappointment when they received advice that they had already tried in vain from professionals, friends, relatives, magazines and the internet. Likewise it was disappointing when others believed that there was a quick fix for colic, and when absolutely nobody understood their situation or believed in their story.

*Even my mom … she herself has seven children but had never encountered colic. So she thought it was me being a bit impatient, that I was too young, that maybe it wasn’t the right time to start a family. (M8)*

The nurse at the CHC trivialized parents’ experiences of the colicky symptoms and did not take the parents’ situation seriously. After four years the parents still experienced how they felt like failures because no one understood. When the nurses belittled the situation and said “all children cry” and “this is what it is like to have children” parents thought that the fault was with them, that they were weaker than other parents.

*The nurse said it was normal for babies to cry. She said that colic cannot start as early as the fifth day. But my child did have colic that early, so that was our reality … When I found out that [simethicone] was a medication with evidence of NOT helping colic, I wanted to go back to the clinic and tell them that. (M1)*
Almost nothing helped and the need for treatment remains

The desire was to get a clear diagnosis and a prognosis, a reassurance that colic would eventually pass without any serious side effects. Relief arrived when they were finally reassured that the baby did indeed have colic.

It would have been supportive for us to get the message early: “Sorry, your baby has colic. It’s gonna be tough.” So that it was made clear ... (FG,F6)
Yes, the CHC must be clearer about “this is a colicky baby”... And with “It’s really bad now, but it will pass, though it will take time.”(F7)

The professionals did not realize how much the babies cried and the parents recommended professionals to use a diary to measure the amount of crying and fussing so that it would become obvious that the baby cried more than what was normal. When one family begun to use a diary, it was shown that their baby cried 18 hours/day.

The diary made it undeniable that it was bloody awful. And that it was OK for us to be tired. ... It was not us being cuckoo. This was the reality, she was crying this much. (M7)

When parents found out that acupuncture helped their children, they were surprised that CHC had not recommended it. Several parents considered the acupuncture treatment to have had an effect on the symptoms and it was perceived as mild, simple, fast, and fast-acting. These parents were thoroughly relieved that something finally worked.

We had tried everything else ... I didn’t believe in acupuncture any more than I believed in Father Christmas, but acupuncture worked very well. If only CHC had informed us earlier! We got a new baby after three treatments! (F1)

Parents felt like failures and needed comforting and affirmation that they were good enough as parents. They also needed to be reassured that the colic was not their fault.

A nurse gave me a hug. And I just thought: “Somebody’s hugging me! Somebody’s hugging ME!” She said: ‘You can do this! You will make it there! It’s hard now, and he cries a lot now, but you can handle this!’ And I said: ‘Yes I can, now that you hugged me, I feel strong again! Thank you!’ (laughs). (FG, M10)

A short hospitalization was a saving grace for some families and seen as an acknowledgement of the situation. Only then did people around them seem to understand how serious it was.
We told the nurse that we could not stand it any longer. We said “we are dying now”. (M7)

Psychological counseling was sought for but with some hesitation. On the one hand it would have been difficult to take part in a counseling session with a screaming baby in one’s arms but on the other hand it could have lessened their sense of failure. Others definitely did not want to see a psychologist as they meant it was the child who needed help.

I wish I could have seen someone, some kind of a professional counselor ... Someone who was not the CHC (laughter), where I could have said “I hate the CHC!”. That would have been seriously great. (M1)

To get help one family advertised for an extra grandmother and eventually hired a nanny. One suggestion from the parents was that financial support should be granted for maid service or for enabling both parents to stay at home or at least work less during the extreme colicky period.

Because a colicky baby can create an awful lot of chaos in a perfectly normal family. (FG, M10)

To get emotional support parents would have liked to meet other parents with colicky babies but on the other hand they had no energy to attend, let alone organize group meetings. Yet they expressed a need for a support group with someone who really understood the situation.

DISCUSSION OF METHOD

Qualitative methods and content analyses are well suited to illuminate participants experiences of a certain phenomenon [33]. When 13 individual interviews were conducted and analysed, we invited parents to a focus group interview to further explore their experience. Focus groups are an academic research tool that yields qualitative data in a focused discussion and, thereby, provides insight into complicated topics. We use them to understand how people with certain commonalities feel or think about an issue, and when we are trying to understand differences in perspectives. A response from one participant could trigger memories and thoughts in other participants [31]. The discussion and interaction in the group was lively.

Trustworthiness

By interviewing the same group of parents twice[9], their experience could be followed over the four year period. In the present study, 17 out of 23 parents took part. The parents had various experiences and backgrounds which increased the possibility of shedding light on the research question from a variety of perspectives. Interviews were conducted in a comfortable, permissive, non-threatening environment. The parents showed high levels of motivation to share their experiences and they spoke
openly. Interviews were rich in depth as well as in breadth. The majority of the interviews were conducted individually and supplemented by a focus group interview where skilled moderators enabled parents to discuss experiences without having the pressure of reaching consensus [31], further validating the result of the individual interviews. During the interviews, the interviewers’ checked their understanding with follow-up questions. To add depth and insight to the interpretation, the findings were discussed at research seminars with paediatric nurses and midwives. Quotes from the interviews are used to verify that the findings were retrieved from the data. In the present study, we asked parents to recall how it had been having an infant with colic four years previously. The reliability of memories is an interesting issue. Women’s ability to recall other key events in life, linked with the memory of labour and childbirth have shown that there is substantial agreement between maternal recall and birth records 3-9 years later [35]. The memory of the colic has probably been recalled repeatedly over the years, and as the interviewed parents in this study had been through an earlier interview they might have reflected on the colic more than other parents. Some details might become lost over the years. However, the aim of the present study was not to investigate the accuracy and consistency of long-term memories of the colicky period.

DISCUSSION OF RESULTS AND CLINICAL IMPLICATIONS

Parents’ memories four years after the colicky period are similar to the experiences they had described when they were in the midst of the period [9]. It is striking how vivid, emotional, and detailed the memory of the experience of having a baby with colic is. Parents recall exact details, and some tell their story in the same words as four years earlier. Some weep, some laugh when they recall situations that were especially difficult. However, parts of the memory have faded out, some details have been lost, the wound have healed, and the families have been repaired. What is apparent is that parents have lost their confidence in the CHC, which is an alarming find, and that they had formulated suggestions for changes. Most of all, parents request an effective treatment of colic and the presence of professionals with a sensitive and keen ear to the families with colicky babies and who would pay attention to the suffering of child and the parents.

Parents’ experienced that they had needed to be guided through the colic period. They searched actively for information on colic. Apart from recommendations from professionals, friends, relatives and magazines, they used the Internet for searching for information, including chat rooms, and blogs. This means that they got plenty of information and tips of diverse quality. It is a challenge for professionals to keep up with the parents in seeking and evaluating information about colic and to help the parents to sort out the evidence from mere opinions[36]. When the professionals could not heal the child immediately, the parents in the present study wished that they had at least given clear advice and that advice had been followed up. Parents suggest a manual, a week by week structured set of directions, where treatments are systematically tried and evaluated. To allow this systematical guidance, parents want a more frequent contact with the nurse, as suggested by Long & Johnson [3].
Parents’ experience that nobody understood how much the baby was crying. A clear diagnosis, “Your baby has colic”, combined with “There is no cure” and “You did not cause the colic” is better than not being believed, also expressed in Levitzky & Cooper [37]. A diary was used before inclusion in the first interview study [9] to verify that their baby fulfilled the inclusion criteria, and later when their baby was treated at the acupuncture clinic. Parents appreciated the diary as a tool for reaching an understanding for their situation. For professionals, parent’s documentation of their child’s behavior can help to identify children who actually cry excessively [6], [38]. Therefore diaries allow professionals to discern when to intervene with medical examinations to exclude diseases in order to spare the parents from unnecessary anxiety. The parents had not got, or not understood, information that colic is a common condition that usually, but not always, heals spontaneously by three or four months of age [12]. Examining the baby to exclude the incidence of disease, and repeating the confirmation that the colic will heal spontaneously might assure parents that the baby is healthy. The use of a diary can also detect parents who have normally crying children but feel that they cry more than children do normally. These families merely need reassurance that they are doing a good job, and a discussion about normal crying and parenthood. Moreover, the use of a diary can prevent the baby from unnecessary treatments.

In the present study, parents felt exhaustion, guilt and shame when they could not comfort their baby, and when they got an impulse to harm them, also shown in Long & Johnson [3] and Levitzky & Cooper [37]. Professionals who are aware of this risk and explore parental frustration by asking probing questions can ascertain that parents close to shaking their babies are identified. Time and capacity to build a trustful relationship with parents are important to detect and help families at risk [39].

A delay in the development of “good” feelings for the baby was experienced and not all the parents were emotionally stable, with high capacity and good networks. The experience of the colicky period is for some influenced by variables like depression or substance abuse. In these respects, they represent the clinical reality [5, 6]. Maternal anxiety, depression, and stress during pregnancy and postpartum have been linked to the development of colic and vice versa [25], [40]. Parents also consider their babies’ crying to not only be long-lasting but also as particularly aversive, also described by Zeskind & Barr [2]. Perceptions of the babies’ crying can be altered, for example by depression [41]. Ten per cent of pregnant women are depressed [42] and many stop taking anti-depressants during pregnancy. Professionals, who are aware of mothers showing signs of depression, stress, and substance abuse, can screen those who are at risk. If they also identify families with delayed attachment, they can better be able to help parents to endure the period of colic and provide a secure base for their baby.

The perceived isolation during the colicky period, in line with earlier studies [3], [5]. Parenting groups are important for developing a good parenthood, and if parents with colicky babies feel that they are included and welcome it can break their isolation.
A request for an effective treatment to shorten the period of colic is on the wish list. All parents in the present study tried acupuncture for their babies and several of them had positive experiences. A positive effect is supported by the few articles published on the topic [19], [20], [21], [43]. Although acupuncture is a promising treatment for infantile colic most clinicians request stronger evidence before introducing a new treatment and further research is required. As no negative side effects are reported and no other safe and effective treatment is known, acupuncture can be considered as a treatment.

The birth of a child, especially a first child, represents a landmark event in life that results in parents being very vulnerable [44]. Parents in the present study want to give their eagerly awaited child everything. Not being able to comfort the baby challenge their self-esteem as they perceive a loss of competence as parents, like in Megel et al [5]. Infant crying and parental response is the first language of the new dyadic relationship. Misunderstandings can compromise infant care and parental effectiveness, and undermine the budding relationship [41]. However, parents in the present study experience that having managed a family through the colicky period strengthened their self-esteem. Supportive care may protect parents from a long-lasting negative experience [45]. In the period of infantile colic, the way parents are treated by the professionals may determine their long-term feeling about the experience. Professionals can support parents by helping them remember the baby period with joy and pride and a sense of accomplishment. By focusing on solutions and parents’ strengths, and by commending parents and telling them that they are doing a great job, nurses could minimize the risk of parents being stuck in feelings like helplessness and failure. Praising the child also makes parents feel proud. This could change their behavior towards the child, as well as each other [46], [47]. Active listening, compassion, and empathy are nurturing kinds of behavior associated with raising parents’ self-efficacy beliefs, thereby influencing their performance [15].

**CONCLUSION**

Four years later, parent’s memories of the colicky period are still vivid and emotional, but the family relationships have healed and the colic left only a few residual symptoms. Parents have specific needs when having a baby with colic. Professionals in CHC are advised to identify problems and support the parents and the child. Consequently, there is a need to raise awareness to parent’s situation when having a child that is suspected to have infantile colic.
CONFLICT OF INTEREST

None.

ACKNOWLEDGEMENTS

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REFERENCES


Acupuncture reduces crying in infants with infantile colic: a randomised, controlled, blind clinical study

Kajsa Landgren,1 Nina Kvörning,2 Inger Hallström1

ABSTRACT
Objective To investigate whether acupuncture reduces the duration and intensity of crying in infants with colic.

Patients and methods 90 otherwise healthy infants, 2–8 weeks old, with infantile colic were randomised in this controlled blind study. 81 completed a structured programme consisting of six visits during 3 weeks to an acupuncture clinic in Sweden. Parents blinded to the allocation of their children met a blinded nurse. The infant was subsequently given to another nurse in a separate room, who handled all infants similarly except that infants allocated to receive acupuncture were given minimal, standardised acupuncture for 2 s in LI4.

Results There was a difference (p = 0.034) favouring the acupuncture group in the time which passed from inclusion until the infant no longer met the criteria for colic. The duration of fussing was lower in the acupuncture group the first (74 vs 129 min; p = 0.029) and second week (71 vs 102 min; p = 0.047) as well as the duration of colicky crying in the second intervention week (9 vs 13 min; p = 0.046) was lower in the acupuncture group. The total duration of fussing, crying and colicky crying (TC) was lower in the acupuncture group during the first (193 vs 225 min; p = 0.016) and the second intervention week (164 vs 188 min; p = 0.016). The relative difference from baseline throughout the intervention weeks showed differences between groups for fussing in the first week (22 vs 6 min; p = 0.028), for colicky crying in the second week (92 vs 73 min; p = 0.041) and for TC in the second week (44 vs 29 min; p = 0.024), demonstrating favour towards the acupuncture group.

Conclusions Minimal acupuncture shortened the duration and reduced the intensity of crying in infants with colic. Further research using different acupuncture points, needle techniques and intervals between treatments is required.

INTRODUCTION
Ten per cent of newborn children in the Western world experience colic.1 2 The aetiology is unclear but gastrointestinal factors and allergy to cow’s milk protein have been suggested as possible causes.3 Another suggestion is that colic is a behavioural condition resulting from unfavourable parent–infant interaction.4 In three meta-analyses current medical treatments are evaluated as either inefficient (simethicone) or as having serious side effects like seizures, asphyxia and death5–7 (dicyclomine, presently withheld by the manufacturer). In spite of the good prognosis of infantile colic with full spontaneous recovery,6 colic inhibits optimal family relations8–9 and increases the risk of child abuse.10–12 Acupuncture is widely used and discussed in infantile colic. However, few articles have been published on this subject. Two uncontrolled studies report positive outcomes after acupuncture in children with night crying.13 14 One qualitative study15 and one randomised controlled study16 also indicate that acupuncture has an effect on infants’ crying. The objective of this study was to further investigate whether minimal acupuncture reduces the duration and intensity of crying in infants with colic.

MATERIAL AND METHODS
A prospective, randomised, controlled, blinded clinical trial was performed at a private acupuncture clinic in Sweden, from November 2005 to February 2007. For the past 15 years this acupuncture clinic has offered acupuncture treatment for adult patients with different symptoms and for infants with colic.

Patients
Infants with colic, 2–8 weeks old, whose parents sought help at either a child health centre, the regional hospital’s paediatric clinic or at the acupuncture clinic where the trial was performed, were consecutively preselected by health professionals who were informed of the inclusion criteria: healthy infants, born after gestational week 36, not treated with dicyclomine and fulfilling the modified Wessel criteria for colic: ‘crying/fussing for at least 5 h a day, occurring 3 days or more in the same week’.5 Parents with eligible infants and who were willing to participate reported the extent and degree of their infant’s crying and fussing in a diary for at least 3 days. Exclusion of cow’s milk from the infant’s diet was recommended during the registration period if it had not already been tried. If meeting the criteria, the infant was included in the study and started the structured programme the following Monday or Thursday. Written informed consent was obtained from the parents, and the study was approved by the local research ethics committee (Dnr 583/2005). All infants continued the regular programme at their ordinary child health centre throughout the duration of the study.

Randomisation and blinding
A registered nurse skilled in acupuncture, nurse A, was hired specifically to perform the randomisation, administer the intervention and be the sole person aware of allocation and with access to the records during the study. Nurse A met the infants alone in the treatment room and was only informed of their age and study number. The randomisation procedure divided the infants into an intervention group with a structured programme including acupuncture (acupuncture group) or to the same structured programme not including acupuncture (control group). As we proposed that age was a prognostic variable that might interfere with the result, restricted randomisation was used to achieve
a balance between 2–5 weeks old and 6–8 weeks old infants, respectively, in the groups. Two sets of sealed opaque envelopes, marked ‘2–5 weeks old’ and ‘6–8 weeks old’, respectively, had been prepared by nurse A before the study started. The envelopes contained a card with either ‘control group’ or ‘intervention group’, each in equal amounts. The card in the upper envelope in the pile appropriate to the infant’s age determined the group to which each infant was assigned. Consequently, all infants had an equal probability of assignment to either group. Each infant remained in the initially allocated group throughout the study.

The study was double blind as neither the parents who registered the infants crying nor the nurse who met the parents (nurse B, the first author) knew to which group the infant belonged. Nurse B enrolled parents of potential patients, informed them of the trial, assessed the infant’s eligibility, obtained informed consent and met the parents at the acupuncture clinic. Two closed doors separated the parents from the treatment room and music was always played. Parents were informed that the needle was very thin, usually caused no bleeding or visible marks and that acupuncture does not necessarily provoke crying.

**Intervention**

The structured programme consisted of a total of six biweekly visits to the acupuncture clinic. The first visit lasted for 30 min, during which the parents met nurse B who repeated information on the study and collected baseline demographic data. During the following five visits, parents met nurse B for 15 min appointments, and were asked standardised questions such as ‘How is it going?’; received standardised oral support such as ‘Hopefully it will be better soon’ and were given time for questions. At each visit, the infant was carried to the treatment room by nurse B and left there with nurse A. The initial handling of the infants in the treatment room was identical. Nurse A held each infant’s hand and spoke soothingly. If starting to cry, the infant was comforted by the nurse in her arms. The infants allocated to have acupuncture subsequently received minimal, standardised acupuncture with a sterilised, disposable acupuncture needle, Vinco MicroClean, 0.20 × 13 mm. The needle was inserted unilaterally and left in place for 2 s at an approximate depth of 2 mm at point LI4 of the hand’s first dorsal interossal muscle, a point often used in clinical practice when treating infants with colic and, also used in an earlier randomised controlled trial (RCT) studying acupuncture treatment for colic and known for the generalised analgesic effect.14 Left and right hands were used alternately. After a maximum of 5 min in the treatment room, nurse A carried infants back to their parents. Infants allocated to the two groups went through exactly the same procedure except for the insertion of an acupuncture needle in the acupuncture group.

**Assessments and outcomes**

Definitions of ‘fussing’ (showing dissatisfaction and whimpering despite being carried), ‘crying’ (screaming loudly) and ‘colicky crying’ (crying hysterically and unconsolably) were communicated to the parents both verbally and in writing. Parents reported infants’ fussing, crying and colicky crying in a standardised diary form originally developed and validated by Barr et al.12 and modified and tested by Canivet et al.13 The diary form consisted of sheets, each covering 24 h. Parents filled in boxes, each representing 5 min, to indicate when their infant was fussing (marked as F), crying (marked as C) and colicky crying (marked as CC). All marked boxes were counted manually and transferred into a database. Reports were made on at least 3 days during the baseline week preceding possible inclusion and daily during the three intervention weeks, directly following the baseline week. Twice weekly, parents completed a questionnaire modified from Reinthal et al.,16 in which they described any adverse effects they considered to be caused by treatment. Duration of crying in the treatment room and bending were noted by nurse A. The primary end point was the number of infants who fulfilled the colic criteria during each of the intervention weeks. The secondary end point was the total duration of fussing, crying and colicky crying (TC) during the three intervention weeks as reported by parents in the diary.

**Statistical analyses**

Based on the assumption that 50% of the infants would go into spontaneous remission without treatment and 75% with acupuncture, 40 patients per group were needed in order to have a 90% chance of detecting a significant difference in remission at a two-sided 5% level. The statistical software SPSS version 17 (SPSS, Chicago, Illinois, USA) was used for calculations. As two parameters were not normally distributed all data were analysed with non-parametric statistics. Kaplan–Meier analysis was performed to assess the time for each infant’s crying to fall below 180 min, indicating that the infant no longer fulfilled the criteria for colic. To evaluate differences between intervention and control groups the log rank test was performed. Mann–Whitney U test was used to analyse crying and fussing times, and the relative difference in crying and fussing between the baseline and the intervention weeks was measured as a percentage. p Values <0.05 were considered statistically significant.

**RESULTS**

**Participants and progress throughout the trial**

Of the 210 infants who between November 2005 and February 2007 were suspected to have colic, 90 fulfilled the colic criteria after completing the diary. Three infants randomised to the control group did not meet the criteria and were excluded, and the procedures for analysing the diaries before randomisation were changed (figure 1). Two infants in the acupuncture group who only came to the clinic five times as the symptoms disappeared are counted as fullfillers as their parents continued to complete the diary. Background data were analysed for infants starting the structured programme (n=86) and for infants who completed the three intervention weeks (n=81) (table 1). Outcomes from the intervention weeks are based on the infants’ remaining in the study each week and drop outs are reported as missing values. Infants were stratified by age and age at inclusion was similar in both groups (table 1). However, owing to small numbers in the subgroups, age groups were analysed together.

**Baseline data**

There were no significant differences between the groups for background characteristics such as parents being born in Sweden, educational level, smoking and mother’s complications during pregnancy or delivery; nor were there differences between their baseline levels of fussing and crying (tables 1 and 2).

**Outcome measures**

**Rate of infants fulfilling the colic criterion in each of the intervention weeks**

There was a difference (p=0.084) between groups in the time which passed from inclusion until the infant had a mean value
Table 1: Baseline data for infants

<table>
<thead>
<tr>
<th>Background characteristics</th>
<th>Infants starting the intervention (N=86)</th>
<th>Infants completing 3 weeks (N=81)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acupuncture group (n=46)</td>
<td>Control group (n=40)</td>
</tr>
<tr>
<td>Firstborn, n (%)</td>
<td>22 (48)</td>
<td>22 (55)</td>
</tr>
<tr>
<td>Gender, female, n (%)</td>
<td>22 (48)</td>
<td>19 (48)</td>
</tr>
<tr>
<td>Gestational age, weeks, mean (SD)</td>
<td>39.2 (1.5)</td>
<td>39.5 (1.3)</td>
</tr>
<tr>
<td>Age when colic started, weeks, mean (SD)</td>
<td>1.9 (1.3)</td>
<td>1.5 (1.0)</td>
</tr>
<tr>
<td>Age at inclusion, weeks, mean (SD)</td>
<td>5.0 (1.9)</td>
<td>5.3 (1.7)</td>
</tr>
<tr>
<td>Solely breastfed, n (%)</td>
<td>35 (76)</td>
<td>26 (65)</td>
</tr>
<tr>
<td>Having a parent and/or sibling with food intolerance/allergy, n (%)</td>
<td>17 (37)</td>
<td>18 (45)</td>
</tr>
<tr>
<td>Having a parent and/or sibling who had had infantile colic, n (%)</td>
<td>29 (63)</td>
<td>23 (58)</td>
</tr>
</tbody>
</table>

Table 2: Baseline data for fussing, crying, colicky crying and the total duration of fussing, crying and colicky crying (TC)

<table>
<thead>
<tr>
<th>Categories of fussing and crying, min/day</th>
<th>Infants starting the intervention (N=86)</th>
<th>Infants completing 3 weeks (N=81)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acupuncture group (n=46)</td>
<td>Control group (n=40)</td>
</tr>
<tr>
<td>Fussing, median (q1–q2)</td>
<td>113 (57–178)</td>
<td>146 (66–188)</td>
</tr>
<tr>
<td>Crying, median (q1–q2)</td>
<td>86 (55–123)</td>
<td>72 (36–119)</td>
</tr>
<tr>
<td>Colicky crying, median (q1–q2)</td>
<td>37 (17–127)</td>
<td>57 (21–96)</td>
</tr>
<tr>
<td>TC, median (q1–q2)</td>
<td>260 (218–351)</td>
<td>277 (231–370)</td>
</tr>
</tbody>
</table>

Figure 1: Flow chart of infants through the trial.
for TC of <180 min/day for the first time, indicating that the infant no longer met the criteria for colic. Figure 2 demonstrates this difference by showing the proportion of infants with a mean TC <180 min/day for each of the six treatment periods consisting of 3 or 4 days depending on whether treatment was given on a Monday or a Thursday. Median time until criteria for colic were no longer fulfilled was 7 days in both groups.

**Duration of fussing, crying and colicky crying**

The duration of fussing was shorter in the acupuncture group during the first (p=0.029) and second (p=0.047) intervention weeks. The duration of colicky crying was shorter (p=0.046) in the acupuncture group during the second intervention week. However, TC was lower in the acupuncture group than in the control group as early as the first intervention week (p=0.025) and in the following intervention week (p=0.016) (table 3). A subanalysis showed TC to already be lower (p=0.005) in the acupuncture group after the first treatment. The relative difference between groups, measured as the percentage decrease of crying and fussing from baseline to intervention weeks 1, 2 and 3 showed differences between groups for fussing the first week (p=0.028), for colicky crying the second week (p=0.041) and for TC the second week (p=0.024) (table 4).

**Adverse events**

Slight bleeding (one drop) was detected after needling in one of the 256 acupuncture treatments administered. Thirty-two infants (74%) in the acupuncture group cried for more than 10 s during one to four interventions in the treatment room compared with 14 infants (37%) in the control group (p = 0.009) (table 5). Crying lasted more than a minute in 37 out of 256 needling occasions (14%). No infant cried for more than 2 min. No other adverse events were reported.

**DISCUSSION**

In this study where both acupuncture and control groups were allotted six visits with support and counselling as an intervention beside their ordinary child health centre visits, there was an expected decrease in TC in both groups.19 However, the decrease was slightly faster in the acupuncture group as shown by measuring both absolute and relative differences between groups. There was a small but significant difference between groups already after the first treatment and in the duration until the infants no longer fulfilled the colic criterion. Spontaneous healing might explain the lack of difference between groups during the third intervention week. The results of this study are

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**Table 3** Fussing, crying, colicky crying and total duration of fussing, crying and colicky crying (TC) during the three intervention weeks for the infants still remaining in the trial at each of the intervention weeks

| Categories of fussing and crying, min/day | First intervention week |  |  |  | Second intervention week |  |  |  | Third intervention week |  |  |  |
|------------------------------------------|-------------------------|-------------------------|-------------------------|--------------------------|-------------------------|-------------------------|-------------------------|--------------------------|-------------------------|-------------------------|-------------------------|
|                                           | Acupuncture group (n=46) | Control group (n=40) | p Value                 | Acupuncture group (n=44) | Control group (n=39) | p Value                 | Acupuncture group (n=43) | Control group (n=38) | p Value                 |
| Fussing, median (q1–q3)                  | 74 (53–154)              | 129 (80–183)            | 0.029                   | 71 (41–123)              | 102 (60–148)            | 0.047                   | 69 (36–109)              | 85 (63–151)              | 0.119                   |
| Crying, median (q1–q3)                   | 76 (45–103)              | 81 (50–102)             | 0.428                   | 52 (27–88)              | 55 (24–73)             | 0.964                   | 54 (21–87)              | 46 (22–98)              | 0.846                   |
| Colicky crying, median (q1–q3)           | 20 (6–53)                | 26 (9–46)               | 0.634                   | 9 (0–27)                | 13 (6–49)              | 0.046                   | 3 (0–18)                | 9 (0–18)                | 0.087                   |
| TC/day, median (q1–q3)                   | 193 (143–253)            | 225 (178–316)           | 0.025                   | 164 (103–201)           | 188 (149–273)           | 0.016                   | 149 (92–193)            | 169 (119–267)           | 0.062                   |

**Table 4** Relative difference in fussing, crying, colicky crying and total duration of fussing, crying and colicky crying (TC) between the baseline week and the first, second and third intervention weeks, respectively

| Categories of crying and fussing, median min/day | Difference baseline – first intervention week |  |  |  | Difference baseline – second intervention week |  |  |  | Difference baseline – third intervention week |  |  |  |
|------------------------------------------------|-----------------------------------------------|-------------------------|-------------------------|--------------------------|-------------------------|-------------------------|-------------------------|--------------------------|-------------------------|-------------------------|-------------------------|
|                                                | Acupuncture group (n=46)                      | Control group (n=40)    | p Value                 | Acupuncture group (n=44) | Control group (n=39) | p Value                 | Acupuncture group (n=43) | Control group (n=38) | p Value                 |
| Fussing, difference in % (min—max in %)        | 22 (−956, 84)                               | 6 (−1614, 57)           | 0.028                   | 30 (−210, 98)            | 26 (−2071, 89)          | 0.158                   | 43 (−317, 100)          | 30 (−2242, 98)          | 0.291                   |
| Crying, difference in % (min—max in %)         | 12 (−219, 100)                              | 13 (−786, 89)           | 0.726                   | 34 (−217, 100)           | 30 (−446, 95)           | 0.784                   | 39 (−107, 100)          | 44 (−543, 100)          | 0.936                   |
| Colicky crying, difference in % (min—max in %)| 57 (−443, 100)                               | 57 (−1050, 100)         | 0.921                   | 92 (−700, 100)           | 73 (−191, 100)          | 0.041                   | 92 (6, 100)             | 81 (−600, 100)          | 0.062                   |
| TC, difference in % (min—max in %)              | 27 (−59, 69)                               | 16 (−59, 75)            | 0.060                   | 44 (−25, 92)             | 29 (−67, 84)            | 0.024                   | 48 (−23, 88)            | 42 (−71, 90)            | 0.219                   |
in agreement with the only RCT on acupuncture in infantile colic published, in which 40 infants were included, of whom 20 were needled in LI4 bilaterally for 20 s. Spontaneous remission was more likely to occur in that study as some of the infants were older than 8 weeks. Furthermore, the parents were blinded but not the nurse meeting the parents and administering the acupuncture.

**Strengths and limitations of this study**

The strengths of our study are the randomisation, the blinding of the parents, the small number of drop-outs and strict protocol, including an extensive diary validated in several studies. The strengths of our study are the randomisation, the blinding of the parents, the small number of drop-outs and strict protocol, ensuring equal support and advice to all participating families infl uenced both groups equally, is a strength. Infants in both groups lacked expectations and had limited communication skills, thereby eliminating any difference in placebo effect in them and in their blinded parents.

No test of blinding was done after the three intervention weeks, which is a limitation. More infants in the acupuncture group than in the control group started to cry in the treatment room. Parents might have heard the infants cry and thus suspected that the infant had received acupuncture. However the fussing/crying lasted for ≤10 s in most cases. On one occasion one infant cried for more than a minute after the acupuncture treatment but none cried for more than 2 min, indicating that this light acupuncture treatment was well tolerated by the infants.

The safety of acupuncture is a major concern, particularly during early infancy when responses are difficult to evaluate. In a review, acupuncture was considered a safe modality for paediatric patients, but the authors advised that fewer needles should be used when treating children. In accordance with this our study used one single point with light stimulation. As different acupuncture points result in different effects the option of choosing points individually after analysing all symptoms presented in an ordinary clinical setting may increase efficacy of future acupuncture treatment of colic. The six treatments in this study may be more than needed.

**Possible mechanisms and explanations**

Most basic acupuncture research is conducted with electroacupuncture on animals, and cannot be generalised to manual acupuncture in humans. However, it is known that acupuncture in animals inhibits somatic and visceral pain and has an effect on the autonomous system. Stimulating LI4 bilaterally resulted in more immediate effect than unilateral stimulation. The motility in the intestinal tract and the gastric acid secretion increased or decreased depending on which points were needled. In human adults and children acupuncture had a beneficial effect on visceral symptoms like nausea. Acupuncture increased bowel movement in children, altered gastric motility and affected gastric emptying in adults with motility disorders but caused no effect on gastric motility in healthy individuals. Manual acupuncture applied to LI4 induced an increase in the sympathetic and parasympathetic nervous systems in 12 healthy individuals.

It is possible that infantile colic derives from distension of the intestines and activation of the autonomic nervous system and that acupuncture can influence both visceral pain and the autonomic nervous system. Thus it is plausible that even modest stimulation of LI4, as performed in this study, can influence either or both mechanisms and thereby alleviate infantile colic.

**Generalisability**

This study includes infants with eczema, a rash from a Von Rosen splint, a temperature, a hand burned by boiling water and infants whose mothers had a high level of anxiety or depression. In this aspect the participants represent clinical reality, and these afﬂictions were equally distributed among the groups. Parents who were negative about exposing their children to acupuncture or who lacked the ability to complete the diaries did not participate and infants born prematurely were excluded. This leaves the included sample and the results of this study as reasonably representative of the general population.

**Clinical implications**

Parents have described colic as a strain on the family. As no safe and effective cure is known we assume that even a short reduction of the colicky period can make a difference. Of the 210 infants estimated by the parents to have colic, only 90 fulfilled the criteria after registration of their symptoms in the diary. This indicates that parents have a tendency to overestimate the crying, and a diary in which parents note their infant’s crying could be a valuable diagnostic tool. Another explanation may be that the deﬁnition of colic does not reﬂect the parent’s experience of what they consider to be colic.

**CONCLUSION**

Standardised, light stimulation of the acupuncture point LI4 twice a week for 3 weeks reduced the duration and intensity of crying more quickly in the acupuncture group than in the control group. No serious side effects were reported. Future research is needed to validate the results and to investigate the efficacy of other acupuncture points and modes of stimulation for the treatment of infantile colic.
Summary

- Previous reports suggested acupuncture might reduce infantile colic.
- We conducted a randomised controlled trial in 90 infants.
- Acupuncture showed a small but significant effect on some outcomes.

Acknowledgements

Thanks to Margareta Normark for providing acupuncture, to Per Nyberg for statistical support.

Funding

The authors thank Ekhagastiftelsen, Magor Bergwalls Stiftelse, General Maturity Hospital Foundation, Pampers and Baby Bag for funding.

Competing interests

None.

Ethics approval

This study was conducted with the approval of the Lund University, Research Ethics Committee (Dnr 583/2005).

Provenance and peer review

Not commissioned; externally peer reviewed.

REFERENCES

Feeding, stooling and sleeping patterns in infants with colic - a randomized controlled trial of minimal acupuncture

Kajsa Landgren1†, Nina Kvarning2† and Inger Hallström1†

Abstract
Background: The aim was to describe the feeding- and stooling patterns of infants with colic and evaluate the influence of minimal acupuncture.

Methods: A prospective, randomized, controlled, blind clinical study was conducted at a private acupuncture clinic in Sweden. 90 otherwise healthy 2-8 weeks old infants, born after gestational week 36, fulfilling the criteria for infantile colic and not medicated with dicyclomine, were included. 81 infants went through a structured program consisting of six visits to the clinic, twice weekly. Infants randomized to receive acupuncture were given minimal, standardized acupuncture for two seconds in LI4. Frequency and size of stooling, as well as duration of, and intervals between, feeding sessions were reported by parents in a diary. Parental assessment of sleep and comments on stooling and side effects were collected in a questionnaire.

Results: At baseline when the mean age was five weeks, infants in both groups were fed a median of eight times/day, 148 min/day, with considerable variations. No differences were found between groups in the frequency and duration of feeding during the intervention weeks. Furthermore there were no significant differences between the groups regarding the frequency of stooling, neither at baseline, at which point the infants of both groups had bowel movements 4.2 times/day, nor during the intervention weeks. There was an expected decrease in frequency of stooling in both groups, reaching 2.1 (p = 0.001) in the acupuncture group and 3.1 (p < 0.001) in the control group. The groups differed regarding large bowel movements which decreased linearly in the control group (p = 0.011) but not in the acupuncture group (p = 0.787). More parents in the acupuncture group than in the control group (28% and 15% respectively, p = 0.006) experienced the infant’s sleep to be “better” or “much better.” No other significant differences were found. However, parents described a normalized stooling and experienced an improvement in colic in their infants more frequently in the acupuncture group than in the control group.

Conclusions: Infants with colic in the present study had a higher frequency of stooling than reported internationally in healthy infants. Minimal acupuncture had no major effect on feeding, stooling and sleep, although a minor effect of minimal acupuncture on stooling and sleep cannot be ruled out.

Introduction
Infantile colic, with a prevalence of approximately 10% of infants[1], is often related to gastrointestinal factors by the parents[2] although the aetiology is unclear[3]. Few studies describe feeding frequency and bowel habits during the first months in healthy infants[4-10], even fewer describe this in infants with colic[11,12]. Possible effect of acupuncture on feeding, stooling and sleeping patterns in infants suffering from colic has not been investigated previously.

Background
Parents are encouraged to feed their newborn baby when and for as long as the baby desires in order to
adjust the natural control of appetite, maternal milk production or amount of formula. 6-8 meals/day is the postulated standard [4]. We have not been able to find any scientific data as to how often infants are actually fed. Age is the factor that influences stooling frequency most. Healthy infants have bowel movements approximately four times/day during their first 1-2 weeks [5-7]. At the age of one month infants are registered to have 2.2 stoolings/day [7], approximately three stoolings/day [6,8-10] and in one study six stoolings/day [11]. Following the first weeks there is a radical decrease in stooling frequency till the age of two months when stooling frequency was reported to be one per day [11], 1.8 [7,10] and 2.2 [9] times/day. At three months the mean frequency had decreased to one per day [11], 1.25/day[13] and approximately 1.7/day [7,10]. Breast feeding has been reported to increase the frequency of stooling [11,14,15]. Two trials measured the difference between the bowel movements of colicky and non-colicky infants: one reported that infants with symptoms of colic during the first two months had less frequent bowel movements [11], the other that there was no difference[12].

Parents of infants with colic correlated crying to stomach aches and a disturbed gut function [2,16]. In a qualitative study they remarked that their infants had bowel movements more than ten times/day or hardly at all and that the stools were green, explosive and foul-smelling [2].

Colicky symptoms have been linked to feeding problems and disturbed sleep [17]. In two randomized controlled studies minimal acupuncture in LI4 in infants with colic resulted in a reduction of fussing and crying [18,19]. Possible explanations could be a reduction of pain as shown in adults [20], a beneficial effect on other visceral symptoms such as nausea which has been reduced by acupuncture in adults [21,22] and in children [23], an altered gastric motility [24] or changed gastric emptying as shown in adult patients with motility disorders [25]. Furthermore acupuncture affected constipation in children [26] even though gastric motility in healthy adult humans was not altered [27]. Finally a sedative effect of acupuncture could explain the reduction of colic as it has been demonstrated to promote sleep in adults [28].

The aim of this study was to describe the feeding and stooling patterns of infants with colic. A second aim was to evaluate the influence of minimal acupuncture.

**Methods**

**Design**

The study was performed at a private acupuncture clinic in Sweden comparing acupuncture with no acupuncture in a prospective, clinical, blinded, randomized, controlled trial (RCT). The primary outcome of the RCT was the frequency of fussing and crying of the infants, described in a separate article [19]. The secondary outcomes were the feeding, stooling and sleeping patterns of the infants as presented in the present article. The study was approved by the Regional Ethical Review Board (Dnr 583/2005).

**Participants**

Parents of otherwise healthy 2-8 week old infants, born after gestational week 36, never medicated with dicyclomine and searching help for excessive crying were invited to participate. After giving written informed consent the parents of 210 infants reported the crying and fussing of their infants in a diary for at least three days to assess whether or not the infants fulfilled the modified Wessel-criteria for colic: “crying/fussing for at least three hours a day, occurring three days or more in the same week” [1]. In the diary the parents also reported the feeding and stooling habits of their infants. During the registration period exclusion of cow’s milk from the infant’s diet was recommended if this had not been tried previously. Of these 210 infants 120 were not included as they cried less than the stipulated hours. Some of them may have improved as they were no longer exposed to cow’s milk protein. The 90 infants fulfilling the criteria for crying were randomized and 81 completed all three intervention weeks (Figure 1).

**Randomisation and intervention**

Infants went through a structured program consisting of six visits to an acupuncture clinic, twice weekly. (Two infants in the acupuncture group went to the clinic only five times as the parents considered the colic to be cured. They were included as the parents continued to register in the diary.) At each visit the parents met a nurse who asked standardized questions and gave standardized support and advice. At every visit the infant was carried to a treatment room and left alone for five minutes with a certified acupuncturist who was also a registered nurse and well qualified in the care of children. She administered minimal, standardized acupuncture to the infants allocated to receive acupuncture. This was performed unilaterally (left and right hands were used alternately for each child), for two seconds at an approximate depth of two millimeters in the point LI4 of the first dorsal interosseus muscle of the hand, innervated by the ulnar nerve by sensory and autonomic, mainly sympathetic, fibres. An acupuncture needle, 0.20 × 13 mm, was used (Vinco Micro Clean). Infants in the control group were treated similarly except for the needle insertion.

**Blinding**

The nurse who met the parents was blinded to the randomization. The acupuncturist performed the randomization...
and never met the parents. Parents were informed that acupuncture does not necessarily cause the infant to cry and that the very thin needle usually would not cause bleeding or a visible mark on the skin.

Outcome and assessments
The parents made notes every 5-minute when applicable, for 24-hours of their infants’ crying, feeding and stooling in a diary modified from Barr et al [29] and Canivet [30]. Reports were made for at least three days during the baseline week and daily during the three intervention weeks. Parents marked large bowel movements with “B” and small bowel movements, “a stain of feces in the nappy,” with “b.” Parents also reported when, and for how long, the infant was eating. At inclusion parents were asked if the appetite of the infant was “bad,” “good” or “gluttonous.” From the second to the sixth visit parents completed a questionnaire modified from Reinthal et al [18] in which they were asked “Has the stooling of your infant changed, yes or no?” Parents could even describe the situation in their own words, responding to the questions “If so, how?” and “Have you detected any symptom that you think can be related to the acupuncture treatment? If so what?” In the same questionnaire parents could describe the present sleep of their infant in a five-point scale as much worse, worse, as before, better or much better. At the last visit parents answered the question “Do you think your baby’s colic is much worse, worse, the same, a little bit better or much better than three weeks ago?”
Statistical and qualitative analyses

The power calculation was based on assumptions of how acupuncture would affect the primary outcome of crying. If 50% of the infants would go into spontaneous remission without treatment and 75% with acupuncture, 40 patients per group were needed in order to have 90% chance of detecting a significant difference in remission rate at a two-sided 5% level. The statistical software SPSS™ version 17 (SPSS Inc., Chicago, IL) was used for calculations. As the Kolmogorov-Smirnov test showed non-normal distribution for core variables, the Mann-Whitney U test was used to analyze differences between groups at each time point. Changes within the groups over baseline and the three intervention weeks were analyzed with Friedman test. P-values < 0.05 were considered statistically significant.

Answers concerning changed stooling and possible side effects were summarised and analyzed with content analysis at a manifest level meaning that the visible content in the text was coded [31]. Similar remarks were grouped together into one code, codes with similar content were grouped into categories and the amount of remarks was registered. The coding was done by the first author and subsequently checked by the third author to ensure intercoder reliability [31].

Results and discussion

There were no significant differences between groups, neither regarding the background characteristics of the infants (Table 1), nor in feeding and stooling patterns, during the baseline registration week (Table 2).

Feeding

During baseline and the three intervention weeks infants in both groups were fed approximately eight times/day with a variation between 5.3 and 14.2 times/day (Table 2), placing this group in the upper level of the previously reported norm of 6-8 times/day [4]. At inclusion the appetite of the infant was described as "gluttonous" by 56% of the parents, as "good" by 42% and as "bad" by 2% with no difference between the groups. This correlates well to the thesis that infants with colic may be comforted with food and thus be fed more often than healthy infants [2]. Furthermore infants who are breastfed, and fed with short intervals consume less of the high-fat hindmilk and more of the low-fat milk which has a more rapid stomach transit time which, in turn, may result in short intervals between meals [4] and increase feeding problems [17].

The duration of feeding in the present study was approximately 148 minutes/day, with considerable variations (min 49, max 458). There were no statistical differences between groups in frequency or duration of meals.

Stooling

At baseline when the infants in the present study had a mean age of five weeks they had bowel movements 4.1 times/day (acupuncture group) and 4.3 times/day (control group). These frequencies are higher than the 2.2 - 3 times/day reported in the majority of previous prospective studies in healthy infants at the age of one month [6-10] and contra dictionary to the findings of Tunc et al. who reported less frequent stooling in colicky infants compared to non-colicky infants [11]. However, as different feeding habits and living conditions may affect stooling, a comparison between trials performed in different countries should be validated in local studies. Many different influences are possible. For example, the frequency of breastfeeding and the consumption of antibiotics which may increase stooling frequency [4] could well vary in the countries in which data have been collected (Sweden, Australia, Germany, Thailand, Turkey, UK and the USA).

Frequency of stooling varied widely between infants in the present study, from the mean of 0,1 to the mean of 12,4 times/day (Table 2) as it has been observed in other studies [5-11]. There were no significant differences between groups in the mean frequency of stooling (Table 2) and there was a decline in both groups during the intervention weeks (p = 0,001 in the acupuncture group and p < 0,001 in the control group). This decrease was expected as previous prospective studies report a decrease in stooling frequency between the first month (2.2 - 6 stoolings/day) and the second month (1 - 2.2 stoolings/day) [7,9-11]. In the present study, the frequency in the third intervention week, mean age eight weeks, was 2.1 times/day in the acupuncture group and 3.1 in the control group. Thus the frequency in the control group remained higher than average whereas infants in the acupuncture group reached a frequency reported in earlier studies of healthy infants. Possibly this could be the result of a normalized gastrointestinal function in the acupuncture group.

The mean value of large bowel movements decreased linearly in the control group (p = 0,011) but not in the acupuncture group (p = 0,787).

Changed stooling patterns and possible side effects

In the acupuncture group parents commented on changes in stooling habits of their infants 56 times as compared to 25 times in the control group. Comments on changes in the stooling frequency and possible side effects consisted of a total of 271 remarks (168 from the acupuncture group, 103 from the control group). The amount of remarks reported from each group, codes and categories are presented in Table 3. Close to twice as many parents in the control group remarked that the infants' stools were “more watery” (22 to 12). In contrast almost three times as many parents in the acupuncture group (16 to 6) remarked that
<table>
<thead>
<tr>
<th>Background characteristics</th>
<th>Infants starting the intervention (N = 86)</th>
<th>Infants completing 3 weeks (N = 81)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acupuncture group (n = 46)</td>
<td>Control group (n = 40)</td>
</tr>
<tr>
<td>Firstborn, n (%)</td>
<td>22 (48)</td>
<td>21 (53)</td>
</tr>
<tr>
<td>Gender, female, n (%)</td>
<td>22 (48)</td>
<td>19 (48)</td>
</tr>
<tr>
<td>Gestational age, weeks. Mean (SD)</td>
<td>39.2 (1.5)</td>
<td>39.5 (1.3)</td>
</tr>
<tr>
<td>Age when colic started, weeks. Mean (SD)</td>
<td>1.9 (1.3)</td>
<td>1.5 (1.3)</td>
</tr>
<tr>
<td>Age at inclusion, weeks. Mean (SD)</td>
<td>5.0 (1.9)</td>
<td>5.3 (1.7)</td>
</tr>
<tr>
<td>Solely breastfed, n (%)</td>
<td>35 (76)</td>
<td>26 (65)</td>
</tr>
<tr>
<td>Having a parent and/or sibling with food intolerance/allergy, n (%)</td>
<td>17 (37)</td>
<td>18 (45)</td>
</tr>
<tr>
<td>Having a parent and/or sibling who had had infantile colic, n (%)</td>
<td>29 (63)</td>
<td>23 (58)</td>
</tr>
<tr>
<td>Have tried simeticone, n (%)</td>
<td>43 (93)</td>
<td>37 (92)</td>
</tr>
<tr>
<td>With no effect, n (%)</td>
<td>28 (61)</td>
<td>25 (63)</td>
</tr>
<tr>
<td>With uncertain effect, n (%)</td>
<td>12 (33)</td>
<td>12 (30)</td>
</tr>
<tr>
<td>Have tried lactobacillus reuteri, Semper Magdroppar®, n (%)</td>
<td>6 (13)</td>
<td>7 (18)</td>
</tr>
<tr>
<td>With no effect, n (%)</td>
<td>5 (9)</td>
<td>7 (18)</td>
</tr>
<tr>
<td>With uncertain effect, n (%)</td>
<td>1 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Have tried a diet free from cow’s protein without effect, n (%)</td>
<td>33 (72)</td>
<td>32 (80)</td>
</tr>
<tr>
<td>Changed to this diet during the intervention weeks, n (%)</td>
<td>1 (2)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Not ensured if this diet is tried, n (%)</td>
<td>12 (26)</td>
<td>7 (18)</td>
</tr>
<tr>
<td>Received antibiotics, either through mother’s medication or by own intake, n (%)</td>
<td>14 (30)</td>
<td>10 (25)</td>
</tr>
</tbody>
</table>
Table 2 Stooling and feeding during the baseline week and the three intervention weeks (Mann-Whitney U test was used.)

<table>
<thead>
<tr>
<th>Categories of feeding or stooling</th>
<th>Baseline</th>
<th>First intervention week</th>
<th>Second intervention week</th>
<th>Third intervention week</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeding, times/day Median (quartiles, 25 and 75%)</td>
<td>8.0 (7.2-10.0)</td>
<td>8.1 (7.0-9.7)</td>
<td>8.1 (7.0-9.7)</td>
<td>8.4 (6.9-9.6)</td>
<td>0.602</td>
</tr>
<tr>
<td>Feeding, minutes/day Median (quartiles, 25 and 75%)</td>
<td>155 (113-198)</td>
<td>154 (107-196)</td>
<td>153 (112-180)</td>
<td>140 (108-108)</td>
<td>0.723</td>
</tr>
<tr>
<td>Stoolings, total times/day Median (quartiles, 25 and 75%)</td>
<td>4.1 (2.2-6.0)</td>
<td>4.1 (2.0-5.6)</td>
<td>3.6 (1.3-4.9)</td>
<td>2.1 (1.1-4.7)</td>
<td>0.463</td>
</tr>
<tr>
<td>Stoolings, large/day Median (quartiles, 25 and 75%)</td>
<td>2.5 (1.3-3.7)</td>
<td>2.6 (1.3-3.0)</td>
<td>2.2 (1.3-3.0)</td>
<td>1.8 (1.3-3.4)</td>
<td>0.583</td>
</tr>
<tr>
<td>Stoolings, small/day Median (quartiles, 25 and 75%)</td>
<td>1.2 (0.3-3.0)</td>
<td>1.0 (0.4-2.0)</td>
<td>0.7 (0.1-1.3)</td>
<td>0.3 (0.0-1.6)</td>
<td>0.827</td>
</tr>
</tbody>
</table>
the infant’s stools were “more firm.” The word “normalized” or a similar word was mentioned 22 times in the acupuncture group and 8 times in the control group. Parents in the acupuncture group gave 16 comments coded into “Can defecate/break wind easier/without help” compared to none in the control group. Comments on stooling, and the fact that the mean value of large bowel movements decreased linearly in the control group but not in the acupuncture group, could indicate that the minimal acupuncture used in this trial actually affected the bowel movements, supporting reports from other trials on autonomic effects of acupuncture on the gastrointestinal system [24,25].

Sleeping and progression of colic

Sleep was rated as “better” or “much better” (see Table 4) more frequently in the acupuncture group than in the control group. During the second week parents in the acupuncture group reported “better” or “much better” 26 times (constituting 30% of the answers) compared to six times in the control group (8% of the answers). During the study period significantly more parents in the acupuncture group experienced an improvement in colic during the study time at the last visit (Table 4).

No definite statistical conclusions can be made on independent variables like the comments of the parents above. However, the parents perception of normalized stooling, better sleep and improvement of the colic are in line with the results reported earlier: the infants in the acupuncture group cried and fussed less and the mean value for crying was below the limit for colic after the first intervention week [19]. The infants in the acupuncture group reached normal levels for their age of the stooling frequency in the third intervention week (Table 2), i.e. < 2.2 stoolings/day, [7,9-11]. The largest reduction of both crying and stooling frequency was measured after the first acupuncture treatment. However, the differences in feeding and stooling patterns between the groups are not significant in the majority of the variables and the present study cannot support a simple correlation between reduction of crying and an improved regulation of these. The effect of acupuncture may as well be of a different origin such as spasmyloytic or sedative.

Strengths and limitations

One strength of the present study is that quantitative and qualitative methods were combined to detect even
subtle changes that are not so easily captured, such as characteristics of bowel movements other than the two variables of frequency and size[32]. Furthermore, frequency and size of bowel movements were reported meticulously in the diaries kept by all parents during the three week study period. Another strength is that parents of all of the infants had been recommended to try a five-day period of not exposing the infant to cow’s milk protein during baseline. Infants improving from this were not included in the study reducing thereby the number of infants with an allergy to cow’s milk protein to a minimum.

Limitations are the lack of precise measurement of the stools in milligrams, and the fact that the infant’s sleep was described by multiple choise alternatives but not measured in minutes in the diary. Furthermore, parents were not asked to evaluate the infant’s sleep during the baseline period. Special feeding habits and living conditions, possibly affecting stooling, were not registered. The parents’ experiences are important but subjective and should be interpreted with care.

In this study only one, unilateral, acupuncture point, minimally stimulated, was investigated. As different points and stimulation techniques have been demonstrated to have different effects on gastrointestinal symptoms [33-36] the results of the present study cannot be generalised to a situation in which other points or to stronger stimulation are used.

Power calculation was done on the variable crying, reported in an earlier article [19] and not on variables as stooling or feeding which might have resulted in another number of participating infants. Another limitation is that no correlation analyses was done to see if the individual crying and stooling patterns were correlated in each child, and if the experience of normalized stooling or general improvement according to the parent was correlated to reduced crying in the infant.

Conclusion

This article reports, for the first time, the feeding and stooling patterns of Swedish infants with colic. Feeding and stooling habits are important topics for many new parents. A description of these patterns can be a valuable tool in everyday clinical practice. Infants with colic in the present study had a higher frequency of stooling than reported internationally in healthy infants.

Minimal acupuncture in the point LI4 twice a week for 3 weeks only showed a minor difference in the frequency of stooling between the groups. The parents in the acupuncture group more frequently commented on a changed and normalized stooling in their infants, and more frequently reported improvement of sleep and colic. As the correlation between relief of colic symptoms and frequency in feeding and stooling is weak there may be other explanations for the effect on crying induced by acupuncture. Further studies are requested to clarify the mechanism of acupuncture in colic.

Acknowledgements and Funding

Thanks to Margareta Normark for providing acupuncture and Per Nyberg for statistical support. Thanks to Biologasstiftelsen, Magni Bergvall Stiftelse, and the General Maternity Hospital Foundation for funding. The funding sources had no involvement in the design, analysis or writing process.

Author details

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Authors’ contributions

KL and IH contributed to planning the study. KL collected data. All three authors contributed to analysing data and writing the article. IH contributed to supervision. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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References


Table 4 Changes in sleep and development of colic during the three intervention weeks

<table>
<thead>
<tr>
<th>Sleep #</th>
<th>Colic#</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acupuncture group (43)</td>
</tr>
<tr>
<td>Much better, n (%)</td>
<td>16 (8)</td>
</tr>
<tr>
<td>Better, n (%)</td>
<td>43 (20)</td>
</tr>
<tr>
<td>As before, n (%)</td>
<td>102 (49)</td>
</tr>
<tr>
<td>Worse, n (%)</td>
<td>41 (20)</td>
</tr>
<tr>
<td>Much worse, n (%)</td>
<td>8 (4)</td>
</tr>
<tr>
<td>Total, n (%)</td>
<td>210 (100)</td>
</tr>
</tbody>
</table>

# comments collected twice weekly during week 1 and 2 and once week 3

## comments collected at the last visit, week 3


Pre-publication history
The pre-publication history for this paper can be accessed here: http://www.biomedcentral.com/submit/1472-6882/11/93/prepub.

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## Appendix A

**Diary** for study number: _____, _____ day the ___ of 20__

<table>
<thead>
<tr>
<th>Time</th>
<th>06.00</th>
<th>06.15</th>
<th>06.30</th>
<th>06.45</th>
<th>07.00</th>
<th>07.15</th>
<th>07.30</th>
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<td>09.30</td>
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Appendix B
Diary, instruction.

Please fill in the diary like this:

Mark in the top row of boxes when the infant is crying and/or fussing. Each box represents five minutes. Don’t write anything when the infant seems fine!

Write F if the infant is fussing. Fussing is defined as “showing dissatisfaction and whimpering despite consolatory efforts, such as holding or carrying”.

Write C if the infant is crying. Crying is defined as “screaming loudly”.

Write B if the crying is so intense that you cannot comfort the baby and consider it to be a bout of colic. A bout of colic is defined by “hysterical crying and an inability to be consoled”.

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Mark the boxes in the middle row when the infant has been eating. Write "X" when the infant has been fed. If the meal takes 15 minutes, mark three boxes. If the meal takes 20 minutes, mark four boxes, etc.

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Mark the boxes in the lowest row for bowel movements. Write "S" if the infant passes a normal or large bowel movement.

Write "s" for a small bowel movement ("a trace in the diaper”).

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Avhandlingar i ämnet vårdvetenskap med inriktning omvårdnad: kvinnor och barns hälsa från Institutionen för hälsa, vård och samhälle, Medicinska fakulteten, Lunds universitet.

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Björk, Maria. Living with childhood cancer. Family Members’ Experiences and Needs. Department of Health Sciences, Faculty of Medicine, Lund University, Sweden 2008.

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Landgren, Kajsa. Infants with colic - Parents’ experiences in short and long perspectives and the effect of acupuncture treatment on crying, feeding, stooling and sleep. Department of Health Sciences, Faculty of Medicine, Lund University, Sweden 2011.

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Lunds universitet
Institutionen för hälsa, vård och samhälle
Box 157, 221 00 Lund