Effects of minimal acupuncture in children with infantile colic

– a prospective, quasi-randomised single blind controlled trial

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Abstract

Background Colic causes crying in 10–30% of infants and is one of the primary reasons parents seek health care. Treatments are generally not totally effective and some cause side effects. In this study we aimed to test the effect of light needling (minimal acupuncture) on crying.

Methods Forty children (median six weeks of age) with excessive crying unresponsive to conventional therapies, were recruited from 21 Child Welfare Clinics within an area of western Sweden, and quasi-randomised to control or light needling treatment. Parents were unaware of which group their child was assigned to. Children were given light needling acupuncture on one point (LI4) on both hands for approximately 20 seconds on four occasions, or received the same care except needling. Parental assessment questionnaires were used pre- and post-treatment to assess crying intensity, frequency, duration of crying and pain related behaviour throughout the day in six hour periods.

Results Light needling resulted in a significant reduction in the rated crying intensity (assessed by a numeric rating scale, 0 to 10). For example, during the morning time period 0600–1200 hours, the median (range) rated crying intensity changed from 6 (1 to 9) pre-treatment to 2 (0 to 5) post-treatment (P=0.002), in the light needling group. The corresponding ratings for the children in the control group was 6 (0 to 10) and 5 (0 to 10) respectively. The difference between the groups was significant (P=0.016). There were also significant differences between the groups for the afternoon (1200–1800 hours), and evening (1800–midnight) time periods. Pain related behaviour like facial expression, was also significantly less pronounced in the light needling group as compared to the control group post-treatment, (P=0.027). The parents rated the light needling as more effective in improving symptoms than the control group (P<0.001).

Conclusion Four treatments with light needling on one point in the hand may alleviate crying and pain related behaviour without any noted side effects.

Keywords

Abdominal pain in childhood, acupuncture, infantile colic, minimal acupuncture.

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Introduction

Infantile colic is a common but poorly defined and understood clinical entity described by parents as excessive crying probably caused by pain. Despite several suggested causative factors, a unifying theory of its pathogenesis is still required.[1-3] Food hypersensitivity or allergy and gut dysmotility are the leading contenders for causative agents. Additional background confounders and co-variables include psychological and social factors. Although the available data fail to describe the exact triggers of infantile colic, they do allow for the hypothesis that, in the first weeks of life, certain infants are predisposed to dietary intolerance and disturbed gut motility, such as visceral hypersensitivity/hyperalgesia. The predominant opinion is that colicky behaviour is associated with pain generated from the intestines filled with gas or from sensitised visceral afferents.[4;5] This can lead to distress and altered perceptions, where normal

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stimuli (ie intestinal distension) are misinterpreted as painful events.

In a small subset of children with colicky behaviour, a specific medical disorder such as gastroesophageal reflux or milk protein allergy may be identified. While the vast majority of children with colic will recover uneventfully, some may be at risk for the later development of behavioural problems, atopy/allergy and irritable bowel syndrome.

A common pharmacological treatment offered for the condition is simeticone (Minifom®)[6] with the purpose of reducing surface tension of gas in the intestine and thereby also reducing the pain. However, its effect has been reported as no different from placebo.[7] A number of other treatments, both pharmacological and non-pharmacological, have been tried with minor or no effect and occasionally described as inducing side effects.[8]

Acupuncture has attracted interest as a complementary method for the alleviation of pain and distress, and acupuncture with minimal stimulation has also been demonstrated to be effective.[9] Furthermore, it has been reported that acupuncture at the acupuncture point LI4 (*Hegu*), situated in the dorsal interosseus muscle, may activate the sympathetic and simultaneously inhibit the gastric parasympathetic nerve activity resulting in the inhibition of gut hyperactivity.[10] This result is in line with studies showing that induced colitis is associated with beta-adrenoreceptor activation.[11] Thus hypothetically light needling at LI 4 may influence gut motility and alleviate infantile colic.

The purpose of the present prospective randomised single blind controlled trial was to evaluate the effects of light needling on crying and the pain related behaviour in children with infantile colic. Furthermore, the parents' overall impression of the treatment was assessed.

Methods

Patients

Newborn breastfed children with infantile colic[12] as diagnosed by doctors and registered at 21 Child Welfare Clinics within an area of western Sweden were recruited. Doctors or nurses at the Child Welfare Clinics informed the parents of children suffering from infantile colic about the study in which a maximum of ten treatments would be offered. If interested, they received written information and were then referred to the clinic where treatments were given by the first author. Parents were told that they joined the investigation voluntarily and that they could withdraw at any stage. After the parents gave informed consent to participate they were included in the study. At the start of the investigation all the children were treated with ten drops of Minifom® solution (simeticone) before each meal. The study was approved of by the human ethics committee at Göteborg University, L024/98.

Design

The present study was carried out as a prospective, quasi-randomised single blind controlled study. The randomisation procedure was carried out by referring the included children alternately to the acupuncture group or the control group. No information was given to the parents about which group their child had been assigned to.

Outcome

For the primary outcome, a pain-diary evaluating different aspects of crying was used for seven days pre-treatment and seven days post-treatment. The parents then assessed the crying daily in four time periods per 24 hours (midnight–0600, 0600–1200, 1200–1800 and 1800–midnight). The assessments included the parents' rating of how they perceived the intensity of their children's crying using a numeric rating scale ranging from 0 to 10, where 0 is equal to no crying at all and 10 means worst possible crying. The frequency of crying episodes and their duration, assessed in minutes, was also recorded by the parents during the same time periods.

As a secondary outcome, the parents also recorded the pain behaviour of their child once daily, seven days pre-treatment and seven days post-treatment according to the three different variables of the Modified Behavioural Pain Scale (MBPS),[13] using verbal rating scales. The assessed variables included facial expression, crying and movements. The facial expression was expressed in four categories with the words – definitely positive, neutral, slightly negative and definitely negative. The crying was assessed with the words laughing, not crying, moaning, full lunged sobbing and full lunged cry. The observed movements were assessed by the words – usual movements, partial movements to avoid pain, and agitation with complex movements.

After the end of treatment the parents were also asked to rate their overall impression of the treatment's efficacy on their child by using a verbal rating scale with the categories – much ameliorated, somewhat ameliorated, unchanged, somewhat worse and much worse.

Intervention – light needling and control

Four sessions of light needling were given twice a week without the parents present in the room. The children were breast fed just prior to the treatment. During light needling (minimal acupuncture) the skin was penetrated by a thin (0.20mm) sterile disposable needle at the acupuncture point LI4, located between the thumb and forefinger, deep enough to reach the dorsal interosseus muscle, on both left and right hands. The needle was briefly rotated for a few seconds (less than 5), left in place for another period of seconds and then removed. The needling was carried out by MR, who is a midwife trained in Western acupuncture and practising it for more than 15 years.

The children in the control group received the same procedure by the parents and caring by MR except for light needling.

In all children of both groups, a plaster was placed over the acupuncture point in both hands after each treatment.

Statistical methods

The collected categorical data from subjective variables was regarded as ordinal and therefore shown as median and range (minimum to maximum) from the assessments pre-treatment and the post-treatment periods containing seven days each. Data of age and age of onset of colic were also shown as median when not normally distributed.

The assessment of post-treatment ratings of the pain diary variables were shown in plot figures. The pattern of systematic change were shown in a kind of relative operating characteristic curve (ROC) based on the cumulated frequency distribution of the pre relative the post-treatment proportions of the assessment in the respective group. A deviation from the main diagonal indicates a systematic change while the opposite holds for a curve close to the main diagonal.

The response frequency of the rated pain related behaviour variables were shown in contingency tables where the cells in the grey shaded main diagonal demonstrate no change, comparing pre- versus post-treatment assessments. The contingency tables also show the marginal distributions of response frequency related to each category.

The hypotheses of no change within the respective group in assessed variables between pre-treatment and post-treatment were analysed by the nonparametric sign test with correction for continuity. The proportions of subjects with increased, unchanged, and decreased rated values on the second occasion were calculated, together with 95% confidence intervals (95% CI), for the difference in proportions between the two independent groups.

The change in the rated variable was further evaluated with a rank based, non-parametric method by Svensson that takes the non-metric properties of the ordinal data into account without predefined assumption of distribution of the data. This method has the potential to identify and measure a systematic change, ie the change related to the group, separately from the individual variations in paired assessments.[14-15] A systematic change between two assessments appears as different, marginal distributions of assessed ratings on the two occasions and defines the measure of relative position (RP) with possible values ranging from -1 to 1. RP=0 means lack of change between the two assessments.

The differences between the groups were analysed by the Mann-Whitney U test.

A P value <0.05 was regarded as significant and the individual P values were adjusted for multiple tests according to Holm.[16] The software package Statistica 8.0 (StatsSoft® Scandinavia AB, Uppsala, Sweden) was used for calculations of descriptive data and for analysis with the sign test and the Mann Whitney U test. The software package Confidence Interval Analysis for Windows (CIA) was used for calculation of the confidence interval of the proportional change in the two groups, and the software package Sysran 1.0 for Matlab 6.0 was used for evaluation of the rank-invariant methods by Svensson.

Results

In total 40 children with a median age of six weeks and excessive crying were included (Figure 1, Table 1) and given four treatments.

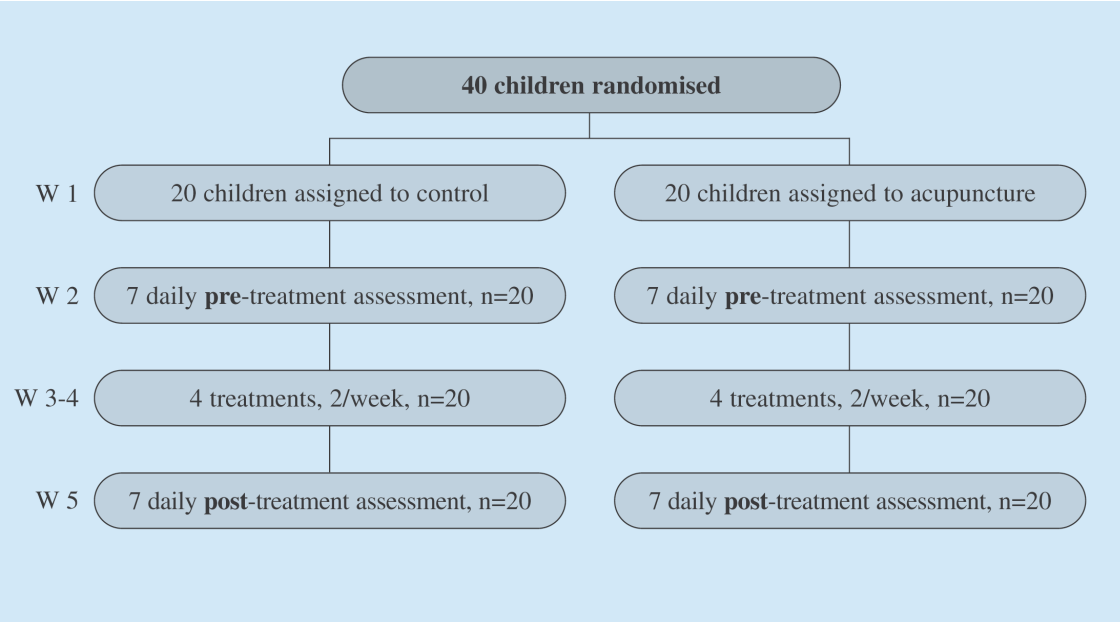

Figure 1 Design of the study (W = week number during the study).

Table 1 **Baseline descriptive data of the children, and the pre-treatment crying and pain related behaviour rated by parents**

	Treatment group	
	Control, n=20	**Light needling, n=20**
Gender	Girls, n=9; Boys, n=11	Girls, n=7; Boys, n=13
Age, weeks	6 (3 to 25)	6 (1 to 11)
Age of colic debut, weeks	1 (0 to 8)	1 (0 to 4)
Pre-treatment pain, rated 4 times/day		
Crying intensity, 0–10		
midnight–0600	3 (0 to 9)	2 (0 to 9)
0600–1200	6 (0 to 10)	6 (1 to 9)
1200–1800	7 (0 to 10)	5 (0 to 10)
1800–midnight	9 (3 to 10)	9 (3 to 10)
Crying frequency		
midnight–0600	1 (0 to 24)	2 (0 to 30)
0600–1200	2 (0 to 18)	3 (1 to 7)
1200–1800	2 (0 to 25)	3 (1 to 15)
1800–midnight	3 (1 to 36)	4 (1 to 4)
Crying duration, minutes		
midnight–0600	8 (0 to 120)	5 (0 to 70)
0600–1200	24 (0 to 120)	20 (3 to 120)
1200–1800	30 (0 to 210)	30 (0 to 140)
1800–midnight	63 (20 to 180)	53 (5 to 130)
General impression of pain behaviour (MBPS)		
Facial expression	Definite negative (slightly negative to definite negative)	Definite negative (slightly negative to definite negative)
Cry	Full lunged cry (moaning to full lunged cry)	Full lunged sobbing (moaning to full lunged cry)
Movements	Agitation (partial movements to avoid pain-agitation)	Agitation (partial movements to avoid pain-agitation)

Data shown as median (minimum to maximum) of rated assessments seven days pre-treatment for four time periods
MBPS – Modified Behavior Pain Scale: Facial expression – definite positive to definite negative; Cry – laughing to full lunged cry; Movements – usual movements to agitation with complex movements

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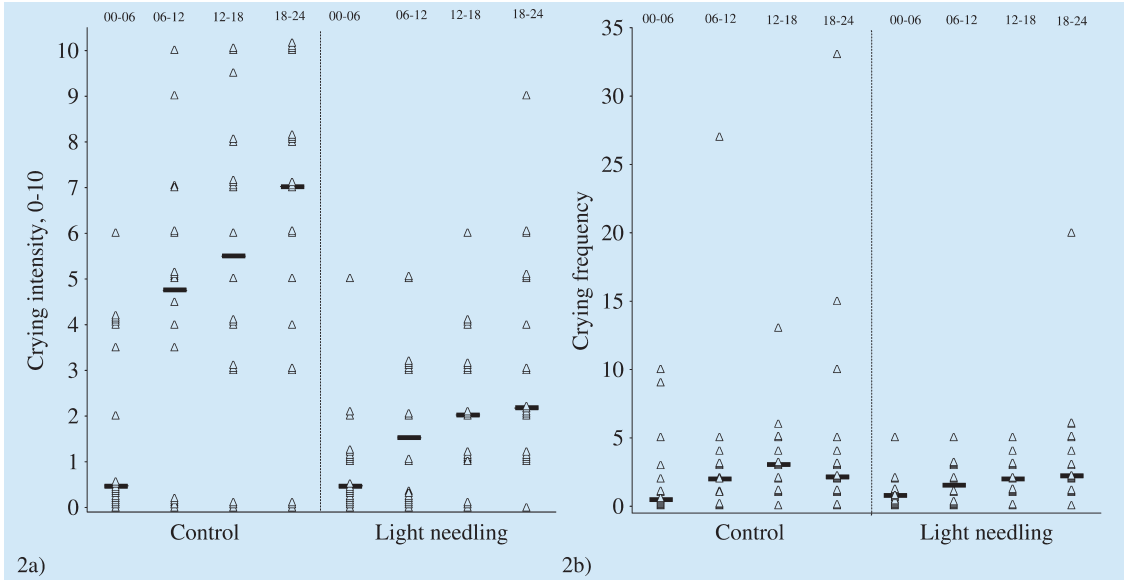
Table 2 **Post-treatment levels of rated crying intensity, frequency and duration, and within group changes shown as frequency (%) assessed for four time periods**

Assessed variable	Control, n=20		Light needling, n=20	
and time point	Median (min to max)	Within group change	Median (min to max)	Within group change
Crying intensity				
Midnight–0600	0 (0 to 6)	↓10 (50%), ~9 (45%), ↑1 (5%)	0 (0 to 05)	↓11 (55%), ~8 (40%), ↑1 (5%)
0600–1200	5 (0 to 10)	↓11 (55%), ~5 (25%), ↑4 (20%)	2 (0 to 5)	↓17 (85%), ~2 (10%, ↑1 (5%)
1200–1800	6 (0 to 10)	↓9 (45%), ~7 (35%), ↑4 (20%)	2 (0 to 6)	↓17 (85%), ~2 (10%), ↑1 (5%)
1800–midnight	7 (0 to 10)	↓12 (60%), ~8 (40%)	2 (0 to 10)	?18 (90%), ~2 (10%)
Crying frequency				
Midnight–0600	0 (0 to 10)	↓7 (35%), ~8 (40%), ↑5 (25%)	0 (0 to 5)	↓13 (65%), ↑7 (35%)
0600–1200	2 (0 to 27)	↓7 (35%), ~8 (40%), ↑5 (25%)	2 (0 to 5)	↓7 (35%), ~12 (60%), ↑1 (5%)
1200–1800	3 (0 to 13)	↓9 (45%), ~5 (25%), ↑6 (30%)	2 (0 to 5)	↓16 (80%), ~2 (10%), ↑2 (10%)
1800–midnight	2 (0 to 33)	↓11 (55%), ~6 (30%), ↑3 (15%)	2 (0 to 20)	↓13 (65%), ~4 (20%), ↑3 (15%)
Crying duration				
Midnight–0600	0 (0 to 120)	↓9 (45%), ~7 (35%), ↑4 (20%)	0 (0 to 10)	↓10 (50%), ~ 10 (50%)
0600–1200	10 (0 to 60)	↓13 (65%), ~4 (20%), ↑3 (15%)	0 (0 to 60)	↓16 (80%), ~2 (10%), ↑2 (10%)
1200–1800	25 (0 to 120)	↓12 (60%), ~2 (10%), ↑6 (30%)	10 (0 to 60)	↓18 (90%), ↑2 (10%)
1800–midnight	31 (0 to 120)	↓18 (90%), ~2 (10%)	20 (0 to 120)	↓18 (90%), ~1 (5%), ↑1 (5%)

Within group frequency change shown as ↓ (decreased), ~ (unchanged) and ↑ (increased)



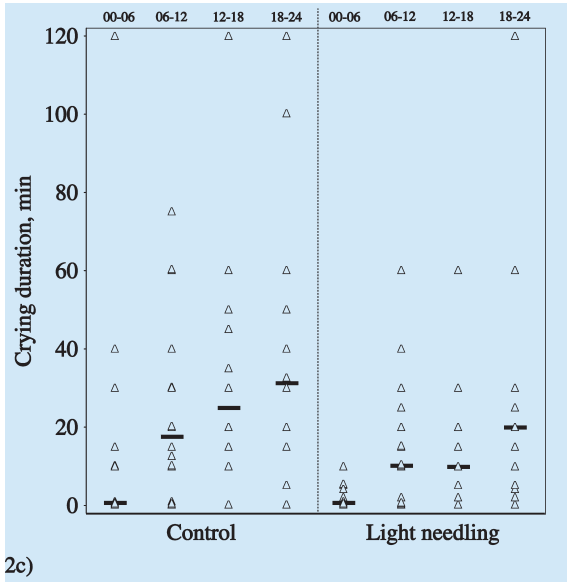


Figure 2a–c Individual post-treatment data are shown, rated for four times periods (midnight–0600, 0600–1200, 1200–1800 and 1800–midnight) of a) crying intensity b) crying frequency and c) crying duration. The bar ▬ indicates the median value of seven post-treatment assessments on each time point; control n=20, light needling n=20.

Crying intensity

During the night, *midnight–0600*, the rated crying intensity was significantly decreased in the light needling group (P=0.038; Table 2, Figure 2a), but there were equal systematic changes in the two groups (Table 3, Figure 3a).

In the morning, *0600–1200 hours*, a significant decrease was seen in the light needling group (P=0.002; Table 2, Figure 2a). The post-treatment level was lower in both groups at this time point but significantly lower in the light needling group compared with the control group (P=0.016), as was the proportional decrease of rated intensity, -30% (95%CI -57% to -3%), shown in Figure 3b. This systematic change was also confirmed by the RP values, shown in Table 3.

During the afternoon, *1200–1800 hours*, the intensity was rated decreased in the light needling group (P=0.002; Table 2, Figure 2a). Also at this time point the post-treatment level was significantly lower in the light needling group as compared with the control group(P=0.004). The proportional decrease of crying intensity was more pronounced in the light needling group than in the control group, -40% (95%CI -67% to -13%), see Figure 3c, and confirmed by the measurement of systematic change, Table 3.

In the evening, *1800–midnight*, the crying intensity was significantly decreased in the control group (P=0.001), as well as in the light needling group (P=0.001; Table 2, Figure 2a). The post-treatment level was significantly lower in the light needling group as compared with the control group (P=0.006). The proportional change was also more pronounced among the light needle stimulated children than among the children in the control group, -30% (95%CI -55% to -5%), shown in Figure 3d, as were the measurements of systematic change, in Table 3.

Crying frequency

At *midnight–0600*, the post-treatment crying frequency was rated decreased in both groups but significantly decreased only in the light needling group (P=0.036; Table 2, Figure 2b). The systematic changes were not separated between the two groups, Table 3.

During the day time recordings *0600–1200 hours*, there was a systematic shift to lower levels of crying frequency in the light needling group (Table 2 and 3, Figure 2b) but without being significantly different to the control group.

In the afternoon assessments, *1200–1800 hours*, the crying frequency was rated significantly decreased in the light needling group (P=0.009; Table 2, Figure 2b), but without being significantly different to the control group, Table 3.

In the evening assessments, *1800– midnight*, the post-treatment crying frequency was rated lower as compared to pre-treatment in the light needling group (P=0.024), though there was a systematic change to lower levels in both groups, Table 3.

Crying duration

Compared to pre-treatment assessments, the assessments of crying duration at *midnight to 0600 hours* post-treatment showed decreased levels in both groups, Tables 2 and 3.

Assessments at *0600–1200 hours*, also showed decreased levels in both groups and with a significant change in the light needling group (P=0.040; Table 2, Figure 2c), though without being significantly different to the control group, Table 3.

The post-treatment afternoon assessments of ratings, *1200–1800 hours*, demonstrated a decrease in both groups and to a significantly decreased level in the light needling group (P<0.001; Table 2, Figure 2c). The post-treatment level was significantly lower in the light needling group than in the control group (P=0.010), though the systematic change from baseline was not different between the two groups, Table 3.

The post-treatment evening assessment, *1800–midnight*, showed significantly decreased crying duration in the control group (P=0.001), as well as in the light needling group (P=0.005), when compared with pre-treatment values, (Table 2, Figure 2c), but with no significant difference between the groups, Table 3.

General observations according to the Modified Behavioural Pain Scale

Facial expression

The post-treatment median level of facial expression in the control group was rated negative (range, definite positive to definite negative) and significantly changed (P=0.041) as compared to pre-treatment

Table 3 **Systematic changes (95% CI) in the crying diary variables over the study period (expressed as relative position, RP) at the different time periods**

Assessed variable/	Time periods for assessments			
Treatment group	**midnight–0600**	**0600–1200**	**1200–1800**	**1800–midnight**
Crying intensity				
Control	-0.37 (-0.59 to -0.15)	-0.22 (-0.42 to -0.01)	-0.17 (-0.46 to 0.11)	-0.49 (-0.73 to -0.25)
Light needling	-0.40 (-0.64 to -0.15)	-0.75 (-0.94 to -0.57)	-0.74 (-0.95 to -0.53)	-0.88 (-1.00 to -0.74)
Crying frequency				
Control	-0.27 (-0.51 to -0.04)	-0.04 (-0.21 to 0.14)	-0.10 (-0.41 to 0.22)	-0.25 (-0.47 to -0.02)
Light needling	-0.48 (-0.73 to -0.24)	-0.36 (-0.61 to -0.11)	-0.43 (-0.63 to -0.22)	-0.24 (-0.39 to -0.09)
Crying duration				
Control	-0.29 (-0.53 to -0.05)	-0.15 (-0.40 to 0.11)	-0.19 (-0.47 to 0.09)	-0.50 (-0.72 to -0.27)
Light needling	-0.39 (-0.64 to -0.15)	-0.41 (-0.63 to -0.18)	-0.49 (-0.68 to -0.30)	-0.60 (-0.83 to -0.37)

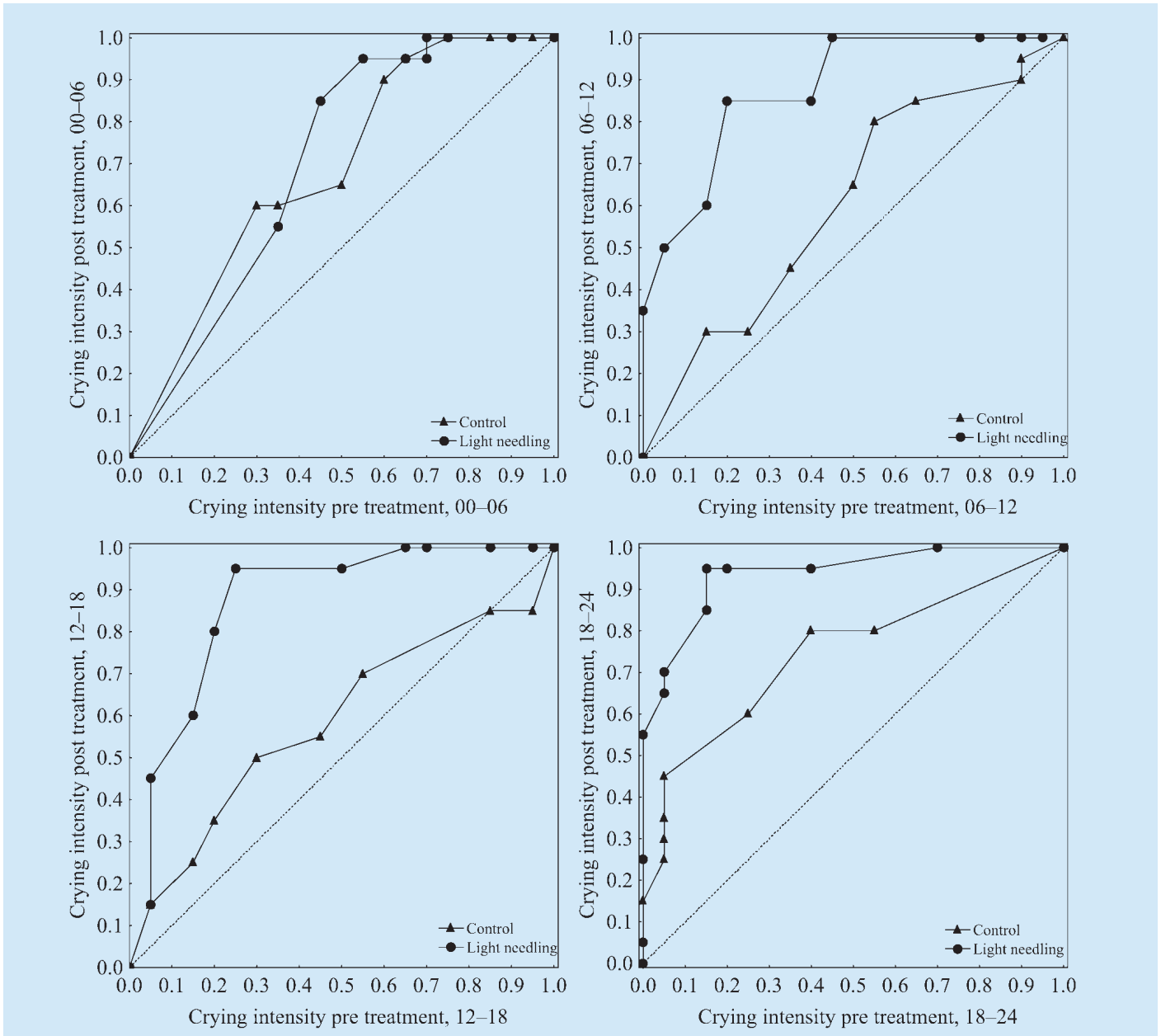


Figure 3a–d Cumulative proportions of crying intensity frequency pre- and post-treatment are shown, rated for four different time periods – a) midnight–0600, b) 0600–1200 hours, c) 1200–1800 hours, and d) 1800–midnight, in the two groups.

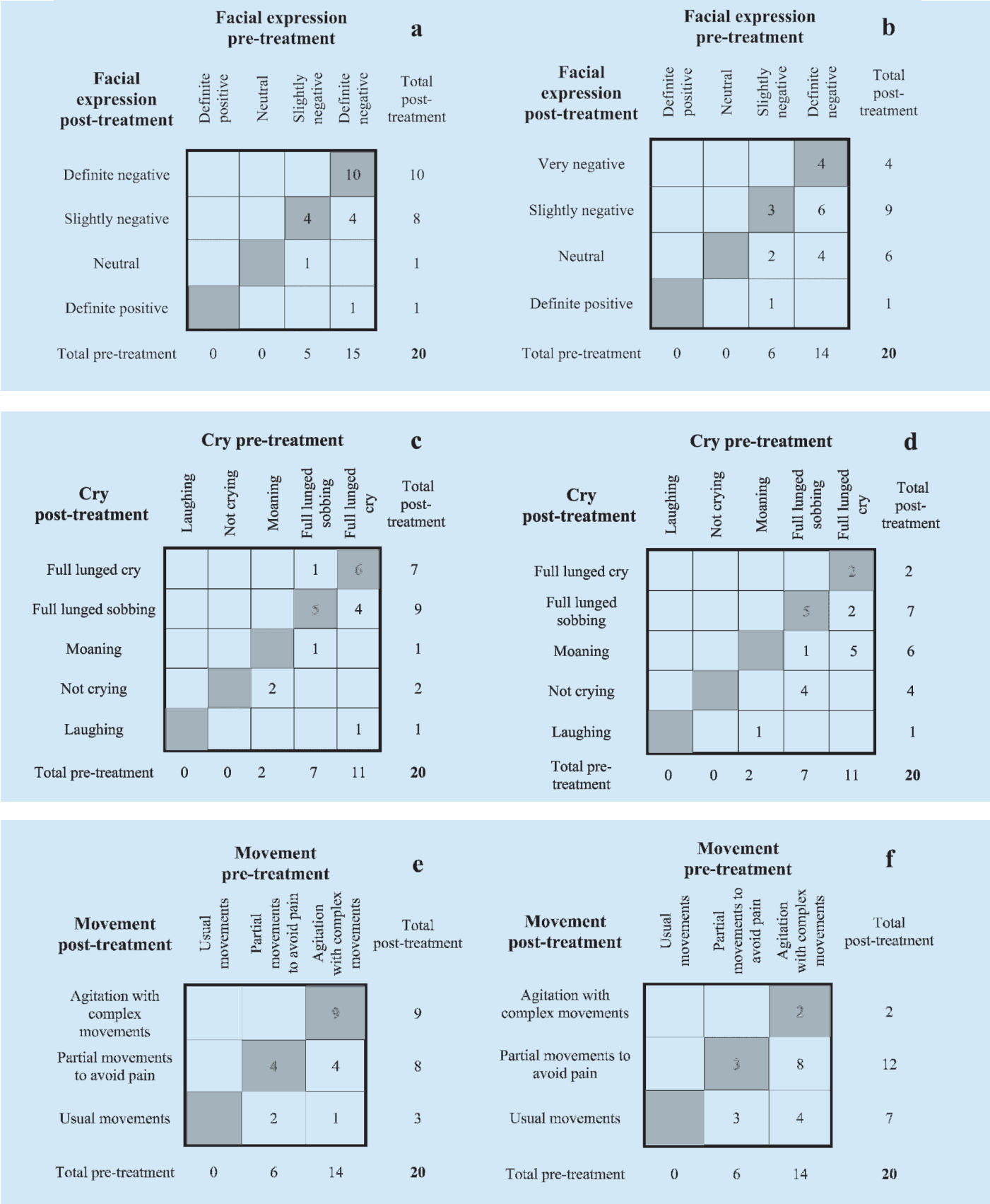


Figure 4 a–f The patterns of change in rated assessments according to variables of MBPS pre- and post-treatment are shown. Facial expression in the control (a) and light needling (b) group; cry in the control (c) and the light needling (d) group; movement in the control (e) and, the light needling (f) group respectively. Total = the marginal frequencies given for each category pre- and post-treatment.

Table 4 **Systematic change (relative position, RP) and its 95% confidence interval (95% CI) of the rated pain related behaviour**

Treatment	Facial expression	Cry	Movements
Control	-0.28 (-0.47 to -0.08)	-0.24 (-0.46 to -0.02)	-0.27 (-0.50 to -0.04)
Light needling	-0.61 (-0.81 to -0.40)	-0.62 (-0.82 to -0.40)	-0.71 (-0.89 to -0.52)

ratings. According to Figure 4a, the facial expressions were less pronounced after the treatment in 6 (30%) of the 20 children and unaffected in 14 (70%) of them. In the light needling group there was a similar post-treatment change towards lower grade of facial expression; negative (range, definite positive to definite negative; P=0.001). The facial expression was rated lowered in 13 (65%) of the light needling treated children and 7 (35%) of them were rated as unchanged (Figure 4b). The post-treatment level was rated lower in the light needling group as compared to the control group (P=0.027), while the systematic changes were not separated in the two groups as measured by the RP values (Table 4).

Crying

After treatment, the median level of the crying variable according to MBPS was observed significantly decreased, in the control group, full lunged sobbing (range, laughing to full lunged cry), as compared to rated level pre-treatment, P=0.046. According to Figure 4c, 7 (35%) of the 20 children cried less post-treatment, 1 (5%) child cried more, while 11 (55%) of them were rated unchanged. In the light needling group the change towards lower level of crying was similar post-treatment, moaning (range, laughing to full lunged cry; P=0.001). Thirteen (65%) of children were rated as crying less and 7 (35%) of them as unchanged. The ratings post-treatment showed significantly lower level in the light needled group as compared to the control group (P=0.028), though the systematic change was not different in the two groups (Table 4).

Movement

The median level of observed movements post-treatment was rated significantly decreased in the control group: partial movements to avoid pain (range, usual movements to agitation with complex movements; P=0.046). Figure 4e show that 13 (65%) of the 20 children were rated as showing decreased levels of movements post-treatment and seven (35%) were unaffected. The children in the light needling group were rated in a similar way towards lower level of painful movements: partial movements to avoid pain (range, usual movements to agitation with complex movements; P<0.001). Fifteen (75%) of the light needling treated children were rated as showing fewer indicators of painful movements, while 5 (10%) of them were rated as unchanged, Figure 4f. The post-treatment level of movements was lower in the light needling group compared to the control group (P=0.028). The proportional decrease was also more strongly expressed in the light needling group -40% (95%CI -68% to -12%), as was the systematic change though this was not statistically significant (Table 4).

Treatment efficacy according to the parents

After treatment, the parents were asked to rate their overall impression of its effects. In the children treated with acupuncture, the parents reported that their child's condition was 'much alleviated', while the parents with children assigned to the control group rated their child's condition as 'unchanged' (Figure 5a-b). The rated impression of the treatment effects was significantly positive among the parents to the children in the needle stimulated group as compared to the ratings of the parents in the control group (P<0.001).

Discussion

Infantile colic with prolonged crying is observed in 10-30% of infants and is one of the primary reasons parents seek health care for their babies. A number of treatments, both pharmacological and non-pharmacological, have been tried out with little or no effect or with undesirable side effects. In this study we report on the effects of light needling (minimal acupuncture) on crying. Light needling resulted in a significant reduction in crying intensity, crying frequency and duration of crying. The effect was significantly changed between the light needling group and the control group regarding crying intensity

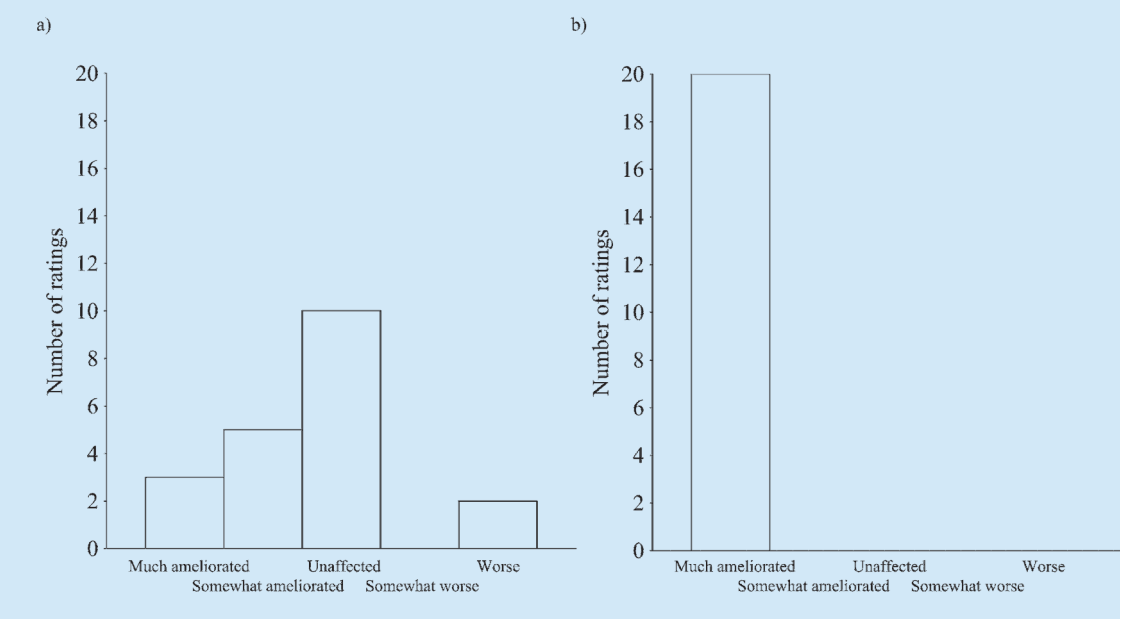


Figure 5a–b The parents' rated perceived treatment efficacy of (a) the control group and, (b) the light needling group.

and duration. Light needling also ameliorated pain related behaviour. We suggest that this simple and safe approach may be tried.

Infantile colic is a common phenomenon that is suffered by approximately 10 000 Swedish infants every year.[17] The current study addresses the possibility of applying light needling (acupuncture) treatment to alter the behaviour pattern of newborn babies classified by the Child Welfare Clinics as suffering from infantile colic and in need of additional treatment. This is an important methodological aspect as it reduces any selection bias which will always be the risk when including a small cohort of 40 cases. The age of the baby at inclusion in the trial (six weeks), the crying pattern and frequency would also indicate that the colicky behaviour was well established.

The behaviour of colicky babies is that of intermittent periods of pain associated with intense crying and movements of arms and legs and with intestines filled with gas.[18] An increase in colon peristalsis was demonstrated by Jorup in 1952 to be associated with intense crying,[18] and the observation that the anticholinergic drug dicyclomine hydrochloride has consistently been found effective in treatment of infantile colic,[19] lends support to the assumption that colicky behaviour may become less marked when peristalsis is reduced.

The purpose of the stimulation by light needling stimulation is to increase sympathetic activity and thereby induce inhibition of the peristaltic intestinal movements. A brief rotation of the needle in the tissue of the chosen point LI4, ie the dorsal interosseus muscle innervated by the median nerve (C8–T1), was given in order to stimulate the afferent nerve fibres.[8-10] The afferent flow of impulses thus generated leads via the dorsal horn to the limbic structures and cortical areas of the brain.[20-22] In the spinal cord there are also connections to cells that mediate spinal reflexes.[20] Some impulses lead to motor neurones in the ventral horn and create somatic motor reflexes while others go to neurons related to the autonomic nervous system. The needle stimulation is therefore able to stimulate both motor and autonomic reflexes. The sympathetic nervous system innervates all visceral organs including the circulatory system via the sympathetic chain originating from the spinal cord segments T1–L3, a sequence of segments activated from LI4. Depending on somatovisceral reflexes and the further connectivity to the autonomic nervous system, there are mechanisms whereby the needling treatment may alter the balance of the function in the autonomic system in a coherent fashion with potential reduction in intestinal peristaltic movements.

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The study design included outcome variables related not only to the crying behaviour of the baby but also to the extent the parent perceived any changes. Improvement in all these variables was already apparent after four sessions. This may be regarded as a short treatment period. However, it is known that colicky behaviour disappears with time and is related to the rapid maturation of the developing brain, and a 2 week period is significant as it constitutes 25% of the postnatal period (2 out of 8 weeks). After four sessions spread over two weeks the investigation was closed for ethical reasons in order not to deprive children in the control group of an effective treatment, since the children in the acupuncture group appeared much better than the children in the control group. We could not justify a continuation of the trial from the ethical aspect, as it would keep the children in the control group from treatment. A possible reason for the effects noted could be that the parents experienced such a clear improvement after a few acupuncture treatments and easily could console, communicate and interplay with their child. Simeticone, with its known placebo effects,[7] was administered to both groups. This approach would serve to reduce any placebo effect from acupuncture as such but we must assume that some children could have improved spontaneously. However, to our knowledge, this is the first randomised controlled trial showing significant improvements in the management of colicky infant disorder using light needling (minimal acupuncture). Although acupuncture may appear to be a safe procedure, it is important to have appropriate qualifications both in relation to child care as well as to acupuncture when undertaking this procedure.

It is likely that infants with colic will require a multifactorial management strategy. Healthcare providers must offer support, reassurance and empathy to the caregiver, and adopt a biopsychosocial approach to the infants and their families by considering any underlying medical diseases in addition to examining the family unit. In a small subset of infants with colicky behaviour, a specific medical disorder such as gastroesophageal reflux or milk protein allergy may be identified. While the vast majority of infants with colic will recover uneventfully, some may be at risk of later development of behavioural problems and atopy/allergy. To reduce the suffering of child and parents, light needling (minimal acupuncture) may be tried. This suggestion is supported by the present result and by the clinical experience of MR now having successfully treated more than 1285 children. Furthermore, the clinical practice of MR was recently scrutinised by representatives of The National Board of Health and Welfare giving full support for the work. Also, preliminary reports of another study carried out in the south of Sweden that has just been completed support the present findings. Nevertheless, further studies are needed before a general recommendation can be made.

Summary box

Infantile colic is common and difficult to treat

In this study, children were quasi-randomised to usual care plus minimal acupuncture or usual care alone

Minimal acupuncture was associated with significant benefits in several outcomes, including frequency of crying and parental global assessment

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Contributions

Marianne Reinthal carried out the initial planning of the study and study protocols, and carried out all the treatments and contributed to the writing of the manuscript. Sven Andersson supervised and planned the study, and contributed to the writing of the manuscript. Marianne Gustafsson supervised the design and execution of the study and the development of the protocols. Kaety Plos has contributed to the design of the study and the data analysis. Iréne Lund contributed to the data analysis and writing of the manuscript. Thomas Lundeberg contributed to the supervision of discussing possible physiological and clinical effects as well as writing of the manuscript. Karl Gustaf Rosén contributed to the data analysis and writing of the manuscript.

Conflict of interest

TL chairs the charity The Foundation of Acupuncture and Alternative Biological Treatment Methods' which has received grants from AKAB Utbildning AB to support acupuncture research. No conflict of interest declared by any other authors.

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