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ORIGINAL PAPER

Comparison of the short-term effects of chiropractic spinal manipulation and occipito-sacral decompression in the treatment of infant colic: A single-blinded, randomised, comparison trial

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KEYWORDS
Colic;
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Summary

Objective: To compare two interventions in the treatment of infant colic.
Design: A single-blinded, randomised, and comparison trial.
Setting: Anglo-European College of Chiropractic teaching clinic.
Participants: Forty-three infants of less than 8 weeks of age who cried >3 h/day for at least 4 of the previous 7 days.
Interventions: Two weeks of spinal manipulative therapy (SMT, $n = 22$) or occipito-sacral decompression (OSD, $n = 21$).
Main outcome measures: Change in daily hours of crying.
Results: At day 7 of the trial, the mean hours of crying per day were significantly reduced in both groups (SMT, by 2.1 h/day, $p < 0.001$; OSD, by 2.0 h/day, $p < 0.001$). At day 14, the mean hours of crying per day were significantly reduced in both groups (SMT, by 3.1 h/day, $p < 0.001$; OSD, by 2.5 h/day, $p < 0.001$). At day 14, the mean hours of sleep per day were significantly increased in both groups (SMT, by 1.7 h/day, $p < 0.01$; OSD, by 1.0 h/day, $p < 0.01$). Four weeks after completion of the treatment trial, colic had resolved in 82% of the SMT group and 67% of the OSD group.
Conclusion: Both treatments appear to offer significant benefits to infants with colic. Infants treated by SMT or OSD cried less and slept more after 2 weeks of treatment. There were no differences in outcomes between the two treatment approaches. Although the participants completed the trial of therapy prior to the usual age of remission for infant colic, the natural course cannot be ruled out. Therefore, the treatment approaches as a cause of the observed benefits in this study must be appropriately interpreted.

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Introduction

Infant colic is commonly described as paroxysmal crying, difficult to soothe, clustering in the late afternoon and/or evening, in an otherwise healthy, well-fed infant.[1–4] The definition of colic has been discussed extensively in the research literature and for some time many authors have used Wessel's 'rule of threes' definition of colic which is 'crying and/or fussing for three hours a day, on three or more days a week, for three weeks or more'.[5] The incidence of colic is broadly similar across different societies with a reported incidence of 8–26% in infants up to 3 months old.[4,6–9]

The onset of colic tends to be from birth to 24 weeks of age[8,10,11] with a peak in excessive crying between 3 and 6 weeks of age.[3,8,10,12] Although colic tends to remit by 3 months of age in 86.3% of cases, 51.4% of infants who have colic at 6 weeks continue to have colic after 3 months of age.[10] Few risk factors have been identified in the literature but an association has been suggested between infant colic and mothers' smoking in excess of 15 cigarettes per day during pregnancy[13] or postpartum depression.[14,15]

Infant colic can have serious and long-term ramifications. Persistent infant crying has been implicated as a major predisposing factor in some cases of shaken baby syndrome, child abuse and neglect, particularly in the first 4 months of life.[16–18] In addition, there is evidence that colicky infants cause increased maternal stress.[19,20] Colic can cause disruption to family life for several years after resolution.[9,21–23] Further, there is a higher risk of behavioural problems and lower academic achievement in later years in children who had untreated colic as infants.[24,25]

There are no proven treatments for infant colic although a number have been suggested in the literature. Simethicone (Mylicon) is commonly used but studies have found it to be no more effective than placebo.[26,27] Glucose or sucrose solution appears to reduce crying duration in some infants with colic with no reported side effects[28–30] but this may be due to an analgesic or soporific effect[31] and in the majority of cases the effect lasted less than 30 min. Increased carrying[32,33] and crib vibration (car ride simulator)[34,35] have no effect on the course of colic. However, it has been suggested that counselling on more effective responses to crying can result in a reduction in reporting of unsettled behaviour and maternal anxiety but has no effect on colic symptoms.[12,36–38]

There are also manual therapies that have been used to treat this condition. Three published studies have indicated that spinal manipulative therapy (SMT) by chiropractors is effective in reducing crying time in infant colic.[39–41] However, one study failed to demonstrate any beneficial effect of SMT beyond massage placebo on infant colic.[42] One study indicated that cranial osteopathy can be effective in reducing crying time and increasing sleep in colicky infants.[43] There are however a number of limitations to these manual therapy studies. In the case of the current study, the limitations of other trials, which in some cases were not randomised, had less rigorous categorization of infant colic, used older subjects or did not reach a therapeutic level of care, are addressed. This trial also differs from previous research in that it compares two chiropractic manual therapies, spinal manipulative therapy and occipito-sacral decompression (OSD), in the treatment of infant colic. Occipito-sacral decompression is a chiropractic paediatric technique for infants and has been taught at undergraduate level at the Anglo-European College of Chiropractic, Bournemouth since 2001. With the infant supine the occiput and the sacral base are contacted simultaneously and gentle distraction is applied for up to 30 s. It is not a cranial technique but rather a technique that affords gentle spinal distraction. This study aims to determine whether there is a reduction in crying times with administration of either of these types of manual therapy and if so, how this reduction compares between the two approaches.

Methods

Study design

Consecutive infants presenting to the AECC outpatient clinic were recruited to the study. The study design was a single-blinded, randomised, comparison trial.

Participants

During the initial consultation, the infants were assessed by a senior clinic tutor (JM) for eligibility to enter the study after which written, informed consent was obtained from the parent/guardian. To be eligible, the participants had to be less than 8 weeks of age, born with birth weight equal to or more than 2500 g, born at or after 38 weeks gestation, cry for 3 h or more per day with one or more inconsolable crying episodes for at least four of the previous 7 days and show typical restless behaviour (i.e. motor unrest, flexing knees against abdomen, extending the trunk, neck, and extremities). The parent/guardian had to be fluent and literate in the

English language. Infants were excluded if they or any siblings had received previous chiropractic or cranial treatment, showed symptoms that could be a sign of conditions other than infant colic that may be associated with increased crying (such as birth trauma, cow's milk protein intolerance, musculoskeletal irritability, and gastro-oesophageal reflux) or suffered from any known past or present disease.

Randomisation

A pre-determined, computer-generated, randomisation schedule was used to assign the infants into one of two treatment groups: group A (spinal manipulative therapy) or group B (occipito-sacral decompression). The parents were not informed as to which treatment group their infant was assigned.

Outcome measures

The parents were asked a number of questions, as outlined in Table 1, and given a crying diary to complete daily, beginning on the date of the initial consultation (2—3 days prior to the first treatment so as to provide the baseline measurements) and completing it 14 days after the first treatment. The diary provided the amount and duration of daily crying, typical time of day when colic behaviour occurred and amount of sleep and non-distressed awake behaviour. The crying diary has been validated in previous studies.[44,45]

All of the outcome measures were taken from the crying diaries. The primary outcome measure was any change in the group mean number of hours of daily crying at the end of the 2-week treatment trial

Table 1 Baseline data.

Variable	SMT group (n = 22)	OSD group (n = 21)	p value
Boys/girls	15/7 (n)	12/9 (n)	0.45
First born/not first born	10/12 (n)	11/10 (n)	0.65
Birth weight (g)	3358.6 (473.1)	3425.8 (537.0)	0.38
Birth (gestation) week	39.7 (1.6)	39.1 (1.6)	0.96
Birth: normal vaginal delivery	13 (n)	16 (n)	0.31
Forceps/venteuse	4 (n)	4 (n)	0.31
Caesarean section (elective)	3 (n)	0 (n)	0.31
Caesarean section (unplanned)	2 (n)	1 (n)	0.31
Breast fed only	8 (n)	11 (n)	0.001
Formula fed only	12 (n)	1 (n)	0.001
Mixed (breast + formula)	2 (n)	8 (n)	0.001
Age of mother (years)	30.8 (5.2)	30.7 (5.0)	0.87
Mother smokes: yes/no	3/19 (n)	1/19 (n)	0.34
Mother employed: yes/no	16/6 (n)	16/5 (n)	0.80
Mother co-habits with infant's father: yes/no	19/1 (n)	20/0 (n)	0.31
Age of father	32.5 (5.6)	35.1 (6.8)	0.43
Father's occupation: manual/non-manual	10/11 (n)	11/10 (n)	0.76
Age at onset of colic symptoms (days)	11.6 (7.5)	10.1 (10.3)	0.16
Age on entry to treatment trial (weeks)	5.3 (1.8)	5.2 (1.9)	0.88
Number of weeks with colic on entry to trial	3.6 (1.8)	3.8 (2.0)	0.42
Symptoms during a typical colic episode			
Motor unrest	5 (n)	5 (n)	0.66
Gastrointestinal (GI) symptoms (wind)	8 (n)	7 (n)	
Motor unrest plus GI symptoms	9 (n)	9 (n)	
Infant able to be briefly comforted during colic episode: yes/no	17/5 (n)	15/6 (n)	0.66
On colic medication during study: yes/no	14/8 (n)	9/11 (n)	0.23
Hours of crying/day pre-trial	5.6 (2.0)	5.1 (1.6)	0.36
Hours of sleep/day pre-trial	11.8 (2.1)	11.3 (1.4)	0.08
No. of crying episodes/day pre-trial	4.8 (1.9)	5.9 (2.5)	0.12
Hours of crying 6 a.m. to noon	1.3 (0.7)	0.8 (0.5)	0.01
Hours of crying noon to 6 p.m.	1.3 (1.2)	1.4 (0.7)	0.14
Hours of crying 6 p.m. to midnight	2.1 (1.0)	2.2 (1.0)	0.75
Hours of crying midnight to 6 a.m.	0.9 (0.8)	0.6 (0.7)	0.60

Figures represent mean values (±S.D.) or numbers (n) where stated.
Comparison of categorical data was performed using the Chi-squared test and of continuous data using the unpaired t-test.

compared to baseline measurements. Secondary outcomes were any change in the group mean number of crying episodes and hours of sleep per day compared to baseline measurements over the same time period. The baseline measurements were calculated as the mean number of hours of crying and sleep and the number of crying episodes over 2—3 days prior to the initial treatment. Four weeks after completion of the treatment trial the parents were interviewed by telephone as to whether there was complete resolution of colic symptoms (yes/no).

Interventions

Beginning on the second visit, the infant was treated in the normal way by an intern in a teaching clinic accompanied by a clinical tutor but only using either treatment A or B, according to which group that infant had been randomly assigned. Treatment was given 2—3 times per week, for 2 weeks, or less if the symptoms resolved. Group A received spinal manipulative therapy (SMT) appropriate for neonates and appropriate to the age of the patient as indicated on examination. Group B received occipito-sacral decompression (OSD) as previously described.

Sample size

Forty-eight subjects were recruited to this study as previous studies of chiropractic treatment of colic have shown a clinically significant reduction in daily hours of crying in 30—50 subjects.[41,42]

Statistical analysis

Data analysis was carried out by an independent observer (MB), who was blinded as to which treatment the infant had received. The data were analysed using SPSS version 13.0™. The significance level was set at $p < 0.05$. Comparison of categorical data was performed using the Chi-squared test and of continuous data using the unpaired *t*-test. To test changes within the groups, the paired *t*-test was used. The data were analysed according to an intention to treat analysis.

Results

Of the 48 infants recruited for the trial, 1 infant in the OSD group was excluded from the trial after the initial consultation because she did not fulfil the inclusion criteria for birth weight. Upon completion of the 2-week treatment trial, two infants from each group were excluded from the trial because their crying diaries were incomplete. The diaries of the remaining 43 infants were analysed (22 in the SMT group and 21 in the OSD group).

Table 1 shows the baseline data of the infants in the two treatment groups. As can be seen, there were no significant differences between the two groups in presenting characteristics except for a significantly higher number of formula-fed infants in the SMT group ($p = 0.001$). The mean number of hours of crying between 6 a.m. and noon was also significantly higher in the SMT group ($p = 0.01$). Fig. 1 shows the mean crying pattern of the two groups over 24 h during the pre-treatment period. Both groups demonstrated an 'evening peak' of crying.

The infants in both groups received between three and seven treatments each during the 2-week trial. There were no statistically significant differences between the two groups regarding the number of treatments received. Two infants in the SMT group and one infant in the OSD group received both SMT and OSD during the trial. These infants were kept in their original groups for statistical analysis (intention to treat analysis).

Table 2 shows the mean change in hours of crying/day, number of crying episodes/day and hours of sleep/day in the two treatment groups at day 7 and day 14 of the trial. Considering the primary outcome measure, the reduction in hours of crying/day at day 7 and day 14 was significant in both groups (day 7: SMT group by 2.1 ± 2.2 h/day, $p < 0.001$ and OSD group by 2.0 ± 1.4 h/day, $p < 0.001$; day 14: SMT group by 3.1 ± 2.4 h/day, $p < 0.001$ and OSD group by 2.5 ± 1.5 h/day, $p < 0.001$). The change in the number of crying episodes/day was not significant at day 7 in either group. At day 14 there was a reduction in both groups which was significant in the OSD group but not in the SMT group (SMT group by 0.5 ± 1.9 episodes/day, $p = 0.24$; OSD group by 1.4 ± 1.9 episodes/day, $p = 0.01$). The increase in hours of sleep/day at day 7 was not significant in either group.

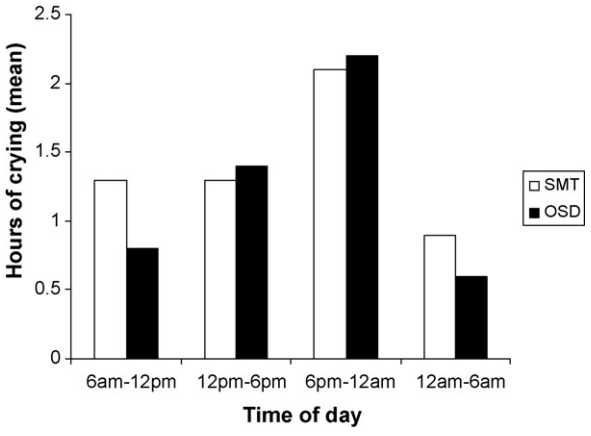

Figure 1 Time of day when crying occurred (pre-trial).

Table 2 Within group differences in crying and sleeping behaviour in infants treated with SMT and OSD.

Outcome measure	SMT (n = 22)			OSD (n = 21)		
	Mean (±S.D.)	95% CI	p value	Mean (±S.D.)	95% CI	p value
Change in hours of crying/day						
From baseline to day 7	−2.06 (2.20)	−1.08 to −3.04	0.001	−1.98 (1.36)	−1.36 to −2.60	0.001
From baseline to day 14	−3.08 (2.35)	−2.01 to −4.15	0.001	−2.52 (1.49)	−1.84 to −3.20	0.001
Change in no. of crying episodes/day						
From baseline to day 7	0.05 (1.53)	0.73 to −0.63	0.88	−0.79 (1.71)	−0.01 to −1.57	0.05
From baseline to day 14	−0.51 (1.91)	0.36 to −1.38	0.24	−1.43 (1.94)	−0.55 to −2.31	0.001
Change in hours of sleep/day						
From baseline to day 7	1.05 (2.64)	2.22 to −0.13	0.08	0.77 (1.75)	1.57−0.26	0.06
From baseline to day 14	1.66 (2.83)	2.95−0.37	0.01	1.03 (1.77)	1.84−0.23	0.01

However, the increase in hours of sleep at day 14 was significant in both groups (SMT group by 1.7 ± 2.8 h/day, p = 0.01; OSD group by 1.0 ± 1.8 h/day, p = 0.01).

Table 3 shows the absolute difference between the two groups and the difference in the change in values between the groups in mean daily hours of crying and sleep and mean daily number of crying episodes. For all outcomes the difference between the two groups was not significant. There was a progressive reduction in mean daily hours of crying in both groups (SMT: from 5.6 h/day (±2.0) at day 0 to 2.5 h/day (±1.4) at day 14; OSD: from 5.1 h/day (±1.6) at day 0 to 2.6 h/day (±1.4) at day 14; $p > 0.05$). There was little change in the mean number of daily crying episodes (SMT: from 4.8 episodes/day (±1.9) at day 0 to 4.4 episodes/day (±2.1) at day 14; OSD: from 5.9 episodes/day (±2.5) at day 0 to 4.5 episodes/day (±2.3) at day 14; $p > 0.05$). There was a progressive increase in mean daily hours of sleep in both groups (SMT: from 11.8 h/day (±2.1) at day 0 to 13.3 h/day (±1.7) at day 14; OSD: from 11.3 h/day (±1.4) at day 0 to 12.4 h/day (±2.0) at day 14; $p > 0.05$). The decline in the number of hours of crying between the two groups in both the first and second week of the treatment trial is graphically illustrated in Fig. 2.

At 4 weeks post-trial there was complete resolution of colic symptoms in 18 out of a total of 22 infants in the SMT group and 14 out of total of 21 infants in the OSD group as perceived by the parent, giving a rate ratio of 1.23 (95% CI 0.86−1.76). This implies that infants treated with SMT are 20% more likely to resolve compared to infants treated with OSD. Although this may be clinically significant, the difference is not statistically significant.

Discussion

To our knowledge this is the first randomised trial that compares two manual therapies in the treatment of infant colic. The results suggest that both

Table 3 Between group differences in crying and sleeping behaviour in infants treated with SMT and OSD.

Outcome measure	SMT group (n = 22)	OSD group (n = 21)	Comparison 1 [a]	Comparison 2 [b]	CI (95%)	p value
Hours of crying/day						
Baseline	5.6 (2.0)	5.1 (1.6)	0.5 (2.1)	–	−0.68 to 1.60	0.36
Days 1−7 of trial	3.5 (1.6)	3.1 (1.1)	0.4 (1.6)	0.8 (1.8)	−0.47 to 1.22	0.37
Days 8−14 of trial	2.5 (1.4)	2.6 (1.4)	0.1 (1.4)	0.6 (2.2)	−0.97 to 0.80	0.85
No. of crying episodes/day						
Baseline	4.8 (1.9)	5.9 (2.5)	1.1 (1.7)	–	−2.45 to 0.27	0.12
Days 1−7 of trial	4.9 (2.0)	5.1 (2.2)	0.2 (2.0)	0.8 (2.0)	−1.54 to 1.04	0.70
Days 8−14 of trial	4.4 (2.1)	4.5 (2.3)	0.1 (2.2)	0.9 (2.4)	−1.48 to 1.29	0.89
Hours of sleep/day						
Baseline	11.8 (2.1)	11.3 (1.4)	0.5 (2.0)	–	−0.68 to 1.52	0.08
Days 1−7 of trial	12.8 (1.6)	12.1 (1.6)	0.7 (2.0)	0.28 (2.3)	−0.28 to 1.67	0.16
Days 8−14 of trial	13.3 (1.7)	12.4 (2.0)	0.9 (2.5)	0.63 (2.6)	−0.20 to 2.11	0.10

Figures represent mean values (±S.D.). p values were calculated by the unpaired t-test.
[a] Absolute difference between the groups.
[b] Difference in the change in values between the groups.

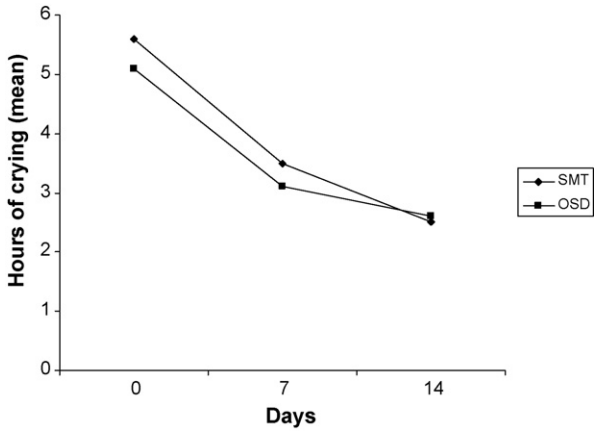

Figure 2 Reduction in mean number of hours of daily crying.

SMT and OSD are effective in reducing crying and increasing sleep in infants with colic. If indeed these treatments are effective then the aetiology of colic may have a strong biomechanical and/or neurophysiological component and these infants may be crying due to neuromusculoskeletal discomfort. In this regard, it has been suggested that the diagnostic term of colic should be abandoned for a more clinically relevant definition.[46]

Our results strongly support previous chiropractic and osteopathic trials as the reduction in mean daily hours of crying is similar over an equivalent time period. Three chiropractic studies and one osteopathic study have demonstrated a significant positive effect of manual treatment on colic. In a prospective study of 316 colicky infants, 94% improved with SMT over a 2-week period.[39] In an RCT of 30 infants with colic 93% had complete resolution of their symptoms when treated with SMT over a 2-week period (compared to the control group who were given a sham treatment).[40] In an RCT of 50 colicky infants comparing SMT with the drug dimethicone, there was a significant reduction in hours of crying per day in the SMT group compared to the dimethicone group after 11 days.[41] The reduction in hours of crying in the SMT group was similar to that of our study. In a RCT of 28 infants with colic, cranial osteopathic manipulation was compared with untreated controls.[43] There was an overall decline in crying of 63% and 23%, respectively, and an increase in sleeping of 11% and 2% for treated and controls after 4 weeks. These results in the treatment group are similar to that of both groups in our study. Notably, the presence of multilevel spinal dysfunction in previous studies also reflects that of our study. This may be partly explained by the hypothesis that irritability in infants occurs along a continuum of dysfunctions that may derive from or affect multiple systems, including the digestive and musculoskeletal systems, amplified through the autonomic nervous system.[46] However, one large RCT of 86 colicky infants failed to demonstrate any significant difference between SMT and placebo treatment.[42] A dose—response phenomenon may explain the lack of a positive treatment effect as the trial group received treatment over 8 days compared to 14 days in our study and previous chiropractic studies. Also, there may have been a treatment effect in the placebo group (who were held by a nurse and stroked spinally).

In our study, there were no significant differences in baseline values between the two groups except for two variables (i.e. morning crying and type of feeding). The infants in the SMT group cried significantly more from 6 a.m. to noon but this is likely to be an incidental finding as the infants in both groups cried the least between these times. There were significantly more formula-fed only infants in the SMT group and significantly more mixed (breast-fed plus formula-fed) infants in the OSD group. Some studies have reported that colic is just as common in breast-fed as in formula-fed infants[10,47] whilst others have reported that colic affects more breast-fed than formula-fed infants.[6] As there is no strong evidence that breast-feeding has any effect on the development or course of colic, we did not consider method of feeding to be a confounding factor. The baseline values demonstrated an 'evening peak' of crying which has been previously reported in the literature[2,4,48,49] and supports the diagnosis of infant colic in our sample.

A limitation of our study is that the inclusion criteria were so strict that approximately half of the presenting excessively crying infants who otherwise fulfilled the criteria were excluded because their siblings had received previous chiropractic or cranial treatment. Therefore, the subjects represented only a small proportion of excessively crying infants who presented to the clinic for treatment. The purpose of this was to enable blinding of the parents. However, as the infant is receiving a physical style of treatment of one form or another, previous experience of either intervention is not likely to affect the outcome. Also, parents cannot usually differentiate between different styles of paediatric chiropractic treatment and therefore would not necessarily know which treatment their child had received. Further limitations are that the treating interns are relatively inexperienced in administering SMT and OSD compared to chiropractors in the field. It is also possible that the pretreatment data collection period of 2—3 days may have been subject to short-term fluctuations. However, parents with excessively crying infants do not want to wait long to commence treatment.

In our study, 53.5% of the infants continued to take colic medication (simethicone) during the treatment trial. As there is evidence suggesting that simethicone is no more effective than placebo in the treatment of colic [26,27] we did not consider this to be a confounding factor.

We addressed a number of limitations of previous manual therapy studies of colicky infants by recruiting younger subjects over a narrower age range and using strict inclusion criteria to exclude conditions such as cow's milk protein intolerance and reflux. To obtain objective outcome measures, crying diaries were used prospectively. Additionally, to reduce the possibility of parental bias, all subjects received a manual form of treatment and we did not recruit any infant from a family with previous chiropractic experience. Our study was ethically sound as the specific design in comparing two chiropractic treatments meant that crying infants were not left untreated. The power of randomisation clearly showed that there were no significant differences between the two groups according to their demographic and baseline characteristics. Both interventions can be considered safe to administer to infants as there were no reported side-effects.

The results of this study should help clinicians to make an informed decision as to the effectiveness of manual therapy in the treatment of infant colic. Future research could include examining infants from newborn to 2 weeks old for spinal dysfunction and monitoring them over the first 12 weeks of life to see how many of them later develop colic. A link may then be established between spinal dysfunction and colic.

Conclusion

This study has provided data on the effectiveness of manual therapy by demonstrating a significant reduction in hours of crying/day and an increase in hours of sleep/day over a 14-day trial of treatment. No side effects were reported.

Conflict of interest

There was no external funding and no competing interests with either author.

Acknowledgement

The study was approved by the Anglo-European College of Chiropractic Research Ethics Sub-Committee.

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