

Collected Scientific Research Relating to the Use of Osteopathy with Unsettled babies/"Colic"

Important:

1) Osteopathy involves helping people's own self-healing abilities to work better, rather than focussing primarily on particular conditions.

2) Each person is different, and osteopathy treats them differently.

Therefore people respond to osteopathic treatment in different ways. Treatments that work for one person cannot be guaranteed to work for another person in the same way. The fact that there is scientific research supporting a treatment in a group of people does not mean that it will always work in the same way (which is probably true of all research).

A number of things make research into osteopathy challenging. These include the two aspects of osteopathy mentioned above, and also the lack of major commercial interests to provide funding in expectation of financial returns. At the same time, there is an emerging body of research demonstrating the usefulness of osteopathic treatment.

Please note: there is room for debate about the classifications used for these studies. Please let John Smartt know if you believe that any of these classifications are incorrect.

About "colic"

There are many reasons why babies may be unsettled. Infantile colic is one; and it, in turn, can have a range of causes. Some of the following studies look at unsettled babies as a group, some looked at colic, and some called it "colic" while actually looking at unsettledness. Because the condition is hard to pin down, the two systematic reviews give guarded support for osteopathic treatment in this situation.

Osteopaths would say that because osteopathy looks for underlying causes within individuals, it is ideally suited to the treatment of conditions which may have a range of causes.

These studies are from peer-reviewed journals

Number of studies: 11

Clinically and statistically significant results

Number of studies: 10

Systematic reviews

Number of studies: 2

Carnes D, Plunkett A, Ellwood J, Miles C 2018 **Manual therapy for unsettled, distressed and excessively crying infants: a systematic review and meta-analyses**. *BMJ Open* Jan 24;8(1): e019040 <http://bmjopen.bmj.com/content/8/1/e019040>

This review questions whether an average reduction in crying time of 100 minutes per day is something that parents would find meaningful. Parents will have to make up their own minds about that.

"Objective To conduct a systematic review and meta-analyses to assess the effect of manual therapy interventions for healthy but unsettled, distressed and excessively crying infants and to provide information to help clinicians and parents inform decisions about care.

Methods We reviewed published peer-reviewed primary research articles in the last 26 years from nine databases (Medline Ovid, Embase, Web of Science, Physiotherapy Evidence Database, Osteopathic Medicine Digital Repository, Cochrane (all databases), Index of Chiropractic Literature, Open Access Theses and Dissertations and Cumulative Index to Nursing and Allied Health Literature). Our inclusion criteria were: manual therapy (by regulated or registered professionals) of unsettled, distressed and excessively crying infants who were otherwise healthy and treated in a primary care setting. Outcomes of interest were: crying, feeding, sleep, parent-child relations, parent experience/satisfaction and parent-reported global change.

Results Nineteen studies were selected for full review: seven randomised controlled trials, seven case series, three cohort studies, one service evaluation study and one qualitative study. We found moderate strength evidence for the effectiveness of manual therapy on: reduction in crying time (favourable: -1.27 hours per day (95% CI -2.19 to -0.36)), sleep (inconclusive), parent-child relations (inconclusive) and global improvement (no effect). The risk of reported adverse events was low: seven non-serious events per 1000 infants exposed to manual therapy (n=1308) and 110 per 1000 in those not exposed.

Conclusions Some small benefits were found, but whether these are meaningful to parents remains unclear as does the mechanisms of action. Manual therapy appears relatively safe."

Dobson D, Lucassen PL, Miller JJ, Vlieger AM, Prescott P, Lewith G 2012 **Manipulative therapies for infantile colic** *Cochrane Database Syst Rev* Dec 12;12:CD004796 <http://www.ncbi.nlm.nih.gov/pubmed/23235617>

"We identified six studies for inclusion in our review, representing a total of 325 infants. There were three further studies that we could not find information about and we identified three other ongoing studies. Of the six included studies, five were suggestive of a beneficial effect and one found no evidence that manipulative therapies had any beneficial effect on the natural course of infantile colic. Tests for heterogeneity imply that there may be some underlying difference between this study and the other five. Five studies measured daily hours of crying and these

data were combined, suggesting that manipulative therapies had a significant effect on infant colic - reducing average crying time by one hour and 12 minutes per day"

Randomised controlled trials

Number of studies: 5

Nahidi F, Gazerani N, Yousefi P, Abadi AR 2017 **The Comparison of the Effects of Massaging and Rocking on Infantile Colic.** Iran J Nurs Midwifery Res Jan-Feb;22(1):67-71 <https://www.ncbi.nlm.nih.gov/pubmed/28382062>

"Infantile colic is a painful condition in the first months of infancy. This study was carried out with the aim of testing the hypothesis that massage treatment has a clinically relevant effect on this condition.

MATERIALS AND METHODS:

This randomized clinical trial was conducted among 100 infants of < 12 weeks of age with infantile colic. They were randomly assigned to either infant massage (n = 50) or rocking groups (n = 50). In the massage group, trained individuals taught the parents of the infants the massage technique and gave them a brochure. Rocking group parents was recommended to rock their infants three times a day for 1 week. Parents recorded the pattern of crying (numbers, length, and severity of crying). After 1 week of intervention, data were analysed using t-test, Chi square test, and repeated measurement analysis of variance (P < 0.05).

RESULTS:

Significant differences were not observed in infant and mother demographic information. Before intervention, the mean of total number, length, and severity of crying were 6.12 (1.76) time/day, 4.97 (1.37) hour/day, and 6.60 (1.54) in the massage group and 6.96 (2.9) time/day, 3 (1.31) hour/day, and 5.98 (2.22) in the rocking group, respectively. After 1 week of intervention, the mean difference of total number, length, and severity of crying were 4.08 (1.83) time/day, 2.81 (1.77) hour/day, and 2.9 (2.37) in the massage group and 0.56 (2.28) time/day, 0.27 (1.09) hour/day, and 0.02 (1.64) in the rocking group, respectively.

CONCLUSIONS:

This trial of massage treatment for infantile colic showed statistically significant or clinically relevant effect in comparison with the rocking group."

Sheidaei A, Abadi A, Zayeri F, Nahidi F, Gazerani N, Mansouri A 2016 **The effectiveness of massage therapy in the treatment of infantile colic symptoms: A randomized controlled trial.** Med J Islam Repub Iran Apr 9;30:351 <https://www.ncbi.nlm.nih.gov/pubmed/27453882>

"Infantile colic, cry-fuss and sleep problems are transient in the initial months of life, but they contribute to maternal depression, parenting stress and family mental health problems. In this randomized clinical trial, we aimed to explore the efficacy of massage therapy compared to rocking in reducing infantile colic symptoms including duration and number of cries, sleep duration and severity of infant colic.

METHODS:

This was a single blind RCT study with a one-week follow-up. One hundred colicky infants aged younger than 12 weeks old were randomly assigned into massage and rocking groups. Infants in the massage group received a massage for 15-20 minutes once during a day and once at night before sleeping for a week. In the control group, mothers rocked their infants gently for 5-25 minutes when the symptoms of colic appeared. Parents recorded the details of the colic symptoms in a diary every day. A GEE approach was applied to explore the effect of the intervention.

RESULTS:

Efficiency of massage therapy was significantly higher than rocking. At the end of the study, the mean number of daily cries was 4.26 ± 1.40 in the massage and 6.9 ± 2.14 the rocking groups ($p < 0.01$). The mean of the severity score was 1.39 ± 0.19 less in the massage group ($p < 0.01$). Moreover, the mean differences of massage and rocking groups were -0.82 ± 0.20 hour ($p < 0.01$) and 0.72 ± 0.35 ($p = 0.04$) in the duration of cries and duration of sleep, respectively.

CONCLUSION:

Massaging significantly improved colic symptoms during a one-week intervention for all

outcomes. In addition, significant differences were found between the intervention and control groups in favor of massaging. Therefore, massage therapy is more effective than rocking for treating infant colic symptoms."

Miller JE, Newell D, Bolton JE 2012 **Efficacy of chiropractic manual therapy on infant colic: a pragmatic single-blind, randomized controlled trial.** J Manipulative Physiol Ther Oct;35(8):600-7 <https://www.ncbi.nlm.nih.gov/pubmed/23158465>

"The purpose of this study was to determine the efficacy of chiropractic manual therapy for infants with unexplained crying behavior and if there was any effect of parental reporting bias.

METHODS:

Infants with unexplained persistent crying (infant colic) were recruited between October 2007 and November 2009 at a chiropractic teaching clinic in the United Kingdom. Infants younger than 8 weeks were randomized to 1 of 3 groups: (i) infant treated, parent aware; (ii) infant treated, parent unaware; and (iii) infant not treated, parent unaware. The primary outcome was a daily crying diary completed by parents over a period of 10 days. Treatments were pragmatic, individualized to examination findings, and consisted of chiropractic manual therapy of the spine. Analysis of covariance was used to investigate differences between groups.

RESULTS:

One hundred four patients were randomized. In parents blinded to treatment allocation, using 2 or less hours of crying per day to determine a clinically significant improvement in crying time, the increased odds of improvement in treated infants compared with those not receiving treatment were statistically significant at day 8 (adjusted odds ratio [OR], 8.1; 95% confidence interval [CI], 1.4-45.0) and at day 10 (adjusted OR, 11.8; 95% CI, 2.1-68.3). The number needed to treat was 3. In contrast, the odds of improvement in treated infants were not significantly different in blinded compared with nonblinded parents (adjusted ORs, 0.7 [95% CI, 0.2-2.0] and 0.5 [95% CI, 0.1-1.6] at days 8 and 10, respectively).

CONCLUSIONS:

In this study, chiropractic manual therapy improved crying behavior in infants with colic. The findings showed that knowledge of treatment by the parent did not appear to contribute to the observed treatment effects in this study. Thus, it is unlikely that observed treatment effect is due to bias on the part of the reporting parent."

Hayden C, Mullinger B 2006 **A preliminary assessment of the impact of cranial osteopathy for the relief of infantile colic** Complementary Therapies in Clinical Practice Volume 12, Issue 2, May , Pages 83–90 <http://www.ncbi.nlm.nih.gov/pubmed/16648084>

"A progressive, highly significant reduction between weeks 1 and 4 in crying (hours/24 h), was detected ($p < 0.001$) in treated infants; similarly there was a significant improvement in the time spent sleeping ($p < 0.002$). By contrast, no significant differences were detected in these variables for the control group. Overall decline in crying was 63% and 23%, respectively, for treated and controls; improvement in sleeping was 11% and 2%. Treated infants also needed less parental attention than the untreated group."

Wiberg JM, Nordsteen J, Nilsson N 1999 **The short-term effect of spinal manipulation in the treatment of infantile colic: a randomized controlled clinical trial with a blinded observer.** J Manipulative Physiol Ther Oct;22(8):517-22 <https://www.ncbi.nlm.nih.gov/pubmed/10543581>

"OBJECTIVE:

To determine whether there is a short-term effect of spinal manipulation in the treatment of infantile colic.

DESIGN:

A randomized controlled trial.

SETTING:

A private chiropractic practice and the National Health Service's health visitor nurses in the suburb Ballerup (Copenhagen, Denmark).

SUBJECTS:

Infants seen by the health visitor nurses, who fulfilled the diagnostic criteria for infantile colic.

INTERVENTION:

One group received spinal manipulation for 2 weeks, the other was treated with the drug dimethicone for 2 weeks.

OUTCOME MEASURE:

Changes in daily hours of crying as registered in a colic diary.

RESULTS:

By trial days 4 to 7, hours of crying were reduced by 1 hour in the dimethicone group compared with 2.4 hours in the manipulation group ($P = .04$). On days 8 through 11, crying was reduced by 1 hour for the dimethicone group, whereas crying in the manipulation group was reduced by 2.7 hours ($P = .004$). From trial day 5 onward the manipulation group did significantly better than the dimethicone group.

CONCLUSION:

Spinal manipulation is effective in relieving infantile colic."

Cohort studies

Number of studies: 2

Wiberg KR, Wiberg JM 2010 **A retrospective study of chiropractic treatment of 276 danish infants with infantile colic.** J Manipulative Physiol Ther Sep;33(7):536-41 <https://www.ncbi.nlm.nih.gov/pubmed/20937431>

"The aim of this study was to investigate if the outcome of excessively crying infants treated with chiropractic manipulation (1) was associated with age and/or (2), at least partially, can be explained by age according to the natural decline in crying.

METHODS:

This was a retrospective evaluation of clinical records of 749 infants from a private Danish chiropractic practice. All of the infants were healthy, thriving infants born to term within the age of 0 to 3 months who fulfilled the diagnostic criteria for excessively crying infants (infantile colic), whose parents sought chiropractic treatment. The infants were treated using chiropractic management as decided by the treating doctor of chiropractic, and changes in crying based upon the parents' report were noted as improved, uncertain, or nonrecovered. Age predictor groups were cross-tabulated against the outcome variables, and difference between classification groups was tested with χ^2 tables and confidence intervals.

RESULTS:

Slightly older age was found to be linked to excessively crying infants who experienced clinical improvement. However, no apparent link between the clinical effect of chiropractic treatment and a natural decline in crying was found for this group of infants.

CONCLUSION:

The findings of this study do not support the assumption that effect of chiropractic treatment of infantile colic is a reflection of the normal cessation of this disorder."

Miller JE, Phillips HL 2009 **Long-term effects of infant colic: a survey comparison of chiropractic treatment and nontreatment groups.** J Manipulative Physiol Ther Oct;32(8):635-8 <https://www.ncbi.nlm.nih.gov/pubmed/19836599>

"OBJECTIVE:

Investigation into the alleviation of long-term effects of infant colic on the toddler is a neglected area of research. The aim of this study was to document any behavioral or sleep disturbances experienced by post-colicky toddlers who were previously treated with chiropractic care vs those who had not experienced this treatment as an infant.

METHODS:

Two groups of children were sampled from clinic records from a chiropractic clinic and from a child care center in similar regions of England. Patients were classified in the treatment group if they had been treated for infant colic with routine low-force chiropractic manual therapy. The nontreatment group consisted of post-colicky children in the same age group who had received no chiropractic care for their diagnosed colic as infants. A survey of parents of 117 post-colicky toddlers in a treatment group and 111 toddlers in the nontreatment group was performed.

RESULTS:

Toddlers who were treated with chiropractic care for colic were twice as likely to not experience long-term sequelae of infant colic, such as temper tantrums (relative risk, 2.0; 95% confidence interval, 1.3-3.0) and frequent nocturnal waking (relative risk, 2.0; 95% confidence interval, 1.5-2.8) than those who were not treated with chiropractic care as colicky infants.

CONCLUSION:

Untreated post-colicky infants demonstrated negative behavioral patterns at 2 to 3 years of age. In this study, parents of infants treated with chiropractic care for excessive crying did not report as many difficult behavioral and sleep patterns of their toddlers. These findings suggest that chiropractic care for infants with colic may have an effect on long-term sequelae."

Case reports

Number of studies: 1

Alcantara J, Anderson R. 2008 **Chiropractic care of a pediatric patient with symptoms associated with gastroesophageal reflux disease, fuss-cry-irritability with sleep disorder syndrome and irritable infant syndrome of musculoskeletal origin.** J Can Chiropr Assoc Dec;52(4):248-55 <https://www.ncbi.nlm.nih.gov/pubmed/19066699>

"The mother of a 3-month old girl presented her daughter for chiropractic care with a medical diagnosis of gastroesophageal reflux disease. Her complaints included frequently interrupted sleep, excessive intestinal gas, frequent vomiting, excessive crying, difficulty breastfeeding, plagiocephaly and torticollis. Previous medical care consisted of Prilosec prescription medication. Notable improvement in the patient's symptoms was observed within four visits and total resolution of symptoms within three months of care. This case study suggests that patients with complaints associated with both musculoskeletal and non-musculoskeletal origin may benefit from chiropractic care."

No clinically and/or statistically significant results

Number
of studies:
1

Randomised controlled trials

Number of studies: 1

Olafsdottir E, Forshei S, Fluge G, Markestad T. 2001 **Randomised controlled trial of infantile colic treated with chiropractic spinal manipulation.** Arch Dis Child Feb;84(2):138-41 <http://adc.bmj.com/content/84/2/138.long>

"AIMS:

To investigate the efficacy of chiropractic spinal manipulation in the management of infantile colic.

METHODS:

One hundred infants with typical colicky pain were recruited to a randomised, blinded, placebo controlled clinical trial.

RESULTS:

Nine infants were excluded because inclusion criteria were not met, and five dropped out, leaving 86 who completed the study. There was no significant effect of chiropractic spinal manipulation. Thirty two of 46 infants in the treatment group (69.9%), and 24 of 40 in the control group (60.0%), showed some degree of improvement.

CONCLUSION:

Chiropractic spinal manipulation is no more effective than placebo in the treatment of infantile colic. This study emphasises the need for placebo controlled and blinded studies when investigating alternative methods to treat unpredictable conditions such as infantile colic."