

# Collected Scientific Research Relating to the Use of Osteopathy with Children

## 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.

# These studies are from peer-reviewed journals

Number of studies: 50

## Clinically and statistically significant results

Number of studies: 46

### Systematic reviews

Number of studies: 6

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."

Lanaro D, Ruffini N, Manzotti A, Lista G 2017 **Osteopathic manipulative treatment showed reduction of length of stay and costs in preterm infants: A systematic review and meta-analysis**. *Medicine (Baltimore)* Mar;96(12):e6408 [http://journals.lww.com/md-journal/Fulltext/2017/03240/Osteopathic\\_manipulative\\_treatment\\_showed.43.aspx](http://journals.lww.com/md-journal/Fulltext/2017/03240/Osteopathic_manipulative_treatment_showed.43.aspx)

"Background: Osteopathic medicine is an emerging and complementary method used in neonatology.

Methods: Outcomes were the mean difference in length of stay (LOS) and costs between osteopathy and alternative treatment group. A comprehensive literature search of (quasi)-randomized controlled trials (RCTs), was conducted from journal inception to May, 2015.

Eligible studies must have treated preterm infants directly in the crib or bed and Osteopathic Manipulative Treatment (OMT) must have been performed by osteopaths. A rigorous Cochrane-like method was used for study screening and selection, risk of bias assessment and data reporting. Fixed effect meta-analysis was performed to synthesize data.

Results: 5 trials enrolling 1306 infants met our inclusion criteria. Although the heterogeneity was moderate ( $I^2=61\%$ ,  $P=0.03$ ), meta-analysis of all five studies showed that preterm infants treated with OMT had a significant reduction of LOS by 2.71 days (95% CI  $-3.99$ ,  $-1.43$ ;  $P<0.001$ ). Considering costs, meta-analysis showed reduction in the OMT group ( $-1,545.66\text{€}$ ,  $-1,888.03\text{€}$ ,  $-1,203.29\text{€}$ ,  $P<0.0001$ ). All studies reported no adverse events associated to OMT. Subgroup analysis showed that the benefit of OMT is inversely associated to gestational age. Conclusions: The present systematic review showed the clinical effectiveness of OMT on the reduction of LOS and costs in a large population of preterm infants."

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"

Gleberzon BJ, Arts J, Mei A, McManus EL 2012 **The use of spinal manipulative therapy for pediatric health conditions: a systematic review of the literature** J Can Chiropr Assoc Jun; 56(2): 128–141 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3364062/>

**In general, osteopaths would tend to treat children with asthma differently to the way that chiropractors would, but osteopaths are trained to use the same techniques identified here; if they don't use these techniques, that will probably be because they are using something which they believe will work better.**

#### Introduction

This study had two purposes. These were: (i) to conduct a search of the literature between 2007 and 2011 investigating the use of spinal manipulative therapy (SMT) for pediatric health conditions and (ii) to perform a systematic review of eligible retrieved clinical trials.

#### Methods

The Index of Chiropractic Literature and PubMed were electronically searched using appropriate search words and MeSH terms, respectively, as well as reference tracking of previous reviews. Studies that met the inclusion criteria were evaluated using an instrument that assessed their methodological quality.

#### Results

Sixteen clinical trials were found that met the inclusion criteria and were scored.

#### Discussion

Six clinical trials investigated the effectiveness of SMT on colic, two each on asthma and enuresis, and one each on hip extension, otitis media, suboptimal breastfeeding, autism, idiopathic scoliosis and jet lag. None investigated the effectiveness of SMT on spinal pain.

#### Conclusion

Studies that monitored both subjective and objective outcome measures of relevance to both patients and parents tended to report the most favorable response to SMT, especially among children with asthma. Many studies reviewed suffered from several methodological limitations. Further research is clearly required in this area of chiropractic health care, especially with respect to the clinical effectiveness of SMT on pediatric back pain."

Alcantara JD, Alcantara J 2011 **The chiropractic care of infants with colic: A systematic**

**"PURPOSE:**

To perform a systematic review of the literature on the chiropractic care of patients with infantile colic.

**METHODS:**

The following databases were interrogated: MANTIS [1965-2010]; Pubmed [1966-2010]; Index to Chiropractic Literature [1984-2010]; EMBASE [1974-2010]; AMED [1967-2010]; CINAHL [1964-2010]; Alt-Health Watch [1965-2010], and PsychINFO [1965-2010]. Inclusion criteria were manuscripts addressing the chiropractic care of infantile colic published in the English language.

**RESULTS:**

Our systematic review of the literature revealed 26 articles meeting our inclusion criteria. These consisted of three clinical trials, two survey studies, six case reports, two case series, four cohort studies, five commentaries, and four reviews of the literature. Our findings reveal that chiropractic care is a viable alternative to the care of infantile colic and congruent with evidence-based practice, particularly when one considers that medical care options are no better than placebo or have associated adverse events.

**CONCLUSIONS:**

Chiropractic care is an alternative approach to the care of the child with colic. We encourage more research, both quantitative and qualitative, in this area of pediatric care."

Pepino VC, Ribeiro JD, Ribeiro MA, de Noronha M, Mezzacappa MA, Schivinski CI. 2013 **Manual therapy for childhood respiratory disease: a systematic review.** Journal of Manipulative and Physiological Therapeutics Jan;36(1):57-65 <http://www.ncbi.nlm.nih.gov/pubmed/23380215>

"Of the 8 studies included in the present review, 5 consisted of asthmatic children and the others of children with the following conditions: cystic fibrosis, bronchiolitis, recurrent respiratory infections, among others. Only 2 studies did not identify positive results with the use of manual therapy. The other 6 studies found some benefit, specifically in spirometric parameters, immunologic tests, anxiety questionnaire, or level of salivary cortisol."

"The use of manual techniques on children with respiratory diseases seems to be beneficial. Chiropractic, osteopathic medicine, and massage are the most common interventions. The lack of standardized procedures and limited variety of methods used evidenced the need for more studies on the subject."

## Other reviews

Number of studies: 1

Bolin DJ 2010 **The application of osteopathic treatments to pediatric sports injuries.** Pediatr Clin North Am Jun;57(3):775-94 <https://www.ncbi.nlm.nih.gov/pubmed/20538156>

"The application of manual techniques to pediatric athletic injuries has been considered alternative medicine. There are many injuries that are associated with loss of normal motion. Altered biomechanics can be readily identified and treated using manual methods. These include articular or thrust techniques, muscle energy, strain-counterstrain, and myofascial treatments, among others. Although there are few high-quality studies available, most available literature reports effectiveness of manual techniques in combination with therapeutic exercise for common pediatric motion restrictions."

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."

Herzhaft-Le Roy J, Xhignesse M, Gaboury I. 2016 **Efficacy of an Osteopathic Treatment Coupled With Lactation Consultations for Infants' Biomechanical Sucking Difficulties.** J Hum Lact Dec 1:890334416679620 <https://www.ncbi.nlm.nih.gov/pubmed/28027445/>

#### "Abstract

##### BACKGROUND:

Despite well-known recommendations from national and international bodies including the World Health Organization, few mothers achieve the goal of breastfeeding exclusively for 6 months. Half of mothers stop breastfeeding due to biomechanical issues in the first month, despite increasing support from lactation consultants. Osteopaths worldwide work with these babies, but there is little empirical evidence for this type of treatment. Research aim: This study aimed to determine the efficacy of an osteopathic treatment coupled with usual lactation consultations on infants' ability to latch. Secondary objectives included assessment of nipple pain and mothers' perceptions of the effect of treatment.

##### METHODS:

We conducted a single blind, randomized controlled trial at a mother-to-mother support group between January and December 2015. Data were collected at four different times over a 10-day period (T0-T10) from 97 mother-infant dyads using the LATCH assessment tool, a visual analog scale (VAS) to document mothers' nipple pain, and a de novo questionnaire for breastfeeding management and potential treatment side effects.

##### RESULTS:

There were consistent statistical and clinical differences in the mean LATCH scores between the treatment and the control groups ( p < .001). However, no significant differences in the VAS scores were reported over time ( p = .713). Mothers reported no serious or unexpected side effects during the follow-up period.

##### CONCLUSION:

This study is one of the first to bring together lactation consultants and osteopaths to address infants with biomechanical sucking difficulties. Findings support the hypothesis that the addition

of osteopathy to regular lactation consultations is beneficial and safe."

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."

Aarts M, Sterenberg A, Wijnen U 2009 **Migraine in children and adolescents. A randomized control trial** Akademie für Osteopathie (AFO), Deutschland October, 01 [http://www.osteopathic-research.com/index.php?option=com\\_jresearch&view=publication&task=show&id=14078&lang=en](http://www.osteopathic-research.com/index.php?option=com_jresearch&view=publication&task=show&id=14078&lang=en)

**Objective:**

Evaluation of the effectiveness of osteopathic treatment in children and adolescents suffering from migraine.

**Study design:**

Randomized controlled trial including a Follow-up.

**Setting:**

The study was performed by three at the "College Sutherland" qualified osteopaths in their private practices.

**Patients:**

28 children and adolescents suffering from migraine aged between 8 and 15 years (average age  $11.6 \pm 2.2$  years) participate in the study. By means of randomization 13 children were allocated to the intervention group and 15 to the control group. In each group one dropout was recorded.

**Intervention:**

The children of the intervention group received four osteopathic treatments in three-weeks intervals. Six month after treatment initiation a Follow-up was conducted. In both groups continuing medication intake was admitted, completion date of migraine-prophylactic drugs had to be 12 month backdated. The children of the control group stayed untreated otherwise.

**Outcome parameters:**

Frequency, duration and intensity of migraine seizures as primary outcome parameters were recorded by keeping a migraine-diary extended by a visual analogue scale. Secondary parameters were localization of headache/migraine, other discomforts previous or during the migraine, nausea/emesis, vision disorders, sensitivity to light and/or noise and medication intake

collected by the migraine-diary and via specific questionnaires.

Results:

During the 12-week study period the number of migraine-days in the control group was more than twice as much compared to the intervention group (26 days vs. 11 days,  $p=0.07$ ). Over the last acquisition period of the study a statistically significant difference could be detected with 1.5 migraine-days in the intervention group compared to 7.5 in the control group ( $p=0.01$ ). Duration of migraine seizures decreased in the intervention group from 0.8 hours to 0.3 hours and both maximal and average intensity reduced. Long-term results after six months showed an extensive stability of the improvements. The results of the secondary parameters present a lower medication intake in the intervention group (3 days with medication use vs. 11 days in the control group). With reference to the other parameters no conspicuous differences between groups could be observed.

Conclusion:

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."

Shor-Posner G, Miguez M, Hernandez-Reif M, Perez-Then E, Fletcher MA 2004 **Massage treatment in HIV-1 infected Dominican children: a preliminary report on the efficacy of massage therapy to preserve the immune system in children without antiretroviral medication** *Journal of Alternative & Complementary Medicine* Dec;10(6):1093-1095 <https://www.ncbi.nlm.nih.gov/pubmed/15674006>

"Objectives: More than 1.4 million children are living with HIV and global access to antiretrovirals is not yet readily available. Massage therapy, which has been shown to improve immune function in HIV+ adults and adolescents, may provide an important complementary treatment to boost immune status in young children living with HIV disease, especially those without access to antiretroviral medications. No studies have been conducted, however, that specifically target massage therapy to enhance immune function in HIV+ children.

Design: Clinical trial with eligible, consented HIV+ children randomized to receive either massage therapy or a friendly visit (controls).

Settings/Location: CENISMI/Robert Reid Cabral Hospital, Santo Domingo, Dominican Republic.

Subjects: HIV+ children ages 2–8 years.

Intervention: Massage therapy sessions (20 minutes, twice weekly, for 12 weeks), conducted by trained nurses, following a structured protocol of moderate pressure stroking and kneading of muscles, using a nonscented oil. The friendly visit control group, (reading, talking, playing quiet games), met with the nurse twice weekly for 12 weeks.

Outcome Measures: At the initial evaluation, and following the 12-week intervention, blood was drawn to determine absolute helper (CD4/T4) and suppressor (CD8/T8) counts.

Results: Children in the control arm had a greater relative risk of CD4 count decline ( $>20\%$ ) than massagetreated children ( $RR = 5.7, p = 0.03$ ). Lymphocyte loss was also more extensive in the controls ( $p < 0.02$ ), and more of the control group than the massage group lost  $>50$  CD8 lymphocytes ( $p = 0.03$ ).

Conclusions: The efficacy of massage therapy in maintaining immunocompetence may offer a viable alternative to the thousands of children worldwide without antiretroviral access."

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."

Cerritelli F, Pizzolorusso G, Renzetti C, Cozzolino V, D'Orazio M, Lupacchini M, Marinelli B, Accorsi A, Lucci C, Lancellotti J, Ballabio S, Castelli C, Molteni D, Besana R, Tubaldi L, Perri FP, Fusilli P, D'Incecco C, Barlafante G. 2015 **A multicenter, randomized, controlled trial of osteopathic manipulative treatment on preterms.** PLoS One May 14;10(5):e0127370 <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0127370>

"The present multi-center randomized single blind parallel group clinical trial enrolled newborns who met the criteria for gestational age between 29 and 37 weeks, without any congenital complication from 3 different public neonatal intensive care units. Preterm infants were randomly assigned to usual prenatal care (control group) or osteopathic manipulative treatment (study group). The primary outcome was the mean difference in length of hospital stay between groups."

"A total of 695 newborns were randomly assigned to either the study group ( $n = 352$ ) or the control group ( $n = 343$ ). A statistically significant difference was observed between the two groups for the primary outcome (13.8 and 17.5 days for the study and control group respectively,  $p < 0.001$ , effect size: 0.31). Multivariate analysis showed a reduction of the length of stay of 3.9 days (95% CI -5.5 to -2.3,  $p < 0.001$ ). Furthermore, there were significant reductions with treatment as compared to usual care in cost (difference between study and control group: 1,586.01€; 95% CI 1,087.18 to 6,277.28;  $p < 0.001$ ) but not in daily weight gain. There were no complications associated to the intervention."

"Osteopathic treatment reduced significantly the number of days of hospitalization and is cost-effective on a large cohort of preterm infants."

Pizzolorusso G, Cerritelli F, Accorsi A, Lucci C, Tubaldi L, Lancellotti J, Barlafante G, Renzetti C, D'Incecco C, Perri FP 2014 **The Effect of Optimally Timed Osteopathic Manipulative Treatment on Length of Hospital Stay in Moderate and Late Preterm Infants: Results from a**

"Little research has been conducted looking at the effects of osteopathic manipulative treatment (OMT) on preterm infants. Aim of the Study. This study hypothesized that osteopathic care is effective in reducing length of hospital stay and that early OMT produces the most pronounced benefit, compared to moderately early and late OMT. A secondary outcome was to estimate hospital cost savings by the use of OMT. Methods. 110 newborns ranging from 32- to 37-week gestation were randomized to receive either OMT or usual pediatric care. Early, moderately early, and late OMT were defined as <4, <9, and <14 days from birth, respectively. Result. Hospital stay was shorter in infants receiving late OMT (-2.03; 95% CI -3.15, -0.91;  $P < 0.01$ ) than controls. Subgroup analysis of infants receiving early and moderately early OMT resulted in shorter LOS (early OMT: -4.16; -6.05, -2.27;  $P < 0.001$ ; moderately early OMT: -3.12; -4.36, -1.89;  $P < 0.001$ ). Costs analysis showed that OMT significantly produced a net saving of €740 (-1309.54, -170.33;  $P = 0.01$ ) per newborn per LOS. Conclusions. This study shows evidence that the sooner OMT is provided, the shorter their hospital stay is. There is also a positive association of OMT with overall reduction in cost of care."

Steele KM, Carreiro JE, Viola JH, Conte JA, Ridpath LC. 2014 **Effect of osteopathic manipulative treatment on middle ear effusion following acute otitis media in young children: a pilot study.** J Am Osteopath Assoc Jun;114(6):436-47 <http://www.ncbi.nlm.nih.gov/pubmed/24917631>

"Childhood acute otitis media (AOM) is highly prevalent. Its usual sequela of middle ear effusion (MEE) can lead to conductive hearing loss, for which surgery is commonly used."

"Tympanogram data demonstrated a statistically significant improvement in MEE at visit 3 in patients in the SC+OMT group (odds ratio, 2.98; 95% confidence interval, 1.16, 7.62;  $\chi^2$  test for independence,  $P=.02$ ). The AR data analysis showed statistically significant improvement at visit 3 for the SC+OMT group ( $z=2.05$ ;  $P=.02$ ). There was no statistically significant change in MEE before or immediately after the OMT protocol."

"A standardized OMT protocol administered adjunctively with standard care for patients with AOM may result in faster resolution of MEE following AOM than standard treatment alone."

Accorsi A, Lucci C, Di Mattia L, Granchelli C, Barlafante G, Fini F, Pizzolorusso G, Cerritelli F, Pincherle M 2014 **Effect of osteopathic manipulative therapy in the attentive performance of children with attention-deficit/hyperactivity disorder.** J Am Osteopath Assoc May;114(5):374-81 <http://www.ncbi.nlm.nih.gov/pubmed/24778002>

"Children aged 5 to 15 years with a primary diagnosis of ADHD who were admitted to a single neuropsychiatry unit from November 2008 to September 2009 were randomly assigned to an intervention group (OMTh [osteopathic manipulative therapy] + conventional care) or a control group (conventional care only). Biancardi-Stroppa Modified Bell Cancellation Test accuracy and rapidity scores were recorded for both groups at baseline and after 10 weeks. Statistical analyses included univariate tests and multivariate linear regressions."

"Multivariate linear regression showed that OMTh was positively associated with changes in the Biancardi-Stroppa Test accuracy ( $\beta=7.948$  points;  $P=.04$ ) and rapidity ( $\beta=9.089$  points;  $P=.03$ ) scores."

"Participants who received OMTh had greater improvement in Biancardi-Stroppa Test scores than participants who received conventional care only, suggesting that OMTh can potentially increase performances of selective and sustained attention in children with ADHD."

Cerritelli F, Pizzolorusso G, Ciardelli F, La Mola E, Cozzolino V, Renzetti C, D'Incecco C, Fusilli P, Sabatino G, Barlafante G 2013 **Effect of osteopathic manipulative treatment on length of stay in a population of preterm infants: a randomized controlled trial.** BMC Pediatr Apr 26;13:65 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3648440/>

"The term osteopathic manipulative treatment (OMT) currently encompasses more than twenty

types of osteopath-performed manual treatments. The OMT techniques of choice in treating preterm infants are myofascial release, balanced ligamentous/membranous tension, indirect fluidic and v-spread."

"In the present study, 8 osteopathic practitioners were involved and randomly divided in two groups: 4 osteopaths performing the evaluation (group A), and 4 osteopaths performing the evaluation and the treatment (group B). Osteopaths from group A and B entered to the NICU in different hours of the schedule days, to provide blinding and to avoid possible confounding. None of the osteopathic practitioners were involved in the study design, data entry or statistical analysis. In addition all practitioners, except for the treating osteopath, were unaware of patients allocation."

"Results showed a significant association between OMT [osteopathic manipulative therapy] and LOS [length of stay] reduction (mean difference between treated and control group: -5.906; 95% C.I. -7.944, -3.869; p<0.001). OMT was not associated to any change in daily weight gain."

"The present study suggests that OMT may have an important role in the management of preterm infants hospitalization."

Cerritelli F, Pizzolorusso G, Ciardelli F, Mola EL, Renzetti C, Cozzolino V, Barlafante G 2012 **Neonatology-Osteopathy (Ne-O) Study: RCT on the Effect of Osteopathic Manipulative Treatment on Length of Stay** BMC Complement Altern Med 12(Suppl 1): O36 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3373670/>

"Background and Aims The use of osteopathic manipulative treatment (OMT) in preterm infants has been documented and results from previous studies suggest the association between OMT and length of stay (LOS) reduction, as well as significant improvement in several clinical outcomes. The aim of the present study is to show the effect of OMT on LOS in a sample of premature infants.

Methods A double blinded randomized controlled trial was conducted on preterm newborns admitted in a single NICU between 2010–2011. N=51 subjects free of medical complications and with gestational age >28 and < 38 weeks were enrolled and randomized in two groups: study group (N=21) and control group (N=30). All subjects received routine pediatric care and OMT was performed to the study group for the entire period of hospitalization. Endpoints of the study included differences in LOS and daily weight gain.

Results Results showed a significant association between OMT and LOS reduction (mean difference between treated and control group: -1.787; 95% c.i. -3.555, -0.0015; p<0.05). OMT was not associated to any change in daily weight gain.

Conclusions The present study confirms that OMT could play an important role in the management of preterm infants hospitalization."

Mills MV, Henley CE, Barnes LL, Carreiro JE, Degenhardt BF. 2003 **The use of osteopathic manipulative treatment as adjuvant therapy in children with recurrent acute otitis media.** Arch Pediatr Adolesc Med Sep;157(9):861-6. <http://archpedi.jamanetwork.com/article.aspx?articleid=481422>

"The results of this study suggest a potential benefit of osteopathic manipulative treatment as adjuvant therapy in children with recurrent AOM [acute otitis media]; it may prevent or decrease surgical intervention or antibiotic overuse."

"Treatments were gentle techniques on areas of restriction consisting of articulation, myofascial release, balanced membranous tension (according to teachings of William Garner Sutherland, DO, and others<sup>25</sup>), balanced ligamentous tension, facilitated positional release, and/or counterstrain treatments. "

Vandenplan Y, Nenayer E, Vandenbossche T, Vermet L, Hauser B, DeSchepper J, Enelen A 2008 **Osteopathy may decrease obstructive apnea in infants: a pilot study** Osteopathic medicine and primary care 2:8 <http://www.om-pc.com/content/2/1/8>

"Infants presenting with episodes of pallor, that were severe enough to alarm their parents or other caregivers, were submitted to an 8-hour polysomnographic recording measuring heart

rate, respiratory rate and movements, electroencephalogram, oxygen saturation, electromyography, eye movements (Morpheus®, Medatec, Brussels, Belgium). All registrations were read out by one expert (ED). The polysomnographic examination was interpreted according to the criteria of the Belgian National Institute for Insurance and Invalidity (R.I.Z.I.V.), based on published and accepted scientific criteria. These criteria state that an 8-hour polysomnographic recording is abnormal if one of the following criteria is met: (a) more than one central apnea of more than 20 seconds with a desaturation (SaO<sub>2</sub> < 88%); (b) bradycardia of less than 60 beats per minute; (c) more than 3 obstructive apneas lasting more than 3 seconds" "The results of the second polysomnographic recordings showed a significant decrease in the number of obstructive apneas in the osteopathy group (P=0.01, Wilcoxon test), in comparison to the control group showing one a trend suggesting a gradual physiologic decrease of obstructive apneas. However, the difference in the decline of obstructive apneas between the groups after treatment was not significant (p=0.43)."

Duncan B, McDonough-Means S, Worden K, Schnyer R, Andrews J, Meaney FJ. 2008 **Effectiveness of osteopathy in the cranial field and myofascial release versus acupuncture as complementary treatment for children with spastic cerebral palsy: a pilot study.** J Am Osteopath Assoc Oct;108(10):559-70. <http://www.ncbi.nlm.nih.gov/pubmed/18948639>

"Fifty-five patients were included in the study. Individual analyses of the 11 outcome variables revealed statistically significant improvement in two mobility measures for patients who received OMT--the total score of Gross Motor Function Measurement and the mobility domain of Functional Independence Measure for Children (P<.05). No statistically significant improvements were seen among patients in the acupuncture treatment arm."

Nemett D.R., Fivush B.A., Mathews R., Camirand N., Eldridge M.A., Finney K., Gerson A.C 2008 **A randomized controlled trial of the effectiveness of osteopathy-based manual physical therapy in treating pediatric dysfunctional voiding** J. Pediatr. Urol 4: pp. 100-106 <http://www.sciencedirect.com/science/article/pii/S1477513107004676>

"Pediatric dysfunctional voiding (DV) presents physical and emotional challenges as well as risk of progression to renal disease. Manual physical therapy and osteopathic treatment have been successfully used to treat DV in adult women; a pediatric trial of manual physical therapy based on an osteopathic approach (MPT-OA) has not been reported. The aim of this study was to determine whether MPT-OA added to standard treatment (ST) improves DV more effectively than ST alone."

"The treatment group exhibited greater improvement in DV symptoms than did the control group (Z = -2.63, p = 0.008, Mann-Whitney U-test). Improved or resolution of vesicoureteral reflux and elimination of post-void urine residuals were more prominent in the treatment group."

"Results suggest that MPT-OA treatment can improve short-term outcomes in children with DV, beyond improvements observed with standard treatments, and is well liked by children and parents."

Monaco A, Cozzolino V, Cattaneo R, Cutilli T, Spadaro A 2008 **Osteopathic manipulative treatment (OMT) effects on mandibular kinetics: kinesiographic study.** Eur J Paediatr Dent Mar;9(1):37-42 <http://www.ncbi.nlm.nih.gov/pubmed/18380529>

"The study was conducted on 28 children with non-specific TMD [temporo-mandibular dysfunction] symptoms, limited mouth opening, history of trauma (delivery trauma, accident trauma). Patients were randomly divided into two groups: an OMT group (study group) and a no-intervention group (control group). All subjects underwent a first kinesiographic recording to evaluate the amplitude and velocity of maximal opening-closing movements. Study group patients underwent a second kinesiographic recording 2 months after OMT. Control group patients were submitted to a control kinesiographic recording six months after the first one. Kinesiographic tracings were acquired using the K7I system."

"The kinesiographic data of the study group showed a moderate statistically significant difference (p<.07) of maximal mouth opening (MO) parameter and a high statistically significant

difference ( $p < .03$ ) of maximal mouth opening velocity (MOV) parameter. No statistically significant difference (null hypothesis confirmed) of kinesiographic parameters in the control group was observed."

"The results of this study suggest that OMT can induce changes in the stomatognathic dynamics, offering a valid support in the clinical approach to TMD."

Philippi H, Faldum A, Schleupen A, Pabst B, Jung T, Bergmann H, Bieber I, Kaemmerer C, Dijs P, Reitter B 2006 **Infantile postural asymmetry and osteopathic treatment: a randomized therapeutic trial**. *Dev Med Child Neurol* Jan;48(1):5-9; discussion 4 <http://www.ncbi.nlm.nih.gov/pubmed/16359587>

"The aim of this study was to assess the therapeutic efficacy of osteopathic treatment in infants with postural asymmetry. A randomized clinical trial of efficacy with blinded videoscoring was performed. Sixty-one infants with postural asymmetry aged 6 to 12 weeks (mean 9wks) were recruited. Thirty-two infants (18 males, 14 females) with a gestational age of at least 36 weeks were found to be eligible and randomly assigned to the intervention groups, 16 receiving osteopathic treatment and 16 sham therapy. After a treatment period of 4 weeks the outcome was measured using a standardized scale (4-24 points). With sham therapy, five infants improved (at least 3 points), eight infants were unchanged (within 3 points), and three infants deteriorated (not more than -3 points); the mean improvement was 1.2 points (SD 3.5). In the osteopathic group, 13 infants improved and three remained unchanged; the mean improvement was 5.9 points (SD 3.8). The difference was significant ( $p=0.001$ ). We conclude that osteopathic treatment in the first months of life improves the degree of asymmetry in infants with postural asymmetry."

"At each visit the osteopathic technique, and the area it was applied to, was adapted depending on the diagnostic palpation of the osteopath who assessed and treated position, tissue quality, mobility, and relation to the environment of the skull, sacrum, iliac and coccygeal bones, thorax, sternum, diaphragm, and abdomen. The specific procedures were recorded by the osteopath. For instance, so-called primary respiration and the cranial rhythmic impulse, thought to be very fine autonomous rhythmic changes of tissue quality, were used to disengage fixations of adjoining structures"

Guiney PA, Chou R, Vianna A, Lovenheim J 2005 **Effects of osteopathic manipulative treatment on pediatric patients with asthma: a randomized controlled trial**. *J Am Osteopath Assoc* Jan;105(1):7-12 <http://www.ncbi.nlm.nih.gov/pubmed/15710659>

"Osteopathic manipulative treatment (OMT) is an underutilized noninvasive treatment method for patients with asthma. The use of OMT may help decrease mortality and morbidity rates among this patient group. The authors conducted a randomized controlled trial attempting to demonstrate the therapeutic relevance of OMT in the pediatric asthma population. With a confidence level of 95%, results for the OMT group showed a statistically significant improvement of 7 L per minute to 9 L per minute for peak expiratory flow rates. These results suggest that OMT has a therapeutic effect among this patient population"

## Case controlled studies

Number of studies: 1

Kelmanson IA, Adulas EI 2006 **Massage therapy and sleep behaviour in infants born with low birth weight.** *Complementary Therapies in Clinical Practice* Aug;12(3):200-5 <http://www.ncbi.nlm.nih.gov/pubmed/16835031>

"Babies in the experimental group were assigned massage intervention therapy that include gentle rubbing, stroking, passive movements of the limbs and other means of kinaesthetic stimulation performed by professionals until the infant is 8 months old. The findings suggest that 8-month-old LBW infants who received massage intervention were less likely to snore during sleep, required less feeding on waking-up at night, and appeared more alert during the day. These apparent correlations remained significant after adjustment was made for major potential confounders."

## Other controlled clinical trials

Number of studies: 6

von Stülpnagel C, Reilich P, Straube A, Schäfer J, Blaschek A, Lee SH, Müller-Felber W, Henschel V, Mansmann U, Heinen F 2009 **Myofascial trigger points in children with tension-type headache: a new diagnostic and therapeutic option.** *J Child Neurol* Apr;24(4):406-9 <https://www.ncbi.nlm.nih.gov/pubmed/19339283>

**There was no independent control group in this study**

The goal of this pilot study was to evaluate the effect of a trigger point-specific physiotherapy on headache frequency, intensity, and duration in children with episodic or chronic tension-type headache. Patients were recruited from the special headache outpatient clinic. A total of 9 girls (mean age 13.1 years; range, 5-15 years) with the diagnosis of tension-type headache participated in the pilot study from May to September 2006 and received trigger point-specific physiotherapy twice a week by a trained physiotherapist. After an average number of 6.5 therapeutic sessions, the headache frequency had been reduced by 67.7%, intensity by 74.3%, and duration by 77.3%. No side effects were noted during the treatment. These preliminary findings suggest a role for active trigger points in children with tension-type headache. Trigger point-specific physiotherapy seems to be an effective therapy in these children. Further prospective and controlled studies in a larger cohort are warranted.

Philippi H, Bauer K, Jung T, Bergmann H, Müller S, Thomann P, Groß D 2016 **Effect of early intervention on infantile postural asymmetry: a prospective 2 years follow-up** *Neuropediatrics* Issue 01 <https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-2006-973981>

"The prognosis of infantile postural asymmetry (IPA) is currently unclear. This leads to a substantial uncertainty about the indication of early intervention. During a prospective 2 years follow-up the effect of early intervention on IPA was investigated using a video based scoring. Methods: Thirty-nine infants (18 male) with IPA were examined for their postural asymmetry at the age of 3 months, 1 and 2 years. At age 1 and 2 years cervical rotation deficit, cervical lateral flexion and trunk convexity in the sitting position as well as trunk convexity while crawling were videotaped and scored on a 5-points scale for each item by 5 independent and blinded observers. At the age of 3 months the asymmetry was documented using a 24 points scale [1] and the results were transformed to the 20 points scale for older children. During the 2 years the parents chose the treatment of their children independently. Results: Thirty-one of the basal videos, 33 videos at 1 year of age and 34 videos at 2 years of age could be analysed. During the first/second year 10/20 infants received no treatment (nt), 4/2 infants received physiotherapy (pt), 14/9 infants received osteopathy (o) and 5/2 infants received osteopathy plus physiotherapy. Only 13 children stayed on the same treatment during both years (nt n=5, pt n=2, o n=6). The postural asymmetry showed the following mean (range)

changes on a 20-points scale: Group nt first year: -0.22 (-6.25 to +3.75), second year: -0.38 (-5.75 to +4). Group pt first year: +0.08 (-2.25 to +2), second year -1.37 (-2.25 to -0.5). Group o first year +2.0 (-2.5 to +6.5), second year +1.7 (-2.25 to +4.75). Group o plus pt first year +5.15 (2.75 to +7), second year +4.25 (+1.25 to +7.25).

Conclusions: The results indicate that on average the IPA does not disappear in untreated children and may deteriorate severely in a single case and a combined therapy consisting of physiotherapy and osteopathy seems to be the most effective intervention."

Pizzolorusso G, Turi P, Barlafante G, Cerritelli F, Renzetti C, Cozzolino V, D'Orazio M, Fusilli P, Carcini F, D'Incecco C 2011 **Effect of osteopathic manipulative treatment on gastrointestinal function and length of stay of preterm infants: an exploratory study** *Chiropractic and Manual Therapies* 19:15 <https://www.ncbi.nlm.nih.gov/pubmed/21711535>

"Osteopaths performing OMT [osteopathic manipulative treatment] were trained to use only indirect and fluidic techniques which included: indirect myofascial, sutural spread, balanced membranous tension and balanced ligamentous tension (according to teachings of William Garner Sutherland, DO, and others)."

"The study suggests that osteopathic treatment may reduce a high occurrence of gastrointestinal symptoms and the rates of long-term stays."

Castellarina IB, Drysdale I, Patel V 2013 **Evaluation of behavioural and gastrointestinal symptoms in autistic children after visceral osteopathic treatment** *International Journal of Osteopathic Medicine* Volume 16, Issue 1, March, Pages e13–e14 <http://www.sciencedirect.com/science/article/pii/S1746068913000096>

"Autism or Autistic Spectrum Disorder (ASD) is a Pervasive Developmental Disorder (PDD) with abnormal or impaired development in reciprocal social interaction, abnormal or impaired social communication and social imagination. Recent theories focused on the possibility of autism being linked with gastrointestinal (GI) abnormalities. Moreover, the problem behaviour typical of autism might be linked to the underlying medical symptoms such as abdominal pain, diarrhoea, and bloating typical of GI dysfunction."

"The study utilised VOT [visceral osteopathic technique] on 49 autistic children aged 3–8 yrs to investigate possible effects of the techniques. The children in the study were suffering from gastrointestinal symptoms and presented with impaired social relationship and communication, but were otherwise healthy. VOT was applied to the abdomen (duodenum, ileo-caecal valve, sigmoid and pancreas areas) and gastrointestinal and behavioural changes were measured after 6 osteopathic treatment sessions, once a week for six weeks. Each intervention session was for thirty minutes. The evaluation of the study was accessed via 8 questionnaires given to the parents who were asked to grade the child's response following the VOT intervention e.g. frequency of bowel movement, appetite eye contact and other parameters. "

"Statistical analysis indicated improvement in the gastrointestinal symptom of vomiting ( $p = 0.00029$ ) and in the parameter of poor appetite ( $p = 0.039$ ) after application of VOT. The subjects also had a significant improvement in eye contact ( $p = 0.035$ ) one of the most characteristic social behavioural symptoms of autistic patients."

"The experimental hypothesis has been supported indicating a positive effect of VOT on the measured symptoms and behavioural patterns of Autistic children. This data indicates that the use of VOT on GI function may be of benefit to autistic children."

Lessard S, Gagnon I, Trottier N. 2011 **Exploring the impact of osteopathic treatment on cranial asymmetries associated with nonsynostotic plagiocephaly in infants.** *Complementary Therapies in Clinical Practice* Nov;17(4):193-8 <http://www.percorsiagrate.com/wp-content/uploads/2014/06/plagiocefalia.pdf>

### **This was a time-series study without an independent control**

"Objectives: To document the evolution of cranial asymmetries in infants with signs of nonsynostotic occipital plagiocephaly (NSOP) who were to undergo a course of four osteopathic treatments (in addition to the standard positioning recommendations) as well as to determine

the feasibility of using this methodology to conduct a randomized clinical trial investigating the impact of osteopathic intervention for infants with NSOP.

Design: Pilot clinical standardization project using pre-post design in which 12 infants participated. Ten infants presented an initial Oblique Diameter Difference Index (ODDI) over 104% and five of them had an initial moderate to severe Cranial Vault Asymmetry (CVA) (over 12 mm).

Interventions: Infants received four osteopathic treatments at 2-week intervals.

Main outcome measures: Anthropometric, plagiocephalometric as well as qualitative measures were administered pre-intervention (T1), during the third treatment (T2) and two weeks after the fourth treatment (T3).

Results: Participants showed a significant decrease in CVA ( $p \leq 0.02$ ), Skull Base Asymmetry (SBA) ( $p \leq 0.01$ ), Trans-Cranial Vault Asymmetry (TCVA) ( $p < 0.003$ ) between the first and third evaluations.

Conclusions: These clinical findings support the hypothesis that osteopathic treatments contribute to the improvement of cranial asymmetries in infants younger than 6.5 months old presenting with NSOP characteristics."

Tarsuslu T, Bol H, Şimşek IE, Toylan IE, Çam S, 2009 **The Effects of Osteopathic Treatment on Constipation in Children With Cerebral Palsy: A Pilot Study** Journal of Manipulative and Physiological Therapeutics Volume 32, Issue 8, October , Pages 648–653 <http://www.sciencedirect.com/science/article/pii/S0161475409002000>

**Osteopathic manipulative treatment was included with both groups studied. (One group had other medical treatment). There was no control used in this study that did not include osteopathic treatment.**

"This study included 13 children with cerebral palsy diagnosed as having chronic constipation by a gastroenterologist. The subjects were separated into 2 groups. Group 1 was treated with osteopathic methods and group 2 underwent both medical and exactly the same osteopathic treatments of group 1."

"Osteopathic treatments included fascial release, iliopsoas muscle release, sphincter release, and bowel mobilizations."

"The satisfaction of the subjects or the families with the treatments was not different when the groups were compared ( $P > .05$ ). Constipation Assessment Scale scores decreased significantly in both groups ( $P < .05$ ). Pretreatment (initial evaluation) and posttreatment (follow-ups at 3 and 6 months) results revealed no difference between the groups in either aspects ( $P > .05$ ). However, both groups showed significant improvements compared with baseline evaluations ( $P < .05$ )."

"Osteopathic methods were as effective as osteopathic methods in addition to medical care for both treatment groups. The results of this study suggest that osteopathic methods may be helpful as an alternative treatment in constipation. "

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  $\chi^2$  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."

Harrison RE, Page JS 2011 **Multipractitioner Upledger CranioSacral Therapy: descriptive outcome study 2007-2008.** The Journal of Alternative and Complementary Medicine Jan;17(1):13-7 <http://www.ncbi.nlm.nih.gov/pubmed/21214395>

"Outcome by diagnostic groups suggested that UCST [Upledger craniosacral therapy] is particularly effective for patients with headaches and migraine, neck and back pain, anxiety and depression, and unsettled babies. Seventy percent (70%) of patients on medication decreased or discontinued it, and patients' average general practitioner consultation rate fell by 60% in the 6 months following treatment."

"Patients' ages ranged from neonates to 68 years. Seventy-four percent (74%) of patients reported a valuable improvement in their presenting problem. Sixty-seven percent (67%) also reported a valuable improvement in their general well-being and/or a second health problem. Outcome by diagnostic groups suggested that UCST is particularly effective for patients with headaches and migraine, neck and back pain, anxiety and depression, and unsettled babies."

Hayes NM, Bezilla TA. 2006 **Incidence of iatrogenesis associated with osteopathic manipulative treatment of pediatric patients.** J Am Osteopath Assoc Oct;106(10):605-8 <http://www.ncbi.nlm.nih.gov/pubmed/17122030>

"To determine the incidence of iatrogenesis (ie, aggravations and complications) derived from OMT [osteopathic manipulative therapy] in the pediatric patient population."

"A retrospective review of medical records was conducted looking for documentation of aggravations or complications subsequent to OMT. Treatment-associated aggravations were defined as worsening of symptoms or complaints after treatment. Treatment complications were defined as cerebrovascular accidents, dislocation, fracture, pneumothorax, sprains and strains, or death as a treatment outcome. The authors documented all occurrences of treatment-associated aggravations or complications recorded at each office visit, as well as the timing of an aggravation between office visits."

"502 pediatric patients' medical records reviewed"

"No treatment-associated complications were documented. Thirty-one (9%) patients had documented treatment-associated aggravations."

"Osteopathic manipulative treatment appears to be a safe treatment modality in the pediatric population when administered by physicians with expertise in OMT. Future studies should be prospective and include larger numbers of patients to document the safety of OMT in this clinical application."

Degenhardt BF, Kuchera ML. 2006 **Osteopathic evaluation and manipulative treatment in reducing the morbidity of otitis media: a pilot study.** J Am Osteopath Assoc Jun;106(6):327-34 <http://www.ncbi.nlm.nih.gov/pubmed/16790538>

**This was a time-series study, with no independent control**

"Pilot cohort study with 1-year posttreatment follow-up. At follow-up, subjects' parents or legal guardians and their referring and/or family physicians were contacted to determine recurrence of otitis media since intervention."

"Five (62.5%) subjects had no recurrence of symptoms. Of the three remaining subjects in this cohort, one had a bulging tympanic membrane, another had four episodes of otitis media, and the last underwent surgery after recurrence at 6 weeks posttreatment. Closer analysis of the posttreatment course of the last two subjects indicates that there may have been a clinically significant decrease in morbidity for a period of time after intervention."

"The present study indicates that osteopathic manipulative treatment may change the progression of recurrent otitis media."

Frymann VM, Carney RE, Springall P. 1992 **Effect of osteopathic medical management on neurologic development in children.** J Am Osteopath Assoc Jun;92(6):729-44 <http://www.ncbi.nlm.nih.gov/pubmed/1377192>

"For 3 years, children between 18 months and 12 years of age with and without recognized neurologic deficits were studied at the Osteopathic Center for Children. Their response to 6 to 12 osteopathic manipulative treatments directed to all areas of impaired inherent physiologic motion was estimated from changes in three sensory and three motor areas of performance."

Houle's Profile of Development was used to compare neurologic with chronologic age and rate of development, and scores were age-adjusted. Results in children after treatment were compared with those following a waiting period without treatment. Neurologic performance significantly improved after treatment in children with diagnosed neurologic problems and to a lesser degree in children with medical or structural diagnoses. The advances in neurologic development continued over a several months' interval. The results support the use of osteopathic manipulative treatment as part of pediatric healthcare based on osteopathic medical philosophy and principles."

## Case series

Number of studies: 2

Gemelli M, Ulbricht L, Romaneli EFR 2014 **Evaluation of gastroesophageal reflux in infants treated with osteopathy using the I-GERQ-R questionnaire** IFMBE Proceedings 41, pp. 1067-1070 [http://link.springer.com/chapter/10.1007/978-3-319-00846-2\\_264](http://link.springer.com/chapter/10.1007/978-3-319-00846-2_264)

"This is a retrospective pilot study of a database where four clinical files of individuals diagnosed with GERD [gastro esophageal reflux disease] in clinical treatment were analyzed. The data used for analysis were taken from questionnaire I-GERQ-R starting and ending at the osteopathic treatment. It was observed that in  $28 \pm 5.72$  days scores fell from an average of  $15.5 \pm 4.45$  to  $0.50 \pm 0.50$ , determining reduction of all symptoms of reflux. A child presenting respiratory disorders has presented total relief of symptoms. Osteopathy has been effective to eliminate reflux symptoms"

Fraval M 1998 **A pilot study: Osteopathic treatment of infants with a sucking dysfunction** Journal of the American Academy of Osteopathy [http://www.osteopathic-research.com/index.php?option=com\\_jresearch&view=publication&task=show&id=12345&lang=en](http://www.osteopathic-research.com/index.php?option=com_jresearch&view=publication&task=show&id=12345&lang=en)

**This was a time-series study without independent controls**

"A pilot study of six infants".

"At the time of first measurement, the difference between pre- and post fed fat estimations of breast milk was small in infants with a dysfunctional suck. Following osteopathic treatment, the difference between pre- and post fed fat estimations were comparable with the fat estimations from the breast milk of infants who were feeding normally."

## Case reports

Number of studies: 4

Apoznanski TE, Abu-Sbaih R, Terzella MJ, Yao S 2015 **Resolution of dacryostenosis after osteopathic manipulative treatment.** J Am Osteopath Assoc Feb;115(2):110-4 <http://www.ncbi.nlm.nih.gov/pubmed/25637617>

"Dacryostenosis is an obstruction of the nasolacrimal duct and is the most common cause of epiphora and ocular discharge in newborns. Whereas most cases resolve spontaneously, invasive treatment may become necessary if symptoms persist past age 6 to 12 months. In the present case, a 9-month-old boy with persistent dacryostenosis was scheduled for lacrimal duct probing after first-line treatments failed. After a single session of osteopathic manipulative treatment, the patient's epiphora and other symptoms resolved, and he no longer needed surgical probing. A review of the literature highlights key pathophysiologic processes, management options, and musculoskeletal aspects of dacryostenosis. Physicians should consider osteopathic manipulative treatment in the management of dacryostenosis."

Andreoli E, Troiani A, Tucci V, Barlafante G, Cerritelli F, Pizzolorusso G, Renzetti C, Vanni D, Pantalone A, Salini V. 2014 **Osteopathic manipulative treatment of congenital talipes equinovarus: a case report.** Journal of Bodywork and Movement Therapies Jan;18(1):4-10 <http://>

"The aim of this paper is to present a case report of bilateral congenital talipes equinovarus treated with two short-leg serial casting in combination with osteopathic manipulative treatment."  
"A newborn, 12 days old, with severe bilateral congenital talipes equinovarus entered to the Department of Orthopedics at the University of Chieti, Italy. The pediatric orthopedic surgeon applied two single series of short-leg casts, at 12 and 20 days of age. The osteopath scheduled 4 indirect myofascial release techniques sessions."  
"At day 33 the newborn achieved a complete correction of the congenital talipes equinovarus deformity and there was no need to apply a third series of casts."

Lund GC, Edwards G, Medlin B, Keller D, Beck B, Carreiro JE. 2011 **Osteopathic manipulative treatment for the treatment of hospitalized premature infants with nipple feeding dysfunction.** J Am Osteopath Assoc Jan;111(1):44-8 <http://www.ncbi.nlm.nih.gov/pubmed/21258016>

"Premature newborns and infants are usually required to successfully transition from gavage to nipple feeding using breast or bottle before discharge from the hospital. This transition is frequently the last discharge skill attained. Delayed acquisition of this skill may substantially prolong hospital length of stay. The authors describe a case of hospitalized premature twins who had considerable delays in attaining nipple-feeding skills. Because of their inability to take all feedings by nipple, preparation for surgical placement of gastrostomy tubes was initiated. Before the surgeries were scheduled, the inpatient osteopathic manipulative medicine service was consulted, and the twins received a series of evaluations and osteopathic manipulative treatment (OMT) sessions. During the OMT course, the twins' nipple feeding skills progressed to full oral feeding, which allowed them to be discharged to home without placement of gastrostomy tubes. The authors also review the literature and discuss the development of nipple feeding in premature newborns and infants and the use of OMT in the management of nipple feeding dysfunction."

Khraim N 1999 **Osteopathic treatment of an infant with a failure to suck** Australian Journal of Osteopathy 10:1 15-16

"The predominant complain was inability to suck either at breast or bottle."  
"The baby was being fed with a nasogastric tube."  
"Osteopathic treatment addressing the cranial and extracranial structures, with particular emphasis on the condylar and sacroiliac compressions, was carried out."  
"Immediately following second treatment, he sucked 60ml of formula on his own. The amounts sucked progressed erratically after that next week."  
"By that time, Baby X was almost 8 weeks old. He presented on this occasion without the nasogastric tube,"  
"At five months of age... he is continuing to thrive. Developmental milestones were age appropriate. Solids were gradually introduced at approximately four months of age."

**Mixed results (significant for some outcomes, not others)**

Number  
of studies:  
2

## Randomised controlled trials

Number of studies: 2

Wahl RA, Aldous MB, Worden KA, Grant KL 2008 **Echinacea purpurea and osteopathic manipulative treatment in children with recurrent otitis media: a randomized controlled trial**. *BMC Complement Altern Med* Oct 2;8:56 <http://www.ncbi.nlm.nih.gov/pubmed>

"Children aged 12–60 months with recurrent otitis media"

"All children were scheduled for osteopathic sessions as soon as possible after entry, then 2, 4, 8, and 12 weeks later. "

"The first group received placebo extract orally and sham manipulation. The second group received Echinacea purpurea extract and sham manipulation. The third group received placebo extract and true OMT. The last group received Echinacea purpurea extract and true OMT. "

"In the same population of children, a preventive regimen of from one to five osteopathic manipulative treatments over three months did not significantly decrease their risk of acute otitis media."

Wyatt K, Edwards V, Franck L, Britten N, Creanor S, Maddick A, Logan S. 2011 **Cranial osteopathy for children with cerebral palsy: a randomised controlled trial**. *Archives of Disease in Childhood* Jun;96(6):505-12 <http://adc.bmj.com/content/early/2011/02/23/adc.2010.199877.abstract>

"Compared with children in the control group, carers of children receiving cranial osteopathy were nearly twice as likely to report that their child's global health had 'improved' at 6 months rather than 'decreased' or 'remained the same' (38% vs 18%; odds ratio 2.8, 95% CI 1.1 to 6.9)"

"This trial found no statistically significant evidence that cranial osteopathy leads to sustained improvement in motor function, pain, sleep or quality of life in children aged 5-12 years with cerebral palsy"

## No clinically and/or statistically significant results

Number  
of studies:  
2

# Systematic reviews

Number of studies: 1

Posadzki P, Lee MS, Ernst E 2013 **Osteopathic manipulative treatment for pediatric conditions: a systematic review.** *Pediatrics* Jul;132(1):140-52 <http://pediatrics.aappublications.org/content/132/1/140.long>

**This study missed at least four randomised control trials which had been published at the time it came out, and which met it's selection criteria, then criticised the paucity of research.**

## "BACKGROUND AND OBJECTIVES:

Most osteopaths are trained in pediatric care, and osteopathic manipulative treatment (OMT) is available for many pediatric conditions. The objective of this systematic review was to critically evaluate the effectiveness of OMT as a treatment of pediatric conditions.

## METHODS:

Eleven databases were searched from their respective inceptions to November 2012. Only randomized clinical trials (RCTs) were included, if they tested OMT against any type of control in pediatric patients. Study quality was critically appraised by using the Cochrane criteria.

## RESULTS:

Seventeen trials met the inclusion criteria. Five RCTs were of high methodological quality. Of those, 1 favored OMT, whereas 4 revealed no effect compared with various control interventions. Replications by independent researchers were available for 2 conditions only, and both failed to confirm the findings of the previous studies. Seven RCTs suggested that OMT leads to a significantly greater reduction in the symptoms of asthma, congenital nasolacrimal duct obstruction (posttreatment), daily weight gain and length of hospital stay, dysfunctional voiding, infantile colic, otitis media, or postural asymmetry compared with various control interventions. Seven RCTs indicated that OMT had no effect on the symptoms of asthma, cerebral palsy, idiopathic scoliosis, obstructive apnea, otitis media, or temporomandibular disorders compared with various control interventions. Three RCTs did not perform between-group comparisons. The majority of the included RCTs did not report the incidence rates of adverse effects.

## CONCLUSIONS:

The evidence of the effectiveness of OMT for pediatric conditions remains unproven due to the paucity and low methodological quality of the primary studies."

# 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."

# It is unclear whether the following journals are peer-reviewed

Number of studies: 1

## Clinically and statistically significant results

Number of studies: 1

### Case reports

Number of studies: 1

Albones E, Gosling C, Cornall D 2005 **The Short and Intermediate Term Effect of Rib Raising on Lung Function on a Child with Asthma: A Comparison Case Study** Osteopathic Medicine, School of Health Sciences, Victoria University, Melbourne (unpublished thesis) [http://vuir.vu.edu.au/740/1/Albones\\_et.al\\_2005.pdf](http://vuir.vu.edu.au/740/1/Albones_et.al_2005.pdf)

**This was a very limited study with only two subjects. At the same time, it did include a control (one of the subjects). It is not published in a peer-reviewed journal.**

"Objective: The aim of this study was to determine whether the use of a specific manual therapy technique, rib raising, could produce short and intermediate term improvements in the lung function in children with chronic asthma.

Clinical Features: A comparative single case study was carried out between two asthmatic children aged 16-17, both with a long history of mild asthma requiring the use of ventolin up to five times a week.

Intervention: One received the rib raising technique and the other a sham technique. Pre and post treatment FEV1 and FVC were recorded for both participants over the short and intermediate term.

Outcomes: The rib raising participant showed, in the short term (20 minutes post treatment), up to a 13.81% increase in FVC and up to an 18.37% increase in FEV1 compared to the sham technique of 3.48% and 8.28%, respectively. In the intermediate term (one week post treatment) the rib raising improved FVC by 10.49% and FEV1 by 24.90%, while the sham yielded FVC improvements of 0.87% and FEV1 of 5.73%. Overall FEV1/FVC increased by 8% in the rib raising compared to only 3% in the sham technique.

Conclusions: These results demonstrate that rib raising produce an increase in the lung function of an asthmatic child in the short and intermediate term.