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## Article being reviewed

Holm LV, Jarbøl DE, Christensen HW, Søndergaard J, Hestbæk L. The effect of chiropractic care on infantile colic: Results from a single-blind randomised controlled trial. *Chiropractic & Manual Therapies*. 2021;29(1). <u>doi:10.1186/</u> <u>s12998-021-00371-8</u>.

# **Study Objective**

Review the outcomes of a single-blind RCT of chiropractic care for the treatment of colic and provide additional clinical considerations.

# Study Design

Single-blind, randomized study performed at four Danish chiropractic clinics.

## **Study Participants**

200 children were recruited, of which 185 participated in the study trial. 96 patients were randomized to the treatment group and 89 were randomized to the control arm. Children were 2 to 14 weeks of age with colic. Colic was defined as having excessive crying or fussiness for at least three hours a day for three or more days a week during the previous two weeks, in an otherwise healthy child with normal weight gain. Randomization (1:1) into the control or treatment group was directed by computer-generated allocations, stratified by age at enrollment (2-6 weeks, 7-10 weeks, or 11-14 weeks) and the treating chiropractor. Children were excluded if they had previously received chiropractic care. No ancillary treatment for colic was permitted during the study.

#### **Study Parameters Assessed**

Children participating in the treatment cohort of the study, received chiropractic care twice a week for two weeks, for a duration of five minutes per session. If they were in the control arm of the study, they were entertained for a comparable duration without receiving care. Parents kept 24-hour diaries (divided into 15-minute increments) during the two-week study to assess their child's behavior. They tracked the frequency of inconsolable crying, time the child needed to be held or rocked to limit crying, the time the child was awake and content, time spent sleeping, feeding patterns, and bowel movements. Parents were asked to record in their 24-hour diary for one to four more days after the fourth chiropractic visit, in addition to completing a final questionnaire.

# **Primary Outcome Measures**

The primary outcome was the change in the duration of crying, with a reduction of at least one hour a day being considered clinically significant. Secondary outcomes were sleep duration, hours spent awake and content, number of bowel movements, burps, hiccups, regurgitation, satisfaction of participation in care, and status of colic.

# **Key Findings**

The treatment group experienced an average reduction of crying by one and one-half hours, while the control group experienced a reduction by only one hour, with the change in hours of crying ranging from -8.5 to +3.5 hours. Improvement of one or more hours in crying was achieved in 63% in the treatment group and 47% in the control group. The difference between the two groups was not statistically significant when adjusted for the baseline hours of crying, age, and chiropractic clinic. Secondary outcomes were insignificantly better in the treatment group for hours of sleep and time awake and content, with no difference between groups in colic status, satisfaction, and GI symptoms. More than 90% of parents were satisfied with participation.

#### Practice Implications and Discussion

In the ever-evolving landscape of understanding colic in infants, significant dialogue has turned to the impact chiropractic care has on this presentation. Pediatric chiropractic care is a growing specialization within the chiropractic profession with a multitude of accredited institutions and private organizations providing education and post-graduate training. A survey of the profession indicated that, on average, 17% of chiropractic patients were under 17 years of age, while pediatric-trained chiropractors had 38.7% of their patient base in the same age demographic.<sup>1</sup> Clearly, parents are seeking chiropractic care for infants and are becoming more informed about the impact care has on pediatric health issues, inclusive of colic. From a clinical awareness perspective, the dialogue must shift toward effectiveness of chiropractic care for those with colic and consider other clinical or lifestyle factors that may impact its efficacy.

The investigators in this study looked to establish if chiropractic care was effective in cases of infantile colic and were guided by several previous studies suggesting that it was.<sup>2-8</sup> They emphasized that, unlike previous studies, this study was unique with a well-powered design that included both parental blinding and a larger cohort.

With the treatment arm of this randomized clinical trial seeing a reduction of colic-related crying by an average of one and one-half hours juxtaposed with the control arm seeing a one hour reduction, the study suggested there was a small positive effect of chiropractic care on infantile colic, but the clinical significance was debatable because it was not statistically significant. It is important to note that the study also concluded that while the mean difference between the groups was small, large individual differences were noted which contributed to investigating subgroups of children. This highlighted an opportunity for further discussion.

While not clearly stated in the original study, statements made by the authors in the conclusion open the clinical discussion and consideration of various factors that could impact efficacy. One of the most critical areas of discussion is the method of intervention, specifically, how the biomechanical dysfunction was analyzed. The study focused on musculoskeletal methodology inclusive of visible and palpable asymmetries, motion restriction, and areas of tenderness. Given the current understanding of the vertebral subluxation complex being inclusive of a neuropathology, no clear assessment was utilized in obtaining a neurological manifestation of biomechanical dysfunction.9 This could involve a variety of dermal thermographic findings, and/ or sudoriferous changes in the skin. While the attention given to the musculoskeletal component of biomechanical dysfunction is noteworthy, a more thorough analysis, inclusive of a functional neurological finding could certainly impact efficacy.<sup>10</sup> Lending support to this position is the use of an objective measure such as heart rate variability, which has demonstrated that there can be significant improvements in visceral neurologic function, an indirect measure of autonomic nervous system function, with the use of manipulative therapies.<sup>11</sup> Clinical practitioners will posit that their improved patient outcomes are proof of this concept and that neurologically informed procedures, as part of an analysis, need to be given consideration.

A second area of discussion in the study, that could certainly impact efficacy, is the singularity of adjusting technique utilized. "Very light short term-pressure with fingertips" was certainly an acceptable approach to chiropractic care, however, the reviewing authors agree that it comes with its limitations. This is especially true if the motion dysfunction of the subluxation is remarkable and leads to a significant fixation and resulting joint misalignment. Approaches such as cranial/dural, instrument assisted, drop-mechanism, and pediatric modified high velocity low amplitude adjusting are also safely utilized techniques by pediatric chiropractors. Clinical observations and case studies suggested that the use of these techniques is correlated with positive outcomes in pediatric care and should be incorporated in the dialogue of improving outcomes with infantile colic.<sup>28</sup>

Another area of this study that warrants attention is the duration of care, which can significantly impact outcomes. The study commented on the project period being two weeks with four chiropractic visits, and how this revolved around the parental willingness to accept the study. The authors of this review acknowledge that parents often are navigating health care within the confines of time and money, and this certainly can impact healthcare access. Pediatric chiropractors must strike a balance between setting realistic expectations and management of parental resources. Studies for spinal manipulation and cranial therapies for infants with colic typically lasted 2-4 weeks in duration, with an average total of four visits. While most of these studies showed an initial improvement in outcomes with chiropractic care, this could also mean that these initial investigatory durations may not be enough time to determine dose-dependent trends or to determine what is a realistic course of care to support an infant with colic. This must then be reconciled with pediatric practitioners who value care beyond the acute presentation phase for the maintenance of health and function.

While the pathogenesis of colic is still not well understood, associations are made with a variety of factors ranging from gastrointestinal status, gestational and parturition distress, to biomechanical dysfunction. The developing fetal microbiome changes in response to the maternal microbiota, delivery mode, how the infant is fed, pharmaceutical and environmental exposure including the members of the family and family pets.<sup>12</sup> Interestingly, in this study, the baseline characteristics of families and infants revealed that 21 study participants had a planned cesarean birth, for example, of which, 15 were in the treatment arm as opposed to seven in the control arm. While a recent study had concluded that exposure to the maternal vaginal microbiome during childbirth did not impact the development of the infant gut biome,<sup>13</sup> opposing perspectives do exist. Two previous studies supported that delivery modes can impact the infant gut biome wherein cesarean born infants tend to have less intrinsically diverse gut microbiota.<sup>14,15</sup> A further positive correlation existed with the restoration of microbiota and crying time reduction.<sup>16</sup> With this rationale in hand, the reviewing authors put forward that having double the number of potentially dysbiotic participants as a result of mode of delivery in the treatment arm, likely detracted from the positive outcome of reduced crying time.

In further inquiry into participant allocation, 50 participants reported that there was a severe incident in the family during pregnancy. Of these 50 participants, 31 were in the treatment group as opposed to 19 in the control group. A recent systematic review and meta-analysis established a relationship between greater maternal stress and the development of disease, inclusive of infantile colic.<sup>17</sup> Once again, given the increased number of stressed participants in the treatment arm, it is plausible that the reduction in crying may be more significant than the statistical analysis recognized.

In closing, it is imperative that clinicians recognize that various areas of pathogenesis may be at play in infantile colic. These need to be reconciled with clinical outcomes when considering the implementation of chiropractic care as an intervention for infantile colic. Overall, the studies show a cumulative range of two hours to  $\geq$  seven hours in

the reduction in crying per week in infants with colic who received care. With adverse events being rare and avoidable with proper examination and adjustments modified for pediatric patients, manual therapies such as chiropractic are a low-risk care method worthy of consideration for infants with colic. Ancillary lifestyle factors contributing to improved gut health and maternal stress reduction are also noteworthy when considering care plans. With all these factors at the forefront, studies with more comprehensive design are needed to fortify these positions further.

## Conflicts to disclose

The completion of this review was not dependent upon any external funding from any entity and the authors have no conflicts of interest to disclose.

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