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# Treatment of infant colic with craniosacral therapy. A randomized controlled trial☆

Mercedes Castejón-Castejón [a,*], M.A. Murcia-González [b], J Todri [a], O Lena [a], R Chillón-Martínez [c]

[a] Health Science Department, UCAM Catholic University of Murcia, Murcia, Spain
[b] Department of Physiotherapy, UCAM Catholic University of Murcia, Murcia, Spain
[c] Faculty of Nursing, Physiotherapy and Podology, University of Seville, Seville, Spain

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ABSTRACT

*Objective:* To evaluate the number of craniosacral therapy sessions that can be helpful to obtain a resolution of the symptoms of infantile colic and to observe if there are any differences in the evolution obtained by the groups that received a different number of Craniosacral Therapy sessions at 24 days of treatment, compared with the control group which did not received any treatment.

*Methods:* Fifty-eight infants with colic were randomized into two groups of which 29 babies in the control group received no treatment and those in the experimental group received 1–3 sessions of craniosacral therapy (CST) until symptoms were resolved. Evaluations were performed until day 24 of the study. **In this study crying hours served as primary outcome**. The secondary outcome were the hours of sleep and the severity, **measured by an Infantile Colic Severity Questionnaire (ICSQ)**.

*Results:* Significant statistical differences were observed in favor of experimental group compared to the control group on **day 24 in crying hours (**mean difference = 2.94, at 95 %CI = 2.30–3.58; $p < 0.001$) primary outcome, **and also in hours of sleep** (mean difference = 2.80; at 95 %CI = − 3.85 to − 1.73; $p < 0.001$) and colic severity (mean difference = 17.24; at 95 %CI = 14.42–20.05; $p < 0.001$) secondary outcomes.

Also, the differences between the groups ≤ 2 CST sessions (n = 19), 3 CST sessions (n = 10) and control (n = 25) were statistically significant on day 24 of the treatment for crying, sleep and colic severity outcomes ($p < 0.001$).

*Conclusion:* Babies with infantile colic may obtain a complete resolution of symptoms on day 24 by receiving 2 or 3 CST sessions compared to the control group, which did not receive any treatment.

## 1. Introduction

Infantile colic is one of the most common disorders in newborns. It affects 20–40 % of babies between birth and 6 months of age until 1 year, although in some cases, it tends to resolve spontaneously around the age of 4 months old.[1] Infantile colic can affect families' health, since parents' anxiety increases when they are unable to find solutions to soothe their babies. This can also influence the baby's psychomotor development in the first months of life, which could be related to a lower psychomotor stimulation. Children who had prolonged crying, had poorer outcomes on many tests of cognitive development.[1]

For years, many studies have tried to give an answer to infants with infantile colic and their families from different therapeutic perspectives. On one hand, we find options such as administration of drugs,[2] dietary modifications,[3] probiotics,[4–7] and behavioral assessment and counseling for parents.[8,9] On the other hand, we find complementary therapies like acupuncture[10–13] and manual therapy treatments. Although there are numerous techniques used in manual therapy to treat infantile colic, on which clinical trials have been carried out, like foot reflexology,[14] physiotherapy and visceral osteopathy,[15] massages,[16–19] vertebral manipulation,[20–25] and craniosacral therapy, more research is needed.[26–28]

During birth, the baby's body is subject to external stress of greater or lesser intensity, depending on the characteristics of the delivery, which can cause strains to the baby's body. The strains experienced in the baby's skull could cause compression of the cranial nerves, leading to sucking difficulties, intestinal hypersensitivity, intestinal motility disorders, irritability and sleep disturbances.[26,27]

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* Corresponding author.
*E-mail address:* mccfisio@gmail.com (M. Castejón-Castejón).

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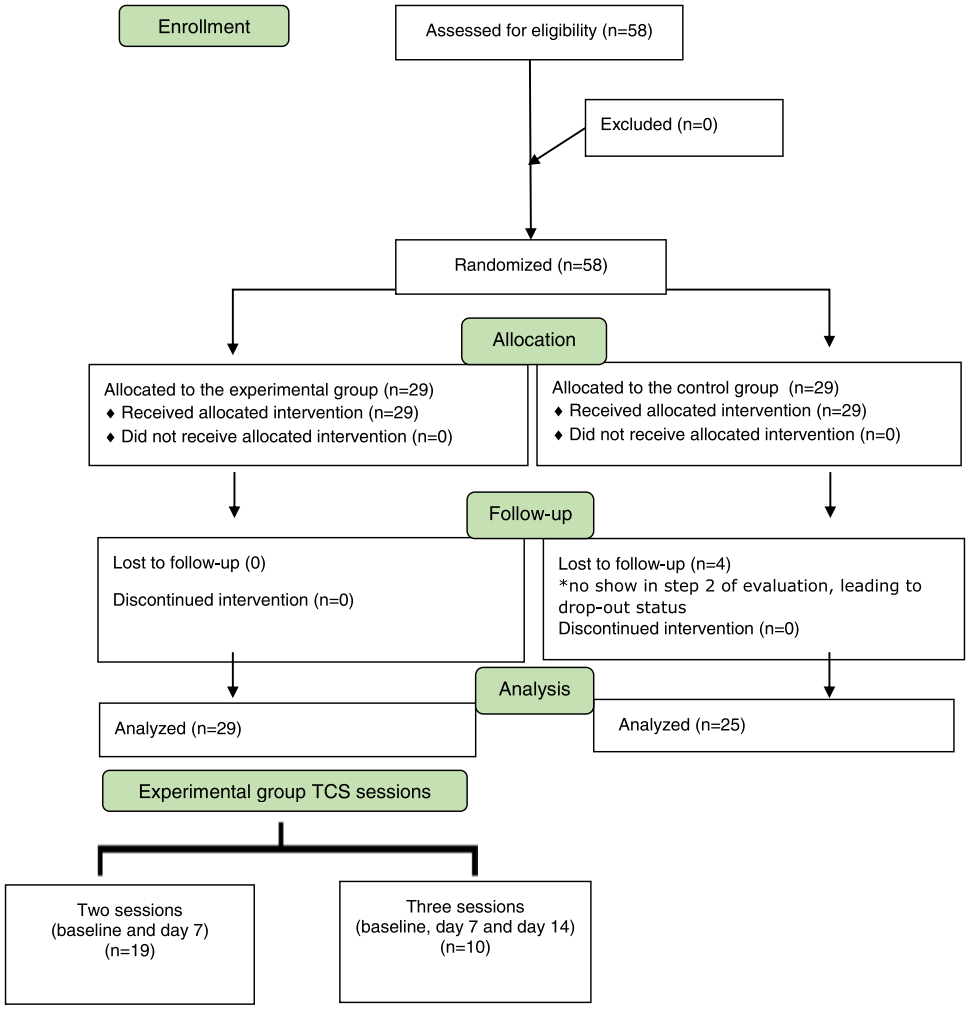


**Fig. 1.** Flow diagram of the study progress.

Cranio-sacral therapists believe that even in a relatively straightforward delivery, restrictions or compressions may persist and inhibit proper growth or development. Also they believe that craniosacral therapy gives great importance to treating the body tensions experienced by the baby **during childbirth to avoid dysfunctions and maintain health and balance in the newborn**.[29]

This is the rationale for treating babies with persistent crying with cranio-sacral therapy according to the cranio-sacral therapists.[29,30]

It consists of a light and respectful manual contact that follows the own movement of body tissues to obtain relaxation.[26,27,29] Concretely, the therapists place their hands gently on the baby's body to identify areas of tension **by following** the subtle internal twists and pulls of the craniosacral system until points of resistance are encountered and released. **The aim is to enable the tissues for returning to proper healthy functioning.** The treatment is generally soothing and comfortable. Babies can be treated while cradled in their mother's arms, and even while asleep.[30]

Craniosacral therapy (CST) usually does not lead to serious adverse effects (AEs) and produces less AEs than other manual treatments such as chiropractic or spinal manipulation.[31]

The objective of this study was to evaluate the number of craniosacral therapy sessions that can be helpful to obtain a resolution of the symptoms of infantile colic and to observe if there are any differences in the evolution obtained on day 24 by the groups that received a different number of Craniosacral Therapy sessions, compared with the control group which did not received any treatment.

## 2. Materials and methods

### 2.1. Participants and setting

This was a randomized controlled intervention study in babies diagnosed with infant colic. The present study complied with the Declaration of Helsinki and was approved by the ethics committee of the Catholic University of San Antonio Murcia (UCAM) (6686). A total of 58 babies with infantile colic and their families were recruited between March 2015 and December 2016. The study protocol was registered retrospectively in the Clinical Trial Registry of the U.S. National Institute of Health (https://clinicaltrials.gov, identifier: NCT03675763).

Babies under 90 days of age diagnosed with infantile colic by a pediatrician were referred to Aidemar's Center on Childhood Development and Early Education and the physiotherapy center La Flota, in Murcia (Spain). Babies who cried for 3 h a day for at least three days in the past week (as established in the definition of infantile colic), who weren't born prematurely, had no other physiological or physical pathology, food allergies or intolerances, and whose parents agreed to complete the study's evaluations were included in this study. The families of the babies involved in the study signed the informed consent form.

The study began with 29 infants in the experimental group and 29 infants in the control group. The families were also present.

From prior experiments[26] we found a standard mean difference/effect size in crying hours of 0.7. To detect this effect with a power of 80 % and a significance level of 0.05 a two-sided t-test required 26

**Table 1**
Sample characteristics at baseline with mean and standard deviation.

| Characteristics | Total | Control (n = 29) | EG with ≤ 2 CST sessions (n = 19) | EG with 3 CST sessions (n = 10) | *Total Experimental group (n = 29)* |
|---|---|---|---|---|---|
| ***Sex (%)*** | | | | | |
| *Female* | 50 % | 52 % | 42.1 % | 60 % | 48.27 % |
| *Male* | 50 % | 48 % | 57.9 % | 40 % | 51.72 % |
| ***Age in days*** *(mean ± SD)* | 36.89 ± 18.52 | 39.14 ± 20.15 | 35.84 ± 13.99 | 29.6 ± 17.92 | 33.69 ± 15.14 |
| ***Type of childbirth (%)*** | | | | | |
| *Vaginal delivery (without complications)* | 50 % | 64 % | 52.6 % | 10 % | 37.93 % |
| *Vaginal delivery (with complications)* | 22 % | 16 % | 15.8 % | 50 % | 27.59 % |
| *Scheduled C-section* | 7 % | 8 % | 10.5 % | 0 % | 6.90 % |
| *Emergency C-section* | 20 % | 12 % | 21.1 % | 40 % | 27.59 % |
| ***Type of feeding (%)*** | | | | | |
| *Breastfeeding* | 64.8 % | 58.6 % | 73.7 % | 70 % | 72.4 % |
| *Formula* | 35.2 % | 41.4 % | 26.3 % | 30 % | 27.6 % |
| ***Feeding behaviour (%)*** | | | | | |
| *2–3 h in between takes* | 46.3 % | 55.2 % | 36.8 % | 40 % | 37.9 % |
| *< 2–3 h in between takes* | 53.7 % | 44.8 % | 63.2 % | 60 % | 62.1 % |
| ***Feeding duration (%)*** | | | | | |
| *Less than 30 min* | 61.1 % | 69 % | 57.9 % | 60 % | 58.6 % |
| *More than 30 min* | 38.9 % | 31 % | 42.1 % | 40 % | 41.4 % |
| ***Anti-colic products (%)*** | | | | | |
| *No* | 81.5 % | 79.3 % | 84.2 % | 80 % | 82.8 % |
| *Yes* | 18.5 % | 20.7 % | 15.8 % | 20 % | 17.2 % |
| ***Vitamins intake (%)*** | | | | | |
| *Never/hardly ever* | 63 % | 62.1 % | 63.2 % | 60.0 % | 62.1 % |
| *Yes/frequently* | 37 % | 37.9 % | 36.8 % | 40.0 % | 37.9 % |
| ***Mothers consumption of dairy products (%)*** | | | | | |
| *No* | 18.5 % | 13.8 % | 31.6 % | 0.0 % | 20.7 % |
| *Yes* | 81,5 % | 86.2 % | 68.4 % | 100.0 % | 79.3 % |
| ***Time-period with colic diagnosis (%)*** | | | | | |
| *2 weeks or less* | 55.6 % | 57.7 % | 52.6 % | 80.0 % | 62.1 % |
| *More than 2 weeks* | 44.4 % | 48.3 % | 47.4 % | 20.0 % | 37.9 % |
| ***Crying hours*** *(mean ± SD)* | 3.52 ± 1.5 | 3.24 ± 1.47 | 3.71 ± 1.45 | 3.9 ± 1.39 | 3.77 ± 1.47 |
| ***Sleep hours*** *(mean ± SD)* | 10.4 ± 2.26 | 10.96 ± 2.24 | 10.26 ± 2.6 | 9.8 ± 1.6 | 10.10 ± 2.28 |
| ***Colic severity**** *(mean ± SD)* | 59.52 ± 6.91 | 58.41 ± 6.73 | 63.42 ± 7.59 | 59 ± 6.03 | 61.9 ± 7.3 |

EG–Experimental Group.
*Measured with ICSQ-Colic severity questionnaire.

babies per group considering 10 % withdrawal. The program used for the sample size calculation was the g-power.

The randomization was performed by a person external to the research group who generated a randomization sequence using a number generator software named Research Randomizer (https://www.randomizer.org/) and assigned a number to every evaluation, keeping them in sealed envelopes. The envelopes were then delivered to the parents and once the baseline assessment was completed, they were opened by the physiotherapist in charge of the craniosacral therapy.

On the first day of the evaluation, the parents of both groups were given recommendations on how to manage infantile colic, including postural, feeding and gas expulsion advice, similar to the pediatric guidelines provided in health centers. The babies of both groups were evaluated on the first day before being assigned to a group at 7, 14 and 24 days after the start of the study.

The parents inserted their evaluations in sealed envelopes with an assigned number and the data was then transferred to a computer by a person outside the research group for subsequent analysis.

Parents were not blinded to the treatment their children were receiving, they were present during the CST sessions and were not separated from the babies following the recommendation of pediatricians.

### 2.2. Outcomes measures

Crying was the primary outcome, evaluating the total number of hours of crying in 24 h through a crying and sleep diary. It was considered as the primary outcome because as per references, crying is the most relevant symptom in infant colic.[32,33]

As per inclusion criteria, severity of infant colic was considered as a functional digestive disorder with unexplained paroxysmal bouts of fussing and crying that lasted more than 3 h per day with a high frequency of days per week, in more than 3 weeks based in the parental experiences.[34]

Based in these data, sleep and severity of colic were the secondary outcomes for completing the interested symptoms.[33]

Sleep records the total number of hours of sleep in 24 h through a cry and sleep journal. Severity of colic is measured in points through the Infant Colic Severity Questionnaire (ICSQ), validated to assess the severity of infantile colic which consists in five subscales to allow the assessment of casual factors of colic based on parental perception of infants' colic symptoms.[15]

### 2.3. Experimental group

Babies from the experimental group received 1–3 sessions of craniosacral therapy depending on the resolution of the symptoms of each particular case. On the first day they received one session, on day 7 they received the second session if they continued with symptoms, but if they showed no symptoms the sessions stopped. Likewise, on day 14 they received the third session if they continued showing symptoms.

In accordance with the sessions of craniosacral treatment that babies received, the experimental group was further divided in two subgroups: babies that received a maximum of 2 sessions, and babies that received a maximum of 3 sessions.

The Craniosacral Therapy intervention included the following techniques as the most adapted for the babies with infant colic: balance of the pelvic, thoracic and clavicular diaphragms (transverse planes), hyoid release, decompression of the sacrum, release of the atlanto-occipital joint, occipital decompression, frontal lift, parietal lift, decompression of the sphenobasilar synchondrosis (SBS), decompression of the temporal bone, decompression of the temporomandibular joints and craniosacral balancing.[26,27,35–37]

CST sessions lasted from 30 to 40 min. The professional applying craniosacral therapy[11] based the treatment on clinical judgment, focusing on light-touch manual therapy. The stress and dysfunctions present in the baby's body were identified and treated until relaxation or resolution.

### 2.4. Control group

Babies in the control group did not receive any craniosacral therapy

**Table 2**
Analysis of Covariance (ANCOVA) the difference between the experimental and control group at baseline, day 7, 14 and 24.

| ANCOVA for the difference between experimental and control group | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| *Outcomes* | *Groups* | *N* | *Mean* | *Std. deviation* | *Mean difference* | 95 % confidence interval | | *Sig*[b] | *Cohen's d* |
| | | | | | | *Lower* | *Upper* | | |
| ***Primary*** | | | | | | | | | |
| Crying baseline | Control | 25 | 3.24 | 1.5885 | -0.5359 | -1.3551 | 0.2833 | 0.195 | 1.099 |
| | Experimental | 29 | 3.776 | 1.4116 | | | | | |
| Crying day 7 | Control | 25 | 3.200 | 1.5811 | 2.1483 | 1.4683 | 2.8283 | 0.000 | 1.692 |
| | Experimental | 29 | 1.052 | 0.8488 | | | | | |
| Crying day 14 | Control | 25 | 3.06 | 1.5567 | 3.0428 | 2.4624 | 3.6231 | 0.000 | 2.759 |
| | Experimental | 29 | 0.017 | 0.0928 | | | | | |
| Crying day 24 | Control | 25 | 2.96 | 1.7012 | 2.9428 | 2.3087 | 3.5768 | 0.000 | 2.442 |
| | Experimental | 29 | 0.017 | 0.0928 | | | | | |
| **Secondary** | | | | | | | | | |
| Sleep baseline | Control | 25 | 10.76 | 2.2413 | 0.6566 | -0.585 | 1.8981 | 0.294 | 0.290 |
| | Experimental | 29 | 10.103 | 2.2889 | | | | | |
| Sleep day 7 | Control | 25 | 10.76 | 2.2413 | -2.24 | -3.3742 | -1.1058 | 0.000 | 1.074 |
| | Experimental | 29 | 13.000 | 1.9133 | | | | | |
| Sleep day 14 | Control | 25 | 11.18 | 2.2494 | -2.8028 | -3.8651 | -1.7404 | 0.000 | 1.427 |
| | Experimental | 29 | 13.983 | 1.6283 | | | | | |
| Sleep day 24 | Control | 25 | 11.34 | 2.1346 | -2.7979 | -3.8579 | -1.7379 | 0.000 | 1.434 |
| | Experimental | 29 | 14.138 | 1.7469 | | | | | |
| Severity ICSQ baseline | Control | 25 | 56.76 | 5.341 | -5.137 | -8.682 | -1.591 | 0.005 | 0.803 |
| | Experimental | 29 | 61.90 | 7.306 | | | | | |
| Severity ICSQ day 7 | Control | 25 | 57.36 | 5.715 | 10.291 | 7.199 | 13.383 | 0.000 | 1.820 |
| | Experimental | 29 | 47.07 | 5.587 | | | | | |
| Severity ICSQ day 14 | Control | 25 | 56.96 | 5.842 | 16.029 | 13.172 | 18.886 | 0.000 | 3.045 |
| | Experimental | 29 | 40.93 | 4.613 | | | | | |
| Severity ICSQ day 24 | Control | 25 | 56 | 6.595 | 17.241 | 14.427 | 20.056 | 0.000 | 3.280 |
| | Experimental | 29 | 38.76 | 3.429 | | | | | |

Based on estimated marginal means.
*. The mean difference is significant at the .05 level.
b. Adjustment for multiple comparisons: Bonferroni.
ICSQ-Colic severity questionnaire.

sessions or manual treatment, but the parents received instructions about how to handle infantile colic. The instructions were similar to those given to the experimental group, specifically elaborated for this research: make frequent postural changes; alternate the position of the baby in the crib by turning the head once on each side; keep a rolled and aligned position in the midline when breastfeeding, with the knees bent when the baby is in the arms; make sure the baby grips the breast tightly, that the nipple and the areola are inserted into the mouth; make sure that the nipple of the feeding bottle is always full of milk; **put the baby in a vertical position after the intake to facilitate the expulsion of gases; positioning adequately the baby in prone when he is awake as per treatment recommendation;** flex and extend the baby's legs simultaneously; carry the baby, gently rock the baby.

### *2.5. Statistical analysis*

Data were analyzed using the Statistical Package for Social Science (SPSS) 25.0 for Windows.

Variance analysis and Chi-squared test were used to analyze the characteristics of babies with infant colic (experimental and control group). The Mann–Whitney test was used to compare continuous and categorical data.

The primary comparison was tested confirmatory using ANCOVA at a p-value of 0.05 with Bonferroni corrected post-hoc comparisons of main effects. All other tests were carried out exploratory also at a p-value of 0.05.

Partial eta squared (η2) was used as an indicator of effect size in different levels, considered small for 0.1, medium for 0.3 and large for 0.5.[38]

In addition, effect sizes were calculated by Cohenś D coefficient. An effect size of less than 0.2 reflects a negligible effect size; 0.2 or greater and less than 0.5 indicates a small effect size; between 0.5 or greater and less than 0.8, a moderate effect size, and 0.8 or greater, a large effect size.

Mean differences and associated 95 % confidence intervals were reported. The threshold for statistical significance was set at $p < 0.05$.

## 3. Results

All 29 babies in the experimental group attended their evaluation according to schedule. 5.8 % of infants required 1 session of CST to obtain a complete resolution of infantile colic symptoms, 58.6 % of infants required 2 CST sessions and 34.4 % of infants required 3 CST sessions. In the control group, 4 babies abandoned the study before the second evaluation (unknown reasons) thus, 25 out of 29 babies from the control group were evaluated on day 24 (Fig. 1).

The initial characteristics of the CST and the control group show that the groups were homogeneously distributed (Table 1). There were no significant differences of baseline characteristics between the control and experimental groups that received ≤ 2 CST sessions or 3 CST sessions ($p \geq 0.05$). The same situation was present in comparing the baseline outcomes between the entire experimental group and the control group (Table 2).

A significant difference between the experimental and control group was shown on day 7 and 14 in the sleep, crying and severity colic questionnaire outcomes performing the covariance ANCOVA analysis ($p < 0.001$ in all the cases) (Table 2). Moreover, significant statistical differences were observed in favor of entire experimental group compared to the control group on day 24 in crying hours (mean difference = 2.94, at 95 %CI = 2.30–3.58; $p < 0.001$) primary outcome, and also in hours of sleep (mean difference = 2.80; at 95 %CI = − 3.85 to − 1.73; $p < 0.001$) and colic severity (mean difference = 17.24; at 95 % CI = 14.42–20.05; $p < 0.001$) secondary outcomes (Table 2).

Also, the differences between the subgroups of the experimental group that received a different number of CST sessions [(≤ 2 CST sessions (n = 19) and 3 CST sessions (n = 10)] were statistically significant

**Table 3**
Analysis of Covariance (ANCOVA) for the difference between the three groups of the study.

| ANCOVA for the difference between three groups | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Outcomes | Groups | N | Mean | Std. deviation | Mean difference | 95 % confidence interval | | Sig[b.] | *η2* |
| | | | | | | *Lower* | *Upper* | | |
| ***Primary*** | | | | | | | | | |
| Crying day 7 | Control | 25 | 3.200 | 1.5811 | 2.253* | 1.312 | 3.194 | 0.000 | 0.681 |
| | ≤ 2 sessions experimental | 19 | 0.947 | 0.6851 | | | | | |
| | 3 sessions experimental | 10 | 1.250 | 1.1118 | | | | | |
| Crying day 14 | Control | 25 | 3.060 | 1.5567 | 3.060* | 2.254 | 3.866 | 0.000 | 0.815 |
| | ≤ 2 sessions experimental | 19 | 0.000 | 0.0000 | | | | | |
| | 3 sessions experimental | 10 | 0.050 | 0.1581 | | | | | |
| Crying day 24 | Control | 25 | 2.960 | 1.7012 | 2.960* | 2.079 | 3.841 | 0.000 | 0.760 |
| | ≤ 2 sessions experimental | 19 | 0.000 | 0.0000 | | | | | |
| | 3 sessions experimental | 10 | 0.050 | 0.1581 | | | | | |
| **Secondary** | | | | | | | | | |
| Sleep day 7 | Control | 25 | 10.760 | 2.2413 | -2.108* | -3.680 | -0.536 | 0.005 | 0.514 |
| | ≤ 2 sessions experimental | 19 | 12.868 | 1.8093 | | | | | |
| | 3 sessions experimental | 10 | 13.250 | 2.1763 | | | | | |
| Sleep day 14 | Control | 25 | 11.180 | 2.2494 | -2.662* | -4.134 | -1.190 | 0.000 | 0.555 |
| | ≤ 2 sessions experimental | 19 | 13.842 | 1.3023 | | | | | |
| | 3 sessions experimental | 10 | 14.250 | 2.1763 | | | | | |
| Sleep day 24 | Control | 25 | 11.340 | 2.1346 | -2.660* | -4.129 | -1.191 | 0.000 | 0.522 |
| | ≤ 2 sessions experimental | 19 | 14.000 | 1.3333 | | | | | |
| | 3 sessions experimental | 10 | 14.400 | 2.4129 | | | | | |
| Severity ICSQ day 7 | Control | 25 | 57.36 | 5.715 | 10.360* | 6.065 | 14.655 | 0.000 | 0.555 |
| | ≤ 2 sessions experimental | 19 | 47.00 | 5.676 | | | | | |
| | 3 sessions experimental | 10 | 47.20 | 5.712 | | | | | |
| Severity ICSQ day 14 | Control | 25 | 56.96 | 5.842 | 17.486* | 13.686 | 21.287 | 0.000 | 0.772 |
| | ≤ 2 sessions experimental | 19 | 39.47 | 4.074 | | | | | |
| | 3 sessions experimental | 10 | 43.70 | 4.473 | | | | | |
| Severity ICSQ day 24 | Control | 25 | 56.00 | 6.595 | 17.263* | 13.353 | 21.173 | 0.000 | 0.766 |
| | ≤ 2 sessions experimental | 19 | 38.74 | 3.525 | | | | | |
| | 3 sessions experimental | 10 | 38.80 | 3.425 | | | | | |

Based on estimated marginal means.
*. The mean difference is significant at the .05 level.
b. Adjustment for multiple comparisons: Bonferroni.
ICSQ-Colic severity questionnaire.
*η2* – partial eta squared.

at day 24 of the treatment for crying, sleep and colic severity outcomes ($p < 0.001$). Specifically, the subgroup with 3 CST sessions ($n = 10$) had a better reaction of symptoms, compared with the ≤ 2 CST sessions ($n = 19$) subgroup (Table 3).

Similarly, covariance ANCOVA with the baseline data covariate showed a significant difference between the three groups (2 sessions CST experimental, 3 Sessions CST experimental and control group) for all outcomes: crying, sleep and colic severity ($p < 0.001$) with a large effect size ($\eta 2 > 0.5$) (Table 3).

## 4. Discussion

In this study, there were significant differences between experimental and control group in the improvement of infantile colic. The study may be useful for determining the potential benefit of craniosacral therapy for babies with infantile colic.

The results show that the number of CST sessions required to resolve infantile colic symptoms in the experimental group was 3 sessions for 10 of the babies (34.4 %), 2 sessions for 17 babies (58.6 %) and 1 session for 2 babies (5.8 %). **It is important to note that no serious adverse effect occurred during the CST implementation.**

The number of CST sessions received depended on the evolution of each particular case, which is similar to the method used in two previous clinical trials[27,28] that applied CST techniques for infantile colic without prescribing a specific number of sessions. In the present study, the experimental group received 1–3 sessions of CST, the number of sessions depended on the symptoms of each baby. They received 1 weekly session and all of the babies were evaluated until day 24. Hayden et al., applied a complete session of cranial osteopathy[27] also carried out weekly sessions: within 21 days the babies of the experimental group received 1–4 sessions depending on the evolution of each case. Browning and Miller only applied the occipito sacral decompression technique[28] against a group of vertebral manipulation carried out 2–3 sessions per week and the babies received a total of 5–7 sessions. We acknowledge that from a statistical and methodological point of view it would be interesting to carry out a study where all babies receive the same number of sessions. **However, in craniosacral therapy, the particular circumstances of each baby are considered, with particular interest in the evaluation and treatment of the areas where the therapist perceives tension or dysfunction.**[26,27,39] Therefore, in the studies that apply CST in infantile colic[27,28] the number of sessions is related to the improvements of each particular case: when the infants manifest a resolution of the symptoms, the treatment stops, although they continue to be evaluated until the end of the study in accordance with the guidelines established.

Following the primary results,[26] this study showed that the groups that received a different number of CST sessions obtained significant improvements on day 24 in crying, sleep and colic severity compared to the group that did not receive any treatment. **None of the previously published trials related to craniosacral therapy techniques carries out any specific analysis comparing the results obtained between groups that receive a different number of CST sessions.**

For future research, a number of sessions should be set for all babies who need to be treated with CTS; considering that 2 or 3 sessions would be helpful to ensure an improvement in the symptoms of infant colic; although based on the results of this study 19 babies (65.5 % of the CST group) improved with 1 or 2 sessions of CST, 10 babies (34.5 %) needed a third session of CST to obtain complete resolution of infant colic symptoms.

A comparison of the primary and secondary outcomes between the

babies of the experimental group that received 2 CST sessions, the babies that received 3 CST sessions and the control group shows that there are significant differences on day 24.

The results obtained in this study show that the number of CST sessions received in the experimental group is not significantly related to the socio-sanitary variables with the exception of the type of delivery ($p = 0.37$; contingency coefficient 0.653). This result could be related to the hypothesis that infantile colic is caused by tensions or dysfunctions acquired by the baby at the time of delivery.[27,40,41] Another hypothesis suggests that the difference in the number of sessions that each baby needs to obtain a resolution of the symptoms could depend on the intensity of the dysfunctions or musculoskeletal tensions found in the baby's body.[27] However, conclusions cannot be drawn in this regard solely with these results, future clinical trials would be necessary for a more specific study of the relationship between the number of CST sessions required for a complete resolution of infantile colic symptoms, the dysfunctions found, the type of delivery and the resolution of symptoms. Pediatricians who referred infants to this trial did not recommend blind parenting, because separating babies from their parents for 30–40 min could increase the infants' crying hours and irritability and enhance the parents' anxiety by not knowing the state of their children while they are being treated by a third party,[27] which could ultimately interfere with the results of the study. For greater methodological quality of the RCTs, it would be advisable to blind the parents of the babies. However, some studies[24,42] support the theory that in the treatment of babies this might not influence the results, without finding a placebo effect in newborns, questioning at what age the placebo effect appears. In most RCTs[20,22,27,28] about manual therapy for infantile colic, the parents were not blinded or a placebo effect was not applied. In this study, it was decided not to apply a light manual treatment as placebo to the control group, since this could lead to a relaxation in the baby's nervous system and influence the results obtained.[26,43]

It would be advisable to carry out future studies with and without parental blindness in order to draw clearer conclusions about the effectiveness of the techniques used and the possible influence of parental blindness on the results.

### 4.1. Strengths and limitations

We consider that the main limitation of this study is the fact that the children's parents were not blinded. Therefore, to obtain more reliable and significant results in future clinical trials, we recommend blinding the parents of the babies.

Future studies, examining the relationship between different types of births and infantile colic, would be necessary to draw firmer conclusions and determine whether the type of childbirth can influence the number of CST sessions required to obtain the resolution of infantile colic.

## 5. Conclusions

Babies with infantile colic may obtain a complete resolution of symptoms on day 24 by receiving 2 or 3 CST sessions compared to the control group, which did not receive any treatment.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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