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Effectiveness of craniosacral therapy in the treatment of infantile colic. A randomized controlled trial☆

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ABSTRACT

Objectives: To determine the effectiveness of Craniosacral Therapy (CST) for the treatment of infantile colic.
Material and methods: This randomized controlled trial was conducted on 58 infants, aged 0–84 days, diagnosed with infantile colic. The babies received a 30–40 minute CST session once a week (experimental group) or no treatment (control group). Babies in the CST group received either 1, 2 or 3 CST sessions over a 14-day period. Data were collected at 4 different times over the 24-day period, day 0 (baseline), day 7, day 14 and day 24. Crying (primary outcome) and sleep (secondary outcome) were evaluated using a crying and sleep diary, and colic severity was measured using the Infant Colic Severity Questionnaire (secondary outcome).
Results: There was a statistically significant difference between groups (CST and control) in crying hours ($F = 188.47$; $p < 0.0005$; $\eta2 = 0.78$), sleep hours ($F = 61.20$; $p < 0.0005$, $\eta2 = 0.54$) and colic severity ($F = 143.74$; $p < 0.0005$, $\eta2 = 0.73$) across all the time points. In comparison with the control group, CST babies reported significant and clinically relevant effects in crying hours on day 7 (−2.47 h (95%CI, −2.95 to −1.99); $p < 0.0005$; $d = 1.73$), on day 14 (−3.29 h (95%CI, −3.7 to −2.8); $p < 0.0005$; $d = 2.87$) and on day 24 (−3.20 h (95%CI, −3.7 to −2.6); $p < 0.0005$; $d = 2.54$); in sleep hours on day 7 (−2.47 h (95%CI, −2.95 to −1.99); $p < 0.0005$; $d = 1.73$) on day 14 (-3.29 h (95%CI, −3.7 to −2.8); $p < 0.0005$; $d = 2.87$) and on day 24 (−3.20 h (95%CI, −3.7 to −2.6); $p < 0.0005$; $d = 2.54$).
Conclusions: Craniosacral therapy appears to be effective and safe for infantile colic by reducing the number of crying hours, the colic severity and increasing the total hours of sleep.

1. Introduction

Infantile colic is a clinical condition accompanied by repeated and prolonged crying with difficulties to soothe and unsatisfied physiological needs.[1] It is found in 3–4 out of 10 young infants[2] with different environmental and socioeconomic conditions. Its intensity and duration vary from one infant to another, beginning in the first 15 days of life and lasting into the sixth month,[1,3] although it can begin to subside in the third or fourth month.[2]

For many years the Wessel Criteria[4] has been used for the diagnosis of colic: uncontrolled and inexplicable crying of more than three hours per day and more than three days per week during three weeks. Nevertheless, more recent studies suggest the existence of other symptoms related to infantile colic, such as difficulty passing gas and constipation.[5]

Being unable to soothe babies is stressful for parents and healthcare professionals,[6] and also affects the quality of family life. Infantile colic is a benign condition of multifactorial etiology. Colic has been associated with gastrointestinal immaturity, alterations in fecal microflora,[7] allergy to cow´s milk protein, food intolerance [8] and traumatic factors in pregnancy, childbirth and postnatal care.[9]

The therapeutic approaches for treating infantile colic are diverse.

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There are studies discussing drug administration,[10] probiotics,[11–14] dietary and nutritional modifications,[15] behavioral counseling for the parents,[16,17] acupuncture,[18–21] reflexology [22] physiotherapy [23–26] and manual therapy,[27–33] among others.

Manual therapy is being readily adopted as a remedy for parents and families, and it is being integrated into the healthcare sector as a safe method for treating infantile colic.[34]

The applications for manual therapy are very diverse. They include osteopathy,[23,26,33,35] spinal manipulation,[28–31,36,37] visceral osteopathy [33] and craniosacral therapy.[31,32] Although most studies of manual therapy and infantile colic show positive data that favors its use as a moderately safe approach, a consensus on the data as to the most accurate manual therapy approach for this clinical condition has not yet been reached.

Craniosacral Therapy (CST) is a non-invasive treatment involving light-touch manual therapy to achieve relaxation of fascial restrictions and improve the cranial rhythmic impulse (CRI).[38,39] Cranial structures, cerebrospinal fluid (CSF), brain membranes and the spinal canal are connected. Therefore, any alteration or movement restriction may cause a somatic response and affect the musculoskeletal system, the vascular and endocrine systems as well as the autonomic nervous system (ANS).[39,40]

Studies of CST report positive clinical outcomes for pain reduction, autonomic nervous system functions and improvement in sleeping patterns.[40,41] Notwithstanding, there is still a need of further investigation using more rigorous methodology in order to be able to draw firm conclusions regarding its effectiveness.[40]

CST shows to be safe for babies and pre-term infants.[42] CST is applicable for babies experiencing difficulty breastfeeding,[43] plagiocephaly,[44] otitis media [45,46] and infantile colic.[31,32] Two randomized clinical trials (RCT) evaluating CST for the treatment of infantile colic [31,32] showed positive results; crying was reduced and sleep increased. One trial [32] measured the effects of a cranial osteopathy session against the control group. The other RCT [31] compared two manual treatments, applying spinal manipulation to one group and occipital-sacral decompression to the other group. The respectful and light touch applied in CST can help to reduce the stress generated in the body of newborns during childbirth and the first days of life.[32,47]

Our hypothesis is that babies with infantile colic who receive CST could show significant improvement in the symptoms of infantile colic (a decrease in crying and colic severity as well as an improvement in sleep) as opposed to a group not receiving CST.

Considering the social and economic impact that infantile colic has on families, we consider it important to validate CST as a remedy for this problem. Therefore, this study aims to investigate the effect that CST have on crying hours, sleep hours and colic severity in infantile colic, in comparison with a control group.

2. Material and methods

2.1. Design and registration

This study consists of a randomized, controlled clinical trial (RCT) based on a parallel-group design. After a baseline assessment, babies were randomly assigned to an experimental group (EG) with treatment, or to a control group (CG) without treatment. Data were collected at 4 different times over a 24-day period, day 0 (baseline), day 7, day 14 and day 24.

The trial was conducted between March 2015 and December 2016. Before recruiting the babies as test subjects, the trial was approved by the ethics committee of the Catholic University of Saint Anthony of Murcia (UCAM) (6686).

The study protocol was registered retrospectively in the Clinical Trial Registry of the U.S. National Institute of Health (https://clinicaltrials.gov, identifier: NCT03675763).

2.2. Study population and sample criteria

The study population consisted in babies diagnosed with colic, aged 0–90 days. This trial was elaborated at Aidemar's Center on Childhood Development and Early Education, as well as at the physiotherapy sports centre La Flota in Murcia (Spain). The babies who participated in this study were referred from these two centres and were recruited with the assistance of paediatrics professionals from the healthcare services in Murcia.

The study population consisted of babies diagnosed with colic, aged 0–90 days. The trial was carried out at the Aidemar's Center for Childhood Development and Early Education, and at the La Flota center for sports physiotherapy, in Murcia (Spain). The babies who participated in this study were referred by these two centers, and were recruited with the assistance of paediatric professionals from healthcare services in Murcia.

The babies in this study were selected using the following criteria:

- Inclusion criteria: babies diagnosed with colic, aged 0–90 days, who have experienced 3 h of unexplainable crying per day, for at least 3 days during the past week.

Exclusion criteria: premature babies, babies diagnosed with any sort of pathological illness, allergies or food intolerance and/or who have suffered any intracranial hemorrhages or skull fractures.

Analysis of the study sample of babies with infantile colic who received CST [32] was performed using G*Power 3.1.9.3 software. The aim was to achieve a statistical power above 80%, estimating a significance level of 0.05 and a mean value of 0.7 as the effect size. The number of babies per group required for a minimum approximate significant difference is 26. Considering a possible loss of statistical strength due to 10% patient withdrawal, the minimum total sample size would be 52 babies. The sample used in this study consisted of 58 babies with infantile colic, 29 per group, 10% more than the required minimum, obtaining a statistical power of 83.85%.

2.3. Randomization

The process of randomization was handled by an independent researcher not involved in the study, who assigned the participants to the CST group or to the control group. Blocked randomization was performed based on numbers generated by the random allocation program software Research Randomizer (https://www.randomizer.org/). The codes for each group was stored in sealed envelopes. The osteopath (primary author) was neither involved in the random sequence generation nor in the assessment of the study outcomes.

On the first patient visit, the osteopath opened the sealed envelopes containing the allocation group codes.

2.4. Blinding

The parents of the babies involved in the study were not blinded to the babies' treatment. The pediatricians who referred the babies to the clinical trial recommended that the babies should not be separated from their parents at any moment during the trial.

The researchers that assessed the trial outcomes were blinded to the babies' group allocation throughout the entire study period. The statistician who conducted the outcome analyses was blinded to the group allocation by renaming the groups with numbers.

2.5. Outcome measures

The primary outcome was crying, and secondary outcomes were sleep and colic severity.

Crying was measured according to the total hours of crying per day. This data was gathered by all the parents and entered in the diary on

the first day of intervention, and on days 7, 14 and 24 of the study.

As for secondary outcomes, sleep measurements consisted of the total amount of hours the infant slept within a day, which was also registered in the diary by the parents on days 7, 14 and 24 of the study. Colic severity was assessed using the Infant Colic Severity Questionnaire (ICSQ),[5] a reliable and validated questionnaire for infantile colic diagnosis and evaluation. Parents completed 25 questions evaluating crying, sleep, suckling, stools, burping, vomiting and gas. The highest score is 100. Babies who scored more than 50 points were considered to suffer from infantile colic.

Both groups were assessed at 4 different times over a period of 24 days: the first day (baseline), and on days 7, 14 and 24.

2.6. Intervention

The parents of the babies who were referred by local health centers attended with the intention of participating in the study. The parents were fully informed of the objective of the RCT and voluntarily agreed to participate in this non-remunerated RCT. They signed a consent form and acknowledged that it was an experimental study in accordance with the policies of the World Medical Association's Declaration of Helsinki, amended version of 2013.

The babies were randomly allocated between two groups, the control group and the experimental group. The CST treatments were implemented by the main author of the study, a professional craniosacral therapist with 7 years of experience as a paediatric craniosacral therapist and osteopath, and 12 years of experience as a child physiotherapist.

During the first visit (baseline), the parents of both groups filled out an initial anamnesis, a colic severity questionnaire (ICSQ) and a crying and sleep diary. Subsequently, the osteopath (primary author) opened the sealed envelopes containing the allocation group codes. She assessed and conducted a CST treatment for the experimental group of babies and administered no treatment to the control group.

In the following 3 visits, which took place on day 7, day 14 and day 24 of the study, the parents of both groups filled in a severity questionnaire (ICSQ) and a crying and sleep diary. On day 7, after evaluation, the babies from the experimental group who continued showing symptoms of colic received a second session of CST. On day 14, after evaluation, the babies from the experimental group who continued showing symptoms of colic received a third session of CST. On day 24, the parents of babies of both groups completed the questionnaire and diary assessments and no baby received CST.

After each evaluation, the assessments were placed in a sealed envelope, each assigned with a unique number, for later analysis. An independent researcher, not involved with the study, collected these envelopes and entered the data associated with each number into the computer program. These data were shared with the statistician in order to analyze the results. The researchers involved in this trial did not have access to the data at any point.

2.7. The treatment group

The babies were convened on 4 different days for assessment: on day 1 (baseline), day 7, day 14 and day 24 of the study. After each evaluation, it was determined whether or not the babies received a CST session. For each baby, the number of sessions was determined by baby's development and the remission of symptoms, this information was reported by the parents of the babies in each evaluation. Babies received 1, 2 or 3 CST sessions with a duration of 30–40 minutes. The first session of CST was conducted on day 1, the second session on day 7 and the third session on day 14.

Two out of the 29 babies from the experimental group (5.8% EG) received only 1 session of CST, on day 1. Seventeen babies (58.6% EG) received 2 sessions of CST, on days 1 and 7. Ten babies (34.4% EG) received 3 sessions of CST, on days 1, 7, and 14. The average of the sessions performed with the CST group was 2.27 and the average duration of each intervention period was 9 days.

The Craniosacral Therapy intervention included the following techniques: balance of the pelvic, thoracic and clavicular diaphragms (transverse planes), The Craniosacral Therapy intervention included the following techniques: balance of the pelvic, thoracic and clavicular diaphragms (transverse planes).[48–50]

In each session, the craniosacral therapist would assess the patient's entire body, following the manual techniques described above and treating the built-up tension in the body tissues with a gentle listening touch until the therapist sensed a release of the tension.

Before the first evaluation, the parents of the babies received written recommendations on how to take care of a baby with infantile colic. The recommendations include: 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 midline positioning when breastfeeding, bend the baby's knees when the baby is being held; make sure the baby grips the breast tightly, make sure 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; raise the baby to a sitting position after feeding to facilitate the expulsion of gases; put the baby upside down when the baby is awake; flex and extend the baby's legs simultaneously; hold and gently rock the baby. These same recommendations appear in the pediatric guidelines provided by health centers to parents of babies suffering from infantile colic. A similar document was given to the control group. On day 1 the parents received a detailed copy of the guidance, so they could easily rely on it and apply the recommendations at home.

2.8. The control group

The parents of the babies in the control group were advised to continue with their usual activities, defined as any normal day-to-day activities. These babies did not receive any manual therapy nor were treated at any point by the therapist conducting this study during its 24-day duration. On day 1 the control group parents received written recommendations identical to those given to the parents of the CST group. The same recommendations appear in the pediatric guidelines provided by health centers to parents of babies suffering from infantile colic.

2.9. Statistical analysis

All the statistical analyses were conducted using SPSS Statistics software version 22.0.

Descriptive statistics were employed to analyze the clinical and demographic information. The data collected from the outcomes of each group that showed the mean and the standard deviation (SD); the Chi-squared test (for the qualitative variables) and Student's *t*-test (for the quantitative or scale variables) were performed to assess the homogeneity of both groups for demographic and clinical characteristics.

Repeated measures analysis of covariance (rANCOVA) with Bonferroni correction were applied to test the effects of the interventions on crying, sleep and colic severity across all time points. rANCOVA was conducted with time (on day 7, day 14 and day 24) as a within-subject variable, with intervention group (CST or control) as a between-subject factor and respective baseline values as covariates. Baseline level of crying was considered as a covariate to crying, baseline level of sleep was considered as a covariate to sleep and baseline level of colic severity was considered as a covariate to colic severity.

Post hoc pairwise comparisons with Bonferroni correction were performed to study at which time point the groups differ significantly. Mean differences and 95% confidence interval (CI) between-group were calculated on day 7, day 14, and day 24 for crying, sleep and colic severity.

Partial eta squared ($\eta 2$) was used as an indicator of effect size in

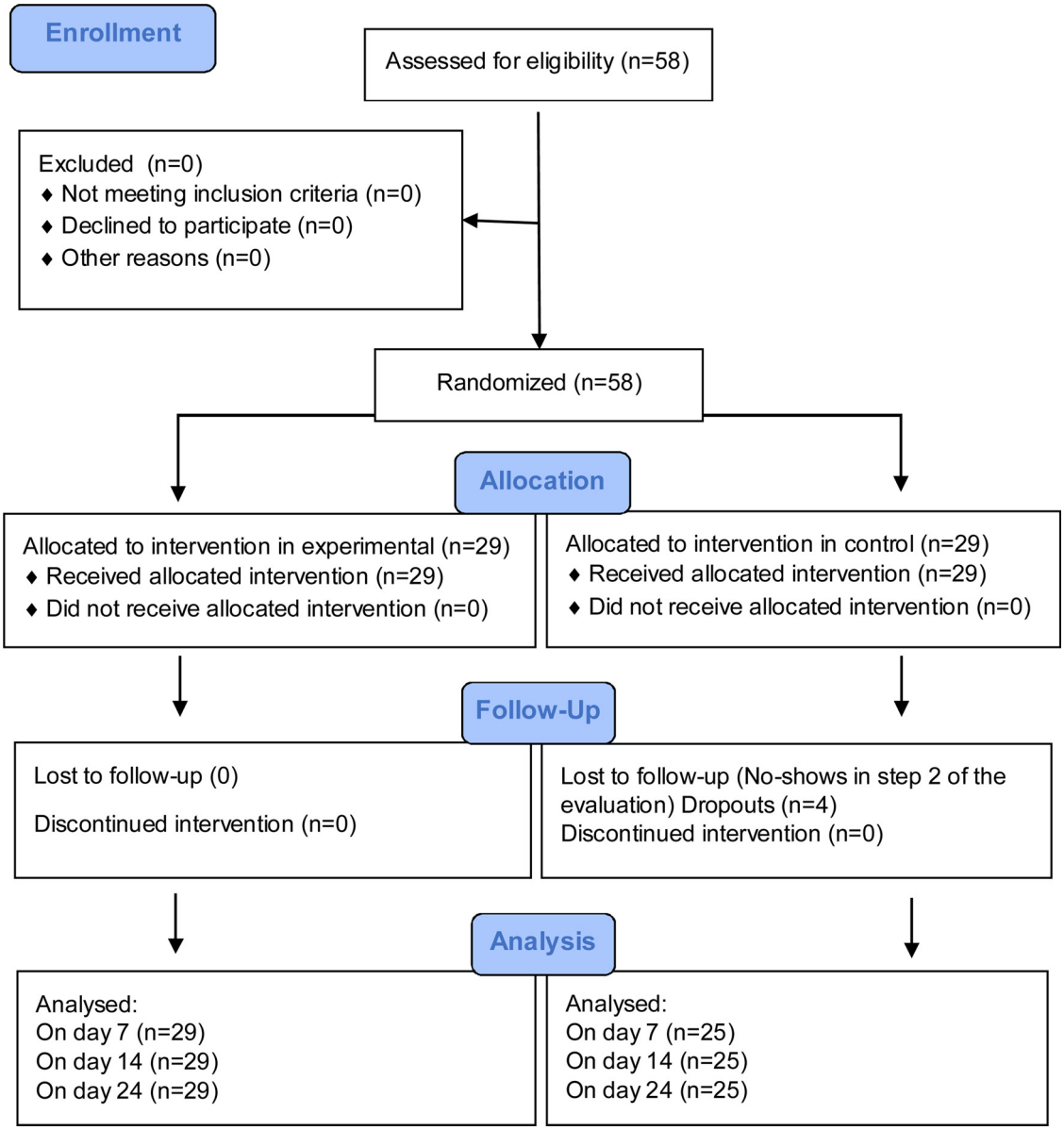

Fig. 1. Flow diagram of the study progress.

different levels which is elucidated as small 0.01; medium 0.06 and large 0.14. In addition, effect sizes were calculated by Cohen´s 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.

3. Results

A total of 29 babies with infantile colic were randomly assigned to the CST group and 29 babies to the control group (see Fig. 1). The missing data found corresponds to the 4 dropouts of the control group. The 4 babies who left only attended the first day in which the socio-demographic characteristics and the base values were registered, they did not attend the rest of the evaluations (days 7, 14 and 24).

The babies' baseline characteristics of the socio-demographic parameters are shown in Table 1. The age of the babies ranged from 10 to 84 days, a mean of 36.5 ± 18, 50% female and 50% male, with various types of birth experiences, feeding and feeding characteristics, equally distributed. No significant differences ($p > 0.05$) were found between the infant's social demography in either study group. The sample was homogeneously distributed between the groups of this study as regards to the socio-demographic parameters (Table 1).

The descriptive analysis (mean, SD) and the effects obtained from primary and secondary outcomes (crying, sleep and colic severity) on day 7, day 14 and day 24 are specified in Table 2.

The progress obtained from beginning to end was reflected in separate charts for crying (Fig. 2), colic severity (Fig. 3) and sleep (Fig. 4).

3.1. Primary outcomes

Results of rANCOVA with baseline crying as covariate demonstrated significant group effect in crying hours ($F = 188.47$; $p < 0.0005$; $\eta 2 = 0.78$), with the CST group showing the greatest improvement across the three study endpoints (Table 2).

Babies from the CST group showed a statistically significant difference in the decrease of crying hours in comparison with the control group, a mean difference of −2.47 h (95%CI, −2.95 to −1.99; $p < 0.0005$; $d = 1.73$) on day 7, -3.29 h (95%CI, -3.7 to −2.8; $p < 0.0005$; $d = 2.87$) on day 14 and -3.20 h (95%CI, -3.7 to −2.6;

Table 1
Sample Characteristics at Baseline: mean, standard deviation and homogeneity.

Characteristics	Total	Experimental (n = 29)	Control (n = 29)	p
Sex (%)				0.793
Female	50%	48.27%	52%	
Male	50%)	51.72%	48%	
Age (mean ± SD)	36.41 ± 18	33.69 ± 15.14	39.14 ± 20.15	0.253
Type of childbirth (%)				0.115
Vaginal delivery (withoutcomplications)	50%	37.93%	64.00%	
Vaginal delivery (withcomplications)	22%	27.59%	16.00%	
Squeduled C-section	7%	6.90%	8.00%	
Emergency C-section	20%	27.59%	12.00%	
Type of feeding (%)				0.269
Breastfeeding	65.5%	72.4%	58.6%	
Formula	34.5%	27.6%	41.4%	
Feedingbehaviour (%)				0.188
2-3 hours in betweentakes	46.6%	37.9%	55.2%	
< 2-3 hours in betweentakes	53.4%	62.1%	44.8%	
Feedingduration (%)				0.412
Lessthan 30 minutes	63.8%	58.6%	69%	
More than 30 minutes	36.2%	41.4%	31%	
Anti-colicproducts*(%)*				0.738
No	81%	82.8%	79.3%	
Yes	19%	17.2%	20.7%	
Vitaminsintake (%)				1
Never/hardlyever	62.1%	62.1%	62.1%	
Yes/frequently	37.9%	37.9%	37.9%	
Mothers consumption of dairy products *(%)*				0.487
No	17.2%	20.7%	13.8%	
Yes	82.8%	79.3%	86.2%	
Time-period with colic diagnosis *(%)*				0.426
2 weeksorless	56.9%	62.1%	57.7%	
More than 2 weeks	43.1%	37.9%	48.3%	
Crying hours *(mean ± SD)*	3.51 ± 1.45	3.77 ± 1.47	3.24 ± 1.47	0.165
Sleep hours *(mean ± SD)*	10.53 ± 2.28	10.10 ± 2.28	10.96 ± 2.24	0.153
Colic severity *(mean ± SD)*	60.16 ± 7.18	61.9 ± 7.3	58.41 ± 6.73	0.064

Table 2
Effects of Craniosacral Therapy in comparison whit control group. SD: standard derivation; SE: standard error: CG: control group; EG: experimental group; CI: confidence interval; η2: Partial eta squared; rANCOVA: repeat measures analysis of covariance, considering respective baseline values as covariate. *significant between group difference (p < 0.001). d: Cohen´s d, effect size (95% CI); CI: confidence interval; η2: partial et η2a squared.

Outcome	Group	Statistic descriptive (unadjusted)				Adjusted		
		Baseline Mean ± SD	Day 7 Mean ± SD	Day 14 Mean ± SD	Day 24 Mean ± SD	Day 7 Mean ± SE	Day 14 Mean ± SE	Day 24 Mean ± SE
Crying	**CG (n = 25)**	3.24 ± 1.5	3.20 ± 1.5	3.06 ± 1.5	2.96 ± 1.7	3.37 ± 0.17	3.19 ± 0.16	3.1 ± 0.18
	EG (n = 29)	3.77 ± 1.4	1.05 ± 0.8	0.01 ± 0.09	0.01 ± 0.09	0.9 ± 0.16	−0.1 ± 0.14	0.1 ± 0.17
Sleep	**CG (n = 25)**	10.76 ± 2.2	10.76 ± 2.2	11.18 ± 2.2	14.13 ± 2.1	10.51 ± 0.27	10.98 ± 0.29	11.15 ± 0.31
	EG (n = 29)	10.1 ± 2.2	13 ± 1.9	13.98 ± 1.6	11.34 ± 1.7	13.2 ± 0.25	14.15 ± 0.27	14.29 ± 0.29
Colic Severity	**CG (n = 25)**	56.76 ± 5.3	57.36 ± 5.7	56.96 ± 5.8	56 ± 6.5	58.32 ± 1.08	57.65 ± 1.04	56.7 ± 1.02
	EG (n = 29)	61.9 ± 7.3	47.07 ± 5.5	40.93 ± 4.6	38.76 ± 3.4	46.23 ± 1	40.33 ± 0.96	38.15 ± 0.94

	Between-group Difference									rANCOVA**		
	Day 7			Day 14			Day 24			*F*	*p*	η2
	Mean (95% CI)	p	*d*	Mean (95% CI)	p	*d*	Mean (95% CI)	p	*d*			
Crying	−2.47* (−2.9, −1.9)	0.000	1.73 (1.10,2.35)	−3.29* (−3.7, −2.8)	0.000	2.87 (2.11,3.63)	−3.20* (−3.7, −2.6)	0.000	2.54 (1.82,3.26)	188.47	0.000	0.78
Sleep	2.69* (1.9,3.4)	0.000	1.08 (0.50,1.65)	3.17* (2.3,3.9)	0.000	1.44 (0.84,2.04)	3.13* (2.2,3.9)	0.000	1.48 (0.88, −2.09)	0.68	0.000	0.54
Colic Severity	−12.08* (−15.1, −9)	0.000	1.82 (1.18,2.45)	−17.31* (−20.2, −14.3)	0.000	3.07 (2.28,3.86)	−18.55* (−21.4, −15.6)	0.000	3.35 (2.52,4.18)	143.74	0.000	0.73

* p < 0.0005, Difference between experimental group (CST) and control group on day 7, 14 and 24.
** rANCOVA: repeated measures analysis of covariance, considering respective baseline values as covariate.

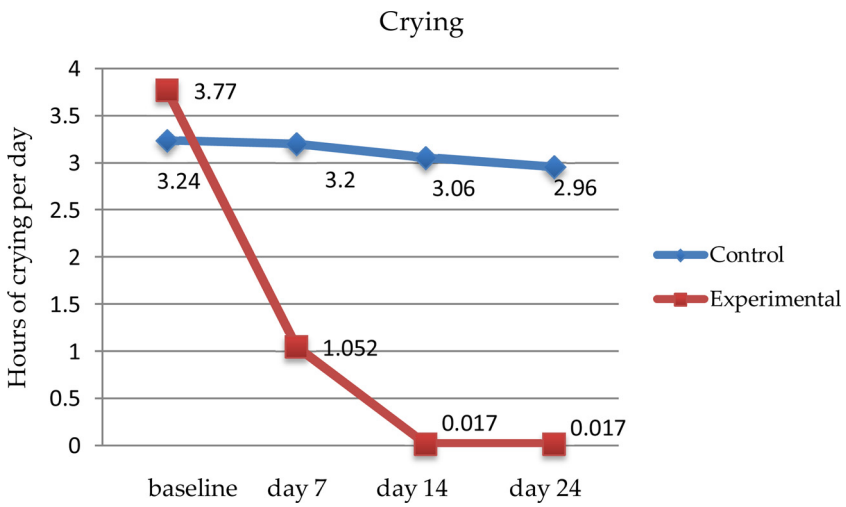

Fig. 2. Average length of crying chart.

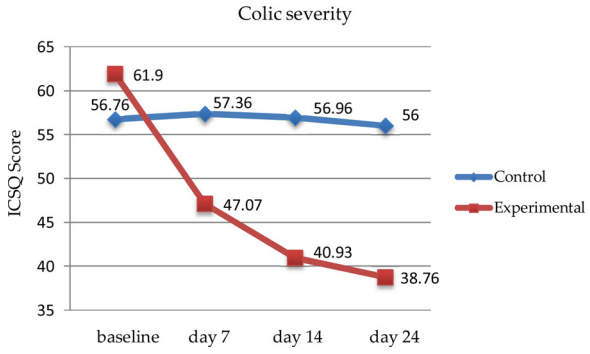

Fig. 3. Average score of colic severity chart.

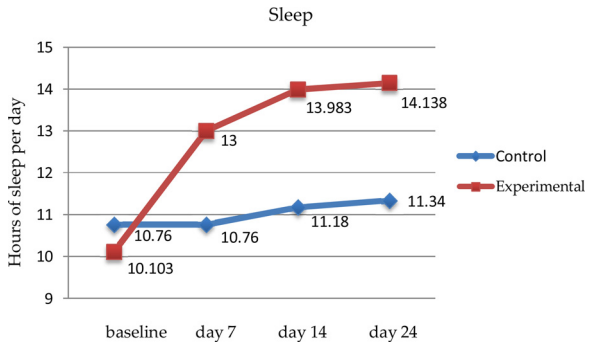

Fig. 4. Average length of sleep chart.

$p < 0.0005$; $d = 2.54$) on day 24, with a large effect size (Table 2).

3.2. Secondary outcomes

Results of rANCOVA with baseline sleep as covariate demonstrated significant group effect in sleep hours ($F = 61.20$; $p < 0.0005$, $\eta 2 = 0.54$), with the CST group showing the greatest improvement across the three study endpoints (Table 2).

Babies from the CST group showed a statistically significantly increase of sleep hours in comparison with the control group: 2.69 h (95%CI, 1.9 to 3.4; $p < 0.0005$; $d = 1.08$) on day 7, 3.17 h (95%CI, 2.3 to 3.9; $p < 0.0005$; $d = 1.44$) on day 14 and 3.13 h (95%CI, 2.2 to 3.9; $p < 0.0005$; $d = 1.48$) on day 24 (Table 2)

Results of rANCOVA with baseline sleep as covariate demonstrated significant group effect in colic severity ($F = 143.74$; $p < 0.0005$, $\eta 2 = 0.73$), with the CST group showing the greatest improvement across the three study endpoints (Table 2).

In comparison with the control group, babies in the CST group reported a significantly lesser colic severity, a mean difference of −12.08 points (95%CI, −15.1 to −9.0; $p < 0.0005$; $d = 1.82$) on day 7, −17.31 points (95%CI, −20.2 to −14.36; $p < 0.0005$; $d = 3.07$) on day 14 and −18.55 points (95%CI, −21.4 to −15.6; $p < 0.0005$; $d = 3.35$) on day 24 (Table 2).

Furthermore, the parents reported no adverse effects on the babies involved in this study.

4. Discussion

This randomized controlled trial showed the effectiveness of Craniosacral Therapy in an experimental group receiving CST, as opposed to a control group where the parents only received guidance on how to manage infantile colic. The results suggest significant and clinically relevant effects regarding crying, sleep and colic severity on day 7, day 14 and day 24 of the study. The babies involved in this study were infants diagnosed with colic, aged 10–84 days.

The differences in primary and secondary outcomes between the CST group and the control group showed improvement in the group that received CST as opposed to the group that did not receive any manual therapy. Results showed an effect size large throughout every stage of the evaluation. The differences between the groups during the final evaluation (on day 24) suggest that the group who received CST registered 18.55 points lower for colic severity and 3.2 h less crying time per day in comparison with the control group. It also showed an increase in the hours of sleep, 3.13 h more per day than the control group.

The previous literature shows studies that underline the effects of CST in infantile colic. One study applied 5–7 sessions (2–3 per week) of occipital-sacral decompression to one group and vertebral manipulation to the other.[31] Another study applied CST techniques in 1–4 sessions (1 per week) to one group, based on the therapist's judgment, while the other group received no manual therapy.[32] Both of these trials [31,32] found that the hours of crying were reduced and sleep increased in infants with colic.

For the study discussed here, we decided to perform 1–3 sessions depending on the cessation or continuation of colic symptoms in each participant receiving CST and to leave a week of margin between sessions in order to let the body adapt to the release of tensions after each session.

We believe that the number of sessions that each infant needs in order to reach a state of relaxation may depend on the different

musculoskeletal dysfunctions and tensions found in each individual. More trials are needed to further investigate this topic.

An ongoing issue facing studies of manual therapies for babies suffering from infantile colic is whether or not to blind the parents from knowledge about the treatments performed on the babies. The ideal from a methodological point of view would be to have the parents evaluate their babies' symptoms without knowing whether or not any treatment had been performed. However, preventing parents from being present while a stranger administers physical therapy lasting more than 30 min to the infants could aggravate the babies' symptoms, provoking increased crying and triggering worry and irritation on the part of the parents.[33] For this reason, some pediatricians advise against the blinding of parents during the studies,[33] and thus was the case in this study. The majority of RCTs [28,29,32,33] involving manual therapy did not blind the subjects' parents. Other more quickly applied treatment types, such as medication or probiotics, facilitate blinding parents to the treatment as there is no need for them to be separated from their infants for the duration of the treatment or sham. In a randomized sham-controlled trial of craneosacral therapy for neck pain was used light-touch sham treatment.[41] In this study a light-touch was not use as sham because light-touch could induce relaxation and activate the parasympathetic nervous system [51] and it could influence in colic symptoms.

In on RCT [30] involving chiropractic manual therapy for infantile colic, three groups of babies were divided into babies treated, parents non-blinded; babies treated, parents blinded; and babies not treated, parents blinded. The results obtained for the treated infants were not significantly different for the blinded compared with non-blinded parents. The findings of Miller (2012) showed that knowledge of treatment by the parent did not appear to contribute to the observed treatment effects. Thus, it is unlikely that observed treatment effect is due to bias on the part of the reporting parent.[30]

Going forward, it would be desirable to perform future studies with and without blinding the parents to the treatments, thus enabling better conclusions to be drawn about the effectiveness of the treatments and any bias on the part of the parents.

From all the manual techniques used for the treatment of infantile colic, we chose CST, which had already been used in two RCTs where the symptoms of infantile colic were reduced and no side effects were found after CST was performed.[31,32]

The theoretical foundation of this study is mostly based on the fact that compression of the vagus nerve can cause somatic symptoms, such as excessive crying [32,47,52] and irritation of nerves IX and X caused by a jugular foramen compression, which may result in gastrointestinal issues and swallowing disturbances, including feeding difficulties for the baby.[49,53,54] Additionally, this can impact higher cognitive functions such as alertness, sleep and emotions.[54,55] Cranial dysfunctions can also be a common factor in newborn babies due to the stress experienced during birth.[47] Kirjavainen et al. did not find any relation between the imbalance of SNA and infantile colic,[56] while Porges et al [57] observed that the bigger the vagal tone of the babies, the more irritability and difficulty is present while trying to soothe themselves.

CST may help to release cranial dysfunctions and enhance the irrigation of the vagus nerve to reduce the symptoms of infantile colic.[49,53,58] Therefore, the focus of a large part of the techniques used in this study was to release cranial dysfunctions and tensions that may be compressing the vagus nerve at any point.

Moreover, excessive crying in young infants has been associated with an abnormal cranial rhythmic impulse (CRI) [59] and one of the bases of CST is to facilitate the improvement of the CRI.[38,39]

The techniques used in this study have been selected based on previous research on CST in infantile colic,[31,32] although we consider further studies as essential to consolidate the effectiveness of this therapeutic procedure.

4.1. Strengths and Limitations for this study

The strengths of this study design include random and blind sequence allocation, and use of a control group that received no treatment and with which the results and the evaluation tools were compared. This study conducted its evaluation with a reliable questionnaire (ICSQ) to measure the severity of infantile colic [5] and a diary to measure crying and sleep, a process that is similar to the RCTs on CST and colic mentioned previously.[31,32]

One limitation of this study was the absence of blinded assessment by the parents. This could be considered a distracting factor and consequently it needs to be addressed in future studies

It would be interesting to perform a RCT with long-term follow-up, to observe the development of both the control group and the experimental group over time.

The manual treatment used in this study leads only to conclusions about the effectiveness of CST given the subjective clinical outcomes. It is yet not clear if CST really affects the fascial structures and articulations specified and, in that case, if these changes would lead to quantifiable physiological responses. Therefore, the design of further studies should include additional objective physiological measures as well as more standardized fascial manual techniques.

5. Conclusion

Craniosacral therapy appears to be effective and safe for infantile colic by reducing the number of crying hours, the colic severity and increasing the total hours of sleep. Further studies with long-term follow-up are needed to draw more specific conclusions supporting the effectiveness of CST in the treatment of infantile colic.

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