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Usual light touch osteopathic treatment versus simple light touch without intent in the reduction of infantile colic crying time: A randomised controlled trial

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ABSTRACT

Background: Many parents seek osteopathic care for their infants with colic. Our aim was to test the effectiveness of usual light touch osteopathic treatment on crying time for infants with 'colic'.
Methods: A superiority, two arm, single blinded (parent) multi-centre (UK, Australia and Switzerland), randomised controlled trial, included healthy infants between 1 and 69 days of age who excessively cried, fussed, or were distressed and difficult to console. The Test intervention consisted of usual light touch osteopathic treatment, the Control intervention simple light touch to random body locations with no treatment intent. Both groups received best practice advice and guidance. The primary outcome was the daily crying time, reported hourly by parents in a diary, for two-weeks. Secondary outcomes were parenting confidence, global change, satisfaction, and experience of care.
Results: Sixty-six infants were recruited (32 Test: 34 Control group). Mean average daily crying time in the Test group was 124 min (SD = 69, n = 26) and in the Control 115 min (SD = 49, n = 29). After adjustment, infants in the Test group cried 2.2 min more per day than those in the Control group (CI95 % −20 to 25 min, p = 0.849). Parents' perceptions of global change in symptoms, satisfaction with, and experience of care were high and similar in both groups. There were no serious adverse events related to the treatments or the trial.
Conclusion: Usual light touch osteopathic treatment was not superior to simple light touch without treatment intent. The biomechanical explanatory models and underpinning assumptions about the mechanisms of osteopathic intentional light touch care may require reconsideration.
Trial registration: ACTRN12620000047998 (January 22, 2020).

1. Background

Infantile colic (undetermined/unexplained acute abdominal pain) is reported in around 18 % of infants (range 2–73 % depending on definition) [1]. Infantile colic is defined as crying and/or fussing for 3 h or more per day, during three or more days per week or in the preceding week (Rome IV criteria) [2]. Infantile colic normally subsides naturally with the prevalence of colic at 10–12 weeks old at around 0.6 % compared to 25.1 % at 5–6 weeks. Normal daily infant crying time has been reported at around 2 h during the first six weeks of life (range of means 117–133 min) [3]. The ramifications of excessive infant crying on the infant, carers and families can be profound with reports of parental bonding issues, maternal depression and child development being affected [4,5].

Available treatments for colic are probiotics, simethicone, and controversially proton pump inhibitors (PPIs) and manual therapy. The most convincing evidence is for probiotics, particularly *lactobacillus reuteri* for breast-fed infants suggesting gastric origins for the condition

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[6]. The evidence for simethicone-based products is less convincing as they have been associated with risks to the infants [7]. PPIs are used in the treatment of GORD but increasingly are being used as an approach to treating colic, despite not being recommended due to potential adverse reactions [8].

In Europe, manual therapy care is given to as many as 10–25 % infants [9–11]. Usual osteopathic treatment for infants is gentle, subtle, and proposed to reduce tissue tension and enhance fluid flow. The rationale offered by osteopaths to parents to explain the mechanisms of action of the manual therapy are theoretically driven with little evidence to support them. They include birth-related trauma affecting the vagus nerve [12,13] and/or cranial bone movement dysfunction [14] and difficulty in infant auto-regulation to everyday stimuli [15]. It has also been suggested that touch may have a role in modulating reactions in internal organs [16,17].

The existing quality of evidence for the effectiveness of manual therapy care for infantile colic is varied and overall inconclusive [18–21]. More robust high-quality research is needed in this area, especially for sufficiently powered, blinded, suitable control comparison group randomised controlled trials [22].

This study aimed to test the effectiveness of usual light touch osteopathic treatment against simple light touch without therapeutic intent for reducing crying time in infants with colic, with best practice advice and guidance provided to all parents regardless of group allocation.

2. Methods

This was an international multi-centre, single blind, two arm (1:1), superiority, randomised controlled trial (RCT) to test the effectiveness of usual light touch osteopathic treatment with advice and guidance (the Test group) compared with simple light touch without intent to treat with advice and guidance (the Control group). The detailed protocol has been published elsewhere [23], as has the study plan, the simplified protocol for participating osteopaths and the statistical analysis plan [24]. Input was sought from parents in the design and development of the methods and protocol.

2.1. Setting

The study was conducted in a 'real world' setting in private osteopathic clinics in the UK, Australia and Switzerland. Participant parents were offered free treatment for their infants, with a registered osteopath providing paediatric care in their usual practice.

2.2. Participants

Participants were infants under 10 weeks old who were excessively crying, distressed and difficult to console but healthy and thriving. 'Excessively crying' was defined using the Rome IV criteria for research: infants who cry and fuss and who are difficult to console for more than 3 h per day, for three days or more, for one week or more [2]. Crying time tends to subside after 12 weeks [3,25], so only infants who were under 12 weeks at the 14-day follow-up were recruited.

2.3. Recruitment, consent and procedures

All parents and or guardians with infants under 10 weeks old attending participating clinics with symptoms of colic were invited to participate in the trial. If interested, they were sent a participant information leaflet, a copy of the consent form and a crying diary. All parents were given at least 24 h or more to consider the information. Parents were asked to monitor their infants crying for 24 h prior to the first consultation.

At the first consultation, if they agreed to be in the trial, valid informed consent was obtained. After this, the infant was examined. If the infant was systemically well and thriving, the parent completed the baseline questionnaire and the infant was then randomly allocated to a study group.

Infants had up to four consultations (as determined by the parent and osteopath and the infant's needs) over a two-week period. Parents were asked to complete a 14-day crying diary, recording the minutes their baby cried every hour.

Fourteen days after randomisation, the parents completed a follow-up questionnaire.

Parents were informed, if they wanted to know, about their infant's group allocation once their follow-up data were collected or, if follow-up data were not received, after 21 days.

2.4. Randomisation and allocation concealment

Infants were randomly allocated to trial arms at a 1:1 ratio, using a randomised block design, with block sizes of 4 and 6 via an electronic clinical trials platform (Castor EDC). Osteopaths accessed the trial software during the first consultation to randomise and allocate the infant: after consent, baseline data capture, case history and examination of the infant. Parents were blinded to their infant's allocation. The osteopath delivered both the Test and Control interventions and therefore was not blinded. To test the effectiveness of the blinding, parents were asked in the follow-up questionnaire (day 14) whether they thought their infant was in the Test group, Control group or if they did not know. The trial statistician was blinded to the Test and Control group allocations.

2.5. Data collection

Baseline data about the parent and infant were collected via an email link to an online questionnaire sent to parents prior to their initial consultation. A follow-up questionnaire was sent automatically 14 days after randomisation. Parents photographed their infant's crying diaries and these were sent directly to the study team. Diary data were entered electronically and independently by two members of the study team, who compared entries and corrected any discrepancies.

The osteopaths also recorded data about the parent and infant, treatment given, the advice and guidance they gave at each consultation and how the infant was responding according to the parent, including whether the infant had unwanted or unexpected reactions to treatment. At baseline parents were asked about the expected response to osteopathic care (5- point Likert scale ranging from 'very well' to 'not well').

2.6. Interventions

Both groups received best practice advice and guidance appropriate to the parent and infant based on NICE Guidance [26].

The Test intervention was designed to be as close as possible to what osteopaths usually do when treating infants with colic. It consisted of usual light touch osteopathic treatment delivered with treatment intent for 10–20 min. High velocity joint manipulations were excluded as they are contraindicated in the treatment of infants.

Light touch osteopathic treatment is delivered using gentle movements of the hands on the infant's body with the aim of reducing tissue tension and encouraging movement of fluids and fascia. The light touch was administered to areas of the body as determined by the osteopath after palpation of the tissues during the osteopathic examination and assessment of the infant. Treatment techniques included light touch to articulations, tension release (to ligaments, articular strains, fontanelles/cranial sutures), facilitated positional release, indirect functional techniques, myofascial release, soft tissue massage and/or stretch and visceral movement.

The Control intervention was designed to mimic the Test intervention to ensure parent blinding and to ensure that all non-specific effects were present in both groups. The Control intervention consisted of simple light touch to the infant, administered with no treatment intent to

the following pre-chosen areas: cranium, thorax, abdomen, sacrum/pelvis. Osteopaths did their normal observations, palpation and testing as they would for a treatment with intent. Osteopaths randomly chose the locations to which they were to place their hands for three to 5 min. To help osteopaths not deliver treatment to the infants in the Control group, they were asked to do a cognitive mental task. This consisted of counting backwards in 6s, 7s or 8s from 200 or to name animals or vegetables for each letter of the alphabet, in their head, while touching the infants in the pre-specified areas. These cognitive tasks have been shown to modify osteopaths' brain touch processing [17] and are believed to prevent touch feedback to prevent therapeutic touch [27].

The light touch protocols were administered for between 10 and 20 min in both groups during one to four visits lasting 30–45 min.

Both interventions were delivered by registered osteopaths, specifically trained for the trial. The training covered the trial procedures, delivering the interventions, best practice advice and guidance as per NICE [26] and good clinical practice in research.

2.7. Fidelity

Fidelity of the intervention delivery was planned to be assessed via observation, the patient records and feedback/reflective interviews with the participating osteopaths. However due to the COVID19 pandemic social distancing restrictions, between 2020 and 2022, we were unable to carry out the observational checking.

2.8. Primary outcome

The primary outcome was total daily crying time in minutes, recorded by parents as the number of minutes of crying time (to the nearest 5 min) for each hour, over each 24-h period. This was recorded for 14 consecutive days. The primary outcome was the average between group difference in daily crying time over 12 days excluding the day prior to enrolment and the day participants received the first treatment.

The crying diary has been validated and is an accepted standard method to record crying time [25].

2.9. Secondary outcomes

Secondary outcomes at follow-up were parenting confidence, global change, experience and satisfaction with care.

Changes in parenting confidence were measured using the Karitane Parent Confidence Score at baseline and at 14-day follow up. This score relies on 15 questions about parenting confidence with a Likert scale of four choices (total score: 0 to 45 points). Movement of 6 points or more was considered as meaningful [28].

Global change in the infant's symptoms were measured using a 7-point Likert scale from completely recovered to vastly worse. Experience was measured using a 5-point Likert scale from 'very good' to 'very poor'. Satisfaction was measured using a 5-point Likert scale from 'very satisfied' to 'very dissatisfied'.

2.10. Additional care, unexpected and/or adverse events

During the trial period parents were asked about additional care they gave to their infants, additional health care consultations during the trial period and any changes in symptoms that caused concern.

2.11. Sample size

To detect a 30-min between group difference (90 min vs. 120 min, SD 45 min), with 80 % power and a two-sided 5 % significance level, 72 participants were needed. Allowing for a 15 % drop-out, 84 infants were to be recruited. The initial estimation from the protocol had set the target to 112 infants with a power of 90 %. In January 2022, following recruitment difficulties due to COVID-19, the data monitoring committee approved the trial steering committee's request to lower the study power to 80 % and suggested improving the statistical power by using serial data and including predictive co-factors in the primary analysis. This new estimated sample size was still conservative as it did not account for increased precision due to multiple measures and adjustment for co-factors. The study was therefore capable of excluding a minimal 30-min between group difference even for a slightly smaller sample size.

2.12. Statistical analysis

All analyses were intent-to-treat (ITT) except for a secondary per protocol analysis on the primary outcome. This meant that participants' data were allocated to the group they were randomised to independently of the true intervention they received or the presence of a protocol deviation. All hypothesis tests were two-sided, and the significance level was set at 5 %. Missing data were not replaced except for those diaries that reported presence of crying at specific hours, without providing the duration in minutes. For these missing values, we imputed median reported crying times specific to each hour slot.

The primary outcome of crying time (i.e. individual daily measures of crying time in minutes) was analysed using linear mixed-effects modelling. The response variable was daily crying time, explanatory variables were: group allocation, baseline crying time, expectations of treatment, age of infant at entry, and day of measurement (2–13 days after randomisation). The additional variables were used to account for eventual between-group imbalances and changes of crying duration over time that were independent of group allocation. Random effects were the infants, modelled as random intercepts. This latter effect was included to account for lack of independence induced by repeated measures. The predictors were determined a-priori. Residuals were analysed to check model assumptions. The same approach was used for secondary outcomes.

Secondary analyses included a per-protocol analysis, worse and best-case scenario to account for missing data and sensitivity analysis. This included comparing: excluding vs imputing crying times, adjusting vs not adjusting for baseline crying time, age of infant at entry, and expectations of treatment, recruitment sites or performance bias (number of treatment sessions, and use of adjunct advice and/or complementary treatments). Each group's 25th and 75th percentile for daily crying time were used to replace missing data; once to evaluate the worst-case scenario (25th for the Treatment group and 75th for the Control group), and once for the best-case scenario (75th for the Treatment group and 25th for the Control group). Bang's blinding index was used to test the effectiveness of parent blinding at the end of the follow-up period [29]. All analyses were conducted using StataCorp. 2017. *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC.

2.13. Protocol amendments

There were three protocol amendments during the trial. The first related to the sample size (see sample size section), the second related to fidelity review (see interventions section) and the third was finalising the set of explanatory and adjusted variables during the development of the statistical analysis plan (see statistic plan). All these changes were proposed and validated by the data monitoring committee, the research management group, and the trial steering committee prior to the release of data.

3. Results

3.1. Participating osteopaths and included infants

Eighty-four osteopaths were trained to participate in the trial, with 22 osteopaths (18 female and 4 males) going on to enrol infants in the trial. Of these the range of practitioner years' of experience was 3–31

years (at start of trial training), with a mean of 13.9 years. All had post-graduate training in paediatric care (courses varied from CPD to diplomas).

We recruited 66 infants. Parents reported 975 days of crying time between September 2019 and July 2022. One in four parents who were approached, participated in the trial. There were 56 infants recruited in the UK, six in Australia and four in Switzerland. Eight osteopaths recruited one infant each, five recruited two, three recruited three, two recruited five, one recruited six, another recruited seven, and two recruited eight infants. Thirty-two infants were allocated to the Test group and 34 to the Control. No significant differences were observed in baseline characteristics between groups (Table 1). Average daily crying time at baseline was 243 min.

3.2. Protocol deviations and missing data

All participants received the treatment they were allocated to (Fig. 1). Protocol deviations could have impacted results for three participants: two received osteopathic care external to the trial, and a third was recruited at 10 weeks old. Missing data were evenly balanced between both groups (p = 0.333).

Table 1
Baseline characteristics for the test and control groups.
SD = standard deviation, SLTWI = Simple Light Touch Without Intent, ULTOT = Usual Light Touch Osteopathic Treatment.

Characteristics	Test group (ULTOT) N = 32	Control group (SLTWI) N = 34
Sex; n (%)		
Female	17 (53.1 %)	19 (55.9 %)
Male	14 (43.8 %)	15 (44.1 %)
Unknown	1 (3.1 %)	0 (0 %)
Age of infant; n (%)		
1–14 days (1–2 weeks)	0 (0 %)	1 (2.9 %)
15–28 days (3–4 weeks)	5 (15.6 %)	5 (14.7 %)
29–42 days (5–6 weeks)	15 (46.9 %)	11 (32.3 %)
43–56 days (7–8 weeks)	8 (25.0 %)	12 (35.3 %)
57–70 days (9–10 weeks)	4 (12.5 %)	4 (11.8 %)
71–84 days (11–12 weeks)	0 (0 %)	1 (2.9 %)
Age of infant in days; mean (SD)	40 (2.6)	43 (2.4)
Infant weight in kg; mean (SD)		
At birth	3.4 (0.5)	3.4 (0.4)
At baseline	4.3 (0.7)†	4.5 (0.8)‡
Age of mother; n (%)		
21–25 years	1 (3.2 %)	2 (5.9 %)
26–30 years	7 (21.9 %)	9 (26.5 %)
31–35 years	14 (43.7 %)	15 (44.1 %)
36–40 years	7 (21.9 %)	8 (23.5 %)
41–45 years	1 (3.1 %)	0 (0 %)
46–50 years	1 (3.1 %)	0 (0 %)
Missing	1 (3.1 %)	0 (0 %)
Siblings; n (%)		
None	14 (43.8 %)	21 (61.8 %)
1	14 (43.8 %)	9 (26.5 %)
2	2 (6.2 %)	2 (5.9 %)
3 or more	1 (3.1 %)	2 (5.9 %)
Missing	1 (3.1 %)	0 (0 %)
Type of parenting; n (%)		
Co-parenting	31 (96.9 %)	34 (100 %)
Missing	1 (3.1 %)	0 (0 %)
Expected response to osteopathic care; n (%)		
Very well	2 (6.2 %)	1 (2.9 %)
Well	7 (21.9 %)	10 (29.4 %)
Unsure	17 (53.1 %)	17 (50.0 %)
Not very well	2 (6.2 %)	4 (11.8 %)
Not well	3 (9.4 %)	1 (2.9 %)
Missing	1 (3.1 %)	1 (2.9 %)
Baseline reported crying time in minutes; mean (SD)	252 (119)	235 (94)
Parenting Confidence Score; n (%)		
Non-clinical range (40–45)	0 (0 %)	0 (0 %)
Mild clinical range (36–39)	4 (12.5 %)	6 (17.6 %)
Moderate clinical range (32–35)	15 (46.9 %)	17 (50 %)
Severe clinical range (31 or less)	12 (37.5 %)	11 (32.4 %)
Missing	1 (3.1 %)	0 (0 %)
Parenting Confidence Score; mean (SD), range 0–45	32.1 (3.3)	32.6 (3.3)

3.3. Blinding success

Blinding was successful. Bang's blinding index (BI) [29] was 0.062 [CI95 % −0.14 to 0.27] in the test group and 0.059 [CI95 % −0.12 to 0.24] in the control group. Hedge's g was 1.2, indicating slightly higher proportion of parents in the Test group believed they received the intervention that was being tested (21.9 % vs. 11.8 %; p = 0.275).

3.4. Infant management during trial

The number of sessions delivered to infants was not significantly different between groups (Test 2.5 vs Control 2.1; p = 0.062). All but three infants (90.6 %) in the Test group received light osteopathic touch with the aim of addressing tissue tension in the cranium, trunk, pelvis and limbs (Fig. 2). Advice was frequent in both groups with approximately 90 % of all parents receiving reassurance about the health of their infant and the natural trajectory of 'colic' symptoms. Medication and remedies administered were similar in both groups. Proportions of infants having visited their paediatrician for additional care were more frequent in the Test group than in the Control group (15.6 % vs. 0 %, p = 0.023).

3.5. Effects of usual light touch osteopathic treatment on crying time

There was no significant difference in crying time between the groups during the 12 days following the initiation of the interventions (Fig. 3). There was an overall reduction of mean crying time in both groups, with an important change between the day before the treatment and the day after the initial treatment took place in both groups (Test group = - 62 min, Control group = −72 min). Following this first drop, crying time decreased by approximately 4 min per day over the next 2 weeks in both groups (Table 2). The crude average daily crying time was 124 min (SD = 69) in the Test group and of 114 min (SD = 49) in the Control group. The adjusted between group difference in daily crying time was 2.2 min (CI95 % −20 to 25, p = 0.849) in favour of the Control group.

3.6. Secondary outcomes

Results from regression analyses for all other outcomes were consistent with no significant treatment vs control effect for parenting confidence scores, perceived changes in symptoms, satisfaction with received care or patient experience of care (Table 2).

3.7. Unexpected reactions and adverse events

Parent-reported unexpected reactions related to Test treatment from the follow-up questionnaire were rare (<10 %) and were equally distributed in both groups (Table 2). Two serious adverse events occurred (unexpected hospital admissions for chest infections), one in each group. However, they were unrelated to patient care and management (reviewed by both the trial management group and a medical physician on the trial steering committee). There were seven non-serious adverse events, 4 in the Test group and 3 in the Control, with five possibly related to the trial (exacerbation of existing symptoms).

3.8. Sensitivity analysis

When replacing missing data with percentiles (25th or 75th), in the worse-case scenario, the Test group would have an added 22 min of daily crying time over the Control group (CI95 % −6 to 49, p = 0.122);

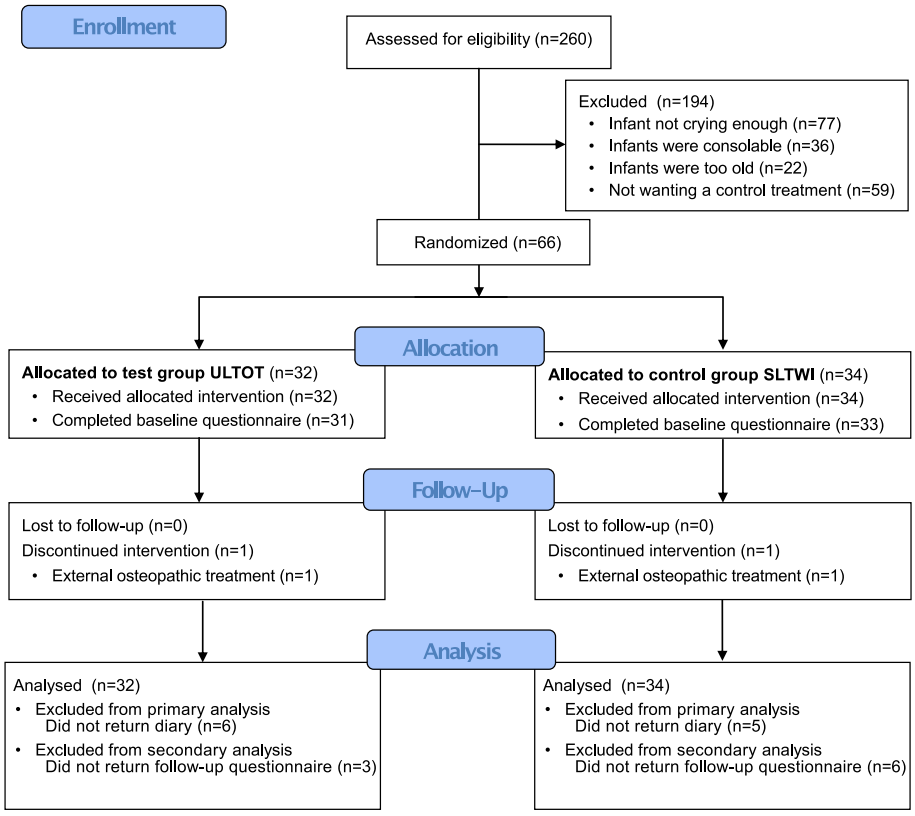

Fig. 1. The CONSORT flow diagram.

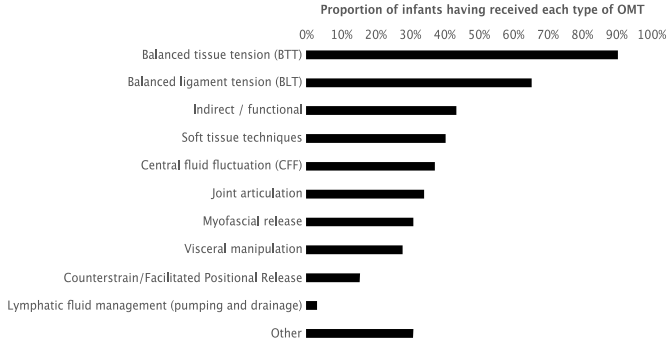

Fig. 2. Prevalence of osteopathic treatment type by infant in the test group (usual light touch osteopathic treatment).

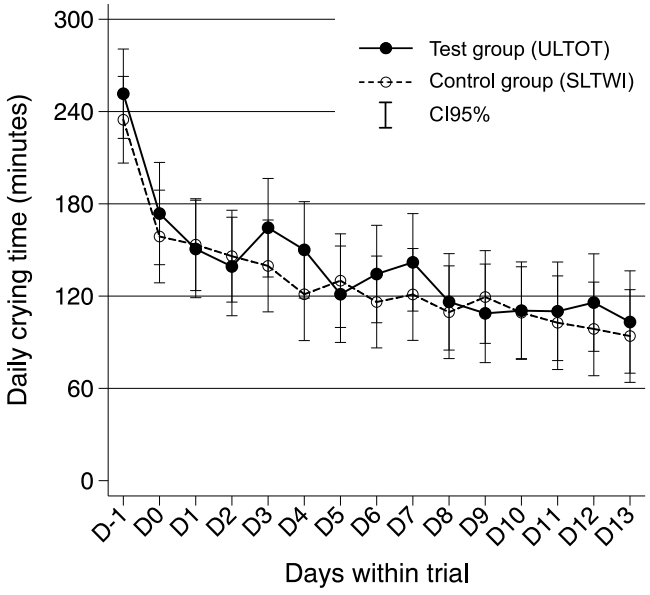

Fig. 3. Daily average crying time within each group; SLTWI=Simple Light Touch Without Intent (Control), ULTOT=Usual Light Touch Osteopathic Treatment (Test).

in the best-case scenario, a reduction of 7 min crying time over the Control group (−35 to 21; p = 0.618).

Per protocol analysis, in which only eligible patients who received the allocated treatment were analysed (n = 51), revealed similar results to the intention-to-treat approach, 4.4 min less crying time in the Control group (CI95 % −20 to 28; p = 0.718). Results were also similar when excluding the three participants whose hourly crying duration was imputed (3.6 min difference favouring the control; CI95 % −20 to 27; p = 0.766).

To account for potential performance bias (i.e. systematic differences in the way groups received care other than the tested intervention), an analysis was run adjusting for number of treatment sessions, use of hypoallergic milk supplements, and having visited a paediatrician. Mixed-effect logistic regression modelling showed these factors did not alter the results (8 min difference favouring the control; CI95 % −20 to 36; p = 0.597). Finally, we verified that results were not affected by lack of independence due to more than one participant being recruited at each site. Using multilevel mixed-effects linear modelling, we observed that most variance was explained at the participant level and that results differed little when accounting for differences at a recruitment site level (2.7 min; CI95 % −18 to 24; p = 0.804).

Table 2
Effects of usual osteopathic light touch osteopathic treatment (ULTOT) compared to simple light touch without intent (SLTWI) on primary and secondary outcomes.
P-values measured using likelihood ratio test in linear regression, Mann-Whitney *U* test for ordinal outcomes, Fisher's exact test for categorical, SD = Standard deviation, SLTWI = Simple Light Touch Without Intent, ULTOT = Usual Light Touch Osteopathic Treatment.

Outcomes	Test group (ULTOT)	Control group (SLTWI)	Between group difference[a]
	N = 32	N = 34	**(CI 95 %; *P*-value)**
Mean daily crying time (minutes); mean (SD)			
From day 1 to day 13	**124 (69)**[b]	**115 (49)**[c]	**2.2 (-20 to 25; p = 0.849)**
From day 1 to day 6	139 (67)[b]	129 (60)[c]	3.0 (−21 to 27; p = 0.810)
From day 7 to day 13	111 (77)[b]	104 (50)[c]	1.3 (−26 to 29; p = 0.926)
Parenting Confidence Score [0–45]; mean (SD)	35.9 (2.8)[c]	36.2 (2.6)[d]	−0.4 (−1.1 to 1.8; p = 0.627)
Perceived changes in symptoms; n (%)			p = 0.896
Completely recovered	0 (0 %)	0 (0 %)	
Much improved	16 (50 %)	14 (41.2 %)	
Slightly improved	5 (15.6 %)	9 (26.5 %)	
No change	6 (18.7 %)	5 (14.7 %)	
Slightly worse	1 (3.1 %)	0 (0 %)	
Much worse	1 (3.1 %)	0 (0 %)	
Vastly worse	0 (0 %)	0 (0 %)	
Did not respond	3 (9.4 %)	7 (17.6 %)	
Satisfaction with received care; n (%)			p = 0.906
Very satisfied	24 (75 %)	24 (70.6 %)	
Fairly satisfied	2 (6.2 %)	4 (11.8 %)	
Neither satisfied nor dissatisfied	3 (9.4 %)	1 (2.9 %)	
Fairly dissatisfied	0 (0 %)	0 (0 %)	
Very dissatisfied	0 (0 %)	0 (0 %)	
Did not respond	3 (9.4 %)	5 (14.7 %)	
Parent's experience of care; n (%)			p = 0.863
Very good	22 (68.8 %)	22 (61.8 %)	
Fairly good	4 (12.5 %)	6 (17.6 %)	
Neither good nor bad	2 (6.2 %)	2 (5.9 %)	
Fairly poor	1 (3.1 %)	0 (0 %)	
Very poor	0 (0 %)	0 (0 %)	
Did not respond	3 (9.4 %)	5 (14.7 %)	
Unexpected reactions; n (%)			
More distress	2 (6.2 %)	1 (2.9 %)	p = 0.608
Crying more	4 (12.5 %)	3 (8.8 %)	p = 0.705
More unsettled	7 (21.9 %)	2 (5.9 %)	p = 0.079
Vomiting more	0 (0 %)	1 (2.9 %)	p = 1.000
Increased feeding difficulties	1 (3.1 %)	1 (2.9 %)	p = 1.000
Increased difficulties sleeping	1 (3.1 %)	1 (2.9 %)	p = 1.000
Other	1 (3.1 %)	2 (5.9 %)	p = 1.000

n = 32.
[a] Adjusted for baseline crying time, infant age, prior expectations for osteopathic care, and days within trial.
[b] n = 26.
[c] n = 29.
[d] n = 28.

4. Discussion

The results indicated that the osteopathic treatment, usual light touch with therapeutic intent, was not superior to simple light touch without therapeutic intent in reducing infant crying time. The data showed that all infants crying time improved over time, suggesting that factors other than intentional manual light treatment touch could be influencing crying time. Expectation, infant age and baseline crying time did not influence the outcome. Parents' perception of positive change in crying, satisfaction with, and experience of care was high and both interventions were safe.

Despite not achieving the original recruitment target, the quality of the parent crying diary entries meant statistical power was achieved to confidently exclude a 30-min difference in the reduction in crying time between groups.

The intentional manual/hands-on light touch treatment component of osteopathic care used in the Test group in this study did not have the modulating effect expected. This means that the value of osteopathic treatment for infantile colic and the explanatory models of physiological mechanisms associated with it may need reconsidering as there was no difference between the outcomes of the different types of light touch.

As we did not have a non-touch treatment control group, we compared our infant crying times with previous observational studies, these indicated peak crying times up to 6 weeks with gradual improvement to 12 weeks and resolution in most cases by 16 weeks [3,25,30]. One study reported the prevalence of colic at 5–6 weeks being 25.6 % and at 10–12 weeks 0.6 %, indicating a significant improvement of colic symptoms between 6 and 12 weeks. In the same study [3], the authors suggest that 'colicky' infants are probably in the 90th percentile range of infant crying times but follow the same trajectory for 'normal' crying. The mean age of infants in our study was 41.5 days (~6 weeks old), meaning that many of the infants were on this natural downward trajectory for crying and that this may have had more impact than the intervention.

All outcomes improved in both groups during the trial period which probably explains the high satisfaction scores and reported global change scores, but it may also indicate a degree of recruitment bias due to self-referral. However, while parenting confidence scores improved in both groups, confidence did not improve to a level that suggested a meaningful and reliable change (6 points or more) and remained lower than the 39 points that would suggest confidence in parenting [28]. This could mean that parents who seek care beyond usual post-natal care services may have additional parenting confidence needs that are not currently being addressed.

In previous RCTs testing the effectiveness of manual therapy interventions for infantile colic and crying time with no intervention control groups, the crying time outcomes favoured the intervention [31–33] whereas in RCTs with an attention control there was either no difference or inconclusive findings between the groups [34–38]. Our results are in keeping with the latter, perhaps indicating the impact of either indirect non-specific or contextual effects on parents' reports of their infants' outcomes. The parents in both groups of our trial engaged with the treating osteopath and we know from other research that belief in the treatment by the clinician can have a beneficial effect on outcome [39]. We postulate that this may have had more influence on the outcomes than the osteopathic light touch intervention.

A limitation of our study was that the treating osteopaths were trained to deliver both interventions. Only those who were able to perform and deliver both interventions participated in the trial. Of the trained osteopaths 75 % did not recruit infants either because they felt unable to deliver light touch without therapeutic intent, they were uncomfortable with the process of random allocation, they had too many other commitments or the infants did not meet the inclusion criteria. We did a sensitivity analysis to assess for performance bias for differences between outcomes by number of recruits, sites and adjunctive treatments, which showed no difference in performance between groups. A further consideration was that the initial sample size for the trial was calculated based on minimal clinically important difference (MCID) of 30 min reduction in crying time from prior data collected from infants with colic [3]. The MCID has however never been fully explored qualitatively from a parent perspective. In light of the findings from this high quality, blinded RCT, existing meta-analyses may have to be updated [18,19].

5. Conclusions

Usual osteopathic light touch care with best practice advice and guidance was not superior to simple light touch with no treatment intent and best practice advice and guidance. Therefore, the intentional manual osteopathic intervention and associated theoretical explanations for the treatment of infants with colic may require reconsideration. The treatment was however safe.

Ethics approval and consent to participate

Ethics approvals were obtained in the UK from the UCO Research Ethics Committee 2019 for the pilot phase, from the London and South East National Research Ethics Committee (main trial) and the London-Surrey National Health Service Research Ethics Committee: IRAS # 268925 19/LO/1620 (09.11.19) for the main trial. In Australia, ethical approbation and approval was obtained from the Southern Cross University Human Research Ethics Committee: 2019/569. In Switzerland, the trial obtained ethical approbation from Swiss Ethics (BASEC-ID 2021-00099). The study was run in accordance to Good Clinical Practice and the Declaration of Helsinki (DoH-Oct2008). All legal representatives provided their revocable, informed consent for their infant to participate.

Availability of data and materials

The study plan, CRFs, ethical approbations, statistical plan, metadata, statistical coding, safety report and statistical report are available in Open Access in the Zenodo repository, 7428494 [24], https://doi.org/10.5281/zenodo.7428494. The datasets containing personal health data used in the analysis for this will be made available on request to those with a clear research question and who are willing to sign a data sharing agreement. Email: hub@uco.ac.uk. The datasets have been deposited on Zenodo with a restricted access, 7428653 [40], https://doi.org/10.5281/zenodo.7428653.

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Implications for practice

The results of this study show no benefit of light touch osteopathic care above that of light touch alone.

It challenges the rationale osteopaths use to justify their treatment of infantile colic.

The treatment was safe.

The natural trajectory of decline in infant crying and best practice advice and guidance may have had most impact on outcomes.

CRediT authorship contribution statement

Dawn Carnes: conceived the idea for the trial and devised the initial design, implemented the protocol, contributed to the trial management, interpretation of results, drafted the paper. **Philip Bright:** contributed to the development of the protocol, contributed to the trial management, interpretation of results, all contributed to the further preparation, Writing – review & editing, of the manuscript. **Kevin Brownhill:** managed the data, and the statistical analysis, contributed to the trial management, interpretation of results, all contributed to the further preparation, Writing – review & editing, of the manuscript. **Karen Carroll:** contributed to the development of the protocol, contributed to the trial management, interpretation of results, all contributed to the further preparation, Writing – review & editing, of the manuscript. **Roger Engel:** contributed to the development of the protocol, implemented the protocol, contributed to the trial management, interpretation of results, all contributed to the further preparation, Writing – review & editing, of the manuscript. **Sandra Grace:** contributed to the development of the protocol, implemented the protocol, contributed to the trial management, interpretation of results, all contributed to the further preparation, Writing – review & editing, of the manuscript. **Steven Vogel:** contributed to the development of the protocol, contributed to the trial management, interpretation of results, all contributed to the further preparation, Writing – review & editing, of the manuscript. **Paul Vaucher:** conceived the idea for the trial and devised the initial design, implemented the protocol, managed the data, and the statistical analysis, contributed to the trial management, interpretation of results, all contributed to the further preparation, Writing – review & editing, of the manuscript.

Declaration of competing interest

PB, KC, SG and PV declare that they have no competing interests.

SV is Editor in Chief, RE is an Associate Editor and KB is Statistical Advisor for the International Journal of Osteopathic Medicine. SV, RE and KB were not involved in any of the editorial process, peer-review or editorial decisions regarding this paper.

DC was the Director of National Council for Osteopathic Research (NCOR) for the first 18 months of the trial and SV is a trustee of the NCOR charity.

List of abbreviations

BI	Bang's blinding Index
CI	Confidence Interval
CPD	Continuous Professional Development
ITT	Intent-to-treat
MCID	Minimal Clinical Important Difference
OMT	Osteopathic Manipulative Treatment
PPIs	Proton Pump Inhibitors
RCT	Randomised Clinical Trial
SD	Standard Deviation
SLTWI	Simple Light Touch Without Intent (Control)
ULTOT	Usual Light Touch Osteopathic Treatment (Test)
UK	United Kingdom

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