

EFFICACY OF CHIROPRACTIC MANUAL THERAPY ON INFANT COLIC: A PRAGMATIC SINGLE-BLIND, RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Objective: The purpose of this study was to determine the efficacy of chiropractic manual therapy for infants with unexplained crying behavior and if there was any effect of parental reporting bias.

Methods: Infants with unexplained persistent crying (infant colic) were recruited between October 2007 and November 2009 at a chiropractic teaching clinic in the United Kingdom. Infants younger than 8 weeks were randomized to 1 of 3 groups: (i) infant treated, parent aware; (ii) infant treated, parent unaware; and (iii) infant not treated, parent unaware. The primary outcome was a daily crying diary completed by parents over a period of 10 days. Treatments were pragmatic, individualized to examination findings, and consisted of chiropractic manual therapy of the spine. Analysis of covariance was used to investigate differences between groups.

Results: One hundred four patients were randomized. In parents blinded to treatment allocation, using 2 or less hours of crying per day to determine a clinically significant improvement in crying time, the increased odds of improvement in treated infants compared with those not receiving treatment were statistically significant at day 8 (adjusted odds ratio [OR], 8.1; 95% confidence interval [CI], 1.4-45.0) and at day 10 (adjusted OR, 11.8; 95% CI, 2.1-68.3). The number needed to treat was 3. In contrast, the odds of improvement in treated infants were not significantly different in blinded compared with nonblinded parents (adjusted ORs, 0.7 [95% CI, 0.2-2.0] and 0.5 [95% CI, 0.1-1.6] at days 8 and 10, respectively).

Conclusions: In this study, chiropractic manual therapy improved crying behavior in infants with colic. The findings showed that knowledge of treatment by the parent did not appear to contribute to the observed treatment effects in this study. Thus, it is unlikely that observed treatment effect is due to bias on the part of the reporting parent. (*J Manipulative Physiol Ther* 2012;35:600-607)

Key Indexing Terms: *Infant; Colic; Chiropractic; Musculoskeletal Manipulations*

Excessive infant crying in otherwise healthy infants, traditionally called *infant colic*, continues to be an enigmatic condition with no known cause and no known cure.¹⁻³ Afflicting between 10% to 30% of all infants and consuming significant health care resources,² infant colic is a problem for parents and clinicians, both of whom try a wide range of therapies with often disappointing results.

Despite decades of research, a clear pathogenesis has not been elucidated. Notwithstanding, what is clear is that underlying disease is rare in the excessively crying baby⁴ and that half of those affected recover by 6 months of age,⁵ with a small proportion at risk of injury⁶ or long-term developmental problems.⁷⁻⁹ In an effort to help their child with what appears to be a painful condition, some parents choose complementary and alternative medicine (CAM), including chiropractic manual therapy.⁹⁻¹² To date, several randomized trials have been reported,¹³⁻¹⁹ and although these trials demonstrate some reduction in crying, weaknesses in study methodologies have compromised their contribution to the evidence base.²⁰⁻²³

A Danish study in 1999¹³ showed manual therapy resulted in a significant reduction in crying in a 2-week trial when compared with simethicone (known to have no effect over placebo³) as a control. However, the parents were not blind to treatment allocation, which could have biased their reports of outcome. Similarly, a British study in 2006, comparing manual therapy with no treatment, showed significant declines in crying in the treatment group, but again, parents were not blind to the intervention received.¹⁴

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In contrast, a Norwegian study in 2002, which did blind the parents to treatment allocation, showed similar reductions in crying with manual therapy and with placebo.¹⁵ However, the manual therapy in that trial was an intervention nonspecific to the patient. A British study in 2005 compared 2 manual therapies, and although participants in both treatment arms showed reductions in crying, there was no placebo group for comparison.¹⁶ Finally, 3 South African studies showed that significant improvements in crying with manual therapy over detuned ultrasound¹⁷ and medication^{18,19} can only be found in conference proceedings and therefore remain unpublished in the peer-reviewed literature. Based on these studies, there is some but not conclusive evidence to make a recommendation of manual therapy for the excessively crying baby.²² For there to be a better understanding about the efficacy of chiropractic treatment for infants with colic, these methodological weaknesses should be addressed.

Therefore, the objectives of this study were to conduct a single-blind, randomized controlled trial comparing chiropractic manual therapy with no treatment and to determine whether parents' knowledge of treatment biases their report of change in infant crying. The questions posed were as follows: (i) in colicky infants, is there a difference in crying time between infants who receive chiropractic manual therapy and those who do not, and (ii) in colicky infants, is there a difference in infant crying time between parents blinded and parents not blinded to treatment?

METHODS

Participants

Infants with unexplained persistent crying (infant colic) presenting to a chiropractic teaching clinic at the Anglo-European College of Chiropractic were recruited between October 2007 and November 2009. The "mother's diagnosis" of colic²⁴⁻²⁶ was used to determine eligibility for the trial, verified by a baseline crying diary of 3 days or more. Other inclusion criteria were as follows: patients had to be younger than 8 weeks, born at a gestational age of 37 weeks or later, and had a birth weight of 2500 grams or more and show no signs of other conditions or illness. The parents of consecutively presenting infants fulfilling the inclusion criteria were informed of the study and gave written consent to participate. Parents completed a questionnaire (baseline) and were then randomized to 1 of 3 groups using permuted blocks of 18 and computer-generated allocations. These allocations were sealed in opaque and consecutively numbered envelopes and revealed to treating practitioners immediately before treatment proceeded. In 2 of the 3 groups, infants received treatment, and in the third, no treatment was administered. In 1 of the 2 treatment groups, the parent was able to observe the treatment and knew that the infant was being treated. In the other 2 groups, the parent was seated behind a

screen and was not able to observe the infant. Thus, in these 2 groups, the parent was "blind" as to whether or not the infant was treated. This resulted in 3 groups: (i) infant treated/parent aware (treated, not blinded, or T[NB]), (ii) infant treated/parent unaware (treated, blinded, or T[B]), and (iii) infant not treated/parent unaware (not treated, blinded, or NT[B]).

Participating parents were not charged for treatment; those parents of infants in the no-treatment group were offered a series of free treatments at the end of the study period. There were no restrictions regarding medication or other health care use during the trial.

Parents were informed of the interventions in all 3 groups and gave informed consent to participate. The study received ethics approval from the Anglo-European College of Chiropractic Research Ethics Sub-Committee in September 2007. A research assistant was partially funded by the British Columbia Chiropractic Association. Tomy Toy Company donated a cuddly toy to each infant at exit of the trial.

Interventions

All treatments were administered by a chiropractic intern with an experienced chiropractic clinician in attendance. Treatments were pragmatic, individualized to examination findings of the individual infant, and consisted of chiropractic manual therapy of the spine. Specifically, this involved low force tactile pressure to spinal joints and paraspinal muscles where dysfunction was noted on palpation. The manual therapy, estimated at 2 N of force, was given at the area of involvement without rotation of the spine. The treatment period was up to 10 days, and the number of treatments during this period was informed by the examination findings and parent reports. Treatment was terminated if parents reported complete resolution of symptoms. Infants in the blinded groups were placed by the parent on the examination table. Thereafter, parents sat in the examination room but behind a screen so they were unable to observe the interaction between the practitioner and their child. Patients in the no-treatment group were not touched by the intern and/or clinician. The same scripted words were spoken by the practitioner for infants in all 3 groups and consisted of "We will begin treatment now; it will be just one more minute; that is the end of treatment; we will stop now." Thus, although parents were informed of the treatment protocols in each of the 3 groups before randomization, the implication to all parents was that their child was being treated.

Outcome Measures

Parents were asked to complete a questionnaire concerning infant demographics at baseline. Starting at baseline, a 24-hour crying diary was completed throughout the study period ending either after 10 days or at discharge

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