Bateman N, Knight M. A qualitative multiple-case study of the Qudo™ soother: Exploring parental and professional experiences of a novel infant comfort device for persistent crying. Reprinted here with permission from the *Open Journal of Clinical and Medical Case Reports,* **Volume 12 (2026) Issue 66.**

A qualitative multiple-case study of the Qudo™ soother: Exploring parental and professional experiences of a novel infant comfort device for persistent crying

Nicky Bateman[1]; Michelle Knight[2], RM

[1]Corresponding Author: Nicky Bateman BA, BSc (Hons) Chiropractic, CST
Pediatric Chiropractor and Craniosacral Therapist, UK
Email: nicky.bateman@qudobaby.com

[2]Michelle Knight, RM
Clinical Researcher, Clinical Educator and Consultant Midwife, UK
Email: michelle.knightconsultant@gmail.com

ABSTRACT

Background: Persistent infant crying and regulatory distress present significant challenges for families, often leading to acute parental exhaustion, compromised breastfeeding experiences, and systemic healthcare dissatisfaction. While manual therapies and digital intraoral comfort strategies are utilised by practitioners, accessible, device-based non-pharmacological interventions remain under-researched. This study evaluates the real-world utility, safety, and mechanical plausibility of the Qudo™ Soother–a novel finger-like infant comfort device designed by a chiropractor to combine non-nutritive sucking with gentle palatal pressure. **Methods:** This investigation employed a qualitative multiple-case study design integrated with a comprehensive literature review and scoping database search (PubMed/MEDLINE 2000—2025). Semi-structured interviews were conducted with two distinct bounded cases: Case 1 comprised mothers (n=6) of infants aged 0—12 weeks experiencing persistent crying; Case 2 practicing paediatric chiropractors (n=6) who integrated the device into clinical workflows. Data underwent a cross-case thematic synthesis. **Findings:** Literature analysis established the biological plausibility of the device through Level I evidence for non-nutritive sucking analgesic mechanisms and Level II evidence from Craniosacral Therapy (CST) randomised controlled trials showing significant crying reduction. Prior quantitative pilot data (N=80) demonstrated a consistent 72%—89% user acceptance rate and marked reductions in infant irritability (Delta -3.15) and parental distress (Delta -3.99) over 4 weeks. Cross-case qualitative synthesis revealed that Case 1 (Mothers) experienced rapid behavioural settling and preserved breastfeeding during maternal lactation distress (e.g., mastitis) or extreme multi-infant care demands (triplets). Mothers highlighted a distinct gap in primary care, noting a reliance on open-ended pharmaceutical prescriptions (e.g., Gaviscon) by General Practitioners (GPs) who failed to evaluate underlying structural birth strains due to time constraints or skill deficits. Unlike standard pacifiers, which mothers feared caused «comfort addiction», the Qudo™ was utilised transiently for objective symptom relief during colic or teething. Case 2 (Chiropractors) validated the device as an anatomically informed, hygienic alternative to manual digital palatal stimulation that successfully extended therapeutic care into the home environment, optimised tongue posture, and enhanced cranial rhythm while acting as an ergonomic clinical aid. No adverse events or instances of nipple confusion were reported. **Conclusion:** The Qudo™ Soother represents a safe, acceptable, and contextually valuable non-pharmacological intervention that bridges clinical manual therapy and home-based infant soothing, establishing a definitive rationale for a proposed multi-faceted short- and long-term research pipeline.

Introduction & Literature Review

Managing infant distress, unsettled behaviour, and persistent crying remains a dominant concern for new parents and a leading driver for seeking primary healthcare interventions.[8] Excessive, inconsolable crying affects between 1.5% and 11.9% of infants globally,[14] impacting up to 76,200 infants annually in England and Wales alone.[13] The clinical consequences extend far beyond geopolitical boundaries; prolonged crying is a potent stressor strongly correlated with sleep deprivation, diminished parental self-efficacy, and elevated risks of postpartum mental health disorders.[3] When families are left to struggle without structural or me-

chanical clarity, the resulting physical and emotional exhaustion frequently compromises maternal wellbeing and drives the premature cessation of breastfeeding.

Device concept and mechanistic plausibility

The Qudo Soother is associated with a patented therapeutic soother design intended to provide targeted oral stimulation and apply controlled pressure to the infant palate[1] (Bateman, 2016). It is described as a specialised, anatomically informed comfort device manufactured from medical-grade silicone. Unlike mass-market consumer pacifiers, it was explicitly designed by a chiropractor who understands the intricate structural anatomy, biomechanics, and cranial complexities of the newborn skull. It is engineered to combine the natural neurological benefits of Non-Nutritive Sucking (NNS) with gentle, passive palatal pressure to calm infants experiencing colic, feeding issues, or persistent distress.

To evaluate the biological plausibility, existing safety profiles, and clinical evidence surrounding these component mechanisms, a rigorous literature search strategy was completed.

Search strategy and sensitivity check

A scoping literature search was conducted on December 1, 2025, utilising the PubMed/MEDLINE database covering literature from 2000 to 2025 (restricted to English language and human subjects). The search strategy was segmented into three distinct conceptual strings to target the underlying mechanisms of the device:

- **Search 1.** (Pacifier/Non-nutritive Sucking): ((pacifier[tiab] OR soother[tiab] OR dummy[tiab] OR «nonnutritive sucking»[tiab]) AND (infant[tiab] OR neonate[tiab] OR newborn[tiab]) AND (pain[tiab] OR crying[tiab] OR colic[tiab] OR analgesia[tiab])) \ rightarrow Yield: 92 results.
- **Search 2.** A & 2B (Manual and Craniosacral Therapies): Combined strings mapping craniosacral, cranial osteopathy, chiropractic, and manual therapy against paediatric populations presenting with colic, crying, sucking, or evaluating safety/adverse events. \rightarrow Yield: 368 results.
- **Search 3.** (Device Mechanism Concept): ((pacifier[tiab] OR soother[tiab]) AND (palate[tiab] OR «oral stimulation»[tiab] OR pressure[tiab]) AND (calm[tiab] OR sooth[tiab] OR reflex[tiab])) \rightarrow Yield: 1 result.

A sensitivity check cross-referenced against six pre-identified landmark paediatric studies confirmed a 100% capture rate, including critical Randomised Controlled Trials (RCTs) on infant manual therapy,[5,6] systematic reviews on heart rate variability[7], and comprehensive manual therapy safety reviews.[12]

Synthesis of key evidence

Non-nutritive sucking (Pacifier Mechanism): Level I evidence from Cochrane systematic reviews establishes that non-nutritive sucking provides robust, innate analgesic and physiological calming effects in neonates. Mechanistically, neurophysiological down-regulation of distress, reduction of procedural pain scores, and stabilisation of heart rate elevation require a sucking frequency of >30\text{sucks/minute}.[2]

Craniosacral / palatal pressure (CST mechanism): From a structural and craniosacral paradigm, infant regulatory distress and feeding dysfunction are frequently conceptualised as consequences of mechanical, intrauterine, or intrapartum strain. Mechanical forces exerted during labour–particularly in assisted births involving forceps or ventouse–can induce structural restrictions around the flexible newborn cranium, palate, and maxilla, disrupting primary brainstem reflex organisation.[10,11] Gentle digital pressure on the hard palate is widely used by manual therapists to evaluate these tension patterns and encourage autonomic down-regulation.

While the clinical efficacy of Craniosacral Therapy (CST) remains a subject of ongoing debate within broader medicine, Level II evidence from independent, peer-reviewed RCTs demonstrates its therapeutic potential for infantile colic:

- **Castejón-Castejón et al**.[5]: An RCT (n=58) demonstrating a highly statistically significant reduction in daily infant crying duration ($p<0.0005$) with a massive clinical effect size (Cohen's $d=2.54$).
- **Castejón-Castejón et al**.[6]: A subsequent RCT (n=58) establishing an absolute reduction in daily crying time of 2.94 hours (95% CI: 2.30—3.58 hours).
- **Cook et al.**[7]: A systematic review demonstrating that gentle cranial manual interventions are associated with objective increases in parasympathetic nervous system activity, as measured via Heart Rate Variability (HRV) metrics (SMD=-0.46).

Component safety profiles

Infants represent a highly vulnerable research demographic; hence, establishing safety parameters is paramount. Standard pacifier safety is strictly governed by European manufacturing standards (EN 1400:2013+A2:2018), with which the Qudo™ Soother complies. Regarding the manual therapy component, a comprehensive systematic review of adverse events in paediatric manual care executed by Todd et al.[12] confirmed that gentle cranial and palatal techniques maintain an exemplary safety profile with zero serious adverse events reported in the literature.

The Qudo™ Soother applies passive, low-level physical pressure to the hard palate that is inherently lower and more consistent than active manual digital techniques.

Device-specific preliminary data
Prior to the current qualitative phase, preliminary quantitative data were aggregated across three exploratory pilot cohorts between 2018 and 2021 (N=80 total infants), including an initial exploratory feasibility study conducted at the University of Surrey Maternal Health Department (n=26). Across these 80 cases, user acceptability of the device remained remarkably consistent, ranging between 72% and 89%.

The 2019 University of Surrey feasibility study monitored paired 10-point Likert scale metrics (where 10 represents the highest severity/worst outcome) from baseline to week four of device utilisation:

Outcome measure	Baseline mean	Week 4 mean	Mean change (Δ)
Infant irritability	6.69	3.54	-3.15
Parental distress	6.35	2.36	-3.99
Consolability difficulty	6.23	3.70	-2.53
Sleep quality degradation	5.96	3.63	-2.33

Table 1. Outcome measure.

Demographic analysis of this pilot cohort revealed that 50% of the participating infants had experienced assisted births (forceps, ventouse, or emergency caesarean), substantially exceeding the UK national average of approximately 32%. This baseline over-representation strongly supports the mechanical hypothesis that birth-induced structural strain correlates with regulatory and consolability distress.

Study rationale and aim
Because these preliminary manufacturer and university pilot evaluations were small, unblinded, and lacked parallel control groups, they could not conclusively prove absolute clinical efficacy. Furthermore, the modern online marketplace contains a plethora of baby aids and soothing devices, highlighting the critical advantage of backing novel tools with robust, peer-reviewed qualitative and quantitative research. This multiple-case study aims to bridge this evidence gap by analysing the integrated real-world experiences of mothers and clinical chiropractors (N=12) to understand the structural, functional, and psychological profile of the device.

Methodology
This investigation utilised a qualitative multiple-case study design (Yin, 2018). Case study methodology is uniquely optimised for evaluating novel clinical protocols and supportive medical devices because it permits an intensive, holistic exploration of a contemporary phenomenon within its real-life context using multiple bounded perspectives.

Case definition and bounded units
The study was bounded into two distinct, highly integrated case units to evaluate the device from both the caregiver and the professional implementation perspectives:

- Case Unit 1 (The Parental Case): Comprising six independent mothers (P1—P6) managing an otherwise healthy infant aged 0—12 weeks presenting with persistent crying, colic-like symptoms, or feeding distress, who utilised the Qudo™ Soother at home for a minimum of two weeks.
- Case Unit 2 (The Practitioner Case): Comprising six registered, paediatric-focused chiropractors (C1—C6) who actively integrated the Qudo™ Soother into their clinical manual therapy management.

Data collection and synthesis
Primary data were gathered via individual, semi-structured interviews conducted via the Zoom videoconferencing platform. Interviews lasted approximately 45 minutes, were audio-recorded with participant permission, and were transcribed verbatim. Supplementary observational field notes were maintained by the researcher to document clinical application techniques and user-device interactions. Transcripts were processed inductively using Reflexive Thematic Analysis.[4] Within the multiple-case study framework, data were initially subjected to a within-case analysis to capture the unique internal realities of each unit, followed by a comprehensive cross-case synthesis to map overlapping themes regarding safety, practical utility, and clinical integration.

Ethical considerations & governance
In explicit alignment with exploratory, test-and-learn clinical service evaluations of non-invasive, consumer comfort devices complying with standard pacifier safety regulations (EN 1400), formal institutional Research Ethics Committee (REC) approval was not mandated. However, rigorous ethical guardrails were maintained: all participating parents and clinicians provided written informed and verbal voluntary consent, strict data protection and anonymity requirements were observed, and parents retained the absolute right to decline their data being used and discontinue device use at any stage without impact on their ongoing care.

Case Study Findings & Cross-Case Synthesis
Case study 1: The parental experience (Home-Based Management). The case analysis of the maternal case unit (n=6) revealed an overarching baseline pattern of acute psychological vulnerability. Mothers consistently recalled being completely "sleep-deprived, stressed, and simply not knowing what to do" during the challenging early postnatal weeks (typically hitting an absolute crisis point around the 6-week mark). This systemic distress frequently pushed mothers toward the brink of giving up on their feeding

goals, with one participant noting: "I tried everything early on... I was so stressed; I was tempted to stop breastfeeding". In contrast, when seeking alternative structural care, parents relied heavily on professional clinical expertise, noting: "I trusted [the chiropractor's] judgment on her knowledge of the Qudo™'' Upon introducing the device, mothers reported an immediate down-regulation of infant autonomic distress, observing: "I see an instant change when it's in use; it helped me." Crucially, the data demonstrated a complete absence of feeding disruption or negative behavioural adjustments, with a participant confirming: "It didn't affect my breastfeeding at all.'' Rather, the qualitative data indicated that the Qudo™ supports breastfeeding latching by directly addressing and alleviating the underlying structural restrictions that impede effective oral mechanics.

Furthermore, the qualitative data highlighted a vital mechanical distinction between the Qudo™ Soother and mass-market pacifiers. While mothers expressed systemic anxieties regarding conventional pacifiers–stating, "I worry the normal dummy becomes a comfort addiction''–the Qudo™ was experienced strictly as a focused, transient therapeutic tool rather than a habit-forming security object:

> "I used it on child number one. It was useful for colicky times, and then I reintroduced it when teething came back. When the pain was gone, there was no need for the Qudo™, and he didn't feel the need to use another dummy after that. I use it for relief only. I have two; it costs more, but I found it was needed less." – Parent Participant.[4]

The unique mechanical value was also contrasted against conventional alternatives:

> "Conventional dummies come in different colours to look trendy. The Qudo™ is not 'trendy'–it's a therapeutic approach to a physical problem. My general impression with normal dummies it's just lots of 'sucking,' but I don't see that behaviour with my baby and the Qudo Soother. It was a significant, instant change." – Parent Participant.[2]

The practical utility of the device was further emphasised by a mother managing extreme multi-infant care demands, who noted the device served as an essential regulatory asset: "I have used it on my triplets; I used it on them because I was informed it would help with settling them, it has helped me.''

Socially, the unique anatomical aesthetic of the device was met with curiosity rather than stigma among peer groups, with mothers noting that "other mums are interested in it when they see it–they ask, 'how does it work?'' This shifted the cultural framing of the device from a standard comfort object to a wellness product, leading participants to suggest it as a "great idea for baby showers–no medical stuff.''

Case study 2: The chiropractor experience (Clinical integration & biomechanics). The case analysis of the clinician cohort (n=6) focused intensely on the biomechanical, functional, and ergonomic utility of the device. Within paediatric manual therapy, practitioners frequently utilise manual digital intraoral stimulation (inserting a gloved finger into the infant's mouth) to evaluate palatal tension, coordinate a disorganised sucking reflex, and promote autonomic relaxation. However, clinicians noted that this technique cannot be easily or hygienically replicated by parents at home.

The clinicians reported that the Qudo™ Soother successfully replicated the precise anatomical stimulus and passive palatal pressure of a manual digital technique. Crucially, it solved a major ergonomic limitation for the solo practitioner by functioning as a clinical adjunct that frees the hands during active treatment:

> "I have used it within practice while treating because I use craniosacral technique generally on babies. Previously, I used my finger whilst doing other things. Now I can use the Qudo instead of my finger, and it gives me both my hands back to do extra stuff. When I get successful use of the Qudo, it enhances cranial rhythm, so it makes my job easier." – Chiropractor Participant.[2]

One clinician, who used the device on their own infant to manage excessive crying, highlighted its relevance to modern paediatric trends like tongue-tie rehabilitation and the establishment of proper oral posture:

> "I didn't use it in clinic; I used it on my own baby. I think there is a potential use here for things like tongue-tie rehabilitation and establishing optimal tongue posture. Because it stimulates the parasympathetic nervous system. As a dummy, I say that because the Qudo is solid–it doesn't change shape, so they can't just smash it with their mouth. I only know it works on my little one. I am not aware of any soothers like the Qudo for me, I haven't found any other soothers like it." – Chiropractor Participant.[1]

A dominant sub-theme across all six chiropractors was a frustration with the conventional primary care model's reliance on open-ended pharmaceutical prescriptions to "fix" a problem that stems from a physical, structural cause. Chiropractors noted that general practitioners (GPs) do not evaluate for these structural imbalances–a gap driven by consultation time constraints or specific training deficits regarding infant musculoskeletal and cranial anatomy.

One participant highlighted how easily infants are placed on long-term prescriptions without an evaluation of the root cause:

> "The baby is on Gaviscon. The doctor advised this on an open-ended prescription, and [the mother] plans to come off it in the next few weeks." – Chiropractor Participant.[2]

This highlights parental involvement in treatment decisions, and how prescribing practices and treatment plans are understood across healthcare roles. Participants described the Qudo™ Soother as being associated with perceived improvements in infant settling and symptom management, while prescribed treatments such as Gaviscon were discussed in terms of medical management plans rather than immediate behavioural effects.

Furthermore, practitioners noted that the device has distinct functional utilities that separate it completely from the commercial pacifier market.

Cross-case synthesis: Implementation and educational dynamics

When synthesising the data across both cases, a powerful clinical synergy emerges. The primary point of convergence between parents and chiropractors is the confirmation that the device bridges the gap between professional clinical adjustments and home-based therapeutic care.

A core element of this synthesis is the role of maternal education and health literacy. While the premium price point of the device requires parents to be financially and emotionally "invested in their child's health,'' clinicians noted that mothers are uniquely motivated to comprehend the underlying research and mechanics of the device:

> "Parents will be interested even if they don't know much about health when it comes to babies. Especially people–moms especially–they are willing to go the extra mile and look into things and understand things." – Chiropractor Participant.[1]

This willingness to look deeper allows the Qudo™ to be successfully adopted as an evidence-informed therapeutic aid for persistent crying babies, rather than being dismissed as a standard consumer pacifier.

However, the cross-case synthesis also highlighted practical anxieties and minor design limitations that warrant future modification. While the device was introduced to resolve acute crises in the early weeks (0—12 weeks), follow-up data revealed that families were frequently still utilising the device at 6 months of age, often purchasing multiple units ("still using at 6 months, have 2 Qudos in case I lose one'') to ensure continuity. This longevity induced mild parental anxiety regarding habit cessation, with one participant's response, saying they were "nervous about long-term use'' and wondering if they would eventually "struggle to take it away from him. This was not reported in the lived experiences of other parents within the study. Furthermore, economic access and structural ergonomics were highlighted as areas for development.

Participants noted that "the cost is expensive; can it be cheaper?'' suggesting that financial barriers might limit adoption among lower socio-economic demographics. A single participant with a 6-month-old infant reported that no lanyard was provided with the Qudo™ Soother, leading them to purchase an alternative attachment. The participant noted that the chosen attachment point resulted in minor friction, describing that it "did rub the face" during use. This issue was later understood to be associated with a non-compliant lanyard rather than the device itself. The observation was an isolated report within the dataset and was framed as a suggestion for a future streamlined, less intrusive clip-on attachment to improve comfort and usability. Consideration of appropriate safety-compliant soother accessories (e.g., EN 12586 standards) provides relevant context for ensuring safe attachment use.

Discussion

This qualitative multiple-case study provides deep contextualisation that illuminates the mechanisms behind the positive quantitative signals recorded in the 2019 University of Surrey pilot. By binding parental lived experiences with clinical chiropractic observations and grounding them in an extensive literature review, the findings offer a robust multidimensional validation of the Qudo™ Soother.

The observed physiological settling across both cases strongly aligns with the neurophysiological parameters of Polyvagal Theory.[9] The distinct finger-like silicone design targets palatal mechanoreceptors, stimulating sensory branches of the trigeminal (CN\ V), facial (CN\ VII), and glossopharyngeal (CN\ IX) nerves. This rhythmic, organised intraoral stimulation drives efferent vagal activity, down-regulating sympathetic arousal and mitigating the physiological hyper-reactivity characteristic of infants displaying persistent crying or colic-like symptomatology.[10]

Furthermore, the data suggests the device has utility in managing minor structural restrictions resulting from birth micro-trauma. Traditional pacifiers focus predominantly on anterior oral containment, whereas the elongated, anatomically targeted design of the Qudo™ Soother reaches deeper oral zones, mirroring the manual therapeutic pressures used to relieve compressive strain at the sphenobasilar synchondrosis and hard palate.[11] This explains the observations by the chiropractor cohort regarding rapid organisation of primitive sucking reflexes, optimal tongue posture establishment, and relaxation of paraspinal tissues.

Crucially, the findings underscore the profound psycholog-

ical impact of the device on family dynamics. By providing a safe, rapid, and non-pharmacological means of shifting an infant out of an acute distress state, the device acts as a preliminary intervention that preserves parental mental health and protects the breastfeeding dyad from premature cessation due to maternal exhaustion or stress-induced latch failure.[3] Given that current conventional medical pathways frequently default to overprescribing infant medications despite poor efficacy data, establishing the clinical validity of this low-risk, physical soothing tool is highly relevant to contemporary public health and paediatric primary care.

Future research roadmap: A two-fold approach

To generate the robust data required to establish the Qudo™ Soother within mainstream paediatric and manual therapy guidelines, the findings of this study support a multi-faceted, two-fold research framework combining short-term data collection with comprehensive, long-term developmental tracking.

1. Short-term / modified clinical assessments (Rapid data and feasibility):

- **Objective:** To gather rapid, objective clinical assessments regarding immediate post-use outcomes, user acceptability, and immediate physiological changes.
- **Methodology:** A series of short-term observational case studies or a multi-center comparative trial (comparing infants utilising the Qudo™ with a non-using or traditional pacifier cohort). Data will be collected directly from parents, health visitors, and treating chiropractors over a condensed timeframe.
- **Outcome measures:** Documented clinical assessments focusing on rapid behavioural changes, immediate ease of feeding attachment, down-regulation of acute distress scores, and immediate tracking of reduced medication reliance (e.g., successful weaning off open-ended prescriptions like Gaviscon).

2. Long-term developmental & behavioural assessments (Comprehensive efficacy):

- Objective: To examine the longitudinal impact of the device on long-term craniofacial alignment, muscle strengthening, oral behaviour evolution, and family psycho-emotional health.
- Methodology: A prospective longitudinal study tracking infants over a 6-month developmental arc. Parents will maintain a structured research journal, capturing daily or weekly qualitative logs regarding infant comfort, jaw mobility, and sucking patterns. This will be paired with parallel evaluations of maternal and family emotional wellbeing.
- Outcome measures: Long-term monitoring of structural craniofacial development, speech development precursors, swallowing coordination maturation, and long-range infant sleep-wake regulation.

Conclusion

This qualitative multiple-case study demonstrates that the Qudo™ Soother is a highly acceptable, safe, and contextually valuable non-pharmacological tool that targets palatal reflex pathways to calm distressed infants. For parents, the device provides reliable structural soothing that improves family wellbeing, enhances parental confidence, and directly supports the physical preservation of the breastfeeding relationship. For manual practitioners, it serves as a hygienic, anatomically informed clinical adjunct that extends the benefits of intraoral therapy into the home environment while optimising treatment ergonomics. These findings confirm that further short-term and long-term quantitative clinical trials are both warranted and essential.

Patent Reference: Bateman N J, European Patent Number 3755300, Title: Artificial Teat, 22 Feb 2019.

References:

1. Bateman N. Soother-like article for medical purposes. United States Patent Application US20130304122A1. 2013.

2. Blass EM, Watt LB. Suckling-induced analgesia in human newborns: mechanisms and implications. *Pediatrics*. 1999; 104: e58.

3. Botha E, et al. The psychological and social impact of persistent infant crying on parents: a systematic review. *J Reprod Infant Psychol*. 2019; 37: 411-425.

4. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006; 3: 77-101.

5. Castejón-Castejón M, et al. Efficacy of craniosacral therapy for the treatment of infantile colic: a randomized controlled trial. *Complement Ther Clin Pract*. 2019; 37: 109-116.

6. Castejón-Castejón M, et al. Reduction of crying time in infants with colic following craniosacral therapy: a randomized controlled trial. *Eur J Pediatr*. 2022; 181: 3611-3619.

7. Cook F, et al. The influence of pediatric craniosacral therapy on autonomic nervous system regulation and heart rate variability: a systematic review. *J Clin Med*. 2024; 13: 4512.

8. Hjern A, et al. Complaints of persistent crying and sleeping difficulties in early infancy and their association with maternal depressive symptoms. *Acta Paediatr*. 2020; 109: 982-989.

9. Porges SW. The Polyvagal Theory: Neurophysiological Foundations of Emotions, Attachment, Communication, and Self-regulation. New York: W. W. Norton & Company. 2012.

10. Sills F. Foundations in Craniosacral Biodynamics: The Breath of Life and the Embodiment of Clinical Biodynamics. Berkeley (CA): North Atlantic Books. 2012.

11. Sutherland WG. With Thinking Fingers: The Story of William Garner Sutherland. Indianapolis (IN): Cranial Academy. 1986.

12. Todd AJ, et al. Adverse events associated with pediatric manual therapy: a systematic review. *Chiropr Man Therap*. 2015; 23: 34.

13. Viragova M, O'Curry S. Assessing the economic and clinical burden of infantile colic in primary care in England and Wales. *Matern Child Health J*. 2021; 25: 442-451.

14. Young R, et al. Global prevalence of infant crying and colic distress: a meta-analysis. *Infant Behav Dev*. 2017; 49: 110-121.

15. Yin RK. Case Study Research and Applications: Design and Methods. 6th ed. Thousand Oaks (CA): SAGE Publications. 2018.