PROTOCOL DOCUMENT FOR THE BREASTFEEDING OSTEOPATHIC MANUAL THERAPY STUDY (BROMS)

Kirsty Greenwood
Professor Sandra Grace
Adjunct Associate Professor Roger Engel
Associate Professor David Todd

Protocol for the Breastfeeding Osteopathic Manual Therapy Study

This Project Description provides the scientific and academic background and context for the research project 'Breastfeeding Osteopathic Manual Therapy Study (*BROMS*)'.

Summary:

This study is a two-armed, multi-centre, pragmatic, randomised clinical trial designed to examine the effect of osteopathic care (OMT) on breastfeeding dyads experiencing breastfeeding difficulty. The trial will be conducted in two stages: preliminary and full. Both stages have the same design.

The preliminary stage will pilot the design at a single clinic in Melbourne by recruiting 16 mother-infant-dyads (MIDs) experiencing breastfeeding difficulty. The full stage will extend the pilot to multiple clinics across Melbourne and Canberra (See Appendix 1.1 – Clinic Consent Form).

Participants in both stages will be randomly allocated to one of two groups: international board-certified lactation consultant (IBCLC) - Standard care (Control) or IBCLC plus osteopathic intervention (OMT) (Experimental). The full stage will continue the pilot stage and see a further 54 MIDs (total N=70) experiencing breastfeeding difficulty randomly allocated to the same two groups. Recruitment for this stage will be from osteopathic clinics, maternal health centres and breastfeeding drop-in centres across metropolitan Melbourne and Canberra.

Each participant will undergo 4 weeks of intervention with a follow-up phone call one-month post-intervention.

The primary outcome of the study is change in infant breastfeeding function as measured by the Bristol Breastfeeding Assessment Tool (BBAT).

Secondary outcomes include maternal breastfeeding confidence, as measured by the Breastfeeding Self-efficacy Scale – Short from (BSES-SF) and changes in breastfeeding symptoms such as maternal breastfeeding-related pain, infant ability to latch and maintain latch to the breast and feeding noise at the breast measured using a series of visual analogue scales (VAS).

1. Study details

1.1 Title: Breastfeeding Osteopathic Manual Therapy Study

1.2 Acronym: BROMS

1.3 Project Team Roles & Responsibilities:

Chief Investigator (CI):

Kirsty Greenwood
PhD Candidate
Faculty of Health
Southern Cross University
Orchid: https://orcid.org/0000-0002-5283-1311
Email:k.greenwood54@student.scu.edu.au

Responsibilities:

> Study design, ethics application, project coordinator, data collection and analysis, manuscript drafting and editing, patient and practitioner follow-up.

Relevant Expertise:

> Kirsty Greenwood is a registered osteopath. She graduated in 2004 from Victoria University with a Masters in Clinical Science. She has 19 years of clinical experience in the paediatric care of infants and is a PhD candidate at Southern Cross University. Kirsty is a director of ASTOT (Australian Society for Tethered Oral issues).

Co-investigators:

Professor Sandra Grace (SG)
Faculty of Health
Southern Cross University
Orcid: 0000-0002-0300-4088
Email: sandra.grace@scu.edu.au

Responsibilities:

> Study design, ethics application, data analysis, manuscript drafting and editing, PhD supervision.

Relevant Expertise:

> Completed a Certificate of Clinical Chiropractic Paediatrics at Preston Institute of Technology, Victoria in 1990 and has treated pregnant women and children in her private practice since that time. CI on the CUTIES (Osteopathic care for crying distressed and unsettled infants) trial. *Related PhD supervision*: Joel Alcantara: The quality of life, sense of coherence, patient satisfaction and lived experience of pregnant patients attending care in a chiropractic practice-based research network; and Trish Long: Strengthening Connections: Trauma-informed care for midwives and adverse childhood experiences screening for pregnant women.

Adjunct Associate Professor Roger Engel (RE)

Faculty of Health
Southern Cross University
Honorary Senior Research Fellow
Faculty of Medicine Health and Human Sciences
Macquarie University
Orcid: https://orcid.org/0000-0001-6021-0497
Email: roger.engel@mq.edu.au

Responsibilities:

Study design, ethics application, data analysis, manuscript drafting and editing, PhD supervision.

Relevant Experience:

CI on CUTIES (Osteopathic care for crying distressed and unsettled infants) trial; CI on several small, medium and large RCTs; trial design; ethics; higher degree research (HDR) supervision.

Related PhD supervision:

Attitudes and behaviours of Australian chiropractors towards reporting adverse events. Christopher Burrell, MRes. Macquarie University 2019.
The relationship between leg length inequality and pelvic kinematics. Simon Vella, MRes. Macquarie University 2020.

Associate investigator:

Associate Professor David Todd (DT)
Faculty of Medicine
Australian National University
Orcid: https://orcid.org/0000-0003-2140-3506
Email: David.Todd@act.gov.au
Current Position: Registered medical practitioner and Neonatologist, Department Neonatology Centenary Hospital for Women and Children.
Associate Professor, Australian National University Medical School Department Neonatology, Centenary Hospital for Women and Children, Canberra, Co-coordinator Neonatology 4th year ANU Medical Students and Director ASTOT (Australasian Society for Tethered Oral Tissues).

Responsibilities:

Study design, ethics application, data analysis, manuscript drafting and editing.

Relevant experience:

CI/co-investigator for several randomised controlled trials including 1) Measurement of lung function following either natural surfactant or Artificial surfactant in preterm infants, 2) Ceasing CPAP at Standard Criteria (CICARDA trial) in preterm infants 3) PROTECT study Pentoxifylline to protect the newborn brain.

Related PhD supervision:

Lung fluid profile in premature infants: Comparison of exogenous surfactants Exosurf and Survanta. Jane Lloyd, MSc, University of Sydney 2001.

Ureaplasmas and adverse pregnancy outcomes. Kirsty Hannaford-Turner, PhD., University of Sydney 2001.

Heated humidification versus heat and moisture exchangers for mechanically ventilated adults and children. Margaret Kelly, Treatise towards MPH, University of Sydney 2005.

Tongue Tie Classification and women's experience of feeding an infant with tongue-tie-Maters of Research; Western Sydney University. Louise Duursma 2020

Tongue Tie Classification and women's experience of feeding an infant with tongue-tie-PhD; Western Sydney University. Louise Duursma 2023 in progress

Tongue Tie: Short term follow up of babies with TT following division. PhD ANU Canberra. Monica Hogan 2023 in progress

Statistics and Data Analyst:

Associate Professor Petra Graham (PG)
School of Mathematical and Physical Sciences
Macquarie University,
Orcid: https://orchid.org/0000-0003-2890-2447
Email: petra.graham@mq.edu.au
Responsibilities: Data and statistical analysis, manuscript drafting and editing.

1.4 Funding:

Applications for funding have been submitted to:

- Osteopathy Australia (awarded – 16th November 2023)
- Sutherland Cranial Teaching Foundation (pending)

1.5 Background

Breastfeeding has been linked to short and long-term health benefits for infants and mothers.[1-6] Despite these benefits, breastfeeding is no longer considered a norm in many communities across the globe.[7] The World Health Organization (WHO) and the Australian Department of Health recommend breastfeeding for the first 6 months after birth and support maintaining the practice for up to 2 years with appropriate complementary feeding.[8-10]

Mothers can experience a range of physical symptoms associated with difficulty breastfeeding. These relate to infant latch, leakage, letdown, engorgement, nipple pain, cracked and bleeding nipples and nipple blistering.[11] In an attempt to manage such symptoms, a number of mothers are turning to manual therapy practitioners for help. In the UK, the number of infants taken to osteopaths annually has been estimated to be 61,000.[12] This corresponds to approximately 9% of all infants born in the

UK each year,[13] while an Australian study reported 48.7% of infants presenting to a chiropractic clinic did so for breastfeeding difficulties.[14] Despite an apparent high level of utilisation, evidence of the effectiveness of OMT care for treating breastfeeding difficulty remains unclear.

1.5.1 Musculoskeletal findings associated with breastfeeding difficulty

Key determinants of effective breastfeeding are latch, suck, swallow, and the respiratory actions of the infant at the breast [15, 16] where musculoskeletal dysfunction in an infant may affect the infant's ability to feed successfully from the breast. Musculoskeletal dysfunction such as congenital torticollis has been linked to breastfeeding difficulties [17]. One osteopathic publication identifies the most common musculoskeletal dysfunction found in infants with breastfeeding difficulties were found in the cranial, cervical and temporomandibular regions [18]. However, this association is based on anecdotal evidence and is yet to be tested under controlled settings.

1.5.2 Safety

Osteopathy has been used and documented in the management of breastfeeding difficulties [18-21]. No studies have reported on adverse events resulting from OMT care for infants with breastfeeding difficulty. While this may represent a failure to report, it could also suggest that manual therapy is a relatively low-risk care for this group of patients, a view that is supported in the literature. [22, 23]

A systematic review by Carnes et al (2017), concluded that the risk of adverse events associated with manual therapy that involved physical and/or manual contact with the infant for therapeutic intent was low (7 per 1000 infants exposed to manual therapy (n=1308)). Of the eight studies that reported on the presence of adverse events, three reported no adverse events, two reported adverse events following manual therapy while the other three reported adverse events in the non-manual therapy control groups. All reported adverse events reported in the above studies were non-serious in nature.

In our study, the treating osteopaths will be carefully selected, they will need to have over 10 years' experience and, have extensive training in paediatric care. This helps manage risks associated with inexperience.

In our study, adverse events will be monitored at every treatment session by the treating osteopath or IBCLC. This approach facilitates early detection, assists with mitigation, and improves management by reducing the risk of recurrence. Regarding the techniques used, the Osteopaths participating in this study are trained in low intensity, gentle techniques suitable for infants and children. High velocity or forceful techniques do not form part of osteopathic paediatric care and are not part of this study. This minimises the risk of iatrogenic injury.

All adverse events will be monitored at every treatment session by the treating osteopath or IBCLC. This approach facilitates early detection, assists with mitigation, and improves management by reducing the risk of recurrence.

1.5.3 Conclusion

The literature on the use of manual therapy intervention in the management of infants experiencing breastfeeding difficulty highlights a growing body of evidence supporting its use, with the majority of studies involving osteopathic care. Osteopathic manual therapy appears to be relatively safe for this group of infants. Despite limited evidence, there is an increasing demand for osteopathic services

among mothers with breastfeeding difficulty. Further research is required before any claim about the benefits of manual therapy intervention for infant breastfeeding difficulty can be relied upon.

1.6 Rationale and Justification for the Research

Lactation consultants, physiologists, speech pathologists and clinicians have extensively studied the biomechanics, fluid dynamics and mechanism of infant sucking while breastfeeding. [24-26] International Board-Certified Lactation Consultants (IBCLCs) are trained to assess difficulties, correct positioning, provide emotional support to mothers and help babies improve the suck, swallow and respiration behavioural sequence. However, these professionals often look for further assistance when biomechanical sucking difficulties persist in infants despite their advice [20, 27, 28] Osteopathy has been used and documented by some to be an additional help to breastfed infants in addition to IBCLC care.[21, 29] More research is needed to explore the clinical partnership of osteopathic care and IBCLC care for infants with breastfeeding difficulties.

1.7 Gaps in the research

- The effectiveness of OMT for infants with breastfeeding issues remains unclear
- Identification of the possible anatomical musculoskeletal structures involved in breastfeeding dysfunction is yet to be determined.
- The benefits of combining IBCLC with osteopathic care are unknown.

2. Aim of Research

The aim of this project is to investigate the efficacy of OMT intervention designed to address musculoskeletal dysfunction in the infant with breastfeeding difficulty.

2.1 Research questions:

This research aims to answer the following research questions:

1. Does OMT intervention deliver additional improvements in breastfeeding compared to standard care (IBCLC) in infants with breastfeeding difficulty?
2. Does OMT intervention deliver additional improvements in breastfeeding mechanical function compared to standard care (IBCLC) in infants with breastfeeding difficulty?
3. Does OMT intervention deliver additional improvements in maternal breastfeeding confidence compared to standard care (IBCLC) in infants with breastfeeding difficulty?

2.2 Research Hypotheses:

This study aims to test the following research hypotheses:

1. OMT intervention to the infant improves breastfeeding more than standard care (IBCLC) in infants with breastfeeding difficulty.
2. OMT intervention to the infant improves breastfeeding mechanical function more than standard care (IBCLC) in infants with breastfeeding difficulty.

2.3 Expected outcomes

We expect that infants receiving OMT intervention designed to address musculoskeletal dysfunction will have greater improvements in breastfeeding and maternal confidence in breastfeeding compared to standard care (IBCLC). We also expect that infant musculoskeletal dysfunction will present in the cranial, facial and cervical regions more than the rest of the body.

3.0 Project Design

3.1 Research Setting

Private osteopathic clinics across metropolitan Melbourne and Canberra.

3.2 Physical Sites

The study will be conducted in 3-5 private osteopathic clinics across metropolitan Melbourne and Canberra. (Both IBCLC and OMT intervention will occur at participating osteopathic clinics. All participating clinicians will be provided with an information sheet (Appendix 2.1) and asked to complete a practitioner consent form. (Appendix 3.1).

4.0 Methodological approach

This study is a two-armed, multi-centre, pragmatic, randomised clinical trial designed to examine the effect of osteopathic care (OMT) on breastfeeding MIDs experiencing breastfeeding difficulty. The trial will recruit 70 MIDs and be conducted in two stages: a preliminary stage leading to the full stage. Both stages have the same design (see Figure 1). Stage 1 (preliminary) is designed to pilot test the design and will involve 16 MIDs randomly allocated to one of the two groups. This will be followed by stage 2 (full stage) involving 54 MIDs randomly allocated to the same two groups.

4.1 Participants

Stage 1 (preliminary):

A total of N=16 MIDs experiencing breastfeeding difficulty will be randomly allocated to one of two equal groups.

Group 1: IBCLC
Group 2: IBCLC + OMT

There will be a two-week pause in the study once Stage 1 is complete to provide time for the researchers to review the trial's processes and procedures and to make any necessary minor modifications to the protocol. The trial will then proceed to Stage 2.

Stage 2 (full):

A total N=54 MIDs experiencing breastfeeding difficulty will be randomly allocated to one of the same two groups.

Group 1: IBCLC
Group 2: IBCLC + OMT

Once allocated to a group, participants may not switch groups.

4.1.1 International Board-Certified Lactation Consultation (IBCLC)

An International Board-Certified Lactation Consultant (IBCLC) is a healthcare professional who specialises in the clinical management of breastfeeding. IBCLCs are certified by the International Board of Lactation Consultant Examiners (IBLCE), an international organisation that sets standards for lactation consulting.

IBCLC intervention includes education, guidance, and support to help mothers overcome breastfeeding challenges such as latch issues, low milk supply, and other breastfeeding-related concerns. IBCLCs work in hospitals, clinics, private practices, and community settings.

Consultations with the IBCLC will include:

- Breastfeeding assessment
- Education
- Latch and positioning techniques
- Advice on pumping and expressing milk
- Breastfeeding and nutritional counselling
- Growth and development monitoring
- Emotional support, counselling and problem solving
- Measurement of weight, length, and head circumference to track growth
- Assessment of vital signs, including heart rate, respiratory rate, and temperature

4.1.2 Osteopathic Manual Therapy

Osteopathy is a form of manual medicine that focuses on the musculoskeletal system and its impact on overall health. Osteopaths use a hands-on approach to diagnose and treat a range of health issues. An OMT treatment only includes gentle manual techniques such as massage, cranial osteopathy, and/or myofascial release to areas of tension in the infant's body.

Consultations with the Osteopath will include:

- Medical history taking, including pregnancy, birth and infant medical history
- Postural education for both mother and baby during feeding, breastfeeding assessment, latch and suck function [20, 30-33]
- Positioning assessment [18, 34, 35]
- Musculoskeletal and health screen of infants including assessment of musculoskeletal trauma or birth trauma, plagiocephaly [36-38] or torticollis [17, 39, 40])
- Monitoring of developmental milestones [41, 42] and cognitive development. [43]
- Sleep habit and sleep safety assessment[38]
- Head preference and infant positioning assessment,
- Crying habit assessment [23, 38]

Osteopathic Paediatric Physical Examination: Includes the following [41,42)

- Examination of the skin, eyes, ears, nose, tongue, palate and throat
- Inspection of the abdomen for any abnormalities or signs of discomfort

- Evaluation of muscle tone and primitive reflexes and established reflexes
- Examination of the spine, pelvis, hips and peripheral joints [38]
- Examination of facial, jaw and cranial asymmetry [17, 44, 45]
- Examination of infant suck function

Gentle Osteopathic Techniques for infant musculoskeletal care may include

Cranial Osteopathy

Paediatric osteopaths may use gentle manual techniques to assess and address any restrictions or imbalances in the infant's musculoskeletal system, including the cranium, face, jaw, cervical spine and associated musculoskeletal structures. The idea is that releasing tension in these areas may help the infant feel more comfortable and relaxed, which then may positively influence breastfeeding and alleviate issues such as difficulty latching, maintaining latch and maternal pain [18, 19, 46].

Oral assessment and suck function:

Paediatric osteopaths may assess the oral anatomy, structure and function, palate shape, buccal and oral muscular tone, as well as infant suck function. This often includes assessment of tethered oral tissues that may be inhibiting infant suck function. Treatment may involve gentle techniques to release tension in the affected area as well as referral to a general practitioner or paediatrician for ankyloglossia assessment and medically guided management [47-49].

Myofascial Release: Paediatric osteopaths may use myofascial release techniques to address tension in the muscles and connective tissues around the baby's mouth, face, and neck. This can be especially relevant for babies experiencing difficulty latching or sucking effectively [50, 51].

4.1.3 Identification and selection of osteopathic and IBCLC practitioners

Practitioners will be selected based on the level of their clinical experience and training. All participating osteopaths and IBCLCs must have post-graduate training (in paediatrics for osteopaths and current board certification in lactation consulting for IBCLCs), be currently registered/certified with their governing bodies, have appropriate insurance, have a minimum 10 years of experience in managing infant breastfeeding and paediatrics and have a valid working with children/vulnerable population check.

All participating practitioners will undergo pretrial procedures training. A section on research ethics, confidentiality, privacy, and sharing/handling of information will form part of the pre-trial training of participating IBCLCs and osteopaths.

All participating practitioners must also complete *the Global Health Training Centre - Good Clinical Practice Course:* https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/

An invitation will be emailed to the IBCLC and osteopathic professions calling for expressions of interest, The information for practitioners and poster will be added as attachments to this email (see Appendices 4.1 and 5.1).

All professionals will then be contacted via a phone call and be selected by the CI and co-investigators.

4.1.4 Trial design

All participants will require a pre-screen appointment to assess their eligibility to join the trail.

All participants will receive a maximum of two IBCLC face-to-face sessions and two IBCLC telehealth calls over a 4-week period. In addition to this, the IBCLC group will receive up to two additional telehealth consultations if required whereas the IBCLC + OMT group will receive up to three OMT consultations.

Outcome measures will be administered at baseline and again at weeks 4 and 8. At 8 weeks, all participants will receive a follow-up phone call/email from the trial coordinator, which will gather information on the breastfeeding status of the MID.

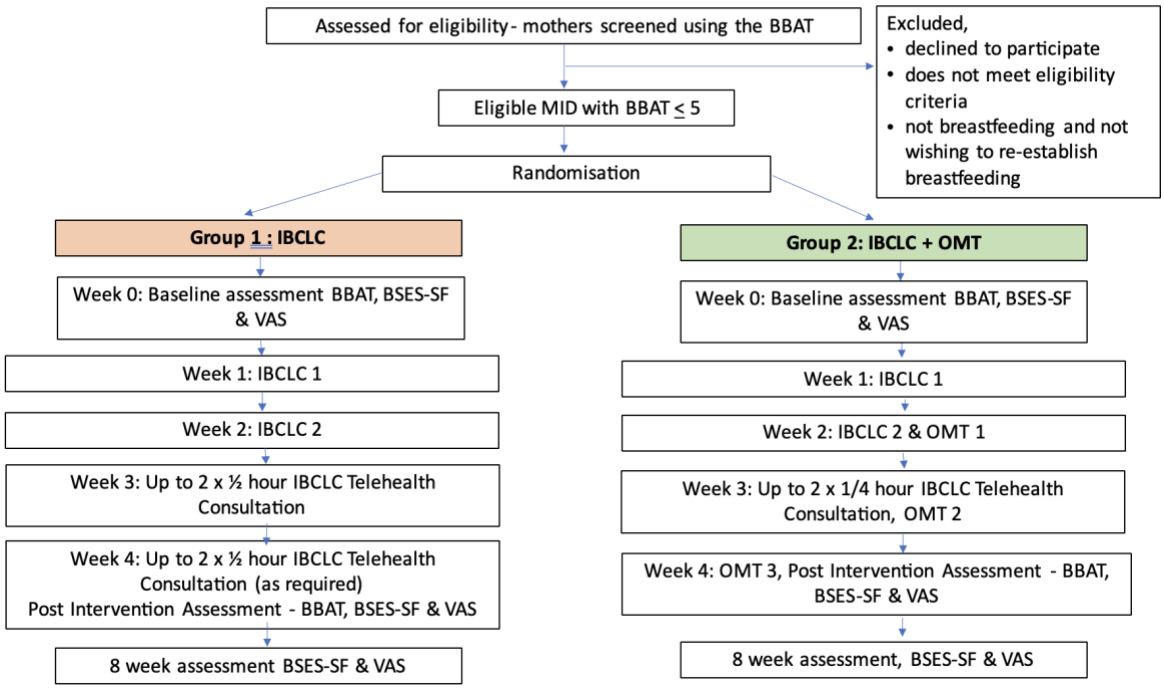

Figure 1: Flow chart

4.2 Randomisation and blinding

MIDs will be randomly allocated to one of two groups using a computer-generated randomisation sequence generated by a person not otherwise involved in the trial. Randomisation will be on a 1:1 allocation.

Assessors will be blinded to group allocation. Given the nature of the interventions, MIDs cannot be blinded to intervention.

4.3 Selection methods – inclusion/exclusion criteria

4.3.1 Inclusion criteria

To be eligible to enrol in the trial, an MID must meet the following criteria:

- Mother must have read the information sheet (Appendix 5.1) and signed the consent form (Appendix 6.1).
- MID must have an intake BBAT score of ≤5
- Mother must be 18 years of age or older
- In order to provide informed consent, the mother requires a certain level of proficiency in English. If she is not sufficiently proficient in English, the mother can use the Federal Government's Telephone Interpreter Service. This can be organised by the CI at short notice. https://www.tisnational.gov.au/Our-services/,https://www.vic.gov.au/interpreters-and-translations. Given prior notice, the CI can organise the translation service to be available at the time of the appointments with the IBCLC and Osteopaths. Alternatively, the mother can provide her own support person to help with translation.
- Mother must self-identify as having difficulty breastfeeding
- Mother must be breastfeeding, attempting to breastfeed, or wishing to re-establish breastfeeding
- Infant must be < 6 months of age at the time of enrolment
- Infant gestation at birth must be ≥ 37 weeks

4.3.2 Exclusion Criteria

An MID will be excluded from the trial if they present with any of the following:

- Infant ≥ 6 months of age at the time of enrolment
- Mother not breastfeeding and does not intend to initiate or reinstate breastfeeding
- Infant has a congenital condition that impacts breastfeeding e.g. cleft palate
- Mother requires medication that is contraindicated for breastfeeding
- Infant is part of a twin or multiple birth

4.4 Outcome measures include the following

Primary:

- Bristol Breastfeeding Assessment Tool (BBAT) (Appendix 7.1)

Secondary:

- Breastfeeding Self-Efficacy Scale – Short Form (BSES-SF) (Appendix 8.1)
- Visual analogue rating scales (VAS) (Appendix 9.1)
    - nipple and breast pain
    - baby's ability to latch to the breast
    - baby's ability to maintain latch to the breast
    - feeding noise

4.4.1 Bristol Breastfeeding Assessment Tool (BBAT) (Appendix 7.1)

The BBAT is a valid and reliable tool for measuring change in infant breastfeeding mechanics. [52] It was developed to measure frequently encountered postpartum breastfeeding difficulties.

The BBAT measures five aspects of breastfeeding:

1. Positioning
2. Attachment
3. Sucking

4 Swallowing
5 Comfort

4.4.2 Breastfeeding Self-Efficacy Scale - Short Form (BSES-SF) (Appendix 8.1)

The BSES-SF is a validated measure of change in maternal breastfeeding confidence [53]. It consists of 14 questions, each on a 5-point Likert scale with a minimum score of 0 and a maximum score of 70. The measure is set within a positive framework with each question preceded by the phrase "I can always". The higher the score, the greater the level of breastfeeding self-efficacy. A BSES-SF score of 50 is considered the threshold for identifying women at risk of ceasing exclusive breastfeeding, with a score $\leq$50 indicating an increased risk of ceasing breastfeeding. This threshold has a sensitivity of 79% and specificity of 52% and reflects those women who are likely to require care to support breastfeeding. The BSES-SF has been validated for cross-cultural adaptation. [54-56]

4.4.3 Visual Analog Scale (VAS) (Appendix 9.1)

The VAS is a valid measure of change over time. [57] A separate VAS will be used to assess four aspects of breastfeeding: nipple and breast pain experienced by the mother while feeding, level of noise made by the infant while breastfeeding, infant ability to latch to the breast, and infant ability to maintain latch. The higher the score for nipple and breast pain and noise while feeding means worse symptoms. The lower the score for ability to latch and maintain latch means more severe symptoms.

4.5 Administration of Outcome Measures

The research assistant, blinded to group allocation, will manage the administration, collection and recording of the outcome measures. All participating practitioners will be blinded to the results of the outcome measures until the data collection phase of the trial has been completed.

4.6 Data collection and collection period

Data will be collected from MIDs enrolled in the study. Data collected includes:

- Participant demographics
- Infant and maternal medical histories and breastfeeding histories
- Birth and neonatal health statistics
- Infant musculoskeletal examination findings as assessed by the initial treating osteopath
- Adverse events
- Pre- and post-BBAT scores
- Pre- and post-BSES-SF scores
- Pre- and post-VAS scores

The planned data collection period for the trial is 12 months. There is scope to extend this period if required. The need for extension will be determined by the recruitment rate.

5.0 Data Analysis

Patient demographic data will be analysed using descriptive statistics and include mean, mode, standard deviation and interquartile range for the chosen variables.

Analyses for the purpose of generating hypotheses will be conducted using the statistical software package R (version 4.1.0 and R Studio version 2022.07.1). Wilcoxon signed rank tests with continuity

correction will be used to calculate p values for changes in BBAT, BSES-SF and VAS scores pre- and post-intervention and Wilcoxon rank-sum tests will be used to determine whether BBAT and BSES-SF scores differ between control and intervention groups.

6.0 Blinding and Quality Assurance

A blinded assessor will collect all BBAT, BSES-SF and VAS data. The treating osteopath will be blinded to this data during the trial but will not be blinded to the medical history, consent form or treatment effects during the trial.

The blinded assessor will transfer all BBAT, BSES-SF and VAS scores into an Excel spreadsheet which will be stored in a password protected file on the CI's laptop and backed up on Southern Cross University's secure storage system. A copy of the data will be sent to a different member of the research team (RE) for quality assurance and data cleansing.

7.0 Sample Size and Statistical Power Calculation

An *a priori* sample size calculation was performed using existing data on the BBAT. With 2 Groups, a standard deviation of 2, a minimum clinically important difference (MCID) of 1.5,[52] an Alpha of 0.05 and power set at 80%, the minimum group size was calculated to be 31, giving a total sample size of 62. Allowing for a 10% drop-out rate means a total sample size of 70 is required.

8.0 Participant recruitment strategies - Posters/advertisements/electronic notices

Posters/advertisements/electronic notices advertising the trial will be placed at maternal health centres, breastfeeding drop-in centres, and private osteopathic and IBCLC clinics (Appendix 10.1) in metropolitan Melbourne and Canberra. They will direct interested mothers to contact the trial coordinator. To reduce the risk of coercion, potential participants will not be directly approached at these centres. Mothers who contact the trial coordinator will receive a copy of the participant information sheet (Appendix 5.1) and instructions on how to book a pre-screening appointment.

If the MID meets all the inclusion criteria and is deemed suitable to participate in the trial, the mother will be asked to complete the participant consent form. The mother can withdraw her infant from the trial at any time without having to give a reason for the withdrawal.

9.0 Information and consent

The information sheets (Appendix 2.1 and 5.1) and consent forms (Appendices 3.1 and 6.1) for provide clear communication and informed decision-making and prioritises the well-being and autonomy of the parents and infants throughout the process.

10.0 Risks

The risks associated with participation in this study are around the potential for physical harm to a member of a vulnerable population, psychological harm to the mother, and familial distress.

Physical harm to a member of a vulnerable population

Participation in this research carries a risk associated with harm and/or discomfort to an infant resulting from IBCLC and/or osteopathic intervention (OMT).

While the literature shows that OMT intervention has the potential to benefit infants experiencing breastfeeding difficulty,[58] there have been no reports of any adverse events associated with manual therapy intervention on infants with breastfeeding difficulty.[59, 60] This suggests that manual therapy administered by an osteopath is a relatively low-risk intervention for this group of patients.

Psychological harm to the mother

Living with an infant experiencing breastfeeding difficulty can be a distressing situation. Maternal distress can be compounded by inadequate familial support, exhaustion and feelings of failure. This may increase familial distress. Breastfeeding difficulty has also been linked to post-natal depression (PND) in a both a positive and negative way. For some women, breastfeeding helps to reduce the chance of PND or shorten how long it lasts. For others, it is the cause of stress and anxiety and can lead to a situation where discontinuing breastfeeding may be the most appropriate course of action to take under the circumstances. To monitor signs of PND or distress the practitioners (IBCLCs and osteopaths) will have access to the Edenborough Postnatal Depression Scale (EPDS) (Appendix 11.1). This 10-item self-reported measure is designed to screen women for symptoms of emotional distress during pregnancy and the postnatal period. If a clinician suspects that a mother is distressed, they will utilise this scale to monitor the level of maternal distress weekly (EPDS refers to the past 7 days). If the mother has a score of >12 on the EPDS, she will be referred to Perinatal Anxiety & Depression Australia (PANDA https://panda.org.au) and/or her GP.

Managing incidents of abuse

The IBCLCs, osteopaths and CI who work on the trial are registered/certified health practitioners. It is standard practice and a mandatory requirement for all registered/certified health practitioners in Australia to report any abuse and/or neglect of children to the appropriate authorities.

10.1 Risk Management

The risks associated with participation in this study will be mitigated and managed along the following lines:

Physical harm to a member of a vulnerable population

In conjunction with the research team, the treating clinician (IBCLC or osteopath) will question parents about the occurrence of adverse events during the trial. If an adverse event requires additional medical care, the treating clinician will refer the mother and infant to a hospital or their GP, depending on which is the most appropriate course of action to take given the circumstances. The adverse event will be recorded and reported to the CI who will then take appropriate action.

Psychological harm to the mother

In conjunction with the research team, the treating clinician (IBCLC or osteopath) will monitor participating mothers for signs of post-natal depression (PND). If signs of PND become apparent, the mother will be referred to their GP for further assessment and management.

Familial distress

In conjunction with the research team, the treating clinician (IBCLC or osteopath) will monitor participating parents for signs of familial distress. If signs of familial distress become apparent, the parents will be referred to their GP for further assessment and management.

11.0 Timeframes

TIMELINE

	2023	2024				2025			
	Nov/ Dec	Jan/ March	April/ May	June/ Sep	Oct/ Dec	Jan/ March	April /June	July/ Sep	Oct/ Dec
Ethics									
Recruitment									
Intervention phase									
Data analysis									
Manuscript preparation									
Final report									

Figure 2. GANTT chart

12.0 Recruitment Duration and Study Duration

It is anticipated that the recruitment phase of the trial will be 12 months. If the target recruitment number is not reached in that time, there is provision to extend the recruitment period by a further 6

months. The entire project will run over a 2-year period (Figure 2). Each participant will be involved for a total of 8 weeks.

13.0 Participant time commitment:

The total time commitment for each participant is 330 or 360 minutes (6-6.5 hours) (See Table 1). We acknowledge that in some circumstances, there will be an inequality of 10% in the total time spent for each group. We believe this is acceptable given the nature of the trial.

	INTERVENTION	IBCLC (Minutes)	IBCLC/OMT (Minutes)
Week 0	Baseline Measurements (Face-to Face)/Paperwork (Online)	60	60
Week 1	IBCLC 1	60	60
Week 2	IBCLC 2	30	30
	OMT 1		60
Week 3	Up to 2 x 1/2-hour IBCLC Telehealth	60	
	Up to 2 x ¼ - hour IBCLC telehealth		30
	OMT 2		30
Week 4	Up to 2 x 1/2 - hour IBCLC Telehealth (as required)	60	
	OMT 3 (as required)		30
	Post Intervention paperwork (Online)	30	30
Week 8	Discharge paperwork - Follow up Phone call	30	30
	Total Minutes	**330**	**360**

Table 1: Participation for each group

IBCLC 1 Initial Consultation with an IBCLC
IBCLC 2 Follow-up Consultation with IBCLC
OMT 1 Initial Consultation with an Osteopath
OMT 2 & 3 Follow-up Consultation with Osteopath

Practitioners must also complete a 4-hour pre-trial training and a 1-hour Global Health Training Centre—Good Clinical Practice Course.

14 Participant follow-up

Participants will be followed up 1 month after finishing the intervention phase of the trial. At that follow-up they will be asked to complete the BSES-SF and VAS measures via email and participate in a short 5-minute telephone conversation with the trial coordinator about their current breastfeeding status.

If they are continuing to have difficulty breastfeeding and need further support, they will be referred to the Australian Breastfeeding Association where breastfeeding support councillors are available free of charge.

15 Data Collection

15.1 Personal Data

1. Full name mother
2. Full name child
3. Mother's date of birth
4. Child's date of birth
5. Child's gender
6. Mother's contact information
7. Mother's emergency contact information

15.2 Medical History Data

1. Existing medical conditions
2. Current medications
3. Allergies
4. Surgical history
5. Family medical history
6. Immunisation history
7. Lifestyle factors
8. Previous medical history
9. Maternal mental health history
10. Pregnancy and birth medical history, including gestation, delivery information, care given, agar scores, birth weight, birth length, and birth head circumference.
11. Current infant weight, length and head circumference
12. Breastfeeding history
13. Breastfeeding and feeding mode
14. Breastfeeding symptoms

16 Participant withdrawal

Participants are free to withdraw from the trial at any time and for any reason. Withdrawal from the trial will not affect the ongoing care of their infant at the participating clinic but may result in standard fee-for-service charges being levied by the respective clinic on consultations provided after withdrawal from the trial.

17 Data Loss:

If a participant withdraws from the trial before completing all of the intervention sessions, any data collected up until withdrawal will be retained and used in the data analysis.

18 Bias:

The withdrawal of certain participants may introduce bias into the results if those who withdraw have different characteristics or experiences compared to those who continue. As part of this research the research team will analyse the characteristics of participants who withdraw and compare them to those who remain in the study. This analysis can help identify potential biases and inform appropriate adjustments or interpretations of the results.

19 Data Safety Monitoring Board

A data safety monitoring board (DSMB) has been established for the trial. It will meet as required (but at least on two occasions) during the trial. The DSMB will consist of the following people:

1. A Paediatrician – Professor Abdal - Latif Mohamed (ACT)
2. A Paediatric Osteopath & IBCLC – Dr. Emily Jones (Victoria)
3. An independent data analyst – Dr. John Smart (NSW)

The purpose of the DSMB is to monitor the progress of a trial and to make recommendations on whether to continue, modify or stop the trial for safety or ethical reasons.

An interim analysis will be conducted at 40% recruitment (28 participants) by the statistician (PG). The results of this interim analysis will be sent to the DSMB for appraisal.

20 Data Management

Data will be housed on Southern Cross University's data storage system in accordance with the University regulations for storing medical information.

Storage:
All digital trial data will be stored on a secure, password protected University server using appropriate technical and data security measures. Prior to being uploaded onto the University's server, trial data will be stored in a password protected file on the CI's university computer. Any hard copy files related to the trial will be stored in a locked filing cabinet at the CI's private office, until it is transferred to a secure data storage system with Prof Sandra Grace at Southern Cross University.

Access:
Access to trial data is restricted to individuals named in this document.

Disclosure:
We will obtain informed consent from participants prior to participating in the study. Research findings and publications will be presented in a manner that preserves the anonymity of participants. The Joanna Briggs [61] and CONSORT [62] guidelines checklist for RCTs will guide the reporting process.

Destruction or Archiving:

Data will be retained in accordance with the National Statement 3.1.45 and 3.1.56. Data will be stored and archived for 25 years (or until the children reach the age of 25). Data will then be destroyed according to the standard procedures for the destruction of health records at Southern Cross University.

21 Adverse events

Training for recognising, managing and reporting adverse events forms part of the practitioner pre-trial training module and is in line with current definitions of adverse events in the manual therapy setting. In this research we classify adverse events in manual therapy as one of three types: [63]

- 'Major' adverse event is a medium to long-term, severe and unacceptable. It requires medical treatment and is serious and distressing.
- 'Moderate' adverse event is medium to long-term but only moderate in severity. It may require additional medical treatment and
- 'Mild' adverse event is short-term, non-serious, transient, and reversible. No additional medical treatment is required to resolve it.

Treating Osteopaths and IBCLCs will manage adverse events reported within their clinical sessions by using their clinical reasoning and judgement to assess the severity of the adverse event. If the adverse event is considered minor, the osteopath or IBCLC will monitor the participant, continue to provide care and record the event in their medical file. The CI will review all medical records daily during the intervention phase of the trial. If moderate, the practitioner will report it to the CI, who will then determine the appropriate referral action in consultation with the practitioner. If a major event occurs, the practitioner will immediately refer the participant for medical care and report it to the CI.

The CI will report all major and moderate adverse events, to the research team and HREC (through the Adverse Event Report form in IRMA) within 72 hours of being notified. All mild adverse events will be reported to the HREC using the same form on IRMA. Adverse events reported outside face-to-face clinic time (e.g., via phone or email) will be managed by the CI in consultation with the practitioners in the same manner as outlined.

All adverse events that occur during the trial will be recorded, regardless of whether they are related to the trial or not (Appendix 12.1). All adverse events (mild, moderate and major will be included in the project's annual report.

22 Dissemination of results

Results from this trial may be used in publications submitted to scientific journals. They may also be used in presentations to the breastfeeding medical community, lactation consultants, midwives, maternal health nurses and the paediatric clinician community.

23 References

[1] Victora CG, Bahl R, Barros AJD, França GVA, Horton S, Krasevec J, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. The Lancet. 2016;387(10017):475-90. https://doi.org/10.1016/S0140-6736(15)01024-7.

[2] Kendall-Tackett K. A new paradigm for depression in new mothers: the central role of inflammation and how breastfeeding and anti-inflammatory treatments protect maternal mental health. International breastfeeding journal. 2007;2(1):6-. https://doi.org/10.1186/1746-4358-2-6.

[3] Boutwell BB, Beaver KM, Barnes JC. Role of breastfeeding in childhood cognitive development: A propensity score matching analysis: Breastfeeding and cognitive development. Journal of paediatrics and child health. 2012;48(9):840-5. https://doi.org/10.1111/j.1440-1754.2012.02547.x.

[4] Binns C, Lee M, Low WY. The Long-Term Public Health Benefits of Breastfeeding. Asia-Pacific journal of public health. 2016;28(1):7-14. https://doi.org/10.1177/1010539515624964.

[5] Mulet M, Filgueira A, Ponce-Taylor J, Servera M, Cardo E, Verd S, et al. Perinatal psychological interventions to promote breastfeeding: a narrative review. International breastfeeding journal. 2021;16(1):1-8. https://doi.org/10.1186/s13006-020-00348-y.

[6] Horta BL, Loret de Mola C, Victora CG. Long-term consequences of breastfeeding on cholesterol, obesity, systolic blood pressure and type 2 diabetes: a systematic review and meta-analysis. Acta Paediatrica. 2015;104(S467):30-7. https://doi.org/10.1111/apa.13133.

[7] Rollins NC, Bhandari N, Hajeebhoy N, Horton S, Lutter CK, Martines JC, et al. Why invest, and what it will take to improve breastfeeding practices? Lancet. 2016;387(10017):491-504. https://doi.org/10.1016/s0140-6736(15)01044-2.

[8] Margreete Johnston SL, Larry Noble, Kinga Szucs, Laura Viehmann. Breastfeeding and the use of human milk. Pediatrics. 2012;129(3):e827-41. https://doi.org/10.1542/peds.2011-3552.

[9] COAG. The Australian National Breastfeeding Strategy: 2019 and Beyond. 2019. Health Do. Canberra, ACT. 23. Available from:https://www.health.gov.au/sites/default/files/documents/2022/03/australian-national-breastfeeding-strategy-2019-and-beyond.pdf.

[10] WHO. Global Strategy for Infant and Young Child Feeding. 2003. Unicef. Geneva, Switzerland. 27. Available from:https://www.who.int/publications/i/item/9241562218.

[11] Kelleher CM. The physical challenges of early breastfeeding. Social science & medicine (1982). 2006;63(10):2727-38. https://doi.org/10.1016/j.socscimed.2006.06.027.

[12] Fawkes C, Leach J, Mathias S, Moore A. A profile of osteopathic care in private practices in the United Kingdom: a national pilot using standardised data collection. . Man Ther 2014 Apr;19(2):125-30. Available from: https://doi.org/10.1016/j.math.2013.09.001.

[13] Alliance. OI. Osteopathy and Osteopathic Medicine: a global view of practice, patients, education and the contribution to healthcare delivery. . 2013. Available from: http://oialliance.org/wp-content/uploads/2014/01/OIA-Stage-2-Report.pdf; .

[14] Fludder C, Keil B. Presentation of neonates and infants with spinal vs extremity joint dysfunction. Chiropr J Aust. 2018;46(1):p 79-91. Available from: http://www.cjaonline.com.au/index.php/cja/article/view/192.

[15] Mulder PJ. A Concept Analysis of Effective Breastfeeding. Journal of Obstetric, Gynecologic & Neonatal Nursing. 2006;35(3):332-9. https://doi.org/10.1111/j.1552-6909.2006.00050.x.

[16] Riordan J, Gill-Hopple K, Angeron J. Indicators of Effective Breastfeeding and Estimates of Breast Milk Intake. Journal of Human Lactation. 2005;21(4):406-12. https://doi.org/10.1177/0890334405281032.
[17] Genna CW. Breastfeeding infants with congenital torticollis. Journal of human lactation : official journal of International Lactation Consultant Association. 2015;31(2):216-20. https://doi.org/10.1177/0890334414568315.
[18] Greenwood K, Engel R, Grace S. Osteopathic intervention for infants with breastfeeding difficulty: A retrospective case series. International Journal of Osteopathic Medicine. 2023;47:100652. https://doi.org/https://doi.org/10.1016/j.ijosm.2022.11.005. Available from: https://www.sciencedirect.com/science/article/pii/S1746068922000992.
[19] Westcott N. The use of cranial osteopathy in the treatment of infants with breast feeding problems or sucking dysfunction. The Australian Journal of Holistic Nursing. 2004;11(1):25-32. Available from: https://search.informit.org/doi/10.3316/informit.492960555411094.
[20] Hazelbaker AK. The Impact of Craniosacral Therapy/Cranial Osteopathy on Breastfeeding. Clinical Lactation. 2020;11(1):21-7. https://doi.org/10.1891/2158-0782.11.1.21. Available from: https://ezproxy.scu.edu.au/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=141697537&site=ehost-live.
[21] Herzhaft-Le Roy J, Xhignesse M, Gaboury I. Efficacy of an Osteopathic Treatment Coupled With Lactation Consultations for Infants' Biomechanical Sucking Difficulties. Journal of human lactation : official journal of International Lactation Consultant Association. 2017;33(1):165-72. https://doi.org/10.1177/0890334416679620.
[22] Todd AJ, Carroll MT, Robinson A, Mitchell EKL. Adverse Events Due to Chiropractic and Other Manual Therapies for Infants and Children: A Review of the Literature. J Manipulative Physiol Ther. 2015;38(9):699-712. https://doi.org/10.1016/j.jmpt.2014.09.008.
[23] Carnes D, Plunkett A, Ellwood J, Miles C. Manual therapy for unsettled, distressed and excessively crying infants: a systematic review and meta-analyses. BMJ Open. 2018;8(1):e019040. https://doi.org/10.1136/bmjopen-2017-019040.
[24] Elad D, Kozlovsky P, Blum O, Laine AF, Po MJ, Botzer E, et al. Biomechanics of milk extraction during breast-feeding. Proceedings of the National Academy of Sciences. 2014;111(14):5230-5.
[25] Negin Mortazavi S, Geddes D, Hassanipour F. Lactation in the human breast from a fluid dynamics point of view. Journal of biomechanical engineering. 2017;139(1):011009.
[26] Bu'Lock F, Woolridge MW, Baum JD. Development of co-ordination of sucking, swallowing and breathing: ultrasound study of term and preterm infants. Dev Med Child Neurol. 1990;32(8):669-78. https://doi.org/10.1111/j.1469-8749.1990.tb08427.x.
[27] Genna CW. Supporting sucking skills in breastfeeding infants (4th ed.). Burlington, MA: Jones and Bartlett Learning; 2022.
[28] Smith LJ. Impact of Birthing Practices on the Breastfeeding Dyad. Journal of Midwifery & Women's Health. 2007;52(6):621-30. Available from: https://pubmed.ncbi.nlm.nih.gov/17984000/.
[29] Hogan M, Westcott C, Griffiths M. Randomized, controlled trial of division of tongue-tie in infants with feeding problems. J Paediatr Child Health. 2005;41(5-6):246-50. https://doi.org/10.1111/j.1440-1754.2005.00604.x.
[30] Fraval MM. A Pilot Study of the Osteopathic Treatment of Infants with a Sucking Dysfunction. AAO Journal. 1998;8(2):40. Available from: https://www.academyofosteopathy.org/assets/aaoj/AAOJ_Summer1998.pdf.

[31] Miller JE, Miller L, Sulesund A, Yevtushenko A. Contribution of chiropractic therapy to resolving suboptimal breastfeeding: a case series of 114 infants. Journal of Manipulative & Physiological Therapeutics. 2009;32(8):670-4. https://doi.org/10.1016/j.jmpt.2009.08.023.
[32] Wescott N. The use of cranial osteopathy in the treatment of infants with breast feeding problems or sucking dysfunction. The Australian journal of holistic nursing. 2004;11(1):25-32. Available from: https://ezproxy.scu.edu.au/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=mnh&AN=19175274&site=ehost-live.
[33] Lund GC, Edwards G, Medlin B, Keller D, Beck B, Carreiro JE. Osteopathic manipulative treatment for the treatment of hospitalized premature infants with nipple feeding dysfunction. The Journal of the American Osteopathic Association. 2011;111(1):44-8. Available from: https://ezproxy.scu.edu.au/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=mnh&AN=21258016&site=ehost-live.
[34] Sacher R, Knüdeler M, Wuttke M, Wüstkamp N, Derlien S, Loudovici-Krug D. Manual therapy of infants with postural and movement asymmetries and positional preference: Effects of one-time treatment. Manuelle Medizin. 2021;59(2):117-27. https://doi.org/10.1007/s00337-020-00760-9.
[35] Miller J, Fontana M, Jernlås K, Olofsson H, Verwijst I. Risks and rewards of early musculoskeletal assessment: An evidence-based case report. British journal of midwifery. 2013;21(10):736-43. https://doi.org/10.12968/bjom.2013.21.10.736.
[36] Blenkinsop A. Plagiocephaly and breastfeeding...Tracey Jackson's article entitled 'The true cost of plagiocephaly' (September issue of RCM Midwives Journal). RCM Midwives. 2007;10(1):45-. Available from: https://ezproxy.scu.edu.au/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=106136732&site=ehost-live.
[37] Parker M. Resolution of inability to latch, breastfeed, excessively recessed jaw and plagiocephaly in a newborn undergoing chiropractic care: A case report and review of literature. J Pediatr Matern & Fam Health - Chiropr. 2019(June):pp. Online access only p 71-7. Available from: https://www.vertebralsubluxationresearch.com/2019/05/30/resolution-of-inability-to-latch-breastfeed-excessively-recessed-jaw-plagiocephaly-in-a-newborn-undergoing-chiropractic-care-a-case-report-review-of-literature/.
[38] Schwerla F, Daake B, Moeckel E, Resch K-L. Osteopathic Treatment of Infants in Their First Year of Life: A Prospective Multicenter Observational Study (OSTINF Study). Complementary Medicine Research. 2021;28(5):395-406. https://doi.org/10.1159/000514413. Available from: https://doi.org/10.1159/000514413.
[39] Green S, Alcantara J. Resolution of torticollis, breastfeeding difficulties and cranial distortion in a twin infant undergoing chiropractic care for vertebral subluxation: A case report and review of the literature [case report]. J Pediatr Matern & Fam Health - Chiropr. 2019(July):pp. Online access only p 78-81. Available from: https://www.vertebralsubluxationresearch.com/2019/06/26/resolution-of-torticollis-breastfeeding-difficulties-cranial-distortion-in-a-twin-infant-undergoing-chiropractic-care-for-vertebral-subluxation-a-case-report-review-of-the-literature/.
[40] Williams S. Improvement of congenital torticollis, plagiocephaly and breastfeeding issues in an infant following subluxation based chiropractic care: A case study [case report] J Pediatr Matern & Fam Health - Chiropr. 2014;Fall(4):pp. Online acces only p 87-94. Available from: https://www.vertebralsubluxationresearch.com/2017/09/10/improvement-in-congenital-torticollis-plagiocephaly-breastfeeding-issues-in-an-infant-following-subluxation-based-chiropractic-care-a-case-study/.

[41] Carriero J. Paediatric Manual Medicine: An Osteopathic Approach. Edinburgh: Elsevier Science; 2009.
[42] Carreiro J. An Osteopathic Approach to Children. Edinburgh:: Elsevier Science; 2003.
[43] Carreiro JE. Pediatric manual medicine: an osteopathic approach. Edinburgh: Churchill Livingstone Elsevier; 2009. 1-3 p.
[44] Wall V, Glass R. Mandibular Asymmetry and Breastfeeding Problems: Experience From 11 Cases. Journal of Human Lactation. 2006;22(3):328-34. https://doi.org/10.1177/0890334406290096.
[45] Gesslbauer C, Vavti N, Keilani M, Mickel M, Crevenna R. Effectiveness of osteopathic manipulative treatment versus osteopathy in the cranial field in temporomandibular disorders - a pilot study. Disabil Rehabil. 2018;40(6):631-6. https://doi.org/10.1080/09638288.2016.1269368.
[46] Sullivan C. Introducing the cranial approach in osteopathy and the treatment of infants and mothers. Complementary Therapies in Nursing and Midwifery. 1997;3(3):72-6. https://doi.org/https://doi.org/10.1016/S1353-6117(97)80037-6. Available from: https://www.sciencedirect.com/science/article/pii/S1353611797800376.
[47] Ballard JL, Auer CE, Khoury JC. Ankyloglossia: assessment, incidence, and effect of frenuloplasty on the breastfeeding dyad. Pediatrics. 2002;110(5):e63. https://doi.org/10.1542/peds.110.5.e63.
[48] Miller A, Miller J. Is tongue tie really the problem? Incidence of ankyloglossia in an infant population presented with suboptimal feeding: A cross-sectional survey. J Clin Chiropr Pediatr. 2017;16(September):1350-4.
[49] Tobey A, Kozar, A. Frequency of Somatic Dysfunction in Infants With Tongue-Tie: A Retrospective Chart Review. The AAO Journal. 2018(Dec;28(4)). Available from: https://ostemed-dr.contentdm.oclc.org/digital/collection/myfirst/id/13842/.
[50] Arcusio A, Villa MC, Felloni F, Migliori C. Myofascial release as neuromotor support to improve the ineffective sucking ability in infants. 2023.
[51] Park T-K, Kim J-R, Park R-J, Cho M-S. Effect of Myofascial Release Therapy on Newborns and Infants with Congenital Torticollis. Journal of Korean Physical Therapy. 2006;18(5):1-11.
[52] Ingram J, Johnson D, Copeland M, Churchill C, Taylor H. The development of a new breast feeding assessment tool and the relationship with breast feeding self-efficacy. Midwifery. 2015;31(1):132-7. https://doi.org/10.1016/j.midw.2014.07.001.
[53] Dennis C-L. The Breastfeeding Self-Efficacy Scale: Psychometric Assessment of the Short Form. Journal of Obstetric, Gynecologic, & Neonatal Nursing. 2003;32(6):734-44. https://doi.org/https://doi.org/10.1177/0884217503258459. Available from: https://doi.org/10.1177/0884217503258459.
[54] Wutke K, Dennis CL. The reliability and validity of the Polish version of the Breastfeeding Self-Efficacy Scale-Short Form: translation and psychometric assessment. Int J Nurs Stud. 2007;44(8):1439-46. https://doi.org/10.1016/j.ijnurstu.2006.08.001.
[55] Dennis C L. The breastfeeding self-efficacy scale: psychometric assessment of the short form. J Obstet Gynecol Neonatal Nurs. 2003;Nov-Dec(32(6)):734-44. https://doi.org/10.1177/0884217503258459.
[56] McQueen KA, Montelpare WJ, Dennis CL. Breastfeeding and Aboriginal women: validation of the Breastfeeding Self-Efficacy Scale-Short Form. Can J Nurs Res. 2013;45(2):58-75. https://doi.org/10.1177/084456211304500209.
[57] Bijur PE, Silver W, Gallagher EJ. Reliability of the Visual Analog Scale for Measurement of Acute Pain. Academic Emergency Medicine. 2001;8(12):1153-7.

https://doi.org/https://doi.org/10.1111/j.1553-2712.2001.tb01132.x. Available from: https://doi.org/10.1111/j.1553-2712.2001.tb01132.x.
[58] Herzaft-LeRoy J, Xhignesse M, Gaboury I. Assessment of the Efficacy of An Osteopathic Treatment in Infants with Biomechanical Impairments to Suckling. Journal of visualized experiments : JoVE. 2019(144). https://doi.org/10.3791/58740. Available from: https://ezproxy.scu.edu.au/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=mnh&AN=30799839&site=ehost-live.
[59] Carnes D, Mars TS, Mullinger B, Froud R, Underwood M. Adverse events and manual therapy: A systematic review. Manual Therapy. 2010;15(4):355-63. https://doi.org/https://doi.org/10.1016/j.math.2009.12.006. Available from: https://www.sciencedirect.com/science/article/pii/S1356689X09002112.
[60] Parnell Prevost C, Gleberzon B, Carleo B, Anderson K, Cark M, Pohlman KA. Manual therapy for the pediatric population: a systematic review. BMC complementary and alternative medicine. 2019;19(1):60. https://doi.org/10.1186/s12906-019-2447-2. Available from: https://ezproxy.scu.edu.au/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=mnh&AN=30866915&site=ehost-live.
[61] JBI. Joanna Briggs Institute, Critical apprasal tools Adelaid, Australia: JBI; 2020 [Available from: https://jbi.global/critical-appraisal-tools.
[62] CONSORT. CONSORT Transparent reporting of trials; Pilot and Feasibility Trials 2021 [Available from: http://www.consort-statement.org/extensions/overview/pilotandfeasibility.
[63] Carnes D, Mullinger B, Underwood M. Defining adverse events in manual therapies: A modified Delphi consensus study. Manual therapy. 2010;15(1):2-6. https://doi.org/10.1016/j.math.2009.02.003.