

RESEARCH SUBJECT INFORMED CONSENT FORM

Protocol Title: Osteopathic Manipulative Treatment (OMT) for the Management of Feeding Dysfunction in Breastfed Newborns

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Why am I being invited to volunteer?

You are being invited to participate in a research study. “Research” designates an activity designed to test a hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge, whereas “practice of medicine” refers to interventions designed solely to enhance the well-being of an individual patient. Research subjects may or may not benefit from research procedures. Federal regulations require that you are informed of the research you are being invited to volunteer for and your signature indicating that you have been informed about the research. You are being invited to volunteer since you meet the requirements for enrollment into this study. Your participation is voluntary which means you can choose whether or not you want to participate. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study,

and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be invited to sign this form. Your signature on this form is voluntary and does not waive any of your legal rights or make any institutions or persons involved in this research any less responsible for your well-being. Your refusal to participate in this trial will not influence your present or future care.

Who is the Principal Investigator for this Study?

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What is the purpose of this research study?

The purpose of this study is to determine whether osteopathic manipulative treatment (OMT) as an adjunct to lactation support will improve outcomes in breastfed newborns with feeding dysfunction.

How long will I be in the study?

We think your baby will be in this study from birth until his or her second outpatient lactation visit (if scheduled), which normally occurs about 2-3 weeks after discharge.

How many other people will be in the study?

About 80 newborns will take part in this study.

What is involved in this study?

Osteopathic manipulative treatment, or OMT, is a form of manual medicine in which a trained physician uses his or her hands to diagnose areas of restriction in a patient's body. The physician then uses his or her hands to manually correct the restriction, to improve body function. The research team will be performing OMT on breastfed newborns that have been identified by lactation consultants as having a feeding dysfunction. The team will then compare the feeding behaviors of these babies to those in the same category who did not receive OMT.

OMT has some similarities to chiropractic manipulation, and many differences. No thrusting techniques that produce a popping or cracking sound, as traditionally associated with chiropractic, will be used in this study. All Doctors of Osteopathy (DOs) and DO medical students receive complete medical education in the United States, and as such have a different training regimen than chiropractic practitioners. DOs and MDs trained to use OMT are taught to use it similarly to medication, with proper doses and frequency to achieve a medical change.

Infants will be assigned to either the OMT group or No OMT group by the research team using a randomized process to help ensure equal enrollment in both groups. All babies will receive standard lactation support. All newborns receiving OMT will undergo the same four treatments, all of which involve light touch and massage. All newborns not receiving OMT will undergo a gentle assessment of their head and neck region but not receive treatment. OMT treatment or sham sessions should be brief, taking no longer than 20 minutes, with each infant receiving two sessions during the study.

During breastfeeding sessions, a lactation consultant will assess the infant's breastfeeding behavior using a tool called the LATCH score. Your child will be scored upon enrolling in the study, daily during hospitalization, and at up to two outpatient lactation visits. The breastfeeding scores of the newborns who received OMT will be compared to the scores of those who did not.

The following is information regarding the types of treatment we will use in the study.

Most treatments will be done with your baby lying on his or her back. All techniques used will be gentle, applying no more force than would be used to test a tomato for ripeness. The provider's touch will be delicate enough so as not to blanch his or her fingernail beds while treating your infant.

Still technique

The Still technique will be used in the cervical (neck) region, focusing on the joints between neck vertebrae and the individual neck muscles, including the sternocleidomastoid muscle. In this treatment, the neck is first brought to a point of relaxation. Then, a gentle force, either a push or stretch, is added. To finish the treatment, the neck is gently moved through its range of motion in the opposite direction as it was placed in the first step. Your practitioner will then recheck the joint for any left-over restriction and re-treat, if needed.

Occipital condylar decompression

This treatment is meant to correct a restriction at the occipital condyle, which is the joint formed by the bone at the base of the skull and the top vertebrae of the neck. Your practitioner will cradle the back of your baby's head with both hands, with his or her fingertips at the base of your baby's head. Gentle pressure is applied through the fingertips toward the condylar joint. The practitioner applies this gentle pressure until he or she

feels the condylar joint relax and release. A slight stretch toward the top of the head or motion to the side of the neck may be added, to help focus the treatment. The practitioner will then recheck motion at the condylar joint to make sure the treatment is successful.

Hyoid bone balancing

The hyoid bone is located in the neck and it aids in tongue movement and swallowing. Your practitioner will apply gentle motion to the hyoid bone, usually using a finger and thumb. They will gently move the hyoid bone to determine which direction(s) it wants to move and then hold where it is most relaxed. This will allow the muscles and tissue that attach to the hyoid bone to relax and unwind. The hyoid bone can then move back to its normal position.

Thoracic inlet release

Your practitioner will apply gentle motion to the fascia circling your baby's upper chest, shoulders, upper back, and lower neck, typically using the thumb and a few fingers on each hand. Your practitioner will then test in which direction(s) the fascia is most relaxed. Finally, your practitioner will hold the fascia where it is most balanced and, as it relaxes and unwinds, move with the fascia to keep it where it is most balanced. When the fascia is finished unwinding, your practitioner will retest to see if the fascia still prefers to move in a certain direction(s).

What are the possible risks or discomforts?

The OMT techniques used in this protocol are gentle and indirect, meaning all treatments will occur at a point of relaxation versus tension; however, as with any medical procedure, OMT carries some risks, as outlined below. If treatment does not work, patients do not usually show side effects.

Likely

- None

Less Likely

- Fatigue
- Headache
- Stiffness
- Tenderness
- Redness or mild swelling to treatment area

Rare but serious

- None

Patients will be assessed for the above listed side effects through observation of vital signs, physical examination findings, latching behaviors, sleep behaviors and/or

irritability/fussiness. It is important to call the researcher or your regular physician when you think you are having problems, even if they are not included on the above list.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

There may be no direct benefit to you if you decide to participate in this research. The value of OMT as an adjunct therapy to improve newborn feeding dysfunction is unproven. A clinical trial is one of the most exact ways to test whether OMT would provide an added benefit to babies with feeding problems.

This new knowledge will benefit future patients and medical investigators. If the newborns who received OMT are found to have better feeding outcomes, you may still receive no direct benefit if you are assigned to the “control” group instead of the OMT group.

Benefits hypothesized by the study may include: improved latch, improved swallow, and reduced pain related to feeding for both mom and baby.

What other choices do I have if I do not participate?

No alternative treatments to OMT will be offered in addition to the lactation support already provided to all breastfeeding infants and mothers. OMT will augment the current standard of care which includes lactation support. Infants needing a speech and/or physical therapy consult in addition to lactation support will be excluded from the study.

Will I be paid for being in this study or will I have to pay for anything?

You will receive no payment for taking part in this study. Taking part in this study will not lead to added costs to you or your insurance company. You or your insurance company will be charged for continuing medical care and/or hospitalization at the usual rate.

What happens if I am injured or hurt during the study?

If you or your baby have a medical emergency during the study, you may contact the Principal Investigator or co-investigators listed on page one of this form. You may also

contact your own doctor or seek treatment outside of this institution. If requested, your physician may call the telephone numbers on the first page of this consent form for further instructions or information related to the study.

In the extremely unlikely event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise available from the University of Illinois College of Medicine at Peoria. If you have an illness or injury during this research trial that is not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

When does the study end?

You may stop participating at any time. However, if you decide to stop participating in this study, we encourage you to talk to the research team first.

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, your baby's physician or the research team because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- The Principal Investigator has decided to stop the study.

Although the study is ongoing, you may discontinue participation or the principal investigator may ask you to withdraw from the study at any time. If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

Your privacy and the protection of your health information are important to us. This section of the consent will cover:

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access research information about you
- Your right to withdraw your authorization (approval) for any future use of your personal health information

1. Personal health information about you that will be collected in this study

The following personal health information will be collected, used for research and may be disclosed or released during your involvement with this research study:

- a. Name
- b. Date of birth (DOB)
- c. Sex

- d. Medical record number
- e. Mother's Name and DOB
- f. Hospital room number
- g. Phone number
- h. Address (street, city, state, and zip code)
- i. Clinic schedule for lactation
- j. Inpatient rounding list for lactation

2. Why your personal health information is being used

Your personal contact information is important for the study team to contact you during the study. Your health information and results of the above procedures are being collected as part of this research study and for the advancement of medicine and clinical care.

3. The personnel who may use or disclose your personal health information

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team
- The Peoria Institutional Review Boards (the committees charged with overseeing research on human subjects)
- The Office of Human Research Oversight (the office which monitors research studies)
- Authorized members of the University of Illinois College of Medicine at Peoria and/or UnityPoint Health-Methodist and/or OSF Healthcare workforce who may need to access your information in the performance of their duties, for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.

4. Who, outside of this institution, might receive your personal health information

As part of the study, the Principal Investigator, study team and others listed above in item number 3, may disclose your personal health information, including the results of the research study tests and procedures to the following:

- University of Illinois College of Medicine at Peoria, Center for Outcomes Research: A statistician with this office will be responsible for processing the data and assisting with data analysis.

The Principal Investigator or study team will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside this institution, the information may no longer be covered by the federal privacy protection regulations.

- In all disclosures outside of this institution's system, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.
- Your personal health information will be stored in a password-protected, secure database that that will be only available to researchers on the team. This database

will include the above personal health information, assigned study grouping, and a de-identified code number. Only the de-identified code number will be provided to individuals (such as the statistician) outside of the research team. Paper documentation will be held in a locked cabinet in the principal investigator's office and will be scanned into the chart after 2 weeks. Once it is scanned into the chart, the paper copy will be destroyed.

5. How long will this institution be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study expires upon the completion of this study. The institution may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. Documentation of procedures done solely for this research study and not as part of your regular care will be included in your or your baby's medical record.

6. Access to your records

During your participation in this study, you will have access to your and your baby's medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

7. Changing your mind

You may withdraw from the study for any reason simply by explaining this to the Principal Investigator or a member of the study team. If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care. You do not have to sign this form. If you do not, you will not be allowed to join the research study. Your decision to not sign this permission will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits to which you are normally entitled.

Who can I call about my rights as a research subject?

If you have questions regarding your participation in this research study or if you have any questions about your rights as a research subject don't hesitate to speak with the Principal Investigator listed on page one of this form. Concerning your rights as a research subject, you may also contact the Peoria Institutional Review Board by calling (309) 680-8630.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting this institution to use your personal health information collected about you for research purposes. You are also allowing this institution to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Printed Name of Subject

Signature of Subject

Date

**Printed Name of Person
Obtaining Consent**

Signature

Date

[If applicable]

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

***Printed Name of Authorized
Subject Representative**

Authorized Subject Signature

Date

*According to Illinois law, unless there is a court-appointed proxy or guardian, the following persons are authorized to make health care decisions on behalf of an incapacitated or otherwise incompetent patient (listed in order of priority): spouse; adult child; either parent; adult sibling; adult grand child; close friend; and guardian of the estate.

Please designate Authorized Subject Representative's relationship to the subject:
