

**Mechanical Massage By An Electric Massage Chair on Lactogenesis Stage II (Onset of Lactation) In First-Time Mothers: A Randomised Controlled Trial**

**RESEARCH PROPOSAL**

**INVESTIGATOR**

**DR NURUL ATIQAH BINTI RADZALI**

**atiqah.radzali@ummc.edu.my**

**SUPERVISORS**

**DR NEHA SETHI A/P NARESH SETHI**

**PROFESSOR TAN PENG CHIONG**

**DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY**

**FACULTY OF MEDICINE**

**UNIVERSITY OF MALAYA**

**2024**

## CONTENTS

1.0 INTRODUCTION AND LITERATURE REVIEW...…………………….. 3

2.0 OBJECTIVES OF STUDY ……………………………………………….. 3

3.0 RESEARCH HYPOTHESIS ……………………………………………... 3

4.0 METHODOLOGY ………………………………………………………... 4

- STUDY DESIGN

- STUDY SITE

- POPULATION OF STUDY

- INCLUSION CRITERIA

- EXCLUSION CRITERIA

5.0 METHODS ……………………………………………………………….. 5

- RECRUITMENT

- RANDOMIZATION

- INTERVENTION

6.0 OUTCOMES……………………………………………………………… 6

7.0 SAMPLE SIZE CALCULATION………………………………………… 6

8.0 STATISTICAL ANALYSIS ……………………………………………… 6

9.0 ETHICAL CONSIDERATION…………………………………………… 6

10.0 STUDY FLOW CHART…………………………………………………. 7

11.0 GANTT CHART………………………………………………………… 8

12.0 REFERENCES……………………………………………………………. 9

13.0 APPENDICES…………………………………………………………….. 10

1.0 INTRODUCTION AND LITERATURE REVIEW

WHO and UNICEF recommend that infants initiate breastfeeding within the first hour of birth and be exclusively breastfed for the first 6 months of life. However, fewer than half of infants under 6 months old are exclusively breastfed.(1)

First-time mothers had a longer time to first breastfeeding attempt, were more likely to have eight or fewer feeding attempts in the first 24 hours, to have reported early breastfeeding problems, were mixed feeding at hospital discharge, and less likely to breastfeed through 6 months.(2)

Our centre is part of the Baby-Friendly Hospital Initiative whereby mothers were helped to initiate breastfeeding within a half hour of birth, shown how to breastfeed, and breastfeeding on demand was encouraged whilst newborn infants were not given food or drink other than breast milk unless medically indicated.(3)

A major factor in initiating and maintaining breastfeeding is delayed or perceived inadequate milk production.(4) Back massage (manually by hand) increases oxytocin and prolactin level.(5) Oxytocin is an essential lactation hormone that causes milk ejection.(6) Moderate-pressure massage of the upper back for 15 minutes increases oxytocin and reduces adrenocorticotropin hormone in the blood.(7) Plasma oxytocin increases after foot massage by both hand or machine, but more potently after massage by hand.(8)

A systematic review of twenty-two studies of mostly “oxytocin”, back or full massages, typically starting on the first postpartum day usually over 1-4 days and cumulative massage duration from 18 to 270 minutes, shows more milk volume, improved ‘milk smoothness’ and better infant weight gain with massage. However, the existing studies mostly had unclear risks of bias, heterogeneous data, lack of control group details and diverse participants’ characteristics which precluded meta-analysis; in addition, many studies have small sample sizes. ‘Oxytocin massage’ was done along the spine to the fifth and sixth ribs by pressing vigorously to form a circular motion in small areas with the thumbs.(9)

Electric massage chairs are designed to provide ‘whole body massage’ and also with programs that can focus on the back, neck or limbs and are widely available. They are relatively costly to purchase for personal use when frequently reused in a hospital care setting, can be more cost efficient. They should provide reliable and uniform massage-stimulation to generate the favourable lactation outcomes, similar to that which can achieve with manual massage by hand.

We hypothesise that mechanical back (vs sham calf) massage by the electric massage chair over 20-minute sessions twice daily in the 48 hours after birth in first time mothers whilst inpatient will contribute to faster onset of lactation (lactogenesis stage II).

1. OBJECTIVE

Main Objective of this study is to evaluate effect of mechanical back massage on the onset of lactation (lactogenesis stage II) .

1. RESEARCH HYPOTHESIS

We hypothesise that mechanical back massage will hasten the onset of lactation (lactogenesis stage II) in first-time mothers after a vaginal delivery

4.0 METHODOLGY

Study design: Randomised Controlled Trial

Study site: Postnatal ward, University Malaya Medical Centre (UMMC)

Study population: Primiparous, spontaneous vaginal delivery (SVD)

Inclusion criteria:

* Primiparous (first-time mothers)
* Spontaneous vaginal deliveries without complications
* 18 - 45 years
* Singleton pregnancy
* Term pregnancy ≥37 weeks
* Birth weight ≥ 2500g
* No serious illness/chronic disease
* Ability to read and write, acceptable ability of listening and speaking to answer the questions
* Intention to breastfeed
* Can communicate in Malay or English
* Access to handphone or internet for communication

Exclusion criteria:

* Contraindication to breastfeeding
* Postpartum complication e.g., haemorrhage, chorioamnionitis, retained placenta, any invasive procedures, obstetric sphincter injury, and blood transfusion
* Newborns with complications (e.g., newborn admission)

First time mothers planning to breast feed for six months will be approached within 24 hours of delivery and assessed with the eligibility form (EF). They will be provided with the Patient Information Sheet (PIS) and the practical details will be explained. Questions are encouraged and will be responded to by the investigator or provider. Written informed consent is required from all participants.

Contact details will be obtained from them. All mothers are advised to follow hospital breastfeeding protocol.

Interventions:

Eligible participants will be randomised into 2 groups:

(1) The intervention group will be given back massage using the electric massage chair twice daily, 20 minutes each session, starting from 3- 6 hours postdelivery, until the day of discharge.

OR

(2) The control (sham) group will sit on massage chair twice daily ( 2 session / day) for 20 min each session with only calf massage, starting from 3-6 hours postdelivery and until the day of discharge.

Onset of lactation ( OL) is defined by period of time from birth to time a mother report on breast fullness.(10) Breast fullness is typically rated on a 5-point scale: from 1 (no change) to 3 (noticeably full) to 5 (uncomfortably full). The timing when mother first felt full in the breasts for a score of 3 or more is recorded and taken as a onset of lactation.(11)

Delayed OL was defined as the mothers’ perception that the breasts were not noticeably full (< 3 on the scale) by 72 hours after delivery.(11)

1. All subjects were interviewed daily on onset of lactation ( OL) until it is reported.
2. Participants who are discharged before the onset of lactation will be contacted daily to determine the timing of their OL. These messaging will stop once participants report the breast milk has come in or until Day 10 if OL has not occurred by then (very delayed OL).
3. Participants will ask to fill evaluation form Infant Breastfeeding Assessment Tool ( IBFAT) prior to discharge. A score of 10–12 indicates completely successful breastfeeding, a score of 7–9 suggests relatively successful breastfeeding, and a score of 0–6 shows unsuccessful breastfeeding.(12)
4. Participants will be requested to rate their satisfaction with their assigned mechanical massage chair experience using a 11-point (0-10) visual numerical rating scale prior to discharge.
5. At a final follow up call at 10 days post-delivery participant to answer the same IBFAT questionnaire about baby’s breastfeeding performance to date.

Data analysis will be conducted after the last subject has completed follow up.

Randomisation

Randomisation sequence will be generated using an online generator https://www.sealedenvelope.com/simple-randomiser/v1/lists, in 1 to 1 ratio and random blocks of 4 or 8, by a co-investigator who will not be involved in the recruitment process.

Randomisation will be implemented using strict sequential opening of the lowest number sealed opaque envelope remaining for the newest recruit.

Envelopes opened inadvertently and unused will be discarded and the reason for not using the envelope will be recorded.

6.0 OUTCOMES

Primary Outcome:

* 1. Time from birth to onset of lactation (lactogenesis stage II) [As reported by the mother on daily assessment]

Breast fullness is self-rated on a 5-point scale: from 1 (no change) to 3 (noticeably full) to 5 (uncomfortably full). Onset of lactation is defined as the first breast fullness score of 3 or greater as reported by the mother.

Secondary Outcomes:

1. Maternal satisfaction with their assigned mechanical massage chair experience using an 11-point (0-10) numerical rating scale before discharge. [As reported by the mother]
2. Baby's breastfeeding performance using the Infant Breastfeeding Assessment Tool (IBFAT) before discharge. [As reported by the mother]
3. Baby's breastfeeding performance using the Infant Breastfeeding Assessment Tool (IBFAT) on Day 10 after birth. [As reported by the mother]
4. Exclusive breastfeeding on Day 10 after birth. [As reported by the mother]

IBFAT score of 10–12 indicates successful breastfeeding, a score of 7–9 indicates relatively successful breastfeeding, and a score of 0–6 indicates unsuccessful breastfeeding.

1. SAMPLE SIZE CALCULATION

In primiparous mothers the time to onset of lactation (lactogenesis II) is reported as mean ± standard deviation 59 ± 14 hours.(13). Southern Thai traditional massage compared to controls (21 vs. 21 women), results in onset of lactation of at mean ± standard 40.57 ± 2.94 vs. 45.71 ± 2.49 hours respectively, a reduction of 5.14 hours with Southern Thai traditional hand massage.(14)

Applying alpha 0.05, power 80%, mean difference of 5.14 hours and standard deviation of 14 hours in both arms (<https://www.openepi.com/SampleSize/SSMean.htm>) as pilot data for onset of lactation, 117 participants are required in each arm for a powered study. We planned to recruit a total of at least 234 women for the trial.

8.0 STATISTICAL ANALYSIS

Data will be entered into SPSS statistical software. Normally distributed continuous data will be analysed with t test. Chi square test will be used for categorical or nominal data and Mann-Whitney U test will be used on non-normally distributed or ordinal data. Analysis is by intention to treat. P < 0.05 will be taken as the level of significance.

9.0 ETHICAL CONSIDERATION

This study will be submitted to University Malaya Medical Research and Ethics committee, our institutional review board for approval. All the participants involved in this study will be reassured about the confidentiality. This trial is designed as randomized parallel arm study. All participants will be given an information sheet, have their oral queries addressed and written informed consent obtained. There is no conflict of interest in this study. Funding is expected from the Department and entirely without the involvement of commercial entities.

10.0 STUDY FLOW CHART

Primiparous women post SVD

and fulfilled trial criteria

PIS, counsel and obtain informed consent

Randomization post-delivery

Intervention group

Patient will be given back massage using the electric massage chair twice daily, 20 minutes each session, starting from 3- 6 hours postdelivery, until the day of discharge.

Control group

Patient will sit on massage chair twice daily (2 session / day) for 20 min each session with only calf massage ON and starting from 3-6 hours postdelivery and until the day of discharge

Patient will interview daily/ online messaging until Onset lactation is reported

Patient will follow up until D10 post delivery

Data will transcribe into Case report form and then data analysis done

11. 0 GANTT CHART

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **2023** | | | | | **2024** | | | | | | | | |
|  | **March** | **April** | **May - June** | **July -Sept** | **Oct – Dec** | **Jan- Feb** | | **March- April** | **May-**  **June** | **July-August** | | **Sept - Oct** | | |
| **Research proposal and preparation** |  |  |  |  |  |  | |  |  |  | |  | | |
| **Presentation to department** |  |  |  |  |  |  | |  |  |  | |  | | |
| **Presentation to ethics committee and approval** |  |  |  |  |  |  | |  |  |  | |  | | |
| **Patient recruitment and data collection** |  |  |  |  |  |  | |  |  |  | |  | | |
| **Data entry** |  |  |  |  |  |  | |  |  |  | |  | | |
| **Data analysis** |  |  |  |  |  |  | |  |  |  |  |  | | |
| **Thesis writing** |  |  |  |  |  |  |  | |  |  | |  | |  |
| **Thesis submission** |  |  |  |  |  |  |  | |  |  | |  |  | |

12.0 REFFERENCES

1. World Health Organisation. Health Topic: Breastfeeding. Accessible on <https://www.who.int/health-topics/breastfeeding#tab=tab_1>. Last accessed May 23 2023.

2. Hackman NM, Schaefer EW, Beiler JS, Rose CM, Paul IM. Breastfeeding outcome comparison by parity. Breastfeed Med. 2015;10(3):156-62.

3. Baby-Friendly Hospital Initiative, Revised, Updated and Expanded for Integrated Care. World Health Organization, Geneva. 2009. ISBN 978-92-4-159495-0

2009.

4. Kiran P, Aanchal A, Apurva M. Factors Affecting Breastfeeding in Early Postnatal Period in Tertiary Care Centre. MVP Journal of Medical Sciences. 2020:201-8.

5. Anita N, Ahmad M, Usman AN, Sinrang AW, Alasiry E, Bahar B. Potency of back message and acupressure on increasing of prolactin hormone levels in primipara postpartum; consideration for midwifery care. Enfermería Clínica. 2020;30:577-80.

6. Oxytocin. Drugs and Lactation Database (LactMed(R)). Bethesda (MD)2006.

7. Morhenn V, Beavin LE, Zak PJ. Massage increases oxytocin and reduces adrenocorticotropin hormone in humans. Altern Ther Health Med. 2012;18(6):11-8.

8. Li Q, Becker B, Wernicke J, Chen Y, Zhang Y, Li R, et al. Foot massage evokes oxytocin release and activation of orbitofrontal cortex and superior temporal sulcus. Psychoneuroendocrinology. 2019;101:193-203.

9. Nuampa S, Payakkaraung S. Effectiveness of Different Massage Techniques for Breastfeeding Mothers to Increase Milk Production: A Systematic Review. Pacific Rim International Journal of Nursing Research. 2020;25(1):114-30.

10. Hiderbrant HM. Maternal Perception of Lactogenesis Time : A clinical Report. Human Lactation 15 (4). 1999.

11. Kathryn G. Dewey PLA. Risk Factors for Suboptimal Infant Breastfeeding Behavior, Delayed Onset of Lactation, and Excess Neonatal Weight Loss. Peadiatric Journal. 2003.

12. Maryam Mahdizadeh-Shahri M, 1 Manijeh Nourian, PhD,corresponding author2 Maryam Varzeshnejad, PhD,2 and Maliheh Nasiri, PhD3. The Effect of Oketani Breast Massage on Successful Breastfeeding, Mothers’ Need for Breastfeeding Support, and Breastfeeding Self-Efficacy: an Experimental Study. nternational Journal of Therapeutic Massage and Bodywork. 2021.

13. Hildebrandt HM. Maternal Perception of Lactogenesis Time: A Clinical Report. Journal of Human Lactation. 2016;15(4):317-23.

14. Khoonpet C, Chunuan S, Phumduong S. Effects of Southern Thai Traditional Massage with Warm Compression on Lactation and Breast Engorgement: A Randomized Controlled Tria. Pacific Rim Int J Nurs Res. 2022;26(3):14.

APPENDIX A

Impact of Measuring Milk Production by Test Weighing

on Breastfeeding Conﬁdence in Mothers of Term Infants

Jacqueline C. Kent,

1

Anna R. Hepworth,

1

Diana

