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

RESEARCH PROPOSAL

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1.0 INTRODUCTION AND LITERATURES 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 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 over 1-4 days usually 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)

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

We hypothesise that mechanical 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).

2.0 OBJECTIVE

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

1.0 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

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4.0 METHODOLOGY

Study design: Randomised Controlled Trial

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

Study population: Primiparous, spontaneous vaginal delivery (SVD)

Inclusion criteria:

- Primiparous
- Spontaneous vaginal deliveries mother 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 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. Queries are encouraged and responded to by investigator or provider. Written informed consent is required from all participants.

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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.

(2) The control group 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.

Onset of lactation (OL) is defined by period of time from birth to time 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 an onset of lactation.(11)

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

- I. All subjects were interviewed daily on onset of lactation (OL) until it is reported.
- II. Participants who are discharged before the onset of lactation will be contacted daily to determine the timing of their OL. These messages 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).
- III. Participants will be asked 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)
- IV. 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.
- V. 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 was completed follow up.

Randomization:

Randomisation sequence will be generated separately for using an online generator, in 1 to 1 ratio, by a co-investigator who will not be involved in the recruitment process. Randomisation will be implemented using strict sequential assignment of the lowest-numbered remaining sealed envelopes to the newest recruit.

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6.0 OUTCOMES

Primary Outcome:

1. Onset of lactation

Secondary outcome

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

1.0 SAMPLE SIZE CALCULATION

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

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

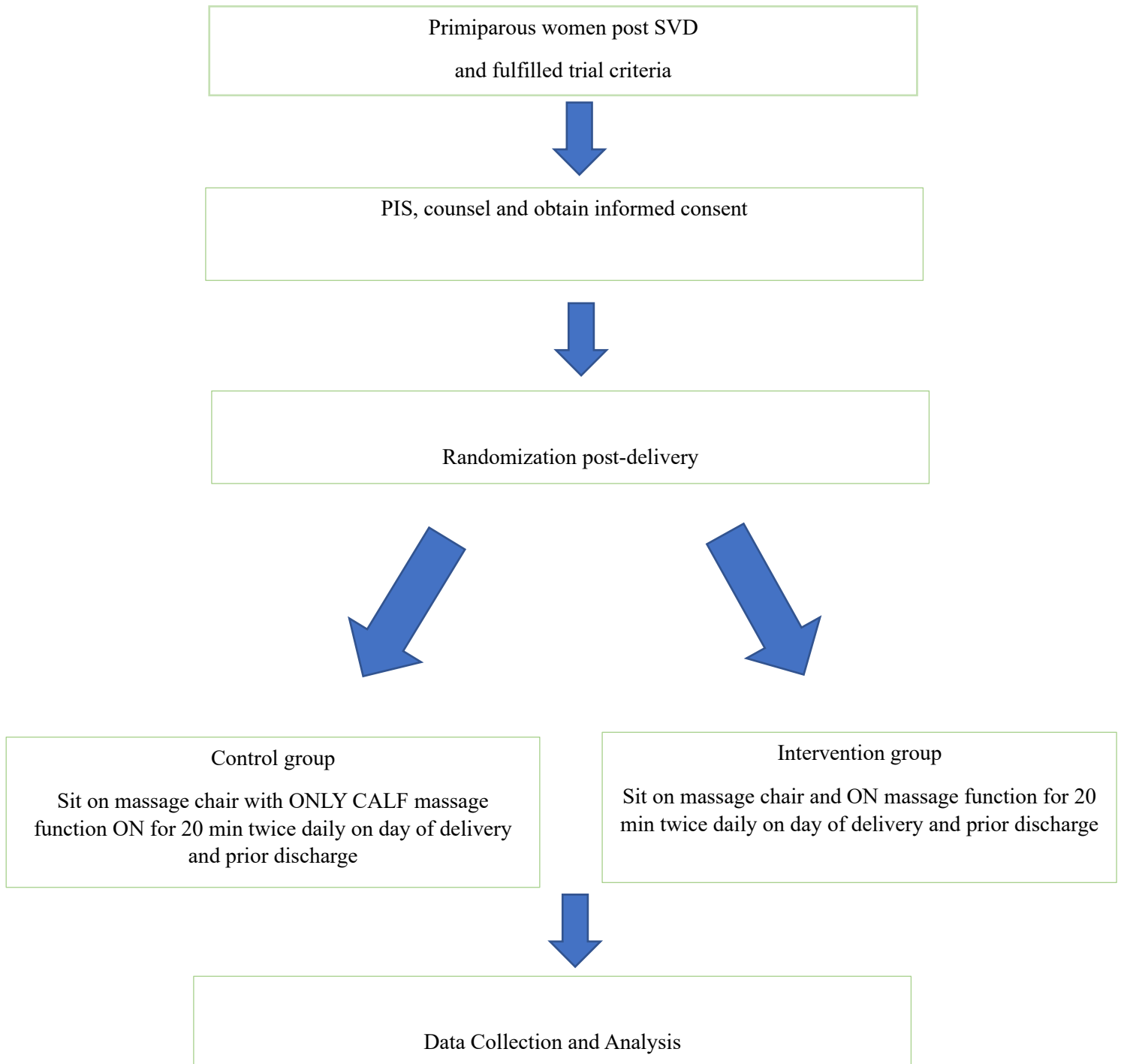
This study will be submitted to University Malaya Medical Research and Ethics committee, our institutional review board for approval. All the participants involved in this study will be reassured about the confidentiality. This trial is designed as randomized parallel arm study. All participants will

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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



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11. 0 GANTT CHART

	2023					2024				
	March	April	May - June	July - Sept	Oct - Dec	Jan-Feb	March-April	May-June	July-August	Sept - Nov
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										■

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12.0 REFFERENCES

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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

Infant Breastfeeding Assessment Tool (IBFAT)

Reprinted from: Matthews, M.K. (1988). Developing an instrument to assess infant breastfeeding behaviour in the early neonatal period. *Midwifery*, 4(4), 154-165, with permission of Elsevier.

Infant Breastfeeding Assessment Tool (IBFAT)

Check the score which best describes the baby's feeding behaviours at this feed.

	3	2	1	0
In order to get baby to feed:	Placed the baby on the breast as no effort was needed.	Used mild stimulation such as unbundling, patting or burping.	Unbundled baby, sat baby back and forward, rubbed baby's body or limbs vigorously at beginning and during feeding.	Could not be aroused.
Rooting	Rooted effectively at once.	Needed coaxing, prompting or encouragement.	Rooted poorly even with coaxing.	Did not root.
How long from placing baby on breast to latch & suck?	0 – 3 minutes.	3 – 10 minutes.	Over 10 minutes.	Did not feed.
Sucking pattern	Sucked well throughout on one or both breasts.	Sucked on & off but needed encouragement.	Sucked poorly, weak sucking; sucking efforts for short periods.	Did not suck.

MOTHER'S EVALUATION

How do you feel about the way the baby fed at this feeding?

3 – Very pleased 2 – Pleased 1 – Fairly pleased 0 – Not pleased

IBFAT assigns a score, 0, 1, 2, or 3 to five factors. Scores range from 0 to 12.
The mother's evaluation score is not calculated in the IBFAT score.