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Real-time Imaging as Visual Biofeedback in Active Second Stage of Labour Among Nulliparas: A Randomised Controlled Trial

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CONTENTS

1.0 INTRODUCTION

The second stage of labour is defined as the period of time from the complete dilation of the cervix to delivery of fetus.[1] Prolonged second stage of labour is associated with severe perineal laceration, postpartum haemorrhage, operative deliveries and poor APGAR score.[1-5] Maternal pushing during the second stage of labour is an important and indispensable contributor to the involuntary expulsive force developed by uterine contraction to deliver the fetus.[6]

Biofeedback is a mind-body technique through which patient actively participate to voluntarily control and regulate their physiology for the purpose of improving their physical, mental, emotional and spiritual health.[7] By using specialized equipment such as mirror or display monitor to provide real time images, the physiological self-signals is converted to meaningful visual cues.[8] During pushing, it allows mothers to witness their responses visible at the introitus and so their technique adapts to maximize their pushing efforts. An increased maternal satisfaction can be associated with the sense of control as the mother sees the impact of her pushing on the fetal descent and delivery.

Previously, visual biofeedback to enhance pushing performance at normal vaginal delivery have used the mirror with its limitations in image clarity.[9] A descriptive cross-sectional study finds 88.5% of the women who used a mirror to witness their delivery process during the second stage of labour agree that the technique stimulates and motivates them to push.[9] A small study done using a camera to facilitate pushing in second stage of labour also agree that mothers are more motivated to push if they observed the descending of the fetal head and their duration of second stage is shortened by 15.7 minutes compared to the standard pushing.[10] Trans perineal ultrasound to improve second stage coaching by observing the angle of progression of the fetal head

descent on the display screen also shows a shorter second stage of labour compared to standard coaching.[7, 11, 12]

The aim of the present study is to evaluate real time video of the introitus compared to of the maternal face (control – sham/placebo) as visual biofeedback during pushing in conjunction with standard care provider verbal coaching on the intervention to delivery interval and maternal satisfaction with the birth experience.

2.0 OBJECTIVES

To evaluate real-time video of the maternal introitus (compared to the face) as a visual biofeedback during pushing in conjunction with standard care provider verbal coaching on the intervention to delivery interval and maternal satisfaction with pushing experience during birth.

3.0 RESEARCH HYPOTHESIS

3.1 Nulliparas who utilized visual biofeedback of the maternal introitus compared to the maternal face (sham/placebo) are more likely to have shorter duration of active second stage of labour and higher satisfaction with pushing experience during birth

4.0 PRIMARY OUTCOME

4.1 Duration of the active second stage of labour which defined as the minutes from the start of biofeedback during active pushing to delivery of fetus

4.2 Maternal satisfaction with pushing experience during birth

5.0 SECONDARY OUTCOMES

5.1 Neonatal outcomes: These are assessed by reviewing patient's and baby's electronic medical notes after deliver

5.1.1 Birth weight

5.1.2 Umbilical cord arterial blood pH and base excess at birth

5.1.3 Apgar score at 1 and 5 minute

5.1.4 Special care nursery/ neonatal intensive care unit admission during birth admission

5.1.5 Indication for neonatal admission

5.2 Maternal outcomes: These are assessed by reviewing patient's electronic medical notes after delivery

5.2.1 Mode of delivery

5.2.2 Estimated blood loss during delivery

5.2.3 Degree of perineal tear

6.0 MATERIALS AND METHOD

6.1 STUDY DESIGN

Single centre randomised controlled trial.

6.2 PLACE OF STUDY

Labour ward University Malaya Medical Centre, Kuala Lumpur

6.3 POPULATION OF STUDY

All nulliparas presented to University Malaya Medical Centre for planned vaginal delivery and satisfying the inclusion and exclusion criteria. Participants' information sheet will be given to all the potential recruits and queries will be answered by the person recruiting for informed consenting. Written consent will be obtained from all who agreed to participate. Once patient is about to start pushing in second stage of labour (final inclusion criterion), a numbered sealed opaque envelope will be opened to reveal the allocated intervention.

Eligibility form

Inclusion Criteria

• Nulliparous	
• Age ≥ 18 years	
• Singleton pregnancy	
• Cephalic presentation	
• No contraindication for vaginal delivery	
• Reassuring fetal status (normal fetal heart rate tracing)	
• About to commence pushing	

Exclusion Criteria

• Patient who is suspected COVID 19 infection or COVID 19 positive	
• Known gross fetal anomaly	
• Planned instrumental delivery to shorten second stage	
• Maternal severe visual impairment	
• History of maladaptive maternal response to visual stimuli provoking e.g., migraine, seizure	

6.4 METHODOLOGY

The Patient Information Sheet is distributed to the whole department and to booked women with study posters displayed in the antenatal clinic, antenatal and labour wards to create awareness of the study. Patients admitted to the ward for planned vaginal delivery and who study criteria will be approached for recruitment. Written informed consent will be taken. Once participants are about to start the active second stage of labour, they will be randomised to biofeedback or sham/placebo control by the opening of the lowest numbered sealed opaque envelope remaining to reveal the allocated intervention.

Interventions

1. **Visual biofeedback (active: maternal introitus)**

A video camera (e.g., isolated handphone procured for the study) will be placed on a stand at the end of the bed with the maternal introitus in focus and a display monitor (e.g., another isolated handphone procured for the study "blue tooth connected" to camera handphone) on a stand will be placed next to the bedside in clear view of the participant.

2. Visual biofeedback (control -sham/placebo: maternal face)

A video camera (e.g., isolated handphone procured for the study) will be placed on a stand at the top the bed with the maternal face in focus and a display monitor (e.g., another isolated handphone procured for the study "blue tooth connected" to camera handphone) on a stand will be placed next to the bedside in clear view of the participant.

Participants in the control group will be coached during the second stage as per standard care. The display monitor of the participants in the control group will show their face during the second stage.

All participants are asked to watch the display screen carefully during pushing and listen to the standard verbal coaching that will be given to all participants by the care providers conducting the delivery. In synchronization with the uterine contraction, participants will be encourage to bear down while observing the movement of the fetal head on introitus the display screen, thus receiving visual biofeedback of her pushing effort.

The live feed video streaming from camera to display will not be captured or recorded.

Demographic data are transcribed onto the Case Report Form

The participants' electronic hospital record will be retrieved to obtain maternal and neonatal outcome data.

6.5 SAMPLE SIZE CALCULATION

1. Intervention to delivery interval [Date/Time delivery - Date/Time biofeedback started]

From the literature [11] intervention to delivery interval with feedback during pushing median 30 IQR 24-42 minutes n = 20 (converted to mean 32 SD 14.3 minutes) and without feedback median 45 IQR 39-55 minutes n = 20 (converted to mean 46.3 SD 12.8 minutes[13]).

Utilising https://www.openepi.com/SampleSize/SSMean.htm and applying alpha 0.02 (Bonferroni correction for 2 primary outcomes), power 80%, t test, pilot data of mean 32 SD 14.3 minutes vs. mean 46.3 SD 12.8 minutes for intervention to delivery intervals for visual biofeedback (maternal introital view) and control visual biofeedback (maternal facial view) respectively, 19 participants are needed in each arm. Anticipating the data to be non-normal in distribution and having to apply the Mann Whitney u test, the sample size is increased by 15% and anticipating 10% dropout, the total sample size needed N = (19x2x1.15)/0.9 = 48.6

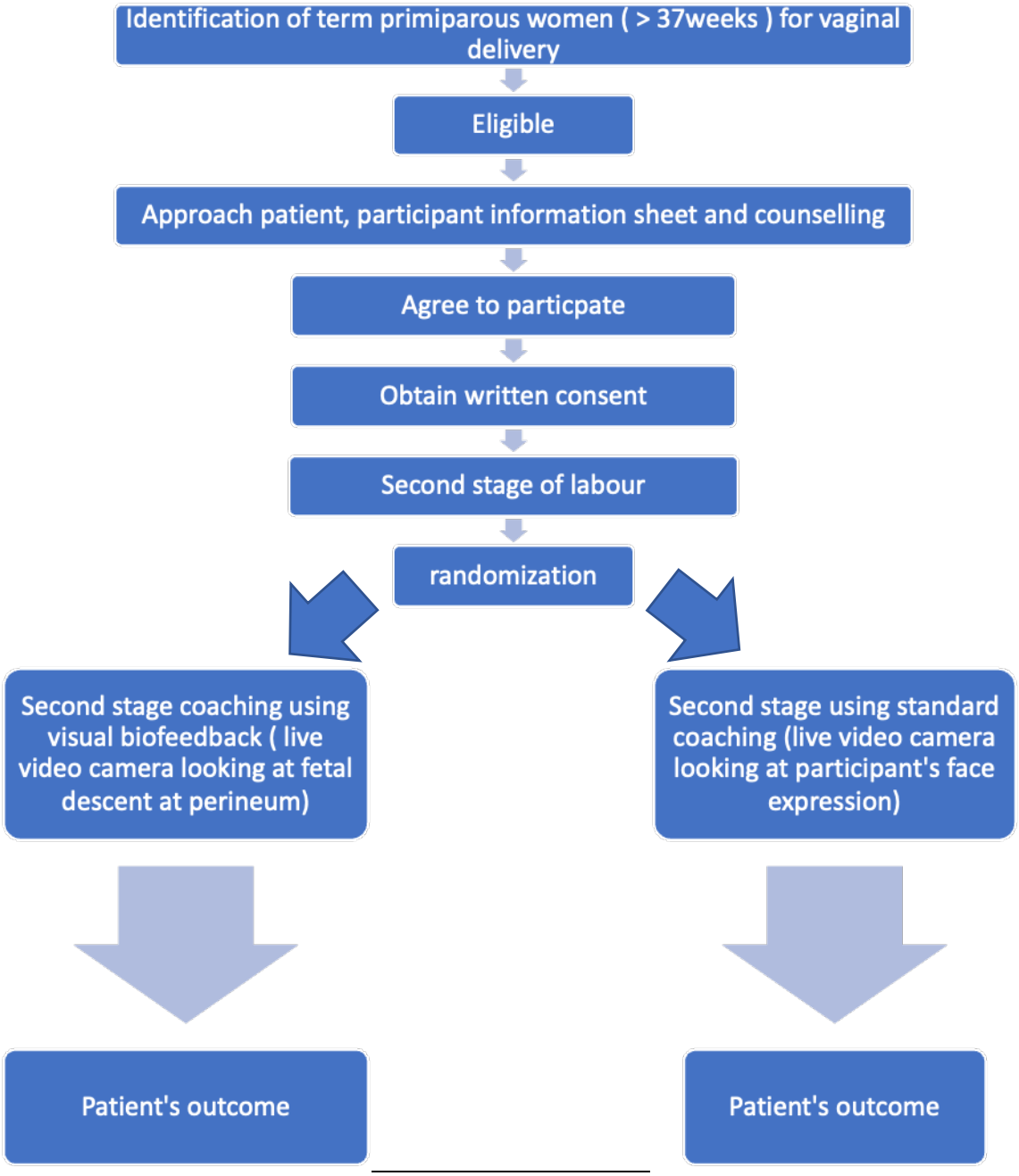
2. Maternal satisfaction with pushing experience during birth

A 1 point difference is assumed to be clinically relevant in the 11-point (0-10) VNRS assessment of maternal satisfaction with pushing experience during birth. Utilising https://www.openepi.com/SampleSize/SSMean.htm and applying alpha 0.02 (Bonferroni correction for 2 primary outcomes), power 80%, t test, mean difference of 1 and standard deviation of 2 for VNRS satisfaction score in both arms, 81 participants are needed in each arm. As maternal satisfaction data is ordinal and having to apply the Mann Whitney u test, the sample size is increased by 15% and anticipating 10% dropout, the total sample size needed is N = (81x2x1.15)/0.9 = 207; further rounded up to 210, sufficient to cover both primary outcomes.

TRIAL PROTOCOL

Primiparous woman admitted to antenatal ward and labour suite UMMC for delivery

PROTOCOL FLOW CHART



6.6 STATISTICAL ANALYSIS

Data will be entered into SPSS statistical software. Normally distributed continuous data will be analyzed with the 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.

6.7 ETHICAL CONSIDERATIONS

This study is submitted to the UMMC Medical Research and Ethics committee, the local institutional review board for approval. Patient will be given an information sheet, have their oral queries addressed and written informed consent obtained to participate in the study.

GANNT Chart

Duration	June-July 2021	August-September 2021	October-November 2021	December 2021- Jan 2023	Jan-Feb 2023	Feb-March2023
Literature Review	✓					
Proposal preparation and Presentation		✓				
Ethics Review			✓			
Data Collection				✓		
Data analysis and writing					✓	
Thesis Submission						✓

7.0 REFERENCES

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10. Purnama, Y., K. Dewiani, and L. Yusanti, *Effect of Labor Camera on the Duration of the Second Stage Labor in Primipara.* Global Medical and Health Communication (GMHC), 2021. **9**.
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CASE REPORT FORM

STUDY NUMBER

Date of recruitment: __ / __ / __ (dd/ mm/ yy)

LMP : __ / __ / __ (dd/ mm/ yy)
EDD : __ / __ / __ (dd/ mm/ yy)

PATIENT STICKER

Patient characteristics

D.O.B : __ / __ / __ (dd/ mm/ yy)

Gravida: _____ Para: _____ Abortion: _____
Gestational age: _____

Latest recorded Weight : _____ kg
Height : _____ cm

Education level:
- Up to primary
- Secondary
- Diploma
- Degree
- Masters
- PhD

Occupation:
- Employed
- Self-employed
- Student
- Housewife
- Other: _____

Ethnicity:
- Malay
- Chinese
- Indian
- Other: _____

Labour onset
- Spontaneous
- Induced

Oxytocin infusion in labour
- Yes
- No

Use of analgesia in labour?

Circle as many as used

a) None
b) Entonox
c) Opiate i.m.
d) Neuraxial analgesia
e) Others. Please specify _____

Primary Outcomes:

1. Intervention to delivery interval [Date/Time delivery - Date/Time biofeedback started]
2. Maternal satisfaction with pushing experience during birth

Dates and Times

1.	Date/Time second stage diagnosed	: ____ /___ / ___ (dd/mm/yy) : ___: ___(hr:min)
2.	Date/Time pushing started	: ____ /___ / ___ (dd/mm/yy) : ___: ___(hr:min)
3.	Date/Time biofeedback started *(If different from start of pushing)*	: ____ /___ / ___ (dd/mm/yy) : ___: ___(hr:min)
4.	Date/Time of delivery	: ____ /___ / ___ (dd/mm/yy) : ___: ___(hr:min)
5.	Date/Time of Discharge (as EMR)	: ____ /___ / ___ (dd/mm/yy) : ___: ___(hr:min)

Maternal Outcome

1. Maternal satisfaction with pushing experience during birth
   (Assessed within 24 hours of delivery).
   Circle the score below:

0	1	2	3	4	5	6	7	8	9	10

0- Totally dissatisfied 10-Totally satisfied

2. I would recommend my allocated biofeedback during pushing protocol to a friend
   a) Strongly disagree
   b) Disagree
   c) Neither agree nor disagree
   d) Agree
   e) Strongly agree

3. Mode of Delivery:
   a) SVD
   b) Caesarean section. *(Indication: _____)*
   c) Instrumental delivery
      a. Forceps
      b. Vacuum. *(Indication: _____)*

4. Estimated blood loss at delivery: _____ ml

5. Type of perineal tear sustained:
   a) Intact perineum
   b) First degree tear
   c) Second degree tear
   d) Third degree tear
   e) Fourth degree tear
   f) Episiotomy
   g) Other
      specify_____

Neonatal outcome

1. Apgar Score:
    a) _____ 1 min
    b) _____ 5 min

2) Cord Arterial pH: _____ Base excess: _____

3) Birth weight: _____ kg

4) Required neonatal admission:
    a) Yes
    b) No

Place of admission: PNW / SCN / NICU / Others

Reason for admission: _____