UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Study Title: Real-time Imaging as Visual Biofeedback in Active Second Stage of Labour Among Nulliparas: A Randomized Controlled Trial
Version No: 1.0
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We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

INTRODUCTION

Maternal pushing is essential to deliver the baby. The time it takes to push the baby out is important because the longer it takes, the higher the risk for caesarean delivery, heavy vaginal bleeding after birth, severe maternal tears and baby admission to neonatal intensive care. Mother's satisfaction with childbirth is often reduced.

Inexperienced first time mothers may not push as effectively. By using equipment such as a camera and display monitor to provide real time images, first time mothers will be able to see the impact of their pushing and adjust their technique according to the visual feedback.

1. What is the purpose of this study?

We plan to evaluate whether the real-time video of the mother as a visual biofeedback in addition to standard healthcare provider verbal coaching can impact the time it takes to push the baby out and maternal satisfaction.

2. Why is this study important?

This study is important as it will evaluate if visual biofeedback can help during pushing, to shorten the time taken and to improve maternal satisfaction as this information can help guide practice on a global basis.

3. What type of study is this?

This a randomised clinical trial. Neither you nor the researcher can choose the visual biofeedback allocated. The allocation process is random (only when you are about to start pushing).

4. What is the procedure that is being tested?

Real time visual biofeedback using a camera and display screen during pushing of the maternal

1) birth canal opening
   or
2) face

5. Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine?

No

6. Why have I been invited to participate in this study?

You fulfil the inclusion criteria of this study:

- Nulliparous (no previous pregnancy beyond 20 weeks)
- Age ≥ 18 years
- Singleton pregnancy
- Cephalic presentation
- No contraindication for vaginal delivery
- Reassuring fetal status (normal fetal heart rate tracing)

7. Who should not participate in the study?

- 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

8. Can I refuse to take part in the study?

Yes. If you decline to take part, your care will not be affected, and you will be offered standard care.

9. What will happen to me if I take part?

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

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 healthcare providers conducting the delivery.

No recording of the real time images will be made.

You have an equal chance of being assigned to either monitor display of

a) Maternal birth canal opening
b) Maternal face

10. How long will I be involved in this study?
Your expected total duration of study participation will be from the start of pushing until the delivery of the baby.

11. What are the possible disadvantages and risks?
Major complications are not anticipated. Visual feedback may prove to be a distraction rather than a help.

12. What are the possible benefits to me?
An effective visual feedback may shorten pushing time and increase maternal satisfaction.

13. Who will have access to my medical records and research data?
Only the investigators. Anonymized (where individuals cannot be identified) trial data may be released to other researchers in the future as permitted by the Ethics committee.

14. Will my records/data be kept confidential?
Yes. Appropriate security will be in place. The real-time image of the delivery process will not be recorded.

15. What will happen to any samples I give? (If applicable)
Not applicable

16. What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time without having to provide any reason and your care will also not be affected in any way. Standard care will be provided.

17. What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)
Not applicable

18. What happens when the research study stops? (If applicable)
You will be offered standard care

19. What will happen to the results of the research study?
The study findings will be published to help guide childbirth care on a global basis.

20. Will I receive compensation for participating in this study?
No payment or compensation will be given.

21. Who funds this study?
Department of Obstetrics and Gynaecology, PPUM.

22. Who should I contact if I have additional questions/problems during the course of the study?

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Name of investigator 3 Dr Syeda Nureena
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23. Who should I contact if I am unhappy with how the study is being conducted?

Medical Research Ethics Committee
University of Malaya Medical Centre
Telephone number: 03-7949 3209/2251