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Imaging of the birth canal opening during labour as a pushing aid among first-time mothers

Submission date
20/11/2021

Recruitment status
No longer recruiting

Registration date
23/11/2021

Overall study status
Completed

Last Edited
23/11/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

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

Who can participate?
Pregnant women aged more than 18 years old who have no previous pregnancy beyond 20 weeks and who is planning for vaginal delivery.

What does the study involve?
During pushing, half of participants will be provided with a display screen showing their birth canal opening or face in order to help and motivate them to push more effectively. The other half will proceed as usual.

What are the possible benefits and risks of participating?
Effective visual feedback may shorten pushing time and increase maternal satisfaction.
Major complications are not anticipated. Visual feedback may prove to be a distraction rather than a help.

Where is the study run from?
Labour room of University Malaya Medical Center (UMMC) (Malaysia)

When is the study starting and how long is it expected to run for?
August 2021 to February 2023

Who is funding the study?
Department of Obstetrics and Gynaecology, UMMC (Malaysia)

Who is the main contact?
Dr Noor Ashikin
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2021105-10643

Study information

Scientific Title
Real-time imaging as visual biofeedback in active second stage of labour among nulliparas women: a randomised controlled trial

Acronym
RIVBASSLAN

Study objectives
Nulliparas women 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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2021, Medical Research Ethics Committee (University of Malaya Medical Centre, Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 (0)3-79493209; no email provided), ref: 2021105-10643

Study design
Single-centre open-label randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Childbirth

Interventions
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.

Patients allocated to the study group will be using visual biofeedback during her second stage of labour. A video camera will be placed on a stand at the end of the bed with the maternal introitus in focus and a display monitor on a stand will be placed next to the bedside in clear view of the participant

Patients 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 encouraged 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 records will be retrieved to obtain maternal and neonatal outcome data.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Measured using patient records at the end of the study:
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
2. Maternal satisfaction with pushing experience during birth

Key secondary outcome(s))
Measured using patient records at the end of the study:
1. Birth weight (kg)
2. Umbilical cord arterial blood pH and base excess at birth
3. Health at birth measured using Apgar score at 1 and 5 minute
4. Special care nursery/ neonatal intensive care unit admission during birth admission
5. Indication for neonatal admission
6. Mode of delivery
7. Estimated blood loss during delivery
8. Degree of perineal tear

Completion date
01/02/2023

Eligibility

Key inclusion criteria
1. Nulliparous
2. Age ≥18 years
3. Singleton pregnancy
4. Cephalic presentation
5. No contraindication for vaginal delivery
6. Reassuring fetal status (normal fetal heart rate tracing)
7. About to commence pushing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Patient who is suspected COVID 19 infection or COVID 19 positive
2. Known gross fetal anomaly
3. Planned instrumental delivery to shorten second stage

4. Maternal severe visual impairment
5. History of maladaptive maternal response to visual stimuli provoking e.g., migraine, seizure

Date of first enrolment
01/12/2021

Date of final enrolment
01/01/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center (UMMC)
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Noor Ashikin (ashikin.hamid@ummc.edu.my)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	07/10/2021	23/11/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	07/10/2021	23/11/2021	No	No