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Live camera viewing by the first-time mother of the birth canal opening as a feedback aid during self-motivated pushing for normal delivery

Submission date
21/10/2024

Recruitment status
Recruiting

Registration date
21/10/2024

Overall study status
Ongoing

Last Edited
03/12/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Getting live visual cues from self-observation of the birth canal (vaginal) opening during their pushing for normal birth can be especially helpful in first-time mothers who also are controlling their pushing. The cues derived can be processed in real-time to improve the participants' mental and physical responses in a process called visual biofeedback. Studies have shown that mothers exposed to visual biofeedback expressed high satisfaction with their experience, their pushing is shortened and connectedness to their baby is improved. One study indicates it may reduce the risk of major childbirth-related injury to first-time mothers. First-time mothers need to push for longer to birth. Nine in 10 first-time mothers who have a vaginal birth sustain injury to the birth canal, which will probably need stitches. Directed pushing is a common practice during the second stage of labour where the healthcare provider instructs the woman to hold her breath and push during each contraction. Conversely, in spontaneous pushing, women are free to follow their instincts and generally push 3 to 5 times per contraction. A woman who uses a spontaneous pushing approach is self-directed in her bearing down technique. She may push with vocalization, using intermittent exhalation technique, or in response to an involuntary urge. These spontaneous pushing efforts vary in intensity and frequency. Studies have shown that spontaneous pushing results in at least the same maternal and newborn outcomes, lower Caesarean section rates and lower incidence of extension of the episiotomy (a cut to the birth canal opening to facilitate normal birth) but it may take longer to give birth. Studies have found that when comparing the hands-off (or poised) technique versus the hands-on technique at the point of birth resulted in a similar degree of birth canal tears. However, the hands off technique resulted in a lower incidence rate of episiotomy. This study aims to evaluate real-time visual biofeedback (using a camera-display monitor set up) trained on the first-time mother's birth canal opening compared to the face during their spontaneous pushing on major birth-related injury.

Who can participate?
Adult first-time mothers who are to start pushing for normal birth during an uncomplicated labour.

What does the study involve?
A video camera (e.g., a GoPro camera) will be placed on a stand at the end of the bed with the maternal introitus or face (depending on random allocation) in focus and a Bluetooth-connected display monitor will be placed next to the bedside in clear view of the participant. Participants will then be allowed to push on their own accord when motivated by contractions or need to bear down sensation. They will be instructed to employ a pushing technique that they are comfortable with and modify it based on feedback that they receive from the live-view display monitor.

What are the possible benefits and risks of participating?
The plausible benefit of visual biofeedback of maternal introitus include:
1. Fewer major birth-related injury
2. Shorter duration of the active second stage of labour
3. Higher satisfaction with the birth experience

The plausible risks of visual biofeedback of maternal introitus include:
1. Major complications are not anticipated
2. May prove to be a distraction resulting in birth delay
3. Seeing a change to the birth canal opening during childbirth may cause distress

Where is the study run from?
University Malaya Medical Centre, Malaysia

When is the study starting
16 Nov 2024 (to 15 Nov 2025)

Who is funding the study?
Internally funded by the Department of Obstetrics and Gynaecology, Faculty of Medicine, University Malaya Medical Centre, Malaysia

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Live visual biofeedback of maternal introitus vs maternal face during self-motivated pushing in nulliparas: a randomised controlled trial

Study objectives
Live viewing of the maternal introitus (compared to face) using a camera linked to a display screen by nulliparous women during self-motivated (non-directed) pushing for normal delivery as visual biofeedback will reduce birth-related injury (defined as major perineal injury or Caesarean delivery).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/08/2024, Medical Research Ethics Committee, University Malaya Medical Centre (Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60379493209/2251; ummc-mrec@ummc.edu.my), ref: 2024715-13916

Study design
Single center parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Self-motivated pushing for normal birth in the second stage of labour

Interventions
Patients admitted to the ward for planned vaginal delivery and who fulfil the study criteria after initial assessment will be approached for recruitment. A participant information sheet will be given to each potential recruit and their questions will be answered by the recruiting care provider. Informed written consent will be obtained from all participants. An instruction leaflet on the self-directed/motivated pushing technique will be distributed to each recruit.

The randomisation sequence will be generated using an online random number generator in blocks of 4 or 8 by an investigator who is not involved in recruitment. Randomisation will be performed and the intention to treat revealed only at the decision to commence pushing.

Randomisation is by opening the lowest number, sealed and opaque envelope still available for the latest recruit.

Trial interventions are:
1. Visual biofeedback of maternal introitus (active)

A video camera (e.g., a GoPro camera) will be placed on a stand at the end of the bed with the maternal introitus in focus and a display monitor (Bluetooth connected to the camera for live viewing) will be placed next to the bedside in clear view of the participant. Participants will then be allowed to push during labour on their own accord when motivated by contractions or need to bear down sensation. They will be instructed to employ any pushing technique that they are comfortable with and modify it based on feedback that they receive from the live-view display monitor.

OR

2. Visual biofeedback of maternal face (control)

A video camera (e.g., a GoPro camera) will be placed on a stand at the top of the bed with the maternal face in focus and a display monitor (Blue Tooth connected to the camera for live viewing) will be placed next to the bedside in clear view of the participant. Participants will then be allowed to push during labour on their own accord when motivated by contractions or need to bear down sensation. They will be instructed to employ any pushing technique that they are comfortable with and modify it based on feedback that they receive from the live-view display monitor.

The live video feed streaming from the camera to the display monitor will not be recorded. The study interventions are complete at birth.

Intervention Type
Mixed

Primary outcome measure
Major birth injury (second-degree or more severe perineal tear, or caesarean delivery) measured using data documented in the participant's hospital chart after randomisation

Secondary outcome measures
1. Duration of active second stage of labour measured using data documented in the participant' s hospital chart from the activation of biofeedback during active pushing to delivery (as contemporaneously recorded)
2. Maternal satisfaction with birth experience measured using scoring from 0 to 10 on a Numerical Rating Scale (NRS) before hospital discharge
3. Maternal outcomes measured using data retrieved from the patient's electronic medical charts at hospital discharge:
3.1 Mode of delivery
3.2 Indication of operative delivery (operative vaginal and caesarean)
3.3 Estimated blood loss during delivery
3.4 Degree of perineal injury
4. Neonatal outcomes measured using data retrieved from the patient's or offspring's electronic medical charts at hospital discharge:
4.1 Birth weight

4.2 Umbilical cord arterial blood pH and base excess at birth
4.3 Apgar score at 1 and 5 minutes of life
4.4 Special care nursery/ neonatal intensive care unit admission during birth admission
4.5 Indication for neonatal admission
5. Major harms measured using data retrieved from the patient's or offspring's electronic medical charts at hospital discharge:
5.1 Hypoxic-ischaemic encephalopathy (neonatal)
5.2 Maternal admission to ICU for trauma sustained at birth

Overall study start date
01/06/2023

Completion date
15/11/2025

Eligibility

Key inclusion criteria
1. Age ≥ 18 years old
2. Nulliparous (no pregnancy after 20 weeks)
3. Singleton pregnancy
4. Cephalic presentation
5. No contraindication for vaginal delivery
6. Term ≥ 37 weeks
7. Reassuring fetal heart rate tracing
8. About to commence pushing for vaginal delivery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
378

Key exclusion criteria
1. Known major fetal anomaly
2. Planned instrumental delivery to shorten the second stage
3. Planned episiotomy
4. Maternal visual impairment (e.g., legally blind)
5. History of maladaptive maternal response to visual stimuli (e.g., migraine, seizure provoked)
6. Significant vulval-vaginal surgery

Date of first enrolment
15/11/2024

Date of final enrolment
15/11/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Medicine, University of Malaya

Alternative Name(s)
Faculty of Medicine - Universiti Malaya, Medicine Department - Faculty of Medicine - Universiti Malaya, medicineumalaya, University of Malaya Faculty of Medicine

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date