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A novel method to gain force awareness in a simulated childbirth and reduce the fetal head traction force

Submission date
26/10/2025

Recruitment status
Recruiting

Registration date
29/10/2025

Overall study status
Ongoing

Last Edited
29/10/2025

Condition category
Pregnancy and Childbirth

[_] 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
When excessive traction force is used on a baby's head during childbirth, studies show that this can cause injuries or complications in the newborn. Application of too much force can happen during a forceps or vacuum-assisted birth, when the baby's shoulders get stuck (shoulder dystocia), or when the baby is very large or not positioned properly. Excessive force can stretch the nerves in the baby's neck (the brachial plexus), which may cause injury. This type of injury, called neonatal brachial plexus injury (BPI), happens in about 0.4 to 4 out of every 1,000 live births and is one of the most common causes of legal cases related to childbirth in the UK. About 10–30% of affected babies are left with long-term nerve damage that affects the growth and movement of the arm. Because of this, it's important for healthcare professionals to be trained to control the amount of force they use during delivery. However, training simulators that can measure the amount of force applied are expensive and not yet widely used. This study aimed to find out, through a randomized controlled trial, whether using a birth simulator that measures force can help trainees become more aware of how much force they use—both in normal births and in complicated births with shoulder dystocia—and whether that awareness lasts over time.

Who can participate?
Third-year midwifery students in their undergraduate studies at the University of Western Macedonia, Greece.

What does the study involve?
The study involves randomization of midwifery students to attend a one-day workshop to group A (intervention) and group B (controls).

All students will be assessed with regards to the traction force applied to the fetal head in both a normal vaginal birth and in a childbirth complicated with shoulder dystocia, using a high-fidelity computerised birthing-simulator with an integrated force-monitoring system.

All students will participate in a pre-training assessment, theoretical and practical training, and completed a post-training assessment.

The intervention involves students acquiring force awareness by applying fetal head traction and at the same time having immediate visual feedback of forces on a screen provided by the simulator's force-monitoring system. The students will receive the intervention following their theoretical and practical training, but prior to the final post-training assessment.

The students from both groups (intervention-controls) will also be invited to attend a single follow-up assessment 6-months in order to assess whether the reduction in traction forces is retained.

What are the possible benefits and risks of participating?
The students participating will have the benefit of improving their fetal head traction skills. There are no risks associated with participating.

Where is the study run from?
University of Western Macedonia in Greece.

When is the study starting and how long is it expected to run for?
May 2025 to November 2026.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Dimitrios Papoutsis, dpapoutsis@uowm.gr

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Dimitrios Papoutsis

ORCID ID
https://orcid.org/0000-0001-9921-1120

Contact details
KEPTSE area, Ptolemaida
Kozani
Greece
50200
+30 24610 68050
dpapoutsis@uowm.gr

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
218/2024

Study information

Scientific Title
A novel method to gain force awareness in a simulated childbirth and reduce the fetal head traction force; a randomised controlled trial

Acronym
FORCE study

Study objectives
This is a randomized controlled trial (RCT) where we seek to explore whether the use of the force-monitoring system of a high-fidelity birth simulator as a training tool in a simulated normal vaginal childbirth and in a simulated childbirth complicated with shoulder dystocia can potentially lead to improved force awareness. Our hypothesis was that the intervention may result in the reduction of the fetal head traction forces in simulated childbirth.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/05/2024, Research Ethics Committee of the University of Western Macedonia, Greece (ZEP area - University of Western Macedonia Kozani Greece, Kozani, 50100, Greece; +30 24610 56500; ehde@uowm.gr), ref: 218/30.05.2024

Study design
Single center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
How to to reduce the forces applied to the fetal head in a simulated normal childbirth and in a simulated childbirth complicated by shoulder dystocia..

Interventions
Midwifery students are invited to participate in a 1-day workshop and are randomized to either group A (intervention) or group B (controls).

All students will be assessed with regards to the traction force applied to the fetal head in both a normal vaginal birth and in a childbirth complicated with shoulder dystocia, using a high-fidelity computerised birthing-simulator with an integrated force-monitoring system.

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Method of randomization: Computer-generated sequence of random numbers against the alphabetical list of students.

Intervention Type
Behavioural

Primary outcome(s)
Fetal head traction force will be measured using a calibrated force sensor embedded in the simulation model at baseline and post-training

Key secondary outcome(s))
Retention of skills at least 6-months later, measured by comparing the value of traction force 6-months later with the post-training values recorded at the end of the baseline workshop

Completion date
30/11/2026

Eligibility

Key inclusion criteria
Third-year midwifery students of the University of Western Macedonia, Greece

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 years

Upper age limit
65 years

Sex

All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
11/05/2024

Date of final enrolment
30/05/2026

Locations

Countries of recruitment
Greece

Study participating centre
Midwifery Department, University of Western Macedonia
KEPTSE area
Ptolemaida
Greece
50200

Sponsor information

Organisation
University of Western Macedonia

ROR
https://ror.org/00a5pe906

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Dimitrios Papoutsis (dpapoutsis@uowm.gr)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes