

# The effect of a leadership and teamwork experiential learning module on managing shoulder dystocia with high-fidelity simulation training

<b>Submission date</b> 21/10/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 24/10/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 24/10/2025	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims:

Shoulder dystocia is a rare but serious emergency that can happen during childbirth. It occurs when the baby's shoulders get stuck after the head has been delivered, making it difficult to complete the birth. In these cases, healthcare providers must use special maneuvers to help deliver the baby safely. This problem can happen unexpectedly, even when there are no known risk factors. It can cause serious harm to the baby, such as nerve injury (brachial plexus injury), brain damage from lack of oxygen (ischaemic encephalopathy), or even death.

Research shows that simulation-based training helps healthcare professionals learn both the technical skills (the physical maneuvers used to free the baby's shoulder) and the non-technical skills (like teamwork, communication, and leadership) needed to handle shoulder dystocia effectively. Because this is an emergency that requires quick, coordinated action, good teamwork is essential. Studies in other medical areas, such as resuscitation, show that leadership and teamwork improve team performance and make care safer for patients. However, in obstetrics, there is limited research on the importance of non-technical skills training and how much it helps when included in shoulder dystocia management courses.

This study was a randomized controlled trial (RCT) designed to fill that gap. It tested whether adding a specific module on leadership and teamwork to standard shoulder dystocia training would improve participants' skills. The researchers wanted to measure how much improvement this extra training produced and whether the benefits lasted over time.

Who can participate?

Final-year midwifery students in the last semester of 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 1-day workshop to group A (intervention) and group B (controls). Shoulder dystocia training and assessment will be performed with a high-fidelity computerised birthing simulator. All students will have a pre-

training assessment, theoretical and practical training, and complete a post-training assessment. Group A students will receive the intervention following their theoretical and practical training, but prior to the final post-training assessment. The intervention the students of group A receive involves a 2-hour leadership and teamwork experiential learning module.

What are the possible benefits and risks of participating?

The students participating will have the benefit of improving their skills in shoulder dystocia management. There are no risks associated with participating.

Where is the study run from?

University of Western Macedonia (Greece)

When is the study starting and how long is it expected to run for?

May 2023 to December 2024

Who is funding the study?

The University of Western Macedonia in Greece is responsible for the study. No specific funding will be received.

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 (0)24610 68050

dpapoutsis@uowm.gr

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

266/2023

## Study information

## **Scientific Title**

The effect of a leadership and teamwork experiential learning module on managing shoulder dystocia with high-fidelity simulation training: a randomized controlled study

## **Study objectives**

This was a randomized controlled trial (RCT) with the aim to address the current gap in the obstetrics related literature and to explore the actual effect of an added-on leadership and teamwork training module alongside the basic training in shoulder dystocia. Our hypothesis was that this add on training module might additionally improve the skills of the participants in managing shoulder dystocia in simulation training settings. We aimed to quantify the magnitude of effect of improvement and to explore whether it may be retained.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 31/08/2023, Research Ethics Committee of the University of Western Macedonia (ZEP area - University of Western Macedonia, Kozani, 50100, Greece; +30 (0)24610 56500; ehde@uowm.gr), ref: 266/2023 31.08.2023

## **Study design**

Single-center interventional randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Efficacy

## **Health condition(s) or problem(s) studied**

Shoulder dystocia

## **Interventions**

Final-year midwifery students were invited to participate in a 1-day workshop. They were subsequently randomized to either group A (intervention) or group B (controls).

All students completed a 30-minute pre-training assessment, participated in 30 minutes of theoretical and practical training, and undertook a 30-minute post-training assessment.

The simulation training and assessment in shoulder dystocia was performed with a high-fidelity computerised birthing simulator.

Students assigned to group A received the intervention following the theoretical and practical training and immediately before the final post-training assessment at the conclusion of the workshop.

The intervention consisted of a 2-hour leadership and teamwork experiential learning module. It consisted of an initial presentation of introducing key concepts and frameworks of leadership styles and stages of team development. Then, the students were actively engaged in experiential activity with guided reflection with the purpose of solidifying their learning and

relating to real life experiences. Finally, the session concluded with reinforcing the key messages of leadership and teamwork by relating their significance to shoulder dystocia management at childbirth.

Finally, the students from both groups (intervention-controls) were invited to attend a single follow-up assessment in shoulder dystocia management one week later in order to assess retention of skills.

Method of randomization: Computer-generated sequence of random numbers against the alphabetical list of students (n = 51).

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Midwifery students' performance during high fidelity simulation of shoulder dystocia at the baseline workshop. The variables measured along with the method of measurement at the baseline workshop are:

1. Simulated delivery success rates
2. The score of maneuvers in managing shoulder dystocia (measured with use of an Objective Structured Assessment of Technical Skills (OSATS) form constructed based on the Royal College of Obstetricians and Gynaecologists (RCOG) guideline for shoulder dystocia management)
3. Actual head-to-delivery time (measured objectively by the birthing simulator)
4. Self-reported perception of delivery time
5. Force applied to the fetal head (measured objectively by the birthing simulator)
6. Communication skill score (measured using a 10-point Likert scale, with points awarded for every item that the student clearly demonstrated against a checklist that was constructed before the start of the study)
7. Self-reported confidence levels
8. Leadership skill score (measured using a 10-point Likert scale, with points awarded for every item that the student clearly demonstrated against a checklist that was constructed before the start of the study)
9. Teamwork skill score (measured using a 10-point Likert scale, with points awarded for every item that the student clearly demonstrated against a checklist that was constructed before the start of the study)

## **Key secondary outcome(s)**

The potential retention of skills 1 week later, measured by comparing all the primary outcome measures 1 week later with the post-training values recorded at the end of the baseline workshop

## **Completion date**

07/12/2024

## **Eligibility**

### **Key inclusion criteria**

Final year midwifery students in the last semester of their undergraduate studies at 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

**Total final enrolment**

51

**Key exclusion criteria**

Students of earlier years in their studies

**Date of first enrolment**

01/10/2024

**Date of final enrolment**

16/11/2024

## **Locations**

**Countries of recruitment**

Greece

**Study participating centre**

**University of Western Macedonia**

Midwifery Department

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](mailto:dpapoutsis@uowm.gr))

**IPD sharing plan summary**

Available on request