

# Using simulation in teaching the Leopold maneuver to nurse students

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<b>Registration date</b> 10/10/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/07/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Leopold maneuvers are used by nurses to monitor the development of the fetus in the womb. The aim of this study was to evaluate the effects of simulated Leopold maneuver training on the safe pregnancy follow-up of nursing students.

### Who can participate?

A representative sample of fourth-year nursing students of Bursa Uludag University, Faculty of Health Sciences Nursing

### What does the study involve?

Data were collected using a form that included 18 issues. The study was carried out through a series of five sequential steps:

Step 1: Theoretical information about the Leopold maneuver was given to all students and a demonstration of the Leopold maneuver was performed on a model.

Step 2: Descriptive questionnaire form, Leopold information test, and scales (Perceived Stress Scale for Nursing Students, Bio-Psycho-Social Response Scale for Nursing Students, Stress Coping Behaviors Scale for Nursing Students) were sent to the students via WhatsApp and they were asked to fill them out. The ability of the students who completed the questionnaire form, knowledge test, and scales completely were evaluated according to the checklist (pre-test).

Step 3: The students were randomly assigned to either the intervention or control groups.

Step 4: The intervention group underwent training in the Leopold maneuver using hybrid simulation.

Step 5: A month after the simulation training, the intervention and control groups were evaluated while performing Leopold skill practice in pregnant women in the obstetrics department. Students completed the Leopold knowledge test and scales (Perceived Stress Scale for Nursing Students, Bio-Psycho-Social Response Scale for Nursing Students, and Stress Coping Behaviors Scale for Nursing Students) for the second time (post-test).

Nursing students in the control group received simulation-based training after the study was completed.

What are the possible benefits and risks of participating?

The research team does not anticipate that any process during the data collection process will cause significant discomfort or distress to nursing students. Nursing students will be informed that their participation is voluntary, that they are not required to answer any questions, and that they can withdraw at any time without giving any reason. Nursing students in the intervention group will need to spend time to complete their simulation training. Nursing students may be a little excited about receiving simulation-based training.

Where is the study run from?

Bursa Uludag University (Turkiye)

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

May 2023 to June 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Nevin Utkualp, nutkualp@uludag.edu.tr

## Contact information

### Type(s)

Principal Investigator

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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**

The effect of the Leopold maneuver training with hybrid simulation on nursing students' stress, bio-psychosocial response and stress coping behaviors: a randomized controlled trial

**Study objectives**

1. The experimental group enhances nursing students' Leopold maneuver knowledge more than the control group.
2. The experimental group enhances nursing students' Leopold maneuver skills more than the

control group.

3. The experimental group enhances nursing students' Correct Assessment of the Leopold Maneuver skills more than the control group.

4. The Perceived Stress Scale for Nursing Students, Bio-Psycho-Social Response Scale for Nursing Students, and Stress Coping Behaviors Scale for Nursing Students scores of the students in the experimental group were lower than those of the control group.

### **Ethics approval required**

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### **Ethics approval(s)**

1. Approved 02/05/2023, Uludağ University Faculty of Medicine Clinical Research Ethics Committee (Bursa Uludag University, Bursa, 16059, Türkiye; +90 (0)224 29 500 20; smigal@uludag.edu.tr), ref: 2023-10/8

2. Approved 02/05/2023, Uludağ University Faculty of Medicine Clinical Research Ethics Committee (Bursa Uludag University, Bursa, 16059, Türkiye; +90 (0)224 29 500 20; smigal@uludag.edu.tr), ref: 2023-10/8

### **Study design**

Randomized controlled experimental design

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital, School, University/medical school/dental school

### **Study type(s)**

Other

### **Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

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

Teaching the Leopold maneuver to nursing students

### **Interventions**

Participants were randomized into an experimental group and a control group.

The experimental group received simulation-based training.

The control group received standard training (theoretical training + demonstration of the Leopold maneuver on a model by the trainer + observation of students by the trainer while practicing on the model)

### **Intervention Type**

Other

**Primary outcome measure**

Leopold knowledge and skill assessed using the Correct Assessment of the Leopold Maneuver skills questionnaire checklist, scale at 1 month

**Secondary outcome measures**

1. Perceived stress measured using the Perceived Stress Scale for Nursing Students after the education given to the nursing students and during the clinical experience 1 month later
2. Bio-psycho-social response measured using the Bio-Psycho-Social Response Scale for Nursing Students after the education given to the nursing students and during the clinical experience 1 month later
3. Stress coping behaviors measured using the Stress Coping Behaviors Scale for Nursing Students scores after the education given to the nursing students and during the clinical experience 1 month later

**Overall study start date**

02/05/2023

**Completion date**

23/06/2023

## Eligibility

**Key inclusion criteria**

1. Fourth-year nursing student
2. Practicing in the obstetrics and gynecology department
3. Volunteer pregnant women who come to the obstetrics and gynecology department and do not have a risky pregnancy

**Participant type(s)**

Learner/student

**Age group**

Adult

**Sex**

Both

**Target number of participants**

66

**Total final enrolment**

65

**Key exclusion criteria**

1. Not volunteering
2. Not being a fourth-year student
3. Not practicing in the obstetrics and gynecology department

**Date of first enrolment**

15/05/2023

**Date of final enrolment**

23/06/2023

## Locations

**Countries of recruitment**

Türkiye

**Study participating centre**

Bursa Uludag University

Bursa

Türkiye

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## Sponsor information

**Organisation**

Bursa Uludag University

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<https://www.uludag.edu.tr/>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan

Planned publication in a peer-reviewed journal

### Intention to publish date

10/10/2024

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Nevin Utkualp (nutkualp@uludag.edu.tr)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/07/2025	02/07/2025	Yes	No