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Using simulation in teaching the Leopold maneuver to nurse students

Submission date	Recruitment status	[_] Prospectively registered
01/10/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/10/2024	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/07/2025	Other	

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)
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Additional identifiers

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
Ethics approval required

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

Primary study design
Interventional

Study design
Randomized controlled experimental design

Study type(s)
Other

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
Bursa Uludag University

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 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?
Results article		01/07/2025	02/07/2025	Yes	No