

# Simulation-based impact on caregivers' abilities and reactions in shoulder dystocia - a randomized trial

<b>Submission date</b> 02/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/09/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of this study is to assess the impact of a virtual reality-based simulation training on caregivers' skills in managing shoulder dystocia (SD). The primary aim was to determine the effectiveness of VR-based training compared to theory-based training in adhering to the modified ALSO algorithm (HELP-RER). The study also looked into various secondary outcomes to evaluate the overall impact of the training methods.

### Who can participate?

Resident and consultant physicians, midwives, and medical students in their final year

### What does the study involve?

Participants completed a questionnaire called the HuFSHI, which assessed their critical self-reflection before training. Participants were assigned to either the study group, which underwent training with a 360-degree video played on a virtual reality (VR) device, or the control group, which received a frontal theoretical lesson via PowerPoint presentation. The 360-degree VR video provided a detailed scenario for the study participants, while the control group received a brief lecture on SD management without direct interaction. All participants' responses were documented, and the principal investigator was kept blinded to the type of intervention and did not take part in the training process. After the initial training, each participant underwent hands-on training using a high-fidelity PROMPT flex-advanced birth simulator manikin. Trainers recorded the time taken to complete the tasks and the correct execution of obstetrical maneuvers based on a modified ALSO algorithm called HELP-RER. Following the first phase of the study, participants underwent a crossover, where they switched to the alternative training method. The study assessed adherence to the modified ALSO algorithm (HELP-RER) based on the training modality. Other outcomes of interest included improvements in diagnosis-to-delivery time, human skill factors, and perceived workload after VR-based versus theory-based training. Additionally, the study explored the influence of clinical experience and the number of training iterations on the final scores.

What are the possible benefits and risks of participating?

Benefit: Improved technical and clinical skills in the management of shoulder dystocia

Where is the study run from?

Medical University of Vienna (Austria)

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

December 2020 to August 2022

Who is funding the study?

Medical University of Vienna (Austria)

Who is the main contact?

Prof. Alex Farr, alex.farr@meduniwien.ac.at

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Alex Farr

### Contact details

Whähringer Gürtel 18-20

Vienna

Austria

1090

+43 (0)14040028220

alex.farr@meduniwien.ac.at

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

21015

## Study information

### Scientific Title

Impact of a virtual reality-based simulation training for shoulder dystocia on human and technical skills among caregivers: a randomized controlled trial

### Study objectives

A 360°-VR simulation training of the obstetrical management is feasible among caregivers

**Ethics approval required**

Ethics approval not required

**Ethics approval(s)**

Only medical personnel, medical students and midwives participated in the clinical trial and no ethics committee votum was required.

**Study design**

Interventional cross-over randomized trial

**Primary study design**

Interventional

**Study type(s)**

Other

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

Feasibility of a 360°-VR simulation training about shoulder dystocia in caregivers

**Interventions**

Study participants completed the validated HuFSHI questionnaire to explore their critical self-reflection before and after training. An immersive 360°-VR scenario was developed to explore all obstetrical maneuvers needed to manage shoulder dystocia and lasted for 2 min and 50 s. A blinded sub-investigator at the Department of Obstetrics and Gynecology, Medical University of Vienna performed blocked simple randomization with a 1:1 allocation ratio and randomly varying block size. The participants in the 360° VR group were allowed to move freely within the delivery room to enhance their immersive VR experience. For the control group, the second trainer gave a brief lecture on SD management using a PowerPoint presentation (Microsoft, Redmond, Washington, United States) for 2 minutes and 50 seconds. After training, each participant completed the NASA Task-Load Index (TLX).

**Intervention Type**

Other

**Primary outcome(s)**

Fidelity to the HELP-RER algorithm during VR-based training. Two different trainers noted the time needed to complete the task as well as the correct execution of the obstetrical maneuvers, as displayed in the modified ALSO algorithm HELP-RER(1). In particular, for each correctly performed letter on this checklist, the participants received one point. Thus, each participant reached a maximum score of 7 on the HELP-RER evaluation. Measured at baseline and after crossover.

**Key secondary outcome(s)**

1. Time needed to solve a shoulder dystocia scenario, recorded at baseline and after crossover
2. Evaluation of the human skills factors using HuFSHi questionnaire at baseline and after crossover
3. Workload evaluated using the NASA Task-Load Index at baseline and after crossover

**Completion date**

31/08/2022

# Eligibility

## Key inclusion criteria

Volunteer participants >18 years old selected among residents, attendants, midwives and medical students

## Participant type(s)

Health professional, Learner/student

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Total final enrolment

61

## Key exclusion criteria

1. Age <18 years
2. No medical background

## Date of first enrolment

03/01/2022

## Date of final enrolment

31/08/2022

# Locations

## Countries of recruitment

Austria

## Study participating centre

**Medical University of Vienna**

Whähringer Gürtel 18-20

Vienna

Austria

1090

# Sponsor information

## Organisation

Medical University of Vienna

## ROR

<https://ror.org/05n3x4p02>

# Funder(s)

## Funder type

University/education

## Funder Name

Medizinische Universität Wien

## Alternative Name(s)

Medical University of Vienna, MediUni Wien

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

Austria

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Prof. Alex Farr ([alex.farr@meduniwien.ac.at](mailto:alex.farr@meduniwien.ac.at)).

The type of data that will be shared: occupational group, years of experience in the field of obstetrics, HuFSHi and NASA Task Load Index questionnaires, HELP-RER and HELP-RER(1) scores, time needed to solve the task.

Dates of availability: 2023-2028.

Signed written consent was obtained from every participant before starting the clinical trial.

Data were pseudonymised after randomisation.

## 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>		03/04/2024	12/09/2024	Yes	No
<a href="#">Protocol file</a>			03/08/2023	No	No