ISRCTN12194978 https://doi.org/10.1186/ISRCTN12194978

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

Submission date
02/08/2023

Recruitment status
No longer recruiting

Registration date
04/08/2023

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Whäringer Gürtel 18-20
Vienna
Austria
1090
+43 (0)14040028220
alex.farr@meduniwien.ac.at

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/12/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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
Whäringer Gürtel 18-20
Vienna
Austria
1090

Sponsor information

Organisation
Medical University of Vienna

Sponsor details
Whäringer Gürtel 18-20
Vienna
Austria
1090
+43 (0)14040028220, +43 (0)14040028210
geburtshilfe@meduniwien.ac.at

Sponsor type
University/education

Website
http://www.meduniwien.ac.at/homepage/1/homepage/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/09/2023

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).
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?
Protocol file			03/08/2023	No	No
Results article		03/04/2024	12/09/2024	Yes	No