Apr 07, 2025

SKILLTRAIN ABS

DOI
https://dx.doi.org/10.17504/protocols.io.dm6gpd8mdgzp/v1

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DOI: https://dx.doi.org/10.17504/protocols.io.dm6gpd8mdgzp/v1

External link: https://app.cristin.no/projects/show.jsf?id=2740579

Protocol Citation: Jaroslav Zlamal, Cristina Barbu, Marie Christine Gulla Baglo, Henny-Mari Devold Hagen, Lena Heyn 2025. SKILLTRAIN ABS. **protocols.io** https://dx.doi.org/10.17504/protocols.io.dm6gpd8mdgzp/v1

Protocol status: Working
We use this protocol and it's working

Created: March 27, 2025

Last Modified: April 07, 2025

Protocol Integer ID: 125385

Keywords: birth simulator, skill training, operative delivery, simulation-based training, healthcare professionals, obstetric skills training, prompt flex advanced birthing simulator from limb, advanced birth simulator, prompt flex advanced birthing simulator, clinical simulation centre, simulator, different interventions during delivery, foetus model, clinical simulation centre at vestfold hospital trust, innovative aspect of this simulator, innovative simulator, such as operative vaginal delivery, simulation of complicated delivery, simulation, obstetric forceps, operative vaginal delivery, foetus, skill training, involving shoulder dystocia, delivery process, shoulder dystocia, complicated delivery, delivery, breech birth, time updates on the delivery process, active learning approach

Funders Acknowledgements:
Vestfold Hospital Trust
Grant ID: Internal innovation funds - P360

Disclaimer

The study is neither associated with nor sponsored by Limbs & Things Ltd, Sussex Street, Bristol, BS2 0RA, UK.

Abstract

We want to implement an advanced birth simulator (Prompt Flex Advanced Birthing Simulator from Limbs & Things ®) at the Clinical Simulation Centre at Vestfold Hospital Trust, Tønsberg, Norway. This innovative simulator enables skill training and simulation of complicated deliveries, such as operative vaginal deliveries (with vacuum and obstetric forceps), breech births, and deliveries involving shoulder dystocia. The innovative aspect of this simulator is that the person delivering the foetus model has access to a digital screen with real-time updates on the delivery process and how it is affected by the measures taken during the simulation. Available data includes real-time updates on the pressure applied to the foetus's neck, logging of different interventions during delivery, and the time it takes to complete the delivery. This facilitates an active learning approach through real-time feedback.

Image Attribution

Photo by **Isaac Quesada** on **Unsplash**.

Guidelines

We refer to the user guide by Limbs & Things for the Prompt Flex Advanced Birthing Simulator and Assisted Vaginal Birth Module (AVB).

https://limbsandthings.com/global/products/80206-birthing-simulator-prompt-flex-advanced-dark-skin-tone
https://limbsandthings.com/global/products/80410-assisted-vaginal-birth-module-dst

Materials

PromptFlex Advanced Birthing Simulator
https://limbsandthings.com/global/products/80206-birthing-simulator-prompt-flex-advanced-dark-skin-tone

Assisted Vaginal Birth Module (AVB) - PROMPT Flex
https://limbsandthings.com/global/products/80410-assisted-vaginal-birth-module-dst

Birthing Lubricant Gel
https://limbsandthings.com/global/products/10199-birthing-lubricant-gel-500ml

Simpson Obsterical Forceps

Medela Bird Reusable Cup (50 mm)

A tablet (Ipad)

ART mat (for augmented reality)

A table with adjustable height for simulator placement

Software:
Prompt Flex (Limbs & Things) from App Store (Apple)
L&T ART - Augmented Reality Training (Limbs & Things) from App Store (Apple)

The instruction manual and maintenance guidelines are attached to
the simulator in the form of a QR code.

Safety warnings

In order to avoid damage to the simulator, use sufficient lubrication during skill training with the Prompt Flex Advanced Birthing Simulator by Limbs & Things.

Ethics statement

The study is approved by Vestfold Hospital Trust, the section manager of Clinical Simulation Centre, the section manager of Maternity and Postnatal Ward at Vestfold Hospital Trust, and by the Innovation and Research Centre at Vestfold Hospital Trust and the Head of Academic Affairs and Research at Vestfold Hospital Trust. The study is also approved by the Norwegian Agency for Shared Services in Education and Research (SIKT). Reference number: 561360.

Participation is voluntary. Each participant can withdraw from the study at any time, for any reason, without any consequences. Each participant must sign an informed consent form. The participants' name will be exchanged by a code. We will maintain a list of codes and connecting names. However, this will only be accessible by the section manager of the Clinical Simulation Centre.

Before start

Read the user guide for the Prompt Flex Advanced Birthing Simulator and Assisted Vaginal Birth Module (AVB) by Limbs & Things (link to be found under "Materials" in this protocol).

Introduction

1 Training foundational skills in obstetrics and midwifery is essential; however, this can be challenging because of limited training possibilities and time constraints [1]. The need for skill training is especially valid for operative/instrumental vaginal deliveries and deliveries with shoulder dystocia[2,3]. Operative/instrumental vaginal deliveries are deliveries that are assisted by instruments, obstetric
forceps, or vacuum [4]. Shoulder dystocia is a complication of vaginal delivery, where during birth, the foetus's shoulder becomes trapped behind the maternal pubic bone [5]. Both operative/instrumental vaginal deliveries and deliveries with shoulder dystocia are associated with elevated complications, such as maternal trauma, trauma to the foetus, neonatal morbidity, and perineal tears [2,3,6,7]. Perineal tears, third- and fourth-degree tears involving the internal and external sphincter and anal mucosa, can lead to long-term and chronic dysfunction and pain, such as urinary incontinence, faecal incontinence, pelvic pain, and sexual dysfunction [8].

The global decline in the fertility rate [9] may have implications for how often obstetricians or midwives
encounter complicated deliveries and, as such, consequences for the possibility of skill training [10].

Simulation-based skill training has emerged as a viable solution in obstetrics and midwifery, allowing skill training to be conducted in a safe and realistic environment without any negative consequences for patients [11]. Such skill training is conducted primarily on birth models or simulators, which can range from low-tech task trainers (such as birthing pelvises) to full-body manikins with specialised mechanics and software that allow a high degree of realism [12,13]. Although simulation and simulation-based skill training in obstetrics and midwifery are well-researched areas, best practices and pedagogical setups are lacking in the implementation of specific birth simulators with a focus on operative/instrumental delivery in
Norway.

This paper outlines a protocol for a pilot study of the implementation of a specific birth simulator, the Prompt Flex Advanced Birthing Simulator by Limbs & Things©, for use with simulation-based skill training of operative/instrumental vaginal deliveries and deliveries with shoulder dystocia.

Background

2 Currently, several birth simulators are available for simulation-based skill training in obstetrics and midwifery, some with advanced features such as mechanical movement

of the mannequin foetus or physiological responses of the manikin during simulated birth [14,15]. However, not all simulators are designed for skill training in operative/instrumental vaginal deliveries. A list of currently available and in-development birth simulators, along with a brief description of their features, is provided in Table 1.

Table 1. The list of available birth simulators with a brief description of their features

Name	Features
PartoPants™	The simulator is made of adapted scrub pants with a birth canal, perineum, urethra, rectum, symphysis pubis, and a mechanism that simulates haemorrhage. Suitable for skill training/simulation of normal birth and complicated birth with eclampsia, haemorrhage, shoulder dystocia, breech birth and prolapsed cord [16].
MammaNatalie	Portable simulator. A simulator "belly" is placed on an operator, which acts as a mother. Suitable for training/simulation of bleeding, delivery of the foetus and placenta, foetal heart sounds, catheterisation of the bladder, uterine massage, and compression [17].
Obstetrical Manikin (Simulaids)	Breech birth, Leopolds maneveur [17].
Gaumard, CS 500	Normal delivery, postpartum haemorrhage, breech birth, shoulder dystocia, foetal heart sound, caesarean section (without dissectible abdomen or vascularization) [17].
Desperate Debra©	Vaginal examination for advanced labour, foetal head impaction, caesarean section with pre-cut caesarean incision [17].
NOELLE S574.100 (Gaumard)	Birth mother, with realistic cervix, birth canal, foetus delivery, normal and emergency delivery, postpartum bleeding, breech birth, should dystocia, foetal heart sounds, operative/instrumental delivery, dissectible abdomen with vascularisation) [17].
SimMom (Lærdal)	Full body simulator. Postpartum haemorrhage, breech birth, shoulder dystocia, foetal heart sounds, operative/instrumental delivery. Additionally, the simulator has cardiac and airway features that allow for skill training/simulation for emergency scenarios [17].

2.1 Aim

The aim is to pilot the implementation of the Prompt Flex Advanced Birthing Simulator from Limbs & Things© with the AVB module (for use with vacuum and obstetric forceps) and the addition of augmented reality in the setting of a clinical simulation centre among resident obstetricians and midwives.

2.2 Objectives

Evaluate the acceptability, feasibility, and usefulness of the pedagogical design/setup/intervention of skill training with the Prompt Flex Advanced Birthing Simulator from Limbs & Things©.

Evaluate the usefulness of the specific features of Prompt Flex Advanced Birthing Simulator from Limbs & Things© for skill training of vacuum extraction, use of obstetric forceps delivery and shoulder dystocia: use of vacuum for naturalistic vacuum extraction, insertion of real obstetric forceps, shoulder dystocia (flexible foetus model), pressure monitoring (sensor in the neck of the foetus), intervention registration (on monitor), 3D model view (through augmented reality).

Evaluate the usefulness and feasibility of the skill-training evaluation questionnaire.

Evaluate potential barriers to participation and dropout.

2.3 Research questions

How feasible, acceptable, and useful is the pedagogical setup of skill training with the Prompt
Flex Advanced Birthing Simulator from Limbs & Things© for midwives and resident obstetricians?

How useful are the specific features of the Prompt Flex Advanced Birthing Simulator from Limbs &
Things©; use of vacuum for naturalistic vacuum extraction, insertion of real obstetric forceps, shoulder dystocia(flexible foetus model),pressure monitoring (sensor in the neck of the foetus model), intervention registration (on monitor), 3D model view (through augmented reality)?

How feasible and acceptable is the skill training evaluation questionnaire among participants
to provide feedback on participants' skill performance?

What are the potential hindrances to participation, and what factors may contribute to dropout?

Methods

3

3.1 Sampling, participants, and recruitment

We will use a convenience sampling strategy to recruit midwives and resident obstetricians from the Vestfold Hospital Trust, Tønsberg, Norway. The eligibility criteria are summarised in Table 2.

Table 2. Eligibility criteria

Eligible	Not eligible
Midwives (irrespective of their previous work experience).	Midwife students.
Resident obstetricians.	Residents who have not started their residency in obstetrics.

We aim to recruit 12 participants, including six midwives and six resident obstetricians. This is based on the recommendations for pilot and feasibility studies by Billingham [18]. Two project members will recruit the participants, one midwife and one obstetrician. The midwife (hereinafter referred to as the "principal midwife") will be responsible for delivering the intervention in the project to midwives, and the obstetrician (hereinafter referred to as the "principal obstetrician") will be responsible for delivering the intervention in the project to resident obstetricians. Recruitment will be conducted through direct contact with potential participants.

3.2 Study setting

The study will be conducted at the Clinical Simulation Centre at Vestfold Hospital Trust in Tønsberg, Norway. The Clinical Simulation Centre serves as a hub for skill training, simulations, and lifelong professional learning within Vestfold Hospital Trust. The centre has five simulation rooms and eight staff members.

3.3 Intervention description, set-up, and procedures

The project group named the intervention “SKILLTRAIN ABS: Skill Training on the Advanced Birth Simulator for Healthcare Professionals”.

The intervention is a case-based pedagogical setup for simulation skill training in operative/instrumental delivery (vacuum extraction, delivery with obstetric forceps) and delivery with shoulder dystocia. The skill training will be mentored and supervised by the principal midwife/obstetrician. Two participants will participate in each session. They will be presented with a case description of a patient related to a resident obstetrician's case involving vacuum extraction or delivery with obstetric forceps, or a midwife's case involving shoulder dystocia. One participant will act as an assistant, and another will

conduct skill training, with the roles reversed. As the participant undergoes skill training, the adjacent software enables the monitoring of the delivery and registration of inputs. This will be carried out by a dedicated assistant who will be the project leader. During skill training, the participants will receive written and verbal feedback. Feedback will be provided by the principal obstetrician/midwife.

Written feedback will be provided with the “Skill training evaluation form” developed by Safer Stavanger and VestReg Sim [19]. Written and verbal feedback will be provided during each skill training session. Additionally, for shoulder dystocia, the software of the Prompt Flex Advanced Birthing Simulator from Limbs & Things© allows for the registration of the pressure exerted on the neck of the foetus model. This is displayed on a monitor as an output and will be used as part of the feedback provided by the principal midwife. In addition, the principal obstetrician and midwife will use adjacent augmented reality software with the use of a tablet and Prompt Flex Advanced Birthing Simulator from Limbs & Things ©, where the anatomical structures can be displayed and used for feedback.

3.4 Delivery of the intervention

The intervention will be delivered in a dedicated location at the Clinical Simulation Centre at Vestfold Hospital Trust by a principal midwife and principal obstetrician. Each group of midwives and resident obstetricians will conduct skill training sessions separately, at a minimum, once a week for 60 minutes each. The intervention will be conducted from April 2025 to December 2025. The project will last until the publication of the data in September 2026.

3.5 Materials

For the intervention, the necessary materials include the PromptFlex Advanced Birthing Simulator from Limbs & Things©; AVB (Assisted Vaginal Birth Module) for the birth simulator to be able to perform skill training for vacuum and use of obstetric forceps, lubricating gel, ART mat (for augmented
reality), tablet, Simpson Obsterical Forceps, Medela Bird Reusable Cup (50 mm), adjacent software for augmented reality and skill training and a table with adjustable height for simulator placement. An instruction manual and maintenance guidelines will be attached to the simulator as a QR code.

3.6 Intervention monitoring

The project leader will monitor the intervention by receiving feedback from the principal midwife and obstetrician. The project leaderwill also participate as an assistant during the skill training intervention.

3.7 Criteria for modifying or discontinuing the SKILLTRAIN ABS intervention

We established a traffic light system to modify or discontinue intervention, as described by Avery [20]. The criteria are summarised in Table 3.

Table 3. Criteria for modifying or discontinuing the SKILLTRAIN ABS intervention

Indicator	Description	Possible challenges	Example of actions
Green	The intervention proceeds according to protocol.	None.	No action is needed.
Amber	Challenges are identified, and appropriate actions are taken to address them.	Participants do not attend the intervention as frequently as planned.	In cooperation with the participants, we will determine the best way to accommodate their needs if the lack of participation is affected by scheduling conflicts or other organisational challenges.
		Technical difficulties or damage to the equipment	The Prompt Flex Advanced Simulator supplier has a dedicated contact person who will be able to assist us promptly if difficulties or damage occurs.
			User manuals with QR codes will be created and attached to the simulator.
			The principal midwife and obstetrician will receive training prior to starting the project.
		The principal midwife/obstetrician is absent due to unexpected leave	We have established a backup midwife/obstetrician who can step in if an unexpected leave of the principal midwife/obstetrician should occur.
Red	Type of challenges that cannot be amended or challenges that are a threat to safety.	The intervention interferes with the daily operation of departments where participants work in such a way that this is a threat to safety.	The intervention is terminated.

3.8 Adherence to the intervention protocol

Adherence to the intervention will be ensured by a principal obstetrician and a principal midwife who will closely follow up with the participants and ensure that they regularly participate in skill training
according to the prescribed pedagogical setup.The project leader will maintain close contact with the principal obstetrician and principal midwife to ensure that the intervention is followed
and the protocol is adhered to, and will also participate as an assistant during skill training.

3.9 Concomitant activities and other activities outside of intervention

Participants can participate in any other activity outside of the intervention.

3.10 Programme theory

The intervention has a theoretical foundation in the pedagogical framework of the "Learn, See, Practice, Prove, Do" framework [21]. The framework focuses on procedural-skill training. During the "learning phase", the participant must learn about the actual procedure or skill training, which can be achieved through reading, online learning activities, or videos [21]. In this intervention, participants must beforehand read the procedures for operative/instrumental delivery with obstetric forceps, vacuum, and delivery complicated by dystocia. The second step involves the "see phase", which consists of an instructor who demonstrates the skill using verbal and non-verbal demonstrations [21]. Here, the principal midwife and obstetrician will demonstrate operative/instrumental vaginal birth (with the use of obstetric forceps and vacuum) and shoulder dystocia. During the "practice phase", participants perform the skills on a simulator. The principal midwife and obstetrician will provide formative assessments with the necessary feedback and corrections. In the "prove phase", the principal midwife and obstetrician will provide a summative assessment of the skills of the participants. In the final phase, the
“do phase”, the skills are performed in a clinical setting on an actual patient [21].

3.11 Data collection

The formative and summative assessments that participants will receive through the "Skill training evaluation form" developed by Safer Stavanger and VestReg Sim [18] will serve as the foundational data that will be collected and analysed. After the participants provide their consent, the feedback form will be continuously collected after each intervention session until the end of the intervention. We will utilise Services for Sensitive

Data (TSD) [22] to facilitate the collection, storage, and processing of such data. Qualitative data will be collected through a face-to-face contextual enquiry with participants who will be present at the start of the intervention. The project leader will perform this task.The aim will be to gain insight into the initial experiences of the participants with the intervention and to determine if necessary adjustments are needed. Notes will be taken during the contextual enquiry.

At the end of the intervention, qualitative data will be collected through focus group interviews. This can be done face-to-face or digitally using Zoom communication software [23], depending on the wishes and availability of the participants. We aim to include three participants in the contextual enquiry and five participants in each group in the focus group interviews. We will also collect demographic data from the participants, including age, previous education, length of work experience, and previous experiences with skill training and simulation-based learning. Data will be collected using a
questionnaire in (TSD) [22].

3.12 Data analysis

The "Skill training evaluation form" [19] will be analysed using descriptive statistics in SPSS v.30. We will
analyse averages, means, standard deviations (SD), and percentages. Qualitative data will be analysed using thematic analysis, with data coding conducted using Maxqda coding software. Data from the contextual enquiry will be analysed using rapid analysis [24]. Data from the focus group interviews will be analysed using thematic analysis[25]. Qualitative data will be coded by two individuals, first individually, and then compared and collated to reach a consensus. Intercoder reliability, as measured by Cohen's K, will be calculated [26].

3.13 Data retention

We will store only the data necessary for this project. We will store demographic data, including age, previous education, length of work experience, and previous experiences with skills training and simulation-based learning. We will keep notes from contextual enquiries. We will also record the focus group interviews and transcribe them for further analysis. If the focus group interview is conducted via Zoom, the video portion of the recording will be immediately deleted, and only the audio file will be retained for transcription. The recording will be deleted after the transcription is complete.The data will be deleted at the end of the project period, 1.9.2026.

3.14 Data management

Each participant will receive a code at the beginning of the intervention, which will serve as their unique identifier in the study. The list of codes and corresponding names will be

compiled in a separate document and stored in a locked safe, accessible and administered only by the Section Manager of the Clinical Simulation Centre at Vestfold Hospital Trust. All other data will be stored by/in(TSD) [22], an approved data collection and storage tool at the Vestfold Hospital Trust. Data will be deleted at the end of the project and
after the publication of results.

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Acknowledgements

The project group want to thank Vestfold Hospital Trust for funding the study.