A randomised educational feasibility trial: 'in situ simulation' versus 'off site simulation' in obstetric emergencies and the effect on knowledge, safety-attitudes, team performance, stress, and motivation

ACRONYM obanop-trial

Version: 14 February 2013

PROTOCOL REGISTRATION NUMBERS:
CTU number: ob-an-op-simulation-trial-CT-91
ClinicalTrials.gov identifier: NCT01792674
The Regional Committee on Biomedical Research Ethics: protocol number: H-2-2012-155
Danish Dataprotection Agency: number 2007-58-0015

Abstract

Background: Care for pregnant and delivering women is a field where unexpected emergencies, as for example emergency caesarean sectio, postpartum bleeding or severe preeclampsia, that may potentially harm both mother and baby, occur. Obstetric emergencies are rare and hence by nature difficult to learn in real life. Therefore, it can be relevant with simulation-based medical education, i.e., training with mannequins and scenarios. In non-systematic reviews it is concluded that repetitive medical simulations are associated with improved learner outcomes. However, many questions on how simulation can optimise learning in emergencies remain unanswered; e.g., how different kinds of simulation settings as 'in situ simulation' versus 'off site simulation' impact learning at the individual and the team level.

Objectives: In a randomised trial on authentic obstetric-anaesthesia teams to study the effect of 'in situ simulation' versus 'off site simulation' on participants learning outcome, safety-attitudes, team performance plus motivational and stress inducing effect of different simulation settings and the potential association with learning and performance.

Interventions: The experimental intervention is training in 'in situ simulation' which means training in the actual patient care unit, in this situation the labour suite and operation theatre. The control group will receive the same training 'off site simulation', i.e., in training rooms away from the actual patient care unit. In the two different simulation settings, the same scenarios will be conducted and the participants will comprise of authentic teams of specialised obstetricians or obstetric trainees in their final training year, trainee obstetricians, midwifes, auxiliary nurses, specialised anaesthetists or anaesthesia trainees in their final training year, trainee anaesthetists, anaesthesia nurses, and surgical nurses.

Design and trial size: Single-centre investigator-initiated randomised superiority trial. We have chosen to calculate the required sample size based on experiences about knowledge tests. We assume a standard deviation at 24%, and a difference in the experimental and control means at 17%. With alpha set at 0.05, beta set at 0.80 and intraclass correlation at 0.05 the sample size added up to 93 participants. It is planned to include 100 participants.

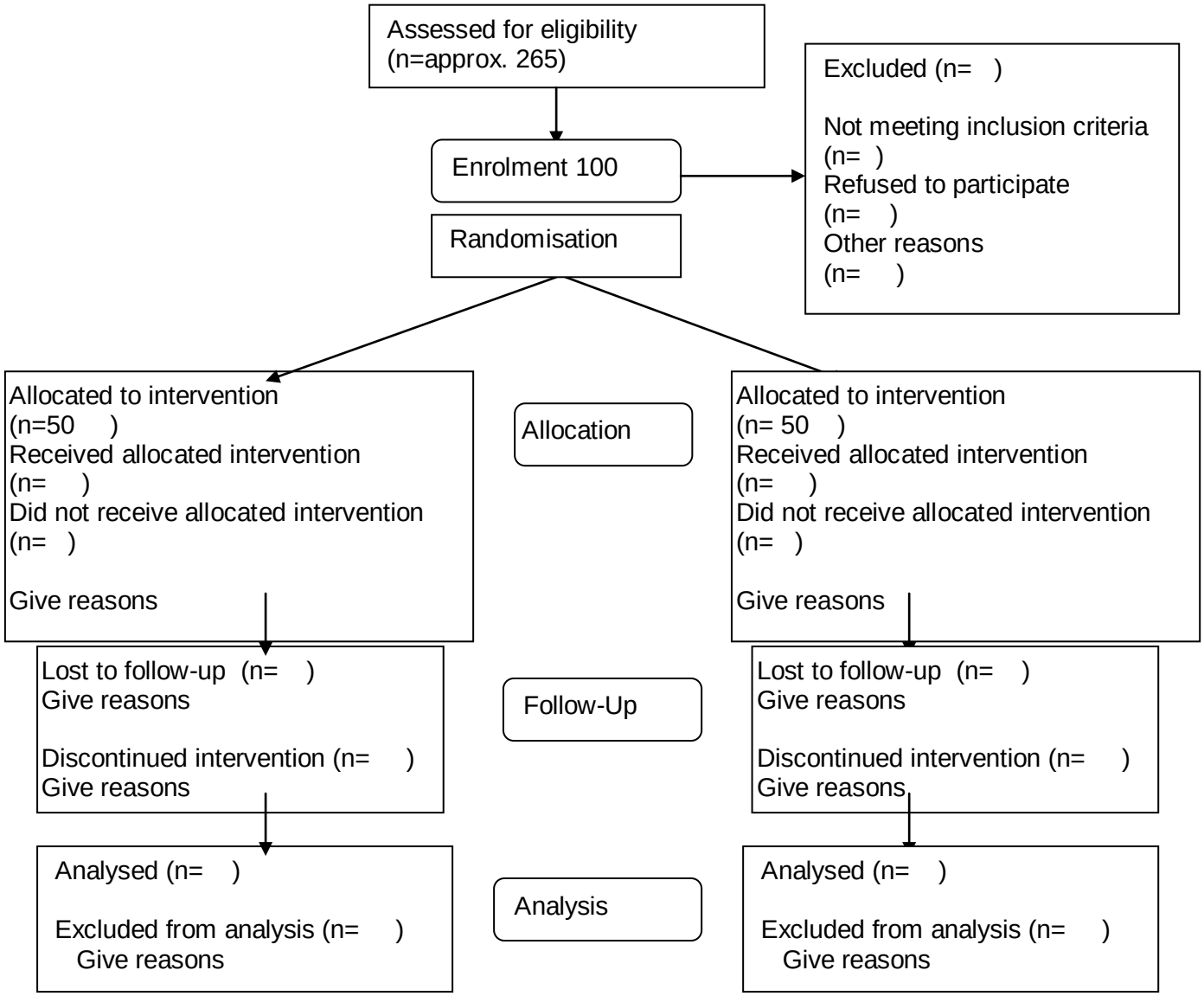
Inclusion criteria: Health-care professionals employed at the Obstetric or Anaesthesia departments at Rigshospitalet and trainee doctors having part of their training programme at JMC, Rigshospitalet. Participants shall work in the evening-, night- and weekend-shift duties with some of their work in the labour ward, and provide signed informed consent before randomisation. Exclusion criteria: Managers with staff responsibilities. Staff taking part in planning of the intervention. Lack of informed consent.

Outcomes: Primary outcome: 1) Knowledge by written test as multiple choice questions. Exploratory outcomes: 2) Safety attitudes questionnaire. 3) Team performance score. 4) Clinical performance in the simulated setting. 5) Salivary cortisol. 6) Validated stress inventory (Stress-trait anxiety inventory and cognitive appraisal). 7) Intrinsic motivation inventory. 8) Questionnaire to evaluate participants' perceptions of the simulation, the debriefing, and changes needed at the organisational level.

Time schedule: 2 years with start planning 1st of April 2012. Randomisation will start after approval from the Regional Ethics Committee and the Danish Data Protection Agency. The intervention with 'in situ simulation' versus 'on site simulation' described in this protocol will be scheduled spring 2013.

Trial flow chart

Refer to the Consort Statement for guideline (http://www.consort-statement.org/).



General information

Name and address of the sponsor of the trial:
Juliane Marie Centre for Children, Women and Reproduction (JMC). Rigshospitalet (RH), Copenhagen University Hospital, Denmark.

Principal investigator:
Jette Led Sorensen, MD, Consultant Obstetric Gynecologist, MMEd, Associate professor, Juliane Marie Centre for Children, Women and Reproduction (JMC)
Rigshospitalet, Copenhagen University Hospital, Denmark.
jette.led.soerensen@regionh.dk
Tel: +45 35458901 or +45 26711484.

PhD Supervisors:
Cees van der Vleuten, Professor, PhD. M.A. in Psychology, Department of Educational Development and Research, Faculty of Health, Medicine and Life Sciences, Maastricht University, Netherlands

Bent Ottesen, Professor, Director, DMSci, MD, Juliane Marie Centre for Women, Children and Reproduction (JMC), Rigshospitalet, Copenhagen University Hospital, Denmark

Research group:
Marianne Johansen, Senior consultant, PhD, MD. Obstetric dep. JMC, Rigshospitalet, Copenhagen University Hospital (Clinical obstetrics and obstetric simulation)

Hanne Kjærgaard, Midwife PhD Associate professor, Head of research for midwifes and nurses, The Research Unit Women's and Children's Health. JMC, Rigshospitalet, Copenhagen University Hospital. (Midwife and nurse research)

Doris Østergaard, Director, Associate professor, DMSci, consultant anaestesist , Danish Institute for Medical Simulation (DIMS), Herlev Hospital, Copenhagen University Hospital

Vicki LeBlanc, Experimental psychologist, PhD, Assistant professor, The Wilson Centre, University of Toronto (Human factors as stress respons and learning)

Cooperation with Copenhagen Trial Unit:
Jane Lindschou Hansen, Cand.scient.san.publ. MSc Demography & Health, Clinical Research Consultant, Copenhagen Trial Unit, Centre for Clinical Intervention Research, Rigshospitalet, Copenhagen University Hospital, Denmark (Randomised trial)

Christian Gluud, Head of Department, DMSc, MD, Copenhagen Trial Unit, Centre for Clinical Intervention Research, Rigshospitalet, Copenhagen University Hospital, Denmark (Randomised trial).

Direction management:
Bent Ottesen, Professor, Director, DMSci, MD, Juliane Marie Centre for Women, Children and Reproduction (JMC), Rigshospitalet, Copenhagen University Hospital, Denmark

Sanne Wilsdahl, Centre chief nurse, Juliane Marie Centre for Women, Children and Reproduction (JMC), Rigshospitalet, Copenhagen University Hospital, Denmark

Table of contents

Abstract **2**
Trial flow chart **4**
General information **5**
Table of contents **7**
List of abbreviations **9**
1. Introduction and background **10**
1.1 The condition and population 10
1.2 Interventions 11
1.3 How the intervention might work / Hypothesis 11
1.4 Previous studies and rational for future studies 12
1.5 Participants rationale 12
1.6 Regimen rationale 13
1.7 Risk and benefits 13
1.8 Ethical consideration 13
1.8.2 Informed consent 15
1.9 Trial conduct 16
2. Trial objectives and purpose **16**
3. Trial design **16**
3.1 Trial design 16
3.2 Randomisation 17
3.3 Trial intervention 17
3.4 Blinding 19
3.5 Duration 19
3.6 Discontinuation of individual participants 20
3.7 Intervention accountability 20
3.8 Data collection 20
4. Selection and withdrawal of participants **21**
4.1 Inclusion criteria 21
4.2 Exclusion criteria 21
4.3 Participant withdrawal 22
5. Experimental interventions **22**
5.1 Concomitant medication/treatment 22
5.2 Monitoring for participant compliance 22
6. Assessment of outcomes **22**
6.1 Efficacy variables 22
7. Assessment of safety **23**
8. Statistical plan and data analysis **24**

8.1 Sample size estimation 24
8.2 Statistical methods 25
9. Data handling and record keeping 25
10. Quality control and quality assurance 26
11. Trial organisation 26
12. Legal aspects 26
12.1 Finance and insurance 27
12.2 Publication plan 27
12.3 Spin-off projects 28
12.4 Acknowledgements 28
13. References 29

List of abbreviations

CRF: Case Record Form

ICC: intraclass correlation coefficient(1;2)

ICMJE: International Committee of Medical Journal Editors

IMI: Intrinsic motivation inventory(3)

ISS: 'in situ simulation'. ISS is described by Riley et al (4) as "a team-based simulation strategy that occurs on the actual patient care units involving actual healthcare team members within their own working environment. ISS is also known as 'fire drills' or 'mock codes'.

JMC: Juliane Marie Centre for Children, Women and Reproduction

MCQ: Multiple-choice questions

OSS: 'off site simulation', i.e., off-site job in simulation centre or in house training facilities

RCT: Randomised clinical trial

RH: Rigshospitalet, Copenhagen University Hospital

SAQ: Safety Attitudes Questionnaire (5-7)

SBME: simulation-based medical education, i.e.: 'In broad, simple terms a simulation is a person, device, or set of conditions which attempts to present education and evaluation problems authentically. The student or trainee is required to respond to the problems as he or she would under natural circumstances. Frequently the trainee receives performance feedback as if he or she were in the real situation. Simulation procedures for evaluation and teaching have several common characteristics' (8;9)

SD: Standard Deviation

STAI: State-Trait Anxiety Inventory(10;11)

Q: Questionnaire

1. Introduction and background

1.1 The condition and population

Care for pregnant and delivering women is a field where unexpected emergencies, as for example emergency caesarean sectio, postpartum bleeding or severe preeclampsia, that may potentially harm both mother and baby, occur(12-15;15). Since obstetric emergencies are rare and hence by nature difficult to learn in real life, simulation-based medical education (SBME) is essential (16). SBME is defined as: 'In broad, simple terms a simulation is a person, device, or set of conditions which attempts to present education and evaluation problems authentically. The student or trainee is required to respond to the problems as he or she would under natural circumstances. Frequently the trainee receives performance feedback as if he or she were in the real situation. Simulation procedures for evaluation and teaching have several common characteristics'(9).

Labour wards have a dual function in both creating a relaxed atmosphere for normal childbirth and at the same time showing readiness to deal with life-threatening emergencies(17). Labour wards are challenging work places and patient safety and medical litigation are high on the agenda(12-14;17-20;20;21). Clinical management of pregnant and parturient women may in certain situations require involvement of a variety of health-care professionals. The primary care team in a delivery room consists of a midwife assisted by an auxiliary nurse. In cases of emergencies more experienced midwifes and obstetricians will be called. In further progress of an obstetric emergency, an anaesthesiologist, the operating room personnel and a neonatologist may get involved. In cases with a severely ill parturient, involvement of both medical and surgical physicians may be required, since a rather common event has evolved into a potentially life-threatening situation calling for multi-professional and multi-disciplinary clinical management.

Such rare and complex clinical situations require complex skills, which cannot be trained and learned in clinical practice. Thus, there is a need for SBME in obstetric emergencies. A review (22) identified 8 out of 97 studies that evaluated simulation-based teamwork training programmes in acute obstetric emergencies, and only few were considered to be of sufficient good-quality (23;24). Overall, the review authors concluded that further trials are needed. From the literature we can conclude that SBME in labour wards is essential and multi-professional and multi-disciplinary team training are important due to the complexities of the skills to be trained and the rareness of the high-risk clinical events.

However, one of the key issues to study is how to improve learning in obstetric emergencies through simulation.

The simulation setting has traditionally been 'off site simulation' (OSS), where the setting is either an 'off site' simulation-centre or in so-called in-house training facilities in hospital rooms set up for the purpose of simulation training. However, within the last 10 years a new

simulation modality the 'in situ simulation' (ISS) has been introduced. ISS is described by Riley as 'a team-based simulation strategy that occurs on the actual patient care units involving actual healthcare team members within their own working environment'(4). ISS is also popularly known as 'fire drills'. An unanswered question is which advantages ISS can add to learning in obstetric emergencies.

1.2 Interventions

The experimental intervention in this trial on obstetric emergency training is 'in situ simulation' (ISS), which means training in the actual patient care unit (i.e., the labour suite and operation theatre). The control group in this trial will receive the same training as 'off site simulation' (OSS), i.e., in training rooms away from the actual patient care unit.

1.3 How the intervention might work / Hypothesis

In this trial we intend to focus on the simulation setting, and will apply a simulation intervention within obstetric emergency training in the actual patient care unit, i.e., the labour ward and the operation theatre, the so-called 'in situ simulation' (ISS).

Apart from some larger observational study (4;25;26) most of the studies about ISS describe an local educational intervention with a local ISS programme. Methodologically, the studies are descriptive and only few include a control group or pre- and post-tests. No randomised trials could be identified. In the existing literature is argued that because ISS takes place in the real working environment, ISS can identify system weaknesses and ISS is described used to test how new processes are functioning in clinical facilities (4;25-30). Some argue (31) how ISS overcomes the feasibility and is cost saving compared to OSS in simulation centres. However, Anderson et al (32) focused on unannounced ISS and potential disadvantages, and argue for instance, how unannounced ISS is time consuming and being intimidating for participants.

Randomised trials are needed to obtain knowledge of advantages and disadvantages of ISS versus OSS.

We hypothesise that ISS is more effective than OSS regarding learning in obstetric emergency training. The participants will consider ISS to be more demanding, and ISS will create higher levels of stress and motivation, which may enhance learning. Further, we hypothesise that training by ISS provide more information about changes needed in the organisation than OSS. These hypotheses are based on the discussion about how the levels of fidelity of simulation effect learning (8;33;34).

Human factors as stress and motivation effect learning (3;35-37). Studies show that simulation can be a stressor, and there are indications that high stress responsiveness is a good

predictor of good performance and retention of skills in simulated emergency scenarios, however, further exploration into these issues have been suggested (35;38;39). Experimental studies have used unspecific measurements of stress level and different stress inventories and measurement of salivary cortisol have been applied. (35;38-40). We assume that there will be a higher psychological fidelity within ISS compared with OSS, and we intend to study how stress under these circumstances relates to learning. Motivational processes are central for learning (3;37;41) and as part of this trial we will investigate phenomena as intrinsic motivation, and how these are moderated by the variation between OSS and ISS.

1.4 Previous studies and rational for future studies

In 2003 the Department of Obstetrics, JMC, RH initiated implementation of OSS in four obstetric emergencies. The implementation was designed as an intervention study with before- and after-testing, but without a control group (42). The training was highly appreciated and the participants reported improved collaboration and communication in obstetric emergencies. However, we did not know if the multi-professional obstetric skills training intervention resulted in improved health care for the women. Therefore, we compared by database-audit the incidence of postpartum bleeding indicated by blood transfusion and time delay in surgical interventions before, during, and after implementation of the programme, and found there was no effect of multi-professional obstetric skills training on the rate of blood transfusion for postpartum bleeding and time delay in surgical interventions(43). It was concluded that future obstetric skills training besides all staff in the Department of Obstetrics also should include all health-care professionals from the Department of Anaesthesia. This is addressed in the present trial.

In the Department of Obstetrics, JMC,RH a study involving unannounced ISS was initiated in 2008 and it was concluded, that the ISS has an important impact on changes on the organisational level, and impact for the staff involved (http://www.rigshospitalet.dk/NR/rdonlyres/F211AE4E-6A90-4694-BDBE-190F6E1664AD/0/uvarsledeoevelser.pdf)

The experimental intervention in the present trial is training by announced ISS. In the literature (4;27-31) several authors argue for ISS, however, little systematic knowledge exists of the advantage and disadvantage of ISS versus OSS, and no randomised trials have been conducted. The present trial is a feasibility trial trying to answer if ISS is better than OSS.

1.5 Participants rationale

Due to the results from the literature and our previous studies, we will in the trial include the following health-care professionals: specialised obstetricians, trainee obstetricians, midwifes, obstetric nurse, auxiliary nurses, specialised anaesthetists, trainee anaesthetists, anaesthesia nurses, and surgical nurses employed at the JMC, RH. Sample size estimation can be seen in

1.8. The complexity of the patient journey and all the health-care professionals involved in the delivery ward, operation theatre, and the postnatal ward can be seen from Figure 1.

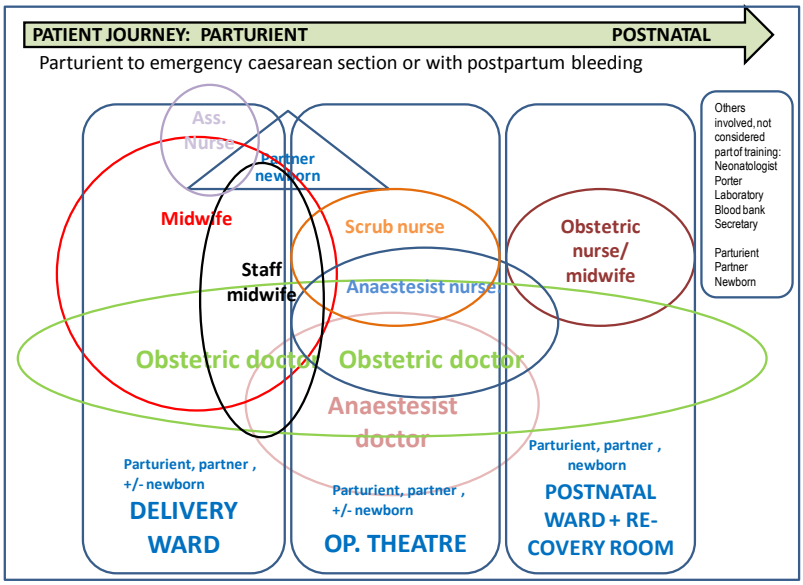


Figure 1. The complexity of the patient journey and all the health-care professionals involved in the delivery ward, operation theatre, and the postnatal ward.

1.6 Regimen rationale

The content and length of the intervention ISS and OSS are based upon results from previous studies(42;43), and on a recent needs analysis among involved health-care professionals.

1.7 Risk and benefits

The trial can bring ideas about the advantages and disadvantage of ISS versus OSS.

Participation in the trial is expected to be of beneficence for the participants, as participants in the intervention group will increase their competences in management of obstetric emergencies. The ISS intervention is not expected to expose participants in the trial to any known risk; discussion about risk is in section 1.8

1.8 Ethical consideration

Participants will be health care professionals and no patients and no data based on patient information will be involved in the trial.

The trial will comply with the current version of the Declaration of Helsinki on biomedical research and with the Act on Processing of Personal Data. Relevant approval from The

Regional Ethics Committee and the Danish Data Protection Agency are obtained and the trial will be registered at clinicaltrials.gov. About informed consent please see 1.8.2.

Participation is voluntary and the participants can at any time withdraw from the trial. The training programme will be planned either during normal working hours or if outside normal working hours; the participants will be paid normal salary per hour. No further compensation will be given to participants.

Participants will be assured that their personal data, data on questionnaires, salivary cortisol and video-recordings will remain anonymous during analysis and reporting. The participants will be asked to respect the confidentiality of their observations about colleagues' performance in the simulated setting.

The research will bring new information about simulation based medical education (SBME). The simulation setting has traditionally been 'off site simulation' (OSS) however an unanswered question is which advantages 'in situ simulation' (ISS) can add to learning in obstetric emergencies, and randomised trials are needed to obtain knowledge of advantages and disadvantages of ISS versus OSS. Educational planners can get new knowledge and ideas about the necessity of cooperation with clinical departments, if ISS under specific situations shows advantage above OSS. Political planning, decision making, rebuilding, and building of hospitals can have use of new knowledge, and whether there is a need for simulation-centres or whether capacity within the hospitals and wards also are needed to perform simulation, if ISS has advantages above the OSS.

Participation in the trial is expected to be of beneficence for the participants, as participants in the both groups are expected to increase their competences in management of obstetric emergencies.

The trial involves an educational intervention as simulation based training with educational equipment as delivery- and anaesthesia-manikins. The educational intervention will be offered to staff employed in the Obstetric and Anaesthesia Department. The participants will be informed by written material, however they also beforehand know about simulation-based training as it is regularly offered to staff employed in the Obstetric and Anaesthesia Department. The ISS intervention or OSS is not expected to expose participants in the trial to any risk; however some potential stress of being included in SBME can be expected. The participants included are health-care professionals who are employed to take care of women in labour; hence their clinical work includes some potential stress. Furthermore, the health-care professionals will through their work and training beforehand have been exposed to SBME, and the intervention is not expected to bring any risk above that. The intervention is planned to be followed by instructional feedback and debriefing session, which will be able to identify the necessity of individual support, if necessary. The departments involved in the trial, have a well established system to provide psychological help to staff involved in real

emergencies, and this system can be activated in situations where participants in the trial unexpectedly should require psychological support.

Work in labour ward can be stressful. Studies show that simulation can be a stressor, and there are indications that high stress responsiveness is a good predictor of good performance and retention of skills in simulated emergency scenarios, however, further exploration into these issues have been suggested(35;36;38).The trial can bring information about stress and learning, which can bring useful information about future simulation based education. A perspective can be future research and intervention studies among healthcare professional about stress management in emergency situations.

This trial involves measurement on biomedical material with testing of salivary cortisol on participants. Details on salivary can cortisol be seen in section 7. Measurement of salivary cortisol do not imply any known risk for the participants involved, and information on salivary cortisol does not give a known risk of diagnosing previous undetected illness. A research biobank will be created in at The Laboratory of Neuropsychiatry, Rigshospitalet and the samples will be maintained in a securely locked freezer. The Research biobank will be destroyed after end of the analysis.

Individual data on participants will be archived under an individual trial number and the link between participants name and individual trial number will only be known by the principal investigator, and will be archived in a locked archive cabinet at Rigshospitalet

1.8.2 Informed consent

The eligible participants will after The Regional Ethics Committee and the Danish Data Protection Agency have approved the trial be informed at conferences, meetings, at a webpage, by written notice on notice boards, and by a personal letter administered by the hospital local post distribution, which will give the participants opportunity to make an informed decision about their participation in the trial.

The eligible participants can obtain more written information from a webpage and by contact to the principal investigator or a contact person of the trial. After reading written information and getting verbal information, the eligible participants can await a week before decision about participation. The eligible participants can involve a colleague or other person in a personal conversation about the trial. The conversation about the trial can take place at Rigshospitalet in a quiet place at the principal investigator’s office. After written and verbal information and if the eligible participants accept to take part in the trial, they will be asked to sign a consent form before being enrolled in the trial.

1.9 Trial conduct

This trial will be conducted in compliance with the protocol approved by the The Regional Ethics Committee, and according to good clinical practice standards. No substantial deviation from the protocol will be implemented without the prior review and approval of the regulatory authorities except where it may be necessary to eliminate an immediate hazard to the trial participants. In such case, the deviation will be reported to the regulatory authorities as soon as possible

2. Trial objectives and purpose

Objective: In a randomised trial on authentic obstetric-anaesthesia teams to study the effect of 'in situ simulation' (ISS) versus 'off site simulation' (OSS) on participants' learning outcome, safety-attitudes, team performance plus motivational and stress inducing effect of different simulation settings and the potential association with learning and performance.

Research questions: What is the effect of ISS versus OSS on:

- Knowledge by written test as multiple-choice questions (MCQ)
- Safety Attitudes Questionnaire (SAQ)
- Team performance in the simulated setting
- Salivary cortisol
- Validated stress inventory
- Intrinsic motivation inventory (IMI)
- Questionnaire to evaluate trainee's perceptions of the simulation, the debriefing and changes needed at the organisational level

Hypotheses:

- ISS is more effective than OSS regarding written knowledge test by as multiple-choice questions (MCQ), Safety Attitudes Questionnaire (SAQ), and team performance in the simulated setting.
- ISS creates higher levels of stress and motivation than OSS measured on salivary cortisol, validated stress inventory, and motivation inventory.
- The participants trained by ISS will provide more information about changes needed in the organisation than after OSS.

3. Trial design

3.1 Trial design

The design is a single-centre investigator-initiated randomised superiority trial.

3.2 Randomisation

Randomisation will be performed centrally by the Copenhagen Trial Unit according to a computer-generated allocation sequence concealed for the investigators. The randomisation will be conducted in two steps.

1. The participants will be individually randomised into the experimental group (ISS) or the control group (OSS). The allocation sequence will be stratified according to health care professional groups (specialised obstetricians or trainee doctors year 4; trainee obstetricians; midwifes; specialised midwifes; auxiliary nurses; specialised anaesthetists; trainee anaesthetists; anaesthesia nurses; and surgical nurses).

2. After individual randomisation, the participants in the experimental group will be randomised into five teams who will receive ISS, and the participants in the control group will be randomised into five teams who will receive OSS. The recruitment is fulfilled when the participants take part in the day of educational intervention.

3.3 Trial intervention

The trial intervention is an educational intervention, where 'in situ simulation' (ISS) which means training in the actual patient care unit (i.e., labour suite and operation theatre). The control group will receive the same training 'off site simulation' (OSS), i.e., in training rooms away from the actual patient care unit.

In the two different simulation settings, ISS and OSS, the same scenarios will be conducted and the participants will comprise of authentic teams of specialised obstetricians or obstetric trainees in their final training year, trainee obstetricians, midwifes, obstetric nurse, auxiliary nurses, specialised anaesthetists or anaesthesia trainee in their final training year, trainee anaesthetists, anaesthesia nurse, and surgical nurse.
The simulated scenarios involve the SimMom mannequin which is an advanced full body interactive birthing simulator (http://www.laerdal.com/dk/SimMom). The SimMom mannequin offers the functionality required to train in a wide range of midwifery obstetric and anaesthesia skills, and the anatomy of the mannequin and functionality allows for multi-professional obstetric training of labour and delivery management. Pre-programmed scenarios can provide standardised training.

The intervention will both in the intervention- and the control group be a training day. Figure 2 illustrates the programme with teaching and simulation to the left and data collection with written tests, questionnaires and salivary cortisol to the right. Figure 3 gives an overview of the randomisation, intervention and outcome.

Q: Questionnaire.

STAI: State-Trait Anxiety Inventory

Tentative programme incl. written test's, questionnaires and salivary cortisol for a training day either 1) intervention group 'In situ simulation' or 2) control group 'off site simulation'						
Lecture, learning module , video etc.	**Simulation Debriefing**	**Start**	**Stop**	**Min .**	**Written test and questionnaires Q)**	**Salivary cortisol testing**
Arrival welcome Presentation Morning coffee		8.00	8.10	10		
Introduction		8.10	8.20	10		
Written test		8.20	8.55	35	Written test: obstetric anesthesia emergency events	
Short break		8.55	9.05	10		Stop drinking and eating 9.05 – 11.00
Lecture, learning module or video		9.05	9.55	50		
End of lecture		9.55	10.00	5	Q: Baseline STAI A0	Baseline A0 cortisol
Preparation for scenario A Introduction to equipment.		10.00	10.15	15		
	Go to room	10.15	10.20	5	Q: Pre STAI A1 ´ Q: Pre cognitive appraisal A1	Pre A1 cortisol
	Scenario A labour room and pt. will be moved as part of scenario	10.20	10.35	15		
	Scenario A op.theatre	10.35	10.50	15		
		10.50	10.55	5	Q: Post STAI A2 Q: Post cognitive appraisal A2	Post A2 cortisol
Move to another room		11.00	11.05	5	Q: Post STAI A3	Post A3 cortisol
Feedback /debriefing + drink		11.05	11.35	30		
Break and Lunch		11.35	12.05	30		Stop eatling and drinking 12.05 – 14.00
Lecture, learning module or video		12.05	13.05	60		
End of lecture		13.05	13.10	5	Q: Baseline STAI B0	Baseline B0 cortisol
Short break Preparation for scenario B		13.10	13.20	10		
	Go to room	13.20	13.25	5	Q: Pre STAI B1 Q: Pre cognitive appraisal B1	Pre B1 Cortisol
	Scenario B labour room and pt. will be moved as part of scenario	13.25	13.40	15		
	Scenario B op.theatre	13.40	13.55	15		
		13.55	14.00	5	Q: Post STAI B2 Post cognitive appraisal B1	Post B2 cortisol
Move to another room		14.00	14.05	5	Q: Post STAI B3	Post B3 cortisol
Feedback + debriefing + drink		14.05	14.35	30		

Break and coffee		14.35	14.50	15		
Plenum summary		14.50	15.05	15		
		15.05	15.15	10	Q: intrinsic motivation inventory	
		15.15	15.50	35	Written test: obstetric anesthesia emergency events	
End of the day		15.50	16.00	10		

Figure 2: Tentative programme with teaching and simulation to the left and data collection with written tests, questionnaires and salivary cortisol to the right.

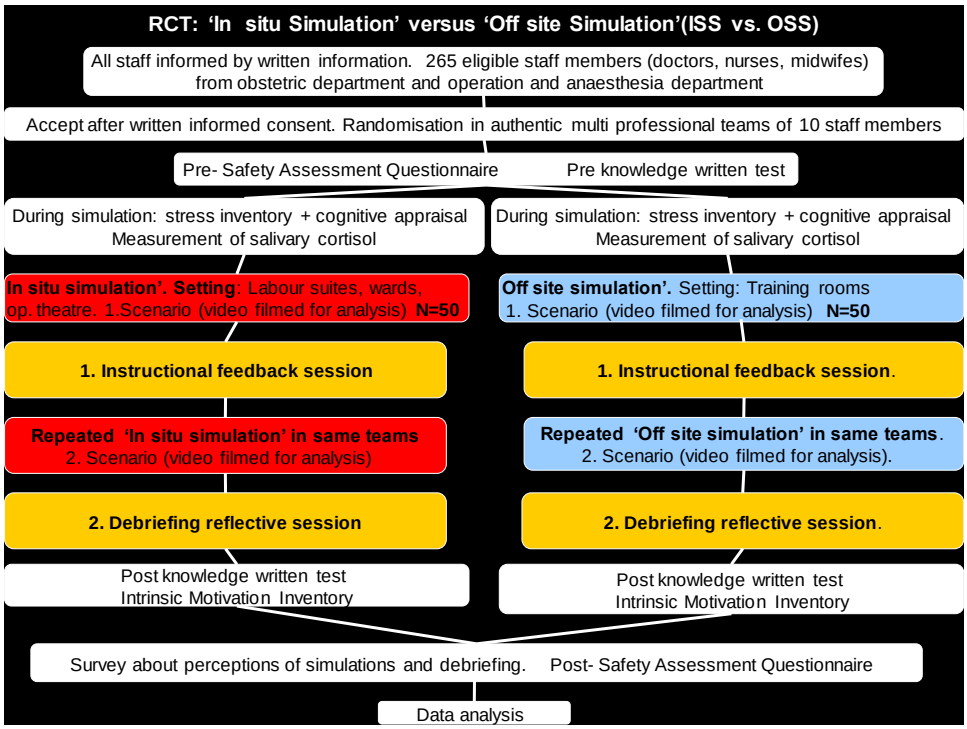


Figure 3. An overview of the randomisation, intervention and outcome.

3.4 Blinding

The participants, the educators providing the educational intervention, and the assessors observing and assessing videos will not be blinded to the intervention. The allocated intervention group will be blinded for the trial coordinator, data managers, statisticians and investigators drawing conclusions.

3.5 Duration

The duration of the training is equal in the intervention group and the control group and consists of a full day of training. This training day will be scheduled into the work plan for the different health-care professionals. Apart from the training day, the participants will receive a questionnaire approximately 4 weeks before and 1 week after and 4 weeks after the training day.

3.6 Discontinuation of individual participants

Participants will be encouraged to take part in the full training programme, however, they will be informed that they can withdraw their consent, and discontinue their participation at any time.

There is a minor risk of situations, where severe emergencies combined with lack of staff, necessitate that some of the randomised health-care professionals will need to discontinue the trial, and take part in emergency situations. Further there is a minor risk, that a full team randomised to ISS need to discontinue if very busy situations results in lack of available rooms in the labour suite and operation theatre for ISS. Through planning we will try to minimise this risk.

3.7 Intervention accountability

Responsible and accountable for the investigational educational interventions: Juliane Marie Centre for Children, Women and Reproduction (JMC). Rigshospitalet, Copenhagen University Hospital, Denmark.

3.8 Data collection

Timing	2-3 months before the training day	2 months before the training day	1-2 months before the the training day	Training day: See section 3.5	1 month after the training day
Information all staff	Oral information on meetings and conferences to all staff about the training	Written information by individual email and letters to all staff	Oral individual information to participants interested in randomisation		
Participants in the trial			Participants will be included consecutively. Written Informed consent obtained		
Randomisation			Randomisation ISS or OSS Randomisation procedure: See section 3		
Participants in the trial			Pre-Safety attitudes questionnaire (5-7)		Post-Safety attitudes questionnaire (5-7)
Data collection on participants			Demographic data Health-care	Written test questions MCQ State and Trait Anxiety	Semi structured questionnaire

in the trial			professional group Age Number of year of obstetric or obstetric-anaesthesia work experience. Previous obstetric training experiences Medication as corticosteroid and oral contraceptive.	Inventory 1 (STAI) (10;11) Cognitive appraisal (39) measured on a VAS scale Salivary cortisol tests(35;38) Team communication performance score by reviewing video recordings of the scenarios(44) Clinical performance by reviewing videos Intrinsic motivation inventory (IMI)(3)	with Likert scales and and few open questions about perceptions of the simulations, debriefing and changes needed at the organisa-tional level

4. Selection and withdrawal of participants

4.1 Inclusion criteria

- Employed in Obstetric department or Anaesthesia Department, JMC, RH or for trainee doctors employed in educational training programme involving JMC, RH within these health-care professionals group:
    - Specialised obstetricians;
    - Trainee obstetricians;
    - Midwifes;
    - Auxiliary nurses;
    - Specialised anaesthetists;
    - Trainee anaesthetists;
    - Anaesthesia nurses;
    - Surgical nurses.
- Participants shall work in the evening-, night- and weekend-shift duties.
- Signed informed consent.

4.2 Exclusion criteria

- Lack of informed consent.
- Staff taking part in planning of the intervention
- Managers with staff responsibilities.

4.3 Participant withdrawal

Participation is voluntary and the participants can at any time withdraw from the trial. If participants withdraw from the trial, the participants will be asked permission to include data already obtained, i.e., demographic data, data from inventories, questionnaires, tests and video observations. Participants that withdraw from the trial will be asked whether they can accept to get follow-up inventories, questionnaires and tests.

5. Experimental interventions

See section 3.3.

5.1 Concomitant medication/treatment

The participants will be asked to inform if they take part in other obstetric-anaesthesia simulation based training after enrolment in the trial and until answering last questionnaire and inventory.

5.2 Monitoring for participant compliance

Participants need to take part in all sequences of the trial (see table in section 3.5). After enrolment the participants will receive a trial number. On checklists will be obtained information on whether participants answer questionnaires and come to training days as planned.

6. Assessment of outcomes

6.1 Efficacy variables

Primary outcome:

Knowledge test by written test as multiple-choice questions (MCQ)

The test will also be applied in the morning before the teaching and simulation (see figure 2). Previous test by multiple-choice test (24) and 'knowledge of skills test' (42) will be used for inspiration, when constructing the new test. The test will be based on aims and objectives developed by a multi-professional working group appointed by the management of the Department of Obstetrics and Anaesthesia, JMC, Rigshopitalet. The test will be tested among midwifes plus medical students compared to specialised obstetricians and anaesthesiologist at other hospitals (construct validity) and the content validity will be tested among specialised obstetricians and anaesthesiologist(45).

Exploratory outcomes:

Safety Attitudes Questionnaire (SAQ) will be applied 1 month after the training day in each group (see figure 2). SAQ is an inventory used in several countries and also applied and validated in a Scandinavian context, and tested in Denmark(5-7). SAQ will as well be used before the intervention.

Team performance score will be assessed by independent observers by reviewing video recordings of the scenarios. A validated rating scale Team Emergency Assessment Measure (TEAM) by Cooper et al(44) will be used.

Clinical performance in the simulated setting will be assessed by independent observers reviewing video recordings of the scenarios. The assessment will be based on a score that will be constructed for this trial and based on international and national guidelines and best medical practice.

Salivary cortisol will be tested before, during and after the scenarios.

Validated stress inventory ,i.e., State-Trait Anxiety Inventory (STAI) will be applied just before, during and after the scenarios(10;11)

Cognitive appraisal, i.e., a 10-point Likert scale is applied to get information of the participants perceived stress of the upcoming event along with their capacity to cope with the stressor (39)

Motivation inventory will be applied after approximately a week after the training day (3)
http://www.psych.rochester.edu/SDT/questionnaires.php

Questionnaire to evaluate participant's perceptions of the simulation and the debriefing will be administered approximately a week after the training day. This questionnaire will include questions on Likert scales and few open questions about personal perceptions of the scenario (i.e., realism, cooperation between health-care professionals, own role in the team, etc) and whether the simulation training inspired to changes in the organisation (i.e., changes in guidelines, practical things etc.).

7. Assessment of safety

No patients will be involved in the trial, and no data based on patient information will be used. The trial involves an educational intervention as simulation based training involving educational equipment as delivery and anaesthesia manikins and other equipment involved in managing obstetric emergencies. The educational intervention will be offered to staff employed in the Obstetric and Anaesthesia Department. The participants will be informed by written material, however they also beforehand will know about the intervention as simulation-based training as it is regularly offered to staff employed in the Obstetric and Anaesthesia Department.

There are no known risks by training, and no adverse events or reactions are expected, and we will not assess and report these. See 1.8.
The trial involves measurement on biomedical material with testing of salivary cortisol on participants. Testing implies a cotton swab in the mouth for 30 seconds, and 500-1500 micro litre salivary will be obtained. Each participant will under each of two simulation scenarios be tested three times and a baseline test, i.e., all together seven time a test of salivary cortisol will be taken on each participant. Measurement of salivary cortisol do not imply any known risk for the participants involved, and information on salivary cortisol does not give a known risk of diagnosing previous undetected illness. A research biobank will be created in accordance with existing regulations. This Biobank will be destroyed after end of the analysis.

Relevant approval from the The Regional Ethics Committee and the Danish Data Protection Agency will be obtained.

Participants will be assured that their personal data on questionnaires, salivary cortisol and video-recordings will remain anonymous during analysis and reporting and subsequently be archived in Danish Data Archive.

8. Statistical plan and data analysis

8.1 Sample size estimation

Crude sample size estimation
There are no data on training effectiveness of 'in situ simulation' upon which to base sample size calculations. We have chosen to calculate the required sample size based on experiences about knowledge tests from results in previous studies (23;42).

We are planning a trial of a continuous response variable from independent control and experimental participants with one control per experimental participant. We assume the response within each intervention group to be normally distributed with standard deviation 24%. If the true difference in the experimental and control means is 17%, we will need to study 32 experimental participants and 32 control participants (total of 64) to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 80%. The two-sided type I error probability associated with this test of this null hypothesis is 5%.

Sample size estimation adjusted for clustering
As the intervention is delivered in teams (clusters), observations on participants on the same team are likely to be correlated. Hence the effective sample size is less than that suggested by

the actual number of individual participants. The reduction in effective sample size depends on the intraclass or cluster correlation coefficient (ICC)(1;2).

I order to adjust the sample size for this ICC, the crude sample size needs to be multiplied by the design effect. The design effect can be calculated using the formula below. The cluster size is ten, as there are ten participants in each team, and we assume the ICC to be 0.05 (2). Design effect = 1 + (cluster size – 1) x ICC → design effect = 1.45. Accordingly, the sample size will then be 64 x 1.45 = 92.8 participants.

Feasibility

10 teams with 10 different health-care professionals are considered to be included, all together 100 participants. Participants available for training approximately 265 (August 2012)
Approximately employed in Department of Obstetrics:

Midwifes: 100;
Auxiliary nurses: 16;
Obstetric nurses: 43;
Obstetric and gynaecology trainee doctors: 11 in rotation employments, more trainee doctors can be potential participants as they have part of their training programme at JMC, Rigshospitalet;
Obstetric specialised consultant or obstetric trainees in their final training year: 22

Approximately employed in the Department of Anaesthesiology:

Anaesthesia nurses: 23:
Surgery nurses: 33:
Anaesthesia trainee doctors: 7 in rotation employments, more trainee doctors can be potential participants as they have part of their training programme at JMC, Rigshospitalet;
Anaesthesia specialised consultant or anaesthesia trainees in their final training year: 12

8.2 Statistical methods

Relevant statistical methods will be applied according to a statistical analysis plan to be developed before all data has been collected. Responsible for statistical analysis will be Statistician Susanne Rosthøj, Department of Biostatistics, Faculty of Health Sciences, University of Copenhagen, Copenhagen, Denmark.

9. Data handling and record keeping

Each participant will have a Case Report Form (CRF), where the consent form, the demographic data, questionnaires, results from tests, salivary cortisol and checklist for participation will be archived. The CRF will be archived under an individual trial number and the CRFs will be placed in a locked archive cabinet at Rigshospitalet. The link between participants name and individual trial number will only be known by the principal investigator.

Double data entry into an Open Clinica database will be performed at Copenhagen Trial Unit. Approval from The Danish Data Protection Agency will be obtained.

Research biobank
For the salivary cortisol test material, a research biobank will be created in accordance with existing regulations. The Laboratory of Neuropsychiatry, Rigshospitalet will make the cortisol analysis and the samples will be maintained in a securely locked freezer. The Research biobank will be destroyed after end of the trial.

10. Quality control and quality assurance

There will be no external monitoring. The trial will be monitored internally, and approximately 10% of the data sample will be controlled from source data (the questionnaires) to the clean database on which statistical analysis is going to be conducted.

11. Trial organisation

Responsible organisation: Juliane Marie Centre for Women, Children and Reproduction (JMC), Rigshospitalet (RH), Copenhagen University Hospital, Denmark.

12. Legal aspects

Trial timeline	Timing
Information in the departments about the trial will be given at meetings, by email and at homepage	Januar 2013
Emails that ask potential participants to give informed consent	January 2013
If participants fulfil inclusion criteria they will be randomised. This will be combined with detailed planning in the department to get the training day scheduled into work plans.	January-February 2013
Training days with simulation based training (approximately one day per week in three months)	April – Mid June 2013
Safety Attitudes Questionnaire (SAQ) will be applied one month before and one month after the training day	March - End July 2013
Questionnaires to evaluate on participants' perceptions of the simulation, the debriefing and changes needed at the organisational level	April - End July 2013

Timing of randomised trial								
	2012 2	2012 3	2012 4	2013 1	2013 2	2013 3	2013 4	2014 1

	quarter	quarter	Quarter	quarter	Quarter	Quarter	quarter	quarter
Writing the protocol	X	X						
Clarification of intervention and outcome		X	X	X				
Training of trainers running the simulation Pilot test			X	X				
Randomised trial					X			
Analysis of data						X	X	X
Writing of articles							X	X

12.1 Finance and insurance

The trial is initiated by JMC, RH. The idea behind the trial is established in JMCs plan og strategy 2020
http://regionh.play.webfighter.dk/Web%20Arkiv/Rigshospitalet/Juliane%20Marie%20Centret/Centerledelsen/Strategi%202020/JMC%20Strategi%202020%20enkeltsidet.pdf
The principal investigator is employed and paid by JMC, RH, that also supports the trial by facilities as office, computer and facilities for simulation based training including a high-tech delivery simulator as SimMom.

The participants are employed at JMC, RH. The participants will either be involved during normal working hours or if outside normal working hours, the participants were paid extra per hour. As the participants are employed at JMC, RH, there will be covered by usual insurance as employees.

There are awarded funding by non-profit organisations: The Danish Regions Development and Research Fund awarded in December 2012: 1.200.000 DKK and The Laerdal Foundation for Acute Medicine awarded in November 2013: 233.300 DKK.
There is further applied for funding at the non-profit organisation Aase og Ejnar Danielsens Fund.

12.2 Publication plan

International committee for Medical Journal Editor's guidelines for authorship will be followed.

This randomised trial is a part of a PhD project with the title: How can we optimise learning in obstetric emergencies through simulation-based training. Apart from publication from this trial, other publications(42;43) will be a part of a PhD thesis. The principal investigator Jette Led

Sørensen is matriculated as PhD student at Graduate School of Health Professions Education, Maastricht University, Netherlands.

Publications planned:
Design article: A randomised educational feasibility trial: In situ simulation versus off site simulation in obstetric emergency training: Effect on team performance, clinical performance in the simulated setting and knowledge gain.

A randomised educational feasibility trial: In situ simulation versus off site simulation in obstetric emergency training: Effect on team performance, clinical performance in the simulated setting and knowledge gain.

All kind of results, negative, positive and inconclusive from the trial will be published. If publication in a scientific journal is impossible, the results will be published in a report and made available on a webpage.

12.3 Spin-off projects

Original data obtained for this trial is expected to be used for further analysis and publications. I.e., differences within the health-care professionals in perceptions of training, responses on stress inventory and cortisol and motivation for training.

12.4 Acknowledgements

This protocol is written under guidance of the Copenhagen Trial Unit's Standard Operating Procedures.

13. References

Reference List

(1) Ukoumunne OC, Gulliford MC, Chinn S, Sterne JA, Burney PG. Methods for evaluating area-wide and organisation-based interventions in health and health care: a systematic review. Health Technol Assess 1999;3(5):iii-92.

(2) Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ 2012;345:e5661.

(3) Kusurkar RA, Ten Cate TJ, van AM, Croiset G. Motivation as an independent and a dependent variable in medical education: a review of the literature. Med Teach 2011;33(5):e242-e262.

(4) Riley W, Davis S, Miller KM, Hansen H, Sweet RM. Detecting breaches in defensive barriers using in situ simulation for obstetric emergencies. Qual Saf Health Care 2010 Oct;19 Suppl 3:i53-i56.

(5) Sexton JB, Helmreich RL, Neilands TB, Rowan K, Vella K, Boyden J, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. BMC Health Serv Res 2006;6:44.

(6) Deilkas E, Hofoss D. Patient safety culture lives in departments and wards: multilevel partitioning of variance in patient safety culture. BMC Health Serv Res 2010;10:85.

(7) Deilkas ET, Hofoss D. Psychometric properties of the Norwegian version of the Safety Attitudes Questionnaire (SAQ), Generic version (Short Form 2006). BMC Health Serv Res 2008;8:191.

(8) McGaghie WC, Issenberg SB, Petrusa ER, Scalese RJ. A critical review of simulation-based medical education research: 2003-2009. Med Educ 2010 Jan;44(1):50-63.

(9) Issenberg SB, McGaghie WC, Petrusa ER, Lee GD, Scalese RJ. Features and uses of high-fidelity medical simulations that lead to effective learning: a BEME systematic review. Med Teach 2005 Jan;27(1):10-28.

(10) Bech P. [Klinisk psykometri]. 1.udgave, 2 oplag ed. Munksgaard Danmark; 2011.

(11) Spielberger C.D., Gorsuch RL, Lushene RE. Manual for the State-Trait Anxiety Inventory. Palo Alto, Calif.: Consulting Psychologists Press; 1970.

(12) Hove LD, Bock J, Christoffersen JK, Hedegaard M. Analysis of 127 peripartum hypoxic brain injuries from closed claims registered by the Danish Patient Insurance Association. Acta Obstet Gynecol Scand 2008;87(1):72-5.

(13) Berglund S, Grunewald C, Pettersson H, Cnattingius S. Severe asphyxia due to delivery-related malpractice in Sweden 1990-2005. BJOG 2008 Feb;115(3):316-23.

(14) Cantwell R, Clutton-Brock T, Cooper G, Dawson A, Drife J, Garrod D, et al. Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer: 2006-2008. The Eighth Report of the Confidential Enquiries into Maternal Deaths in the United Kingdom. BJOG 2011 Mar;118 Suppl 1:1-203.

(15) Bodker B, Hvidman L, Weber T, Moller M, Aarre A, Nielsen KM, et al. Maternal deaths in Denmark 2002-2006. Acta Obstet Gynecol Scand 2009;88(5):556-62.

(16) Johannsson H, Ayida G, Sadler C. Faking it? Simulation in the training of obstetricians and gynaecologists. Curr Opin Obstet Gynecol 2005 Dec;17(6):557-61.

(17) Drife J. Reducing risk in obstetrics. Qual Health Care 1995 Jun;4(2):108-14.

(18) Gold KJ, Kuznia AL, Hayward RA. How physicians cope with stillbirth or neonatal death: a national survey of obstetricians. Obstet Gynecol 2008 Jul;112(1):29-34.

(19) Committee opinion no. 497: Coping with the stress of medical professional liability litigation. Obstet Gynecol 2011 Aug;118(2 Pt 1):389-91.

(20) Veltman LL. Getting to havarti: moving toward patient safety in obstetrics. Obstet Gynecol 2007 Nov;110(5):1146-50.

(21) Pronovost PJ, Holzmueller CG, Ennen CS, Fox HE. Overview of progress in patient safety. Am J Obstet Gynecol 2011 Jan;204(1):5-10.

(22) Merien AE, van d, V, Mol BW, Houterman S, Oei SG. Multidisciplinary team training in a simulation setting for acute obstetric emergencies: a systematic review. Obstet Gynecol 2010 May;115(5):1021-31.

(23) Ellis D, Crofts JF, Hunt LP, Read M, Fox R, James M. Hospital, simulation center, and teamwork training for eclampsia management: a randomized controlled trial. Obstet Gynecol 2008 Mar;111(3):723-31.

(24) Crofts JF, Ellis D, Draycott TJ, Winter C, Hunt LP, Akande VA. Change in knowledge of midwives and obstetricians following obstetric emergency training: a randomised controlled trial of local hospital, simulation centre and teamwork training. BJOG 2007 Dec;114(12):1534-41.

(25) Walker ST, Sevdalis N, McKay A, Lambden S, Gautama S, Aggarwal R, et al. Unannounced in situ simulations: integrating training and clinical practice. BMJ Qual Saf 2012 Dec 4.

(26) Patterson MD, Geis GL, Falcone RA, Lemaster T, Wears RL. In situ simulation: detection of safety threats and teamwork training in a high risk emergency department. BMJ Qual Saf 2012 Dec 20.

(27) Hamman WR, Beaubien JM, Beaudin-Seiler BM. Simulation for the training of human performance and technical skills: the intersection of how we will train health care professionals in the future. J Grad Med Educ 2009 Dec;1(2):245-52.

(28) Guise JM, Lowe NK, Deering S, Lewis PO, O'Haire C, Irwin LK, et al. Mobile in situ obstetric emergency simulation and teamwork training to improve maternal-fetal safety in hospitals. Jt Comm J Qual Patient Saf 2010 Oct;36(10):443-53.

(29) van Schaik SM, Plant J, Diane S, Tsang L, O'Sullivan P. Interprofessional team training in pediatric resuscitation: a low-cost, in situ simulation program that enhances self-efficacy among participants. Clin Pediatr (Phila) 2011 Sep;50(9):807-15.

(30) Bender GJ. In situ simulation for systems testing in newly constructed perinatal facilities. Semin Perinatol 2011 Apr;35(2):80-3.

(31) Calhoun AW, Boone MC, Peterson EB, Boland KA, Montgomery VL. Integrated in-situ simulation using redirected faculty educational time to minimize costs: a feasibility study. Simul Healthc 2011 Dec;6(6):337-44.

(32) Anderson ER, Black R, Brocklehurst P. Acute obstetric emergency drill in England and Wales: a survey of practice. BJOG 2005 Mar;112(3):372-5.

(33) Norman G, Dore K, Grierson L. The minimal relationship between simulation fidelity and transfer of learning. Med Educ 2012 Jul;46(7):636-47.

(34) Douglas JD, Laird C. Clinical fire drills and skill decay: can we develop an evidence base for policy and a language for training? Med Educ 2004 Jan;38(1):14-6.

(35) LeBlanc VR. The effects of acute stress on performance: implications for health professions education. Acad Med 2009 Oct;84(10 Suppl):S25-S33.

(36) LeBlanc VR, Manser T, Weinger MB, Musson D, Kutzin J, Howard SK. The study of factors affecting human and systems performance in healthcare using simulation. Simul Healthc 2011 Aug;6 Suppl:S24-S29.

(37) Ten Cate TJ, Kusurkar RA, Williams GC. How self-determination theory can assist our understanding of the teaching and learning processes in medical education. AMEE guide No. 59. Med Teach 2011;33(12):961-73.

(38) Keitel A, Ringleb M, Schwartges I, Weik U, Picker O, Stockhorst U, et al. Endocrine and psychological stress responses in a simulated emergency situation. Psychoneuroendocrinology 2011 Jan;36(1):98-108.

(39) Finan E, Bismilla Z, Whyte HE, Leblanc V, McNamara PJ. High-fidelity simulator technology may not be superior to traditional low-fidelity equipment for neonatal resuscitation training. J Perinatol 2012 Apr;32(4):287-92.

(40) Arora S, Sevdalis N, Aggarwal R, Sirimanna P, Darzi A, Kneebone R. Stress impairs psychomotor performance in novice laparoscopic surgeons. Surg Endosc 2010 Oct;24(10):2588-93.

(41) Ryan RM, Deci EL. Intrinsic and Extrinsic Motivations: Classic Definitions and New Directions. Contemp Educ Psychol 2000 Jan;25(1):54-67.

(42) Sorensen JL, Lokkegaard E, Johansen M, Ringsted C, Kreiner S, McAleer S. The implementation and evaluation of a mandatory multi-professional obstetric skills training program. Acta Obstet Gynecol Scand 2009;88(10):1107-17.

(43) Markova V, Sorensen JL, Holm C, Norgaard A, Langhoff-Roos J. Evaluation of multi-professional obstetric skills training for postpartum hemorrhage. Acta Obstet Gynecol Scand 2012 Mar;91(3):346-52.

(44) Cooper S, Cant R, Porter J, Sellick K, Somers G, Kinsman L, et al. Rating medical emergency teamwork performance: development of the Team Emergency Assessment Measure (TEAM). Resuscitation 2010 Apr;81(4):446-52.

(45) Schuwirth LW, van der Vleuten C. ABC of learning and teaching in medicine: Written assessment. BMJ 2003 Mar 22;326(7390):643-5.