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Intrapartum care

Simulation-based team training for multi-professional obstetric care teams to improve patient outcome: a multicentre, cluster randomised controlled trial

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Objective To investigate whether simulation-based obstetric team training in a simulation centre improves patient outcome.

Design Multicentre, open, cluster randomised controlled trial.

Setting Obstetric units in the Netherlands.

Population Women with a singleton pregnancy beyond 24 weeks of gestation.

Methods Random allocation of obstetric units to a 1-day, multi-professional, simulation-based team training focusing on crew resource management (CRM) in a simulation centre or to no such team training. Intention-to-treat analyses were performed at the cluster level, including a measurement 1 year prior to the intervention.

Main outcome measures Primary outcome was a composite outcome of obstetric complications during the first year post-intervention, including low Apgar score, severe postpartum haemorrhage, trauma due to shoulder dystocia, eclampsia and hypoxic-ischaemic encephalopathy. Maternal and perinatal mortality were also registered.

Results Each study group included 12 units with a median unit size of 1224 women, combining for a total of 28 657 women. In total, 471 medical professionals received the training course. The composite outcome of obstetric complications did not differ between study groups [odds ratio (OR) 1.0, 95% confidence interval (CI) 0.80–1.3]. Team training reduced trauma due to shoulder dystocia (OR 0.50, 95% CI 0.25–0.99) and increased invasive treatment for severe postpartum haemorrhage (OR 2.2, 95% CI 1.2–3.9) compared with no intervention. Other outcomes did not differ between study groups.

Conclusion A 1-day, off-site, simulation-based team training, focusing on teamwork skills, did not reduce a composite of obstetric complications.

Keywords Multi-professional training, obstetric care, patient outcome, simulation, team training, teamwork skills.

Tweetable abstract 1-day, off-site, simulation-based team training did not reduce a composite of obstetric complications.

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Introduction

Clinical performance of obstetric care teams is associated with the quality of their teamwork skills instead of an individual's performance.[1] Care teams with a good clinical performance are more likely to state the emergency earlier, use more structured handovers and closed loop communication.[1] A lack of such teamwork behaviours is identified as a main contributing factor in approximately 75% of preventable medical errors.[2] As these errors undermine safety of patients,[3,4] improvement of teamwork skills with

Trial Registration: the Dutch Trial Register, NTR 1859; http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=1859

simulation-based team training is recommended by various healthcare institutes.[4,5]

Simulation-based medical education is recommended as it is a more effective learning method than traditional education for teaching medical technical skills.[6,7] For teamwork skills, the learning effect seems to be comparable.[8–10] The strength of simulation-based education lies in the opportunity for sustained, goal-oriented and deliberate practice for the acquisition of knowledge, skills and attitudes without any risks for patients.[11,12] To evaluate the effect of such training courses, Kirkpatrick's classification is often used. This consists of four levels, starting with (1) participants' perception, followed by (2) assessment of knowledge and skills, to (3) actions in clinical practice and (4) patient outcome.[13–15]

Despite the acknowledged importance of simulation-based team training in obstetrics, evidence from randomised controlled trials demonstrating improvement of maternal and perinatal outcome is still lacking.[9,10] To fill in this gap, we set up a cluster randomised controlled trial to investigate the effectiveness of a 1-day, off-site, simulation-based obstetric team training.[16] We previously showed that this simulation-based training was effective on level three of Kirkpatrick with both significant improved teamwork skills (7.5 versus 6.0 on the Clinical Teamwork Scale;[17] $P = 0.014$), and increased use of essential medical technical skills (83% versus 46%, $P = 0.009$; RR 1.8, 95% CI 1.1–3.0).[16] These results correspond with results of other studies.[18,19] The main question is whether this kind of training course will also lead to fewer obstetric complications (Kirkpatrick level four).

In this paper, we evaluated whether a 1-day, simulation-based obstetric team training in a simulation centre affects the number of obstetric complications in comparison with the absence of such team training during a 1-year evaluation.

Methods

Trial design and study population

Between November 2009 and July 2011, we conducted an open, multicentre, parallel, cluster randomised controlled trial to evaluate the effectiveness on obstetric complications of a 1-day, simulation-based obstetric team training in a medical simulation centre in comparison with the absence of such team training (TOSTI study).[20] The simulation-based obstetric team training focused on crew resource management (CRM) skills in obstetric emergency situations. As this was an open randomised trial, no one involved in the study was blinded to the allocation. As the allocation of the intervention was at the cluster level, the institutional review board of the Máxima Medical Centre decided that ethical approval was not necessary. The original study protocol was described online in the Dutch Trial Register (NTR no. 1859)[21] and a study protocol paper was published.[20]

The study was performed in Dutch hospitals, each featuring one obstetric unit that represented one cluster. Obstetric units already participating in multi-professional team training were not eligible for this study. Before randomisation, trial consent was approved by a local obstetrician. The included obstetric units were randomly allocated in a 1:1 ratio to simulation-based obstetric team training or to the control group. This was done by an independent researcher using a computer-generated list. Randomisation was stratified for units being situated in teaching or non-teaching hospitals, as the presence of residents might affect patient care and the effectiveness of the training intervention. The obstetric units in the control group agreed to conduct no simulation-based team training courses during the complete study period. All included units were allowed to continue existing local individual skills training programmes as long as they did not include team training.

All women with a singleton pregnancy beyond 24 weeks of gestation were included during a 1-year evaluation. The evaluation period of 1 year started whenever all staff members had received the intervention. To determine the study period for the units in the control group, each unit was linked to a unit in the intervention group. As cluster randomised controlled trials are commonly affected by an imbalance in baseline characteristics on patient level, and as the potential effect of team training depends on the pre-intervention morbidity rates, an additional pre-intervention measurement was conducted retrospectively over a period of 1 year prior to the intervention.

At the time of the study period, team training courses were not mandatory in Dutch obstetric units, healthcare professionals were obliged to report their perinatal data to a national perinatal registry (Perined)[22] and national perinatal audits were started in 2010. As a randomised design was applied, an even distribution of these factors among the study groups was expected.

Intervention

Units allocated to the intervention group were scheduled for team training. Units allocated to the control group received no team training. The intervention comprised a 1-day (8-hour), simulation-based, multi-professional obstetric team training, focusing on CRM skills (i.e. teamwork skills), in a medical simulation centre (Medsim) in Eindhoven, the Netherlands. The training course was provided once. The entire multi-professional staff of the obstetric units of the intervention group were obliged to participate. They were divided into several multi-professional obstetric teams consisting of a gynaecologist/obstetrician, a secondary care midwife and/or a resident, and nurses. Primary

care midwives and maternity assistants did not participate in the team training, as they work in private practices and are not part of the obstetric unit in the hospital. Anaesthesiologists were not included because they are not part of a standard care team in the delivery room in the Netherlands.

Teamwork training was delivered within the context of clinical training. The main learning objective of the training course concerned the improvement of CRM and communication skills between team members in obstetric emergencies, including the following: leadership and role clarity, distribution of work load, decision making, situational awareness, directed and closed-loop communication, prevention and management of fixation errors and Situation, Background, Assessment, Recommendation (SBAR) handover. Approximately 80% of the training course was spent on teamwork skills and the remaining 20% on medical technical skills. This was reflected in the debriefing sessions and the oral presentations after the first scenario about CRM (30 minutes) and medical technical skills [definition of cardiotocographic nomenclature (5 minutes) and shoulder dystocia (10 minutes)]. To provide the opportunity to rehearse teamwork skills, five clinical scenarios were presented with an increasing difficulty level: shoulder dystocia, eclampsia, umbilical cord prolapse, postpartum haemorrhage and resuscitation of a pregnant woman. In contrast to the protocol paper, a scenario concerning fetal distress was not included.[20] The treatment protocol of these scenarios was based on common national [Dutch Society of Obstetrics and Gynaecology (NVOG)] and international guidelines [Royal College of Obstetricians and Gynaecologists and Managing Obstetric Emergencies & Trauma (MOET)]. As these guidelines are widely recognised, similar treatment protocols were guaranteed in all included units. A more thorough description of the scenarios, learning goals and instructions for facilitators is available online (Appendix S1).

The medical simulation centre was equipped with four simulation and (de)briefing rooms, interactive full-body simulators, a control room, and audio-visual products. Each training day was facilitated by two facilitators, out of a group of ten, with several years of experience: an obstetrician and a communication expert. All facilitators with a medical background underwent instructor training for facilitating a simulation-based team training course (European Simulator Instructor Course provided by EUSIM)[23] and some of them took an additional instructor course (Generic Instructor Course provided by MOET).[24] The communication experts were experienced team coaches working for an international company specialised in learning and development (Schouten & Nelissen, part of Schouten Global). Two full-body mannequins were chosen for their high-fidelity characteristics [Noelle™ (Gaumard, Miami, FL, USA) and the Emergency Care Simulator ECS™ (METI, Sarasota, FL, USA)].

Each training day started with a 15-minute orientation with the simulation centre and simulation equipment. During this introduction, the facilitator emphasised that individual performances should not be discussed outside the simulation centre to assure the safety of all participants. The simulation rooms were furnished as a delivery room, including a delivery bed, resuscitation equipment, a CTG-monitor and a telephone. A table with the usual labour ward equipment was present in the room. Before the start of each scenario, the participants received work clothes (white coats) to put over their normal clothes. The scenarios were introduced to the participants who would encounter the patient in the first place by a short (approximately 5 minutes) standardised briefing video. These videos involved actors who illustrated the situation prior to the hospital submission. Directly after the video, the participants entered the simulation room where the simulated scenario took place. Each scenario ended when the clinical situation was managed (for example after the delivery of the baby in the case of a shoulder dystocia), or when the scenario was under control after approximately 15 minutes. The difficulty of the scenarios could be tailored to the performance of the care team. Each scenario was debriefed by two facilitators (approximately 30 minutes), supported by relevant video recordings. During the debriefing, participants' reactions, a deeper analysis of performance (by group discussion), and take-home messages were discussed. To maintain the learning effect, every unit received hard-copy flowcharts outlining the addressed clinical protocols and SBAR handover (Appendix S1).

Outcomes

Primary outcome was a composite outcome of the number of obstetric complications, i.e. low Apgar score, severe postpartum haemorrhage, trauma due to shoulder dystocia, eclampsia and hypoxic-ischaemic encephalopathy (HIE). The obstetric complications, with their definitions, are listed in Table 1 and are thoroughly described in Appendix S1. Additional secondary outcomes of interest were perinatal and maternal mortality. Perinatal mortality was defined as fetal or neonatal mortality beyond 24 weeks of gestation and within 7 days postpartum. Maternal mortality was defined as the death of a woman during or within 6 weeks after pregnancy. The intervention and all outcome measures were evaluated at the cluster level. All outcomes were collected for the pre- as well as the post-intervention period, both of which lasted for 1 year.

Data collection

All participating units prospectively registered cases in which the outcome measures occurred during the first year

Table 1. Components of composite outcome

Components of composite outcome	Definition
Low Apgar Score	5-minute Apgar score <7*
Severe postpartum haemorrhage	Administration of >4 packed cells blood transfusion, or the performance of an embolisation or hysterectomy in case of a postpartum haemorrhage.
Trauma due to shoulder dystocia	A brachial plexus injury, clavicle fracture, humeral fracture or other injuries (e.g. other fractures, pneumothorax, hypoxia/acidosis, HIE or mortality) due to shoulder dystocia
Eclampsia	Eclamptic convulsions
Hypoxic-ischaemic encephalopathy (HIE)	HIE, described using Sarnat stages

*This outcome measure differs from its prespecified measure 'perinatal asphyxia' defined as 'Apgar score after 5 minutes <7 and/or pH of the umbilical artery <7.05'.[20] This change was made because the units used different protocols for taking umbilical blood samples. The adjustment of the outcome measure was made before analysis.[21] The original definition was added as a secondary outcome measure.

after intervention. A local gynaecologist/obstetrician and a staff member were responsible for registering the outcome measures with provided registration lists to which we provided a monthly update. As data collection by local staff might be open to imprecision, the validity of the data collection for low Apgar score, perinatal and maternal mortality was verified and complemented with data from Perined.[22] The verification of the other outcome measures was done by visiting the hospitals to check their local registrations for missing primary outcome data. Whenever cases were identified which were not registered by the local staff, they were added to the database. These activities were done to increase the reliability of the database as much as possible. Case report forms were designed and filled out to gather more information about the cases. These data were transformed into electronical data files automatically. The demographic characteristics of all deliveries, including the non-complicated ones, were provided by Perined.[22] Three researchers were responsible for the data collection (A.F., J.V. and A.T.). A.F. was responsible for the development of the database.

Statistical analysis and sample size calculation

In the original study protocol, the sample size was set at 8000 women in each study group. This would allow us to assess a reduction in 'perinatal asphyxia' (defined as Apgar score after 5 minutes <7 and/or pH of the umbilical artery <7.05) from 1 to 0.6%.[21] Since the start of recruitment for our study, the sample size has been adjusted. In the recalculation of the sample size, we assumed an intra-cluster correlation coefficient (ICC) of 0.08. We calculated that we needed a sample size of 24 clusters, 12 clusters in each study group, with a cluster size of at least 200 deliveries for a power of 80% and an alpha value of 0.05 (two-sided).[20] This was based on a reduction from 15 to 5% in the composite outcome. The 15% outcome rate in the control group was derived from data from Perined and NVOG guidelines. The definition of the primary outcome has not been changed between the original protocol, trial registration, the published BMC protocol and the current manuscript. The final sample size calculation was finalised before all hospitals had received the intervention (or control) in July 2010, prior to the statistical data analysis, and was formulated in the protocol submitted to BMC in January 2010.

Analyses were performed according to intention-to-treat. The difference in morbidity and mortality rates (at the cluster level) between the two study groups was assessed by calculating the odds ratio (OR) with 95% confidence intervals (95% CI) using a random intercept logistic regression model. The use of a random intercept per hospital was required, as the pre- and post-intervention measurement comprised different women. Stratified randomisation was taken into account by including the presence of residents in a hospital as a covariate to the regression model.[25] Furthermore, to account for possible imbalances in baseline characteristics, the pre-intervention morbidity and mortality rates were added to the model as a covariate as well. To allow comparison with the study of Draycott et al.[26] and as the training could possibly be most effective in term pregnancies, we performed an additional analysis including only women with a term singleton pregnancy in cephalic presentation and without an elective caesarean. The idea for this subgroup analysis was conceived before data analysis was performed. We performed one post-hoc sensitivity analysis in which treatment for severe postpartum haemorrhage was excluded from the composite outcome, as this outcome measure seemed to relate to a behaviour rather than an actual patient outcome.

Results

We approached 36 obstetric units: eight did not meet the inclusion criteria and four units declined participation. The remaining 24 units were randomised and included in the analysis (Figure 1). Each study group contained 12 obstetric units, five teaching and seven non-teaching units. All obstetric units in the intervention group received the simulation-based team training between November 2009 and July 2010. Both post- and pre-intervention periods for each unit are displayed in Figure S1. All teams belonging to one

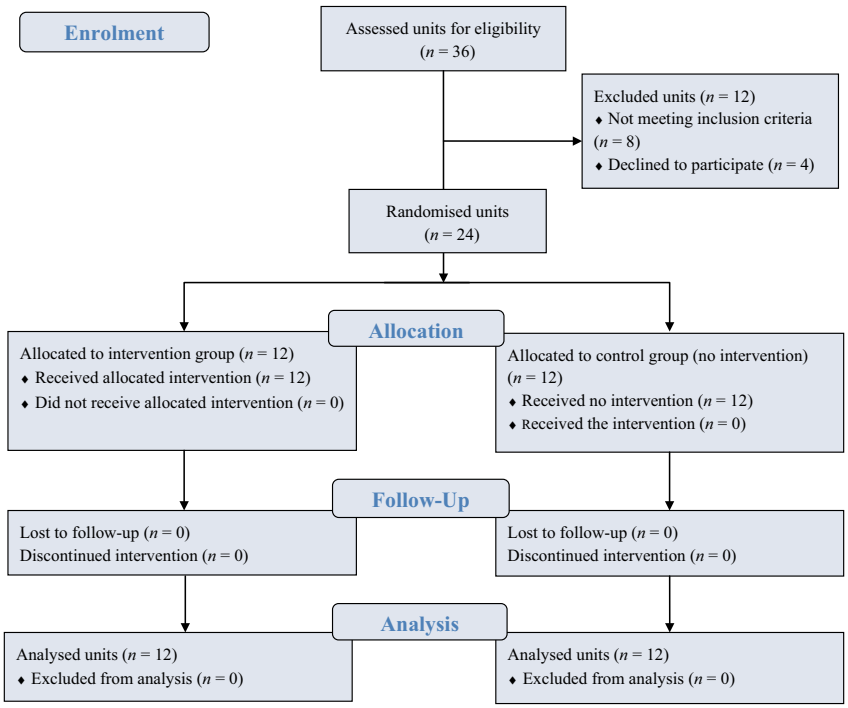

Figure 1. CONSORT flow diagram of enrolment of Dutch obstetric units in the cluster randomised design.

obstetric unit received the training within a time period of 4 weeks. No units were excluded after randomisation.

In the intervention group with 12 units in total, 74 multi-professional teams, comprising 471 healthcare professionals, received the training: 74 gynaecologists/obstetricians, 36 residents, 79 secondary care midwives and 282 nurses. The teams varied between three and nine participants, with a median size of seven. Whenever a small care team was present, one of the facilitators could perform an extra role in the scenario. Participation rates of the healthcare professionals of the included obstetric units were around 95%. The facilitator to participant ratio ranged between 1:2 and 1:4.5.

In the intervention group we studied 14 500 pregnancies of singletons beyond 24 weeks of gestation compared with 14 157 in the control group in the post-intervention period. The median cluster size comprised 1224 women [interquartile range (IQR) of 845 to 1509 women]; the data at cluster level are presented in Figure S1. Demographic characteristics of all deliveries in the pre- and post-intervention period showed significant differences between the intervention and control group for the parity, presentation at birth, (medium and high) socio-economic status, and mean maternal age (Table 2).

Primary and secondary outcomes

The composite of obstetric complications did not differ between study groups (287/14 500 (2.0%) versus 299/14 157 (2.1%); OR 1.0; 95% CI 0.80–1.3). A breakdown of the primary outcome indicated less trauma due to shoulder dystocia in the intervention group (0.16% versus 0.25%; OR 0.50; 95% CI 0.25–0.99) (Table 3), which was mainly driven by a lower number of clavicle fractures. Furthermore, blood transfusion with >4 packed cells, embolisation or hysterectomy for massive postpartum haemorrhage occurred more often in the intervention group than in the control group (0.28% versus 0.13%; OR 2.2; 95% CI 1.2–3.9) (Table 3). No differences between the intervention and the control group were found for low Apgar score or low Apgar score combined with an arterial umbilical pH <7.05. The number of women with eclampsia was lower and HIE higher in the intervention group, but these differences did not reach statistical significance (Table 3). The perinatal mortality rate in the intervention group was 0.45% compared with 0.55% in the control group (OR 0.75; 95% CI 0.53–1.07) (Table 3). One maternal death occurred; this was in the control group and was caused by an amniotic fluid embolism in a multipara woman with a term pregnancy. Resuscitation was started and a peri-mortem caesarean section was performed after more than 5 minutes.

Subgroup analysis of women with singletons in cephalic presentation at term (exclusion of elective caesareans) showed results that were similar to the results found in the analysis of the total study group (Table S1). The post-hoc sensitivity analysis of a modified composite outcome

Table 2. Demographic characteristics of singleton deliveries beyond 24 weeks of gestation: pre- and post-intervention periods for both intervention and control group

Characteristics	Pre-intervention period		*P*-value *	Post-intervention period		*P*-value *
	Intervention group *n* = 13 971	Control group *n* = 13 538		Intervention group *n* = 14 500	Control group *n* = 14 157	
Maternal age, mean (SD), years	30.0 (±5.0)	30.5 (±5.0)	<0.0001	30.0 (±5.0)	30.4 (±5.0)	<0.0001
Parity						
Nulliparous, *n* (%)	7318 (52.4)	7387 (54.6)	0.0003	7352 (50.7)	7530 (53.2)	<0.0001
Multiparous, *n* (%)	6653 (47.6)	6150 (45.4)		7145 (49.3)	6624 (46.8)	
Gestational age, median (IQR), days	279 (±16.0)	279 (±16.0)	0.19	278 (±15.0)	278 (±16.0)	0.56
24w0d–<28w0d, *n* (%)	20 (0.1)	8 (0.1)	0.12	17 (0.1)	17 (0.1)	0.17
28w0d–<32w0d, *n* (%)	26 (0.2)	32 (0.2)		19 (0.1)	32 (0.2)	
32w0d–<37w0d, *n* (%)	1020 (7.3)	1013 (7.5)		973 (6.7)	999 (7.1)	
≥37w0d, *n* (%)	12 905 (92.4)	12 485 (92.2)		13 491 (93.0)	13 109 (92.6)	
Presentation at birth						
Cephalic, *n* (%)	13 072 (93.6)	12 651 (93.5)	0.02	13 622 (93.9)	13 282 (93.8)	0.0008
Transverse, *n* (%)	64 (0.46)	47 (0.35)		39 (0.27)	73 (0.52)	
Breech, *n* (%)	735 (5.3)	809 (6.0)		726 (5.0)	778 (5.5)	
Birth weight, mean (SD), grams	3426 (±582)	3442 (±582)	0.03	3429 (±564)	3433 (±574)	0.54
Socio-economic status						
High, *n* (%)	2448 (17.5)	3415 (25.2)	<0.0001	2553 (17.6)	3468 (24.5)	<0.0001
Medium, *n* (%)	7296 (52.2)	5658 (41.8)		7395 (51.0)	5976 (42.2)	
Low, *n* (%)	4072 (29.2)	4112 (30.4)		4408 (30.4)	4340 (30.7)	

**P*-values are calculated using chi-square tests (for categorical and dichotomous data) and *t*-test (for continuous data). Data have been analysed as a complete case analysis.

without postpartum haemorrhage did not lead to different results.

Discussion

Main findings

Our multicentre, cluster randomised controlled trial revealed that a 1-day, multi-professional, simulation-based obstetric team training in a simulation centre, focusing on teamwork skills, did not reduce a composite of obstetric complications. When we looked at the components of the primary outcome, a two-fold reduction in neonatal damage due to shoulder dystocia and a two-fold increase of treatment with ≥4 packed cells of blood transfusion, embolisation or hysterectomy in the case of a postpartum haemorrhage were found. For the other outcome measures we found no statistically significant differences between the team training group and the control group.

Strengths and limitations

The most important strength of our study is the cluster randomised design. A second strength concerns the intervention itself, with a high participation rate, opportunity for repetition of teamwork skills and a thorough debriefing by two professional facilitators. Thirdly, we assessed the training intervention on the level of patient outcome after we previously observed a positive change in teamwork and medical technical skills.[16] This is desirable, as simulation-based teamwork training has been recommended by previous inquiries to improve patient safety.[4,5]

Limitations of our study should also be considered. First, we changed our original sample size calculation to take into account the cluster design of the study by including an ICC in the sample size calculation. As indicated, this was done while the intervention was running and prior to data analysis. Secondly, the actual incidence of the composite outcome was much lower (2%) than the 15% that was anticipated. This overestimation was mainly caused as we first considered all women with postpartum haemorrhages to suffer the primary endpoint. However, as there was no indication of a difference in the composite outcome between the two groups, it is unlikely a larger sample size would have changed our results. Thirdly, we used a non-validated composite outcome, which may be a disadvantage, as the underlying process of the individual components can be different,[27] as was the case for postpartum haemorrhage. A sensitivity analysis, in which postpartum haemorrhage was not considered a component of the

Table 3. Associations between intervention and patient outcome in singleton pregnancies beyond 24 weeks' of gestation

Primary and secondary outcomes	Pre-intervention		Post-intervention		Odds ratio (95% CI)	*P*-value
	Intervention group *n* = 13 971	Control group *n* = 13 538	Intervention group *n* = 14 500	Control group *n* = 14 157		
Composite of obstetric complications	273 (2.0%)	302 (2.2%)	287 (2.0%)	299 (2.1%)	1.0 (0.80–1.3)	0.90
Low Apgar Score	211 (1.5%)	244 (1.8%)	226 (1.6%)	251 (1.8%)	0.96 (0.74–1.2)	0.72
Severe postpartum haemorrhage	20 (0.14%)	32 (0.24%)	41 (0.28%)	19 (0.13%)	2.2 (1.2–3.9)	0.009
>4 packed cells	16 (0.11%)	31 (0.23%)	34 (0.23%)	18 (0.13%)	2.1 (1.1–3.8)	0.021
Embolisation	8 (0.06%)	9 (0.07%)	10 (0.07%)	3 (0.02%)	4.7 (1.3–17)	0.020
Hysterectomy	1 (0.01%)	4 (0.03%)	10 (0.07%)	1 (0.01%)	10 (0.99–120)	0.051
Trauma due to shoulder dystocia	43 (0.31%)	26 (0.19%)	23 (0.16%)	35 (0.25%)	0.50 (0.25–0.99)	0.048
Brachial plexus injury	13 (0.09%)	9 (0.07%)	8 (0.06%)	6 (0.04%)	1.3 (0.39–4.3)	0.68
Clavicle fracture	23 (0.16%)	11 (0.08%)	13 (0.09%)	26 (0.18%)	0.38 (0.15–0.93)	0.034
Humeral fracture	7 (0.05%)	8 (0.06%)	3 (0.02%)	2 (0.01%)	1.5 (0.25–9.1)	0.65
Other injury	2 (0.01%)	0 (0.0%)	0 (0.0%)	2 (0.01%)	NA	NA
Eclampsia	4 (0.03%)	6 (0.04%)	6 (0.04%)	12 (0.08%)	0.67 (0.19–2.4)	0.54
HIE	7 (0.05%)	5 (0.04%)	14 (0.10%)	4 (0.03%)	3.2 (0.77–13)	0.11
Perinatal mortality	82 (0.59%)	59 (0.44%)	65 (0.45%)	78 (0.55%)	0.75 (0.53–1.07)	0.11
Maternal mortality	0 (0.0%)	1 (0.01%)	0 (0.0%)	1 (0.01%)	NA	NA
Low Apgar score and arterial umbilical pH <7.05	342 (2.4%)	339 (2.5%)	373 (2.6%)	355 (2.5%)	1.0 (0.77–1.3)	0.98

HIE, hypoxic-ischemic encephalopathy; NA, not applicable.
The components of the composite outcome do not add up to the group total as one individual can have multiple components.

composite outcome, showed results similar to the primary analysis. A fourth limitation are the differences in the baseline characteristics at patient level, which were probably caused by the randomisation on cluster level. However, we accounted for this by including the pre-intervention outcome rate as a covariate in our analysis. Finally, all obstetric units were allowed to continue local individual skills training programmes during the study. As information on these training programmes was not collected, we were not able to assess this distribution.

Interpretation

The lack of an effect on obstetric complications is intriguing, as we previously showed that the applied intervention successfully improved teamwork skills and the application of medical technical skills.[16] A similar absence of effect on patient outcome has been observed in a previous randomised controlled trial by Nielsen et al.[28] who investigated the effect of a standardised teamwork training curriculum (without simulation), on the Adverse Outcome Index (AOI) and Weighted Adverse Outcome Score (WAOS). Walker et al.[29] who investigated the effect of a low-tech, simulation-based team training course, also found no effect on maternal complications. Contrary to these findings, non-randomised studies have shown positive effects of simulation-based team training on composite outcome measures like the WAOS[8] and the AOI.[30] It might have been interesting to use these validated composite outcome measures.

The decrease of trauma due to shoulder dystocia in the intervention group compared with the control group is in alignment with results from other studies.[31,32] In contrast to most studies, this decrease was mainly caused by a lower number of clavicle fractures instead of brachial plexus injury. However, in both study groups the number of plexus lesions was very low.

An increased use of >4 packed cells of blood transfusion, embolisation or hysterectomy for the treatment of postpartum haemorrhage was found in the intervention group. As these interventions were encouraged during the training course, the increased use might represent a learning effect comparable to the change in behaviour demonstrated in our previous publication.[16] However, other studies consider an increase in interventions such as blood transfusion to be a negative outcome, as it might indicate insufficient management of postpartum bleeding or over-treatment.[33,34]

The number of babies with a low Apgar score was comparable in both study groups, whereas previous non-randomised studies had reported a decrease of low Apgar score after simulation-based obstetric team training.[26] The

relatively high number of low 5-minute Apgar scores compared with other literature might have been caused by the inclusion of women with gestational ages of 24 weeks onwards.[35,36] For eclampsia and HIE, the numbers were very low. In contrast to Draycott et al.,[26] we found a non-significant higher rate of HIE in the intervention group than in the control group. This might be explained by a non-significant decreased number of perinatal mortalities.

Several factors concerning the intervention itself should be considered to explain the lack of an effect on patient outcome. First, the training model was limited to a 1-day training course, in contradiction to the current recommendation of distributed practice and repetition.[37–40] Secondly, the training course focused on the acquisition of teamwork skills and, as such, time was only provided for repetition of teamwork skills, not for medical technical skills. Thirdly, the training course took place at a simulation centre, whereas 'in-house' training courses are currently recommended.[41,42] Fourthly, the clinical content of the training course was partly based on MOET. However, MOET has not proven to lead to improved patient outcomes in the Netherlands.[43,44] Besides, it could be that CRM training leads to improved teamwork skills but does not result in improved patient outcomes.[45] Fifthly, the use of patient actors instead of high-fidelity mannequins could have resulted in better results for communication skills.[46] Finally, anaesthesiologists were not included in the training as they are not part of a standard obstetric care team in the Netherlands. Future research should consider their involvement in obstetric team training.

Another explanation could be that the primary care midwives, who work independently from the hospital, did not receive the intervention. These midwives initially care for more than 50% of women during labour in the Dutch obstetric care system. Of the women in labour who have been cared for by midwives, 44%[47] are transferred to a secondary care team in the hospital for reasons that include postpartum haemorrhage, fetal distress and obstructed labour. Before women are transferred to a secondary care team, complications such as postpartum haemorrhage or fetal distress may already have occurred.

Future efforts should focus on the optimisation of the design of simulation-based team training courses. The comparison of different training models could be done using a stepped wedge design.[48–50] It would also be interesting to assess patient outcomes at different time points, to decide the right time for repeating the training course. For the Netherlands specifically, it would be worth trying to involve the independently working primary care midwives. This may be feasible in the future, as the Dutch government has recently decided to change the Dutch obstetric care system to a shared care obstetric system.[51]

Conclusion

This open, multicentre, parallel, cluster randomised controlled trial demonstrated that a 1-day, simulation-based obstetric team training of hospital teams in a simulation centre, focusing for 80% on teamwork skills, did not improve a composite of obstetric complications. Other training models for simulation-based training courses should be investigated using the same robust methodologies.

Disclosure of interest

Full disclosure of interests available to view online as supporting information.

Contribution to authorship

SGO, BWM were involved in the conception and design of the study. SGO, BMW and AF were responsible for the integrity of the work. AF, JV and AT were responsible for data collection. ES was, in close collaboration with AF, responsible for conducting the analysis. AF drafted the manuscript. SGO, JV, AT, ES and BWM reviewed the manuscript and approved submission.

Details of ethics approval

The institutional review board of the Máxima Medical Centre judged that ethical approval was not necessary as the intervention was allocated at the cluster level.

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Published study protocol

The published study protocol is accessible at: http://www.biomedcentral.com/1471-2393/10/59 (accessed 16 April 2016).

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Pre- and post-intervention periods for each unit.

Table S1. Associations between intervention and patient outcome in term singletons in cephalic presentation (exclusion of elective caesareans).

Appendix S1. Background information about the TOSTI study. ■

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