Author's response to reviews

Title: Reducing errors in health care: cost-effectiveness of multidisciplinary team training in obstetric emergencies: the TOSTI-trial

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Author's response to reviews: see over
Dear editor,

Herewith we submit our manuscript entitled “Reducing errors in health care: cost-effectiveness of multidisciplinary team training in obstetric emergencies: the TOSTI trial”. A multicenter randomised controlled trial to evaluate the cost-effectiveness of multidisciplinary team training in a medical simulation centre in the Netherlands to reduce the number of medical errors in obstetric emergency situations for publication in the BMC Pregnancy and Childbirth.

Primary outcome is the number of obstetric complications throughout the first year period after the intervention. If multidisciplinary team training appears to be effective a cost-effective analysis will be performed.

This is a second version and this study protocol was submitted and withdrawn earlier (1608797151287673). In comparison to the first draft, we have made the following changes:

- Page 6, Intervention: “These team trainings are given by specially trained instructors and facilitators (gynaecologists, educationalists, medical engineers, communication experts and psychologists).” The list of instructors is shortened.
- Page 6, Intervention: “Fetal distress including CTG analysis, shoulder dystocia, severe postpartum haemorrhage, eclampsia, umbilical cord prolapse and perimortem caesarean section.” The list of trained scenarios is changed.
- Page 6, Outcome measures: Apgar score is changed from 6 to 7 after 5 minutes.
- Page 6, Outcome measures: “Shoulder dystocia is hereby described as every additional manoeuvre for successful alleviation.” Definition for shoulder dystocia is given.
- Page 7, Outcome measures: “Sub analysis will be performed to identify possible changes in subgroups. These groups concern term infants (gestation over 37 weeks), singleton pregnancies and cephalic presentation at birth.” This sub analysis is added to the study protocol.
- Page 8, Statistics, Sample size: “The composite measure of poor perinatal and maternal outcome in the non training group was thought to be 15%, on the basis of data obtained from the National Dutch Perinatal Registry and the guidelines of the Dutch society of Obstetrics and Gynaecology (NVOG). We anticipated that multidisciplinary team training would reduce this risk to 5%. A sample size of 24 centres with a cluster size of each 1000 deliveries, each 12 centres per group, was needed for 80% power and a 5% type 1 error probability (two-sided). We assumed an Intraclass Correlation Coefficient (ICC) value with a maximum of 0.08. In conclusion
we will try to randomise 24 obstetric departments in the Netherlands with an one year follow-up.” The sample size calculation is changed drastically.

We would like to thank the two reviewers for their critical remarks. Following the remarks and our answers and changes we made to our manuscript:

Reviewer Carl J Lombard:
- Question if there are regular workshops for team members? In the Netherlands there are not. There is only individual training by MOET (Managing Obstetric Emergency and Trauma) are there are no regular team trainings.
- What are the standard quality control measures for monitoring and action taken on reported errors in the hospitals? In none of the participating hospitals there is a protocol for monitoring and action taken on reported errors.
- What is meant by frequent multidisciplinary team training? “Multidisciplinary team training for its care workers, as defined by more than once every year.”
- Inclusion criteria for team members and non team members in control sites? All care workers on the delivery rooms will participate.
- All obstetric cases within a site for a period of time will be included? The reviewer is right indeed. We include all at risk cases (denominator) and eventually the obstetric complication is the numerator.
- Why develop special indicators? When eventually the results show no effect in favour of team training, we can check if all steps in a random emergency scenario are taken.
- Will there be multiple teams in the intervention sites? “This means that several teams of the same hospital will be trained. In the real life setting in their own hospitals there will be a different composition of team members but every delivery room care worker has been trained in the simulation centre.”
- Statistical measure: We will assess just one bad outcome per mother-child pair.
- Sample size; a sample size of 200 per hospital will still have 80% power. The reviewer is right indeed so we changed this in our manuscript. But because the incidence of obstetric complication is perhaps lower than we think we took 1000 deliveries per hospital. And even the smallest hospitals in the Netherlands have up to 700 deliveries per year.
- Randomisation process? “Randomisation will be performed through a database which is hosted at the Academic Medical Centre (AMC) in Amsterdam. Randomisation will be 1:1 for intervention and control group and it will be stratified for teaching or non-teaching hospital because we expect differences in outcomes in teaching and non-teaching hospitals.”
- Should death be monitored as adverse event? “Secondary outcomes are perinatal and maternal mortality, divided by causes of death.”
- Interim monitoring? This will not be performed because on the on hand time is too short to perform one. When a interim analysis will be done almost all team trainings will be performed. On the other hand we give standard care and will not cause any harm by our intervention.

Reviewer Justus Hofmeyr:
- Perinatal and maternal death are not specifically mentioned. It would be useful to specify what the denominator will be. “Secondary outcomes are perinatal and maternal mortality, divided by causes of death.” The denominator will be all cases at risk.
- The sample size calculation is only based on perinatal asphyxia. This is not correct. There is a composite measure of poor perinatal and maternal outcome.
- Project indicators; how will these be measured and how will they relate to the primary outcome? We deleted the part about the Delphi-method and “Before the start of the project indicators will be developed to evaluate patient safety, teamwork and human factors. These indicators will be registered in a subgroup of the participating hospitals. This group will consist of 100 obstetric complications equally distributed in the intervention and control group.”
- Specify randomisation process. “Randomisation will be performed through a database which is hosted at the Academic Medical Centre (AMC) in Amsterdam. Randomisation will be 1:1 for intervention and control group and it will be stratified for teaching or non-teaching hospital because we expect differences in outcomes in teaching and non-teaching hospitals.”
- We deleted the sentence “methods will be applied to control for differences in baseline”.

The manuscript can be categorized as a study protocol. The material has not been previously published. There are no personal conflicts of interest of any of the authors. Ethical approval is not required for this type of study in The Netherlands. The study is funded by ZonMw, the Dutch Organization for Health, Research and Development, project number 170992303.

We hope that the changes have made this study protocol suitable for publication in BMC Pregnancy and Childbirth.

We look forward to hear from you.

Yours sincerely,

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