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Multi-professional simulation-based team training in obstetric emergencies for improving patient outcomes and trainees' performance (Protocol)

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[Intervention Protocol]

Multi-professional simulation-based team training in obstetric emergencies for improving patient outcomes and trainees' performance

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The aim of the review is to evaluate whether simulation-based, multi-professional, obstetric team training results in change on the different levels of training evaluation. Change - in educational and real settings - of health workers performance (e.g. learning experience, knowledge, skills and team performance) and, especially, the impact on maternal and neonatal outcomes will be discussed.

BACKGROUND

Description of the condition

The advent of the Millennium Development Goals nos. 4 and 5 - reduction of maternal and infant (including neonatal) mortality - has focused attention on safety in maternity care worldwide (United Nations 2013). Since these goals were set, maternal death rates have declined globally by an estimated 47% - from 543,000 in 1990 to 287,000 in 2010 (WHO 2012). Estimated child mortality has also dropped - by 41%, from 87 deaths per 1000 live births in 1990 to 51 per 1000 live births in 2011 (United Nations 2013). Although this mortality is largely seen in low- and middle-income countries, high-income countries have also been challenged to improve the safety of maternal and neonatal health care. It appears to be even more difficult to reduce mortality rates when they are low, than when they are high (WHO 2012). A further decline in mortality rates needs a stronger focus on access to obstetric emergency care and the presence of skilled personnel (United Nations 2013).

Obstetric emergencies are pregnancy-related conditions that can threaten the well-being of mother and child in pregnancy or around birth. Such emergencies can happen at all times, marked by significant time pressure, high stakes decisions, and technical and ethical challenges associated with caring simultaneously for two patients (mother and child) (Daniels 2010). Provision of safe care in these situations requires the presence of skilled health per-

sonnel. In developing countries, this was only ensured in approximately 66% of births in 2011 (The World Bank 2014; United Nations 2013). Although professional attendance at birth is practically guaranteed in high-income countries, inappropriate management of obstetric emergencies can lead to maternal and neonatal mortality and serious morbidity (CEMACH 2004; CESDI 2001; Cantwell 2011). Both human as well as organisational factors are considered to be major sources for preventable, substandard care (Nance 2008). Similar substandard care is acknowledged in other medical specialties, including surgery and anaesthesiology. However, in obstetrics, it leads to the highest number of patient-driven clinical negligence claims (NHSLA 2012).

Description of the intervention

Simulation-based team training has been proposed to minimise substandard care by improving the overall quality of health care. The driving force for using team training to improve safety in health care originated in the 1999 Institute of Medicine report "To Err is Human" (Kohn 2000), that outlines the incidence and causes of preventable medical errors leading to substandard care.
Simulation-based training means to do something in the "as if", to resemble reality, to train or learn something without the risk of costs and patient safety of doing it in reality (Rall 2005). In this training, a variety of simulation tools are used as alternatives for real patients. Such training can be provided in a medical simulation centre or 'in-hospital'. In combination with deliberate practice, simulation turned out to be superior to traditional educational methods (McGaghie 2011b). The use of simulation in maternity care with phantoms, dates back to the 1600s (Gardner 2008). Nowadays, simulation-based medical education is considered to be a useful educational intervention to improve knowledge and attitudes of health personnel, and patient outcomes (Cook 2011; Issenberg 2005; McGaghie 2010; McGaghie 2011b).
One of the applications of simulation-based medical education is team training (Beaubien 2004; McGaghie 2010). In this case, simulation is used to educate multi-professional teams in clinical skills (technical skills), teamwork (non-technical skills), or both (Salas 2008). Teamwork is defined as those behaviours that facilitate effective team member interaction. It includes behaviours like communication, leadership, situational awareness and decision making (Beaubien 2004). In maternity care, the multi-professional teams consist of junior and senior medical staff, midwives and nurses. The goal of simulation-based team training is to improve team outcomes (i.e. cognitive, affective, process and performance), which, in turn, should result in better patient outcomes (Salas 2008).

How the intervention might work

Team training might prevent errors in two ways. Firstly, by the process of minimising error through education (Nance 2008). However, it is inevitable that humans make errors. Therefore, secondly, the intervention focuses on building a system that will anticipate errors that still occur. One method of doing that is by creating a fully communicative and mutually-supporting team that is focused on the common goal (Nance 2008). In this way, the system does not only expect errors, but is prepared to capture them before they can actually affect the patient (Nance 2008) Therefore, training should include the obstetric team in its entirety, instead of the individual healthcare worker (Kohn 2000; Reason 2000).
In several other sectors, e.g. aviation and the military, team training has already turned out to be a viable approach to enhance team outcomes (Salas 2008). It has also been applied in a variety of medical settings, with the aim of improving patient safety (Morey 2002; Neily 2010). In obstetrics, team training has been described as improving: dealing with fatigue, team building, communication, recognition of adverse events, decision-making and providing feedback (Grogan 2004). However, team training without simulation, was not sufficient to improve maternal and neonatal outcomes (Nielsen 2007). Nonetheless, team training combined with medical simulation appeared to be a useful educational method (McGaghie 2010; Shapiro 2004). Previous research showed that obstetric simulation-based team training was able to improve team performance and the application of essential medical skills (Fransen 2012). Besides, two studies, albeit cohort trials, suggested an improvement in maternal and neonatal outcomes, resulting from simulation-based obstetric team training (Draycott 2006; Phipps 2008). Therefore, it is appealing to think that introduction of simulation-based team training in obstetrics might improve maternal and neonatal safety.

Why it is important to do this review

Simulation-based obstetric team training, however, costs money and time. Even though, medical simulation is continuing to be implemented and evidence to support its potential role in improving patient safety is required. The authors of a previous systematic review concluded that introduction of simulation-based obstetric teamwork training with integrated obstetric skills training, might be potentially effective in the prevention of errors (Merién 2010). However, there was only one, retrospective, publication on patient outcomes included.
However, change in maternal and neonatal outcome requires a preceding change in health worker practice. To evaluate whether training can have this impact, Kirkpatrick's theory can be used (Kirkpatrick 1994). According to this theory, the first two levels of training evaluation will focus on trainees' experience and change in knowledge and skills in an educational setting. The following two levels consist of the downstream change in actual health workers' behaviour and maternal and perinatal outcome (McGaghie 2011a). The latter is labelled as the highest level of translational

science, which corresponds with the highest level of training evaluation according to Kirkpatrick's theory (Kirkpatrick 1994). The current review will discuss all levels of Kirkpatrick's theory in order to evaluate the effect of simulation-based, multi-professional, obstetric team training.

OBJECTIVES

The aim of the review is to evaluate whether simulation-based, multi-professional, obstetric team training results in change on the different levels of training evaluation. Change - in educational and real settings - of health workers performance (e.g. learning experience, knowledge, skills and team performance) and, especially, the impact on maternal and neonatal outcomes will be discussed.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCT) and cluster-RCTs. Since the presence of many possible concurrent health strengthening influences on patient outcome, quasi-randomised trials will be not be included. Cross-over studies will be excluded because of the expected long-term effect of training.

Types of participants

Obstetric, multi-professional teams, with qualified healthcare workers, including medical staff (junior and senior), midwives and nurses are eligible for inclusion. Depending on the country, anaesthesiologists and paediatrician can also participate. A team should have four attributes: two or more members, with assigned and clear roles, who perform interdependent tasks with a common goal (Nielsen 2008; Salas 1995). Teams consisting of non-qualified healthcare providers (e.g. medical students, student nurses) as well as mono-professional teams will be excluded.

Studies conducted in low-, middle- and high-income countries will be included. However, causes of substandard care might be different in high-income countries versus low- and middle-income countries. Subsequently, team training will probably have a different effect in both groups. For this reason, a subgroup analysis will be conducted to investigate the effect of the trial setting.

Types of interventions

We will include trials comparing simulation-based obstetric team training versus no training, or other training (e.g. traditional training, individual training). The criteria that determine whether a group of persons constitute a team, are discussed in Types of participants. Eligible studies are required to use simulation to educate multi-professional obstetric teams in skills, teamwork (non-technical skills), or both. For a subgroup analysis, we will include trials comparing different kinds of simulation-based obstetric team training (e.g. combination of skills and teamwork, solely teamwork or skills, CRM-training). Trials solely concerning individual simulation-based training or simulation-based team training in other medical fields will not be included. Trials about team training, without simulation will also be excluded.
Simulation training is defined as an artificial representation of a real world process to achieve educational goals through experiential learning (Rall 2005). It is characterised by the use of a wide variety of simulation tools that serve as an alternative for real patients. Training can be provided in a medical simulation centre or 'in-hospital'. Furthermore, obstetrical emergencies are defined as pregnancy-related conditions that can threaten the well-being of mother and child during pregnancy or around birth.

Types of outcome measures

Primary outcomes

Maternal and perinatal outcome:

- Mortality: maternal and perinatal mortality rate
- Morbidity: assessed by: e.g. number of admissions to intensive care of mother/child, Apgar score less than seven after five minutes, hypoxic-ischaemic encephalopathy, trauma due to shoulder dystocia

Performance of the obstetric team in practice (behaviour), identified by the following:

- Teamwork performance: e.g. communication, leadership, situational awareness (e.g. assessed by rating scale or checklist)
- Technical skills performance: e.g. applied skills, appropriate use of skills (e.g. assessed by rating scale or checklist)
- Process performance: e.g. time elapsed in emergency situation, adherence to guidelines (e.g. assessed by rating scale or checklist)

Secondary outcomes

Performance of the obstetric team in educational settings:

- Teamwork performance: e.g. communication, leadership, situational awareness(e.g. assessed by rating scale or checklist)
- Technical skills performance: e.g. applied skills, appropriate use of skills (e.g. assessed by rating scale or checklist)
- Knowledge: e.g. about obstetric emergencies, teamwork, technical skills (e.g. assessed by a written or oral test)

Experience (reaction): e.g. learning experience of trainees, satisfaction (e.g. assessed by a satisfaction questionnaire)

Search methods for identification of studies

Electronic searches

We will search the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator.
The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of Embase;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and Embase, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.
Trials identified through the searching activities described above are each assigned to a review topic. The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

Searching other resources

We will handsearch the proceedings of the International Meeting on Simulation in Healthcare (IMSH) from 2001 to current and the conference of the Society in Europe for Simulation Applied to Healthcare (SESAM) from 1994 to current. If these abstracts meet the inclusion criteria, we will contact the authors for further assessment of eligibility.
We will search the reference list of all retrieved studies. If data are missing, we will contact trial authors.
We will not apply any language restrictions.

Data collection and analysis

Selection of studies

Two review authors will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion or, if required, we will consult a third person.

Data extraction and management

We will design a form to extract data. For eligible studies, at least two review authors will extract the data using the agreed form. We will resolve discrepancies through discussion or, if required, we will consult a third person. We will enter data into Review Manager software (RevMan 2014) and check for accuracy.
When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreement by discussion or by involving a third assessor.

(1) Random sequence generation (checking for possible selection bias)

We will describe for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.We will assess the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or date of birth; hospital or clinic record number);
- or unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We will describe for each included study the method used to conceal allocation to interventions prior to assignment and will assess whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assessment.
We will assess the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);

- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We will describe for each included study the methods used, if any, to blind study participants from knowledge of which intervention a participant received. We will consider that studies are at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect results.
We will assess the methods as:

- low, high or unclear risk of bias for participants.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We will describe for each included study the methods used, if any, to blind outcome assessors from knowledge to which intervention group the patient belongs. We will assess blinding separately for different outcomes or classes of outcomes.
We will assess methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We will describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We will state whether attrition and exclusions were reported and the numbers included in the analysis at each stage, reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake.
We will assess methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups), a cut-off point of 20% for missing data will be used;
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found.
We will assess the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We will describe for each included study any important concerns we have about other possible sources of bias.
We will assess whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We will explore the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Measures of treatment effect

Dichotomous data

For dichotomous data, we will present results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

We will include cluster-randomised trials in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the *Handbook* using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.
We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Cross-over trials

We will exclude cross-over trials, as we expect a long-term and irreversible effect of training.

Other unit-of-analysis issues

How to deal with a possible unit-of-analysis issue in cluster-randomised trials is described above. As we will not include cross-over trials, unit-of-analysis issues concerning individuals who undergo more than one intervention, will be prevented.
We might include trials with more than two treatment groups. We will assess if the selected trials have a risk on unit-of-analysis error due to correlated intervention groups. To overcome this error we have chosen to use the recommended method; combining groups to create a single pair-wise comparison. In this method, all relevant experimental intervention groups of the study are combined in a single intervention group and all relevant control groups into a single control group. For dichotomous outcomes in these trials, we will sum both the sample sizes and the numbers of people with events across groups.

Dealing with missing data

For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis. We will not use any form of data imputation, since these assumptions can never reliably compensate for missing data (Unnebrink 2001).
For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and all participants will be analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.
To overcome the problem of trials with high risk of bias, in particular selection, attrition and reporting bias, we will exclude these trials in sensitivity analyses. In this way, we will be able to explore the impact of bias on the results.

Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if an I^2 is greater than 30% and either the T^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

If there are 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually, and use formal tests for funnel plot asymmetry. For continuous outcomes, we will use the test proposed by Egger 1997, and for dichotomous outcomes we will use the test proposed by Harbord 2006. If asymmetry is detected in any of these tests or is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2014). We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials' populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials is considered clinically meaningful. The random-effects summary will be treated as the average range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials.
If we use random-effects analyses, the results will be presented as the average treatment effect with 95% confidence intervals, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

If we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

Subgroup analyses will be performed on the primary outcome measures: maternal and neonatal outcome and behaviour of the obstetric team in practice. We plan to carry out the following subgroup analyses.

1. Context of training: low- and middle-income countries, high-income countries.
2. Type of team training: individual skills or teamwork, or both.
3. Duration of training: one day of training and more than one day of training.
4. Location of training: medical simulation centre or 'in-hospital' training.
5. Time point of assessing outcomes: until six months, one year after the intervention, and more than one year after the intervention.
6. Training design: with or without the principles of deliberate practice.

The following outcomes will be used in subgroup analysis.

- Maternal and perinatal outcome.
- Performance of the obstetric team in practice.

We will assess subgroup differences by interaction tests available within RevMan (RevMan 2014). We will report the results of subgroup analyses quoting the χ^2 statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

A sensitivity analyses will be performed for aspects of the review that might affect the results, for example, where there is risk of bias associated with the quality of some of the included trials. Only primary outcome measures will be included in the sensitivity analyses.

We will take the following forms of bias into account for carrying out sensitivity analyses: attrition, reporting and selection bias. We consider these forms of bias, as the ones with the greatest risk to cause an overestimation of treatment effects.

We will assess whether attrition and exclusions were reported, reasons for attrition were reported, and whether the missing data were balanced across groups or were related to outcomes. Trials in which description of attrition or exclusions is missing or unclear, or more than 20% of data are missing, will be excluded in the sensitivity analyses.

Reporting bias due to selective outcome reporting will be evaluated by assessing the presence of pre-specified outcomes in the results, whether presented data were pre-specified and whether including data about a key outcome is lacking. In case of high risk of reporting bias, trials will be excluded from sensitivity analyses.

Allocation concealment will be judged as adequate if allocation concealment is clearly described and an appropriate way of concealment is used, e.g. sequentially numbered, opaque, sealed envelopes and central randomisation. In the case of unclear or inadequate allocation, concealment trials will be excluded from the sensitivity analyses.

We will also carry out a sensitivity analysis to explore the effects of fixed-effect or random-effects analyses for outcomes with statistical heterogeneity and the effects of the value of the ICC used for cluster-randomised trials.

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As part of the pre-publication editorial process, this protocol has been commented on by four peers (an editor and three referees who are external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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* *Indicates the major publication for the study*

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DECLARATIONS OF INTEREST

None known.