“Het effect van teamtraining van alle betrokken verloskundige zorgverleners in een simulatiecentrum op perinatale sterfte in Nederland.”

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28428

Source
NTR

Health condition

Perinatal mortality in the Netherlands is relatively high compared to other countries in Europe. In the Netherlands, primary care (independent midwives) provides care to low risk pregnancies and secondary care (gynaecologists) takes care of high risk pregnancies. There are a lot of handovers between primary and secondary care. Dutch audits concluded that in this chain of obstetric care process management could be improved. Main causes of perinatal mortality (so called BIG4) are: preterm delivery, congenital anomaly, small for gestational age (SGA) and low Apgar score.
Obstetric team training improves perinatal outcome and teamperformance.
Keywords: multiprofessional, simulation-based obstetric team training, perinatal mortality
Keywords (dutch): multiprofessional simulatietraining verloskunde, perinatale sterfte

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

perinatal mortality and occurrence of BIG 4 disorders

Secondary outcome

team performance and satisfaction of patients and health providers

Study description

Background summary

Introduction: Perinatal mortality and morbidity in the Netherlands is relatively high compared to other countries in Europe. Our country has an unique system with an independent primary care providing care for low risk pregnancies and a secondary care for high risk pregnancies. Data showed that 85.2% of perinatal mortality is caused by one or more of the following disorders, the so called BIG 4: preterm delivery, small for gestational age, congenital anomaly and low Apgar score. Studies have shown that obstetric team training improves perinatal outcome and team performance.

Objectives: The aim of this study is to improve perinatal outcome by transmural multiprofessional simulation-based obstetric team training.

Methods: 4 hospitals will join the study. Each hospital with it’s referring primary care will form a cluster (study group). Within each cluster,teams will be formed by ambulance providers, maternity nurses, primary midwives, obstetric nurses, secondary care midwives, residents, and gynaecologists, The study will be implemented in the south-eastern part of the Netherlands (Zuidoost-Brabant) consisting of nearly one million inhabitants with an annual delivery rate of over 9,000. In this area around 120 independent midwives are providing primary care. Secondary care is provided by four hospitals. Training of the study groups will be provided in a medical simulation center. A stepped wedge trial design will be employed. A stepped wedge trial is a cluster randomized trial in which all study groups (clusters) receive the intervention by a sequential roll out of the trainings over a number of time periods. The stepped wedge design by default controls for changes over time since data are collected for each measurement period for all study groups and study groups serve as a period matched control. Computerized randomization will define the sequence of the study groups.

Outcomes: Primary outcome will be perinatal mortality and occurrence of BIG 4 disorders. Secondary outcome will be team performance and satisfaction of patients and health

providers.
Conclusion: The effect of transmural multiprofessional simulation-based obstetric team training has never been studied. We hypothesize that this team training will improve perinatal outcome, team performance and satisfaction of patients and care providers.

Study objective

Transmural multiprofessional simulation-based obstetric team training, regarding management of the BIG 4 causes of perinatal mortality will improve perinatal outcome, communication and teamwork and satisfaction of patients and care providers.

Study design

Taking into account the design effect, we need 565 deliveries per measurement period per cluster. To achieve this number we need 16 weeks for each period, adding up to a total study period of 82 weeks including a 16-week control period before the first training.

Intervention

multiprofessional, simulation-based obstetric team training

Contacts

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Eligibility criteria

Inclusion criteria

four hospitals will join the trial. Each hospital with surrounding primary care will form a cluster (study group). Within each cluster, teams will be formed by ambulance care providers, maternity nurses, primary midwives, obstetric nurses, secondary care midwives, residents, and gynaecologists.

Exclusion criteria

none specifically

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2014
Enrollment:	3390
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-05-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4453
NTR-old	NTR4576
Other	ZonMw : 2009020010

Study results