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Proof of principle study of the effect of individual and team drill on the ability of labour ward staff to manage acute obstetric emergencies

Submission date
29/08/2006

Recruitment status
No longer recruiting

Registration date
25/09/2006

Overall study status
Completed

Last Edited
07/03/2008

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0270030

Study information

Scientific Title

Acronym
SaFE study

Study objectives
The use of mock drills in simulation centres and labour wards (fire drills) has increased in response to issues of patient safety and the Clinical Negligence Scheme for Trusts (CNST) requirements. These provide opportunities for staff to practise emergency obstetric scenarios. However, there has been little evaluation of the effects of such training on individuals or obstetric teams. The Department of Health has funded this work, to establish proof of principle of the effect of individual and team drill training on the ability of labour ward staff to manage acute obstetric emergencies. The study evaluates training involving simulation centre and local in-house labour ward drills, so that future policies and studies can be based on the most promising methods.

The aim of this study is to evaluate the effect of individual and team drill for the management of acute obstetric emergencies. The specific research questions are:

1. Primary questions
a. Does the use of a high fidelity setting improve clinical skills in obstetric emergencies?
b. Does including team training in emergency drills improve clinical skills in dealing with obstetrics emergencies?

2. Secondary questions
a. Does team training in obstetric emergency drills improve team working?
b. Does the use of a high fidelity setting improve team working in obstetric emergencies?
c. Does team training in emergency drills improve knowledge in obstetric emergencies?
d. Does the use of a high fidelity setting improve knowledge in obstetric emergencies?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southwest Devon Medical Research Ethics Committee (reference number: 04/Q2103/68), approval gained on September 2004.

Study design
Phase II exploratory trial within the format of a factorial 2 x 2 randomised trial.

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute obstetric emergencies

Interventions
Phase II exploratory trial of two aspects of the training intervention, high versus low fidelity and team training versus no team training, will be assessed within the format of a factorial 2 x 2 randomised trial.

The participants will be randomly allocated to one of the four training interventions.
Group A1: One day obstetric emergency training course. This will be within the low fidelity setting in the local participating hospitals and will exclude specific team training.
Group B1: One day obstetric emergency training course. This will be within the high fidelity setting of the Bristol Medical Simulation Centre and will exclude specific team training.
Group A2: Two day obstetric emergency training course. This will be within the low fidelity setting of the local participating hospitals and will include specific team training.
Group B2: Two day obstetric emergency training course. This will be within the high fidelity setting of the Bristol Medical Simulation Centre and will include specific team training.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
1. Global rating scores of individual clinical skills
2. Time taken to execute procedures
3. Number of actions, omissions and inappropriate actions

Secondary outcome measures
1. Knowledge assessed by a multiple choice questionnaire
2. Applied delivery force in shoulder dystocia skill station
3. Communication - as assessed by a content analysis of a sub sample of skill stations
4. Global rating scores of teamwork behaviours on a sub sample of skill stations

Overall study start date
01/11/2004

Completion date
01/11/2006

Eligibility

Key inclusion criteria
All hospital and community midwives and obstetric medical staff (junior and senior) who provide care to mothers and babies are eligible to enter the study.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
144

Key exclusion criteria
Staff who have attended addition accredited training course in the management of obstetric emergencies (Advanced Life Support in Obstetrics [ALSO], Managing Obstetric Emergencies and Trauma [MOET], South West Obstetric Emergency Course) within the past 12 months will be excluded from the study, and also:
1. Staff who have taken part in the Simulation and Fire drill Evaluation study (SaFE) pilot study
2. Staff involved in the delivery of the training interventions
3. Local staff involved in assisting the research team
4. Staff currently on maternity leave or long term sick leave

Date of first enrolment
01/11/2004

Date of final enrolment
01/11/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Michael's Hospital
Bristol
United Kingdom
BS2 8UG

Sponsor information

Organisation
United Bristol Healthcare Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
The trial is funded by Policy Research Programme of the Department of Health as part of the Patient Safety Research Portfolio (PSRP) (reference number: 0270030).

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/03/2008		Yes	No