

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	<input type="checkbox"/> Prospectively registered
Registration date 25/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/03/2008	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Bryony Strachan

Contact details

St Michael's Hospital
Southwell Street
Bristol
United Kingdom
BS2 8UG
+44 (0) 117 9285594
bryony.strachan@ubht.nhs.uk

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)

Sponsor details

Research and Effectiveness Department
Marlborough Street
Bristol
England
United Kingdom
BS1 3NU
+44 (0) 117 923 0000
maria.palmer@ubht.nhs.uk

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