

Trial of Hands-on Interprofessional Simulation Training for Local Emergencies

Submission date 30/07/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/09/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/06/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Safety in labour is a priority for women, their families, staff and the NHS, but unfortunately UK maternity care is not as safe as it could and should be. Over 50% of adverse pregnancy outcomes in the UK could be prevented with better care during childbirth (intrapartum care). These failings have significant impact on both families and the NHS. Training for emergencies during childbirth has been recommended almost annually since 1999. A local, multi-professional and inexpensive intrapartum emergencies training course was developed in Bristol, where its implementation was associated with sustained local improvements in a number of clinically important outcomes. The aim of this study is to determine if a multi-professional training programme for local maternity staff (PROMPT) is clinically effective across a health service.

Who can participate?

The study population consists of the 15 Scottish maternity units with more than 1000 births per year

What does the study involve?

The study is a training programme for intrapartum emergencies. It provides the tools for designated in-house trainers to give multi-professional training for intrapartum emergencies for all maternity workers in their own units. Participating units will identify four multi-professional in-house trainers (two midwives, one obstetrician and one anaesthetist) to attend the two-day PROMPT Train-the-Trainers (T3), which comprises a demonstration PROMPT Course and a Train-the-Trainers (T3) day (lectures and workshops for electronic monitoring of the unborn baby and simulated emergency scenarios) to guide in-house trainers in how to set up training in their local unit. Telephone and email support is also provided by the PROMPT team to each participating unit after attending their T3 training. After participating in the two-day PROMPT T3 programme, in-house trainers will be given time to set up and start the in-house PROMPT courses locally. They should aim to have trained all maternity staff in their unit within a year of starting training.

What are the possible benefits and risks of participating?

This intervention programme can improve compliance with clinical standards and lead to a reduction in clinical errors. The researchers do not believe there are any disadvantages or risks to participating in this study.

Where is the study run from?

University of Aberdeen in collaboration with PROMPT Maternity Foundation, Bristol (UK)

When is the study starting and how long is it expected to run for?

August 2023 to December 2024

Who is funding the study?

Chief Scientist Office (UK)

Who is the main contact?

The co-ordinating trial office - Centre for Healthcare Randomised Trials
chart@abdn.ac.uk

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

134679

Protocol serial number

CZH/4/893, IRAS 134679

Study information

Scientific Title

Trial of Hands-on Interprofessional Simulation Training for Local Emergencies: a stepped-wedge clustered randomised controlled trial

Acronym

THISTLE

Study objectives

Does the implementation of an intrapartum emergencies training package across a health service reduce the rate of Apgar <7 at 5 minutes, in term babies (excluding elective caesarean births)?

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 13/08/2013, North of Scotland, Committee 1 (Summerfield House, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 13/NS/0111

Study design

Stepped-wedge clustered randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Perinatal outcomes

Interventions

The intervention is the 2 day PROMPT Train the Trainers (T3) programme; including a demonstration PROMPT course, a Train-The-Trainers (T3) day and local use of the PROMPT Course-in-a-box (Second edition). Four multi-professional in-house trainers from each unit will undertake the 2 day PROMPT T3 programme and then run in-house PROMPT courses locally for all maternity staff in their unit.

The 2 day PROMPT T3 programme will be performed in collaboration with Scottish Core Obstetric Teaching and Training in Emergencies (SCOTTIE).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Proportion of infants born with a low Apgar score (score < 7 vs. ≥ 7) at 5 minutes for each vaginal or emergency CS term birth (≥ 37 weeks).

Key secondary outcome(s)

1. Descriptive data from the units will be collated:
 - 1.1. Total number of births per annum

- 1.2. Total number of staff in the unit separated into staff groups
- 1.3. Total number of staff trained separated into staff groups
2. Process measures: % of staff trained and time to train local staff.

Completion date

31/12/2024

Eligibility

Key inclusion criteria

The study population will consist of the 15 Scottish maternity units with more than 1000 births per year. Participating units which have not previously undertaken PROMPT training (n=12) will be randomised and be part of the main analysis.

The three units which have already undertaken PROMPT training will not be randomised but will be included in complementary analyses. Their inclusion will allow us to assess the intervention effect at country scale, whilst giving us insight into the long-term sustainability of the intervention effect.

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

15

Key exclusion criteria

Scottish maternity units or midwifery units with less than 1000 births per year are ineligible for recruitment

Date of first enrolment

01/08/2013

Date of final enrolment

31/08/2016

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
University of Aberdeen
ABERDEEN
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

ROR
<https://ror.org/016476m91>

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office - CZH/4/893

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		13/07/2019	19/06/2024	Yes	No
Protocol article	protocol	07/09/2017		Yes	No