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Trial of Hands-on Interprofessional Simulation Training for Local Emergencies

Submission date
30/07/2013

Recruitment status
No longer recruiting

Registration date
09/09/2013

Overall study status
Completed

Last Edited
25/06/2024

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
134679

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Secondary outcome measures
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.

Overall study start date
01/08/2013

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

Age group
Adult

Sex
Both

Target number of participants
15 Scottish maternity units

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
Scotland

United Kingdom

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

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Research and Innovation
Kings College
Regent Walk
Aberdeen
Scotland
United Kingdom
AB24 3FX

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/06/2025

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