ISRCTN01805825 https://doi.org/10.1186/ISRCTN01805825

The effect of participatory womens groups on birth outcomes in Bangladesh: does coverage matter?

Submission date
28/04/2011

Recruitment status
No longer recruiting

Registration date
15/06/2011

Overall study status
Completed

Last Edited
22/05/2013

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] 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
1VTP/07CH05

Study information

Scientific Title
The effect of participatory womens groups on birth outcomes in Bangladesh: does coverage matter? A cluster randomised controlled trial

Acronym
Perinatal Care Project (PCP) Diabetic Association of Bangladesh (BADAS)

Study objectives
We hypothesise that the intervention will lead to a 30% lower neonatal mortality in intervention clusters compared with control clusters, during the last 24 months of the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. UCL Research Ethics Committee approved in March 2008; annually reviewed (ref:ID number: 1488/001)
2. Diabetic Association of Bangladesh Ethical Review Committee approved on 7th July 2010 (but approval was granted before the start of the trial, as part of our ongoing women's group work that had started in 2005)

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Maternal and Child Health

Interventions
The intervention is a participatory learning action cycle with womens groups. In each intervention cluster, facilitators convene womens groups that meet on a monthly basis. The participatory learning and action cycle has 4 phases: First, the groups identify and prioritise health problems, then plan strategies to address these problems, subsequently they put these strategies into practice, and finally, they evaluate their strategies.

As we aim to study the effect of an intervention with a high coverage of womens groups in the population, 648 new groups were formed by newly recruited facilitators and started to meet from January 2009 onwards, in addition to the 162 womens groups that were already set up in the intervention areas as part of an earlier trial in the same study area. These old groups have continued to meet on a monthly basis from late 2004 onwards. The 648 new groups will go through a cycle of monthly meetings on maternal and newborn health (Cycle 1), while from April 2010 the 162 old groups will proceed to a cycle of meetings on under-5 and womens health (Cycle 2), while periodically continuing to review maternal and newborn health issues. The combined 810 womens groups constitute a coverage of 1 group per 300 population, in comparison with 1 group per 1414 population in the previous trial.

The role of the facilitator is to activate and strengthen groups, support them in identifying problems, help to plan possible solutions and support the implementation and monitoring of solution strategies in the community. Although this role requires a grasp of health issues and some knowledge of potential interventions, she needs to be a facilitator rather than a teacher. As such, the facilitator may act as a broker of information and communication but her prime importance is as a catalyst for community mobilisation.

All clusters, control and intervention, receive health system strengthening activities.

Patient information sheets are not used because this was a community trial of a social intervention (i.e. not a clinical trial). The intervention consists of women's groups that discuss and design their own strategies to improve newborn and maternal health. All the women in these women's groups participate voluntarily. At the start of the women's groups, there was extensive discussion of what the aims and structure of the women's groups are. By voluntarily joining a women's group, the participants consent to the intervention (i.e. women's groups). Oral consent was obtained from the respondents in the monitoring and surveillance interviews.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Neonatal mortality (deaths in the first 28 complete days after birth per 1,000 live births), during the last 24 months of the study.

Secondary outcome measures
1. Early and late neonatal mortality rate
2. Stillbirth rate
3. Pregnancy-related mortality ratio and maternal mortality ratio
4. Health care use
5. Home care practices

Overall study start date
01/01/2009

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Women, living in the study area, who are permanent residents in the union in which their delivery or their death was identified.
2. Women and their newborn infants are included after birth, or, if a woman dies during pregnancy, after her death.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
16,000 births to women using the above in/exclusion criteria, during the last 24 months of the trial, in the combined 18 study clusters.

Key exclusion criteria
1. Women who are temporary residents in the union in which their delivery or death was identified
2. Women who decline to be interviewed
3. Women who reside outside the study area

Date of first enrolment
01/01/2009

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Bangladesh

England

United Kingdom

Study participating centre
UCL Institute of Child Health
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Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

Website
http://www.ucl.ac.uk/cihd/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Big Lottery Fund Strategic Grant (UK) IS/2/010281409

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?
Protocol article	protocol	26/09/2011		Yes	No
Other publications	coverage estimates	29/06/2012		Yes	No
Results article	results	01/09/2013		Yes	No