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Facilitated participatory and action groups to improve maternal and newborn health at scale in Jharkhand, India

Submission date
01/12/2018

Recruitment status
No longer recruiting

Registration date
13/02/2019

Overall study status
Completed

Last Edited
05/11/2021

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
In rural areas of eastern India, many women die during pregnancy, during or after birth, and many children die during the first month of life. The aim of this study is to find out whether a participatory intervention with women's groups discussing and resolving common problems in pregnancy, childbirth and the postnatal period could reduce deaths during the first month of life and improve maternal and newborn health practices in three districts of Jharkhand, a state in Eastern India. The groups are facilitated by workers incentivized by government.

Who can take part?
All mothers living in the study areas and who have been pregnant or delivered an infant during the study period

What does the study involve?
The number of deaths among infants aged 0-28 days and maternal and newborn health practices are compared among mothers living in areas who receive the intervention early (in 2017) to those in an area that receive it later (in 2019). The intervention being evaluated is a cycle of women's group meetings to improve maternal and newborn health. Groups usually have around 20 members. Meetings are open to all community members but facilitators and members deliberately seek to attract pregnant women and new mothers. The participatory learning and action cycle consists of around 20 meetings divided into four phases. In the first phase, groups identify and prioritise problems commonly faced by women during pregnancy and the postnatal period. In the second phase, they analyse the immediate and underlying causes of their prioritised problems, then identify and prioritise locally feasible strategies to address these. In the third phase the groups implement their strategies, and in the fourth phase they evaluate the process. The intervention seeks to improve birth outcomes (reduce neonatal deaths, maternal deaths, perinatal deaths and stillbirths) by increasing the use of preventive practices at home, and appropriate care-seeking.

What are the possible benefits and risks of participating?
There are no risks and no immediate benefits of participation.

Where is the study run from?
The study is run by Ekjut (India) and University College London's Institute for Global Health (UK)

When is the study starting and how long is it expected to run for?
December 2015 to August 2020

Who is funding the study?
The Children's Investment Fund Foundation (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1881/003

Study information

Scientific Title
Facilitated participatory and action groups to improve maternal and newborn health at scale in Jharkhand, India: a prospective, controlled, non-randomised evaluation

Acronym

FLAG (Facilitated Learning Action Groups)

Study objectives
The trialists hypothesise that a community intervention involving government-incentivised Accredited Social Health Activists facilitating participatory learning and action meetings with women's groups over two years will reduce neonatal mortality and improve maternal and newborn health practices in six districts of Jharkhand. Specifically, the trialists hypothesise that the intervention will reduce neonatal mortality by 20% in the general population and 30% among the most socio-economically deprived. They also hypothesise that the intervention will improve home care and care-seeking practices for pregnant women and newborn by 5-10%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Independent ethics committee in Ranchi (Jharkhand), 19/08/2016
2. University College London Research Ethics Committee, 24/11/2016, ref: 1881/003

Study design
Prospective non-randomised controlled intervention study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Neonatal mortality; maternal and newborn health

Interventions
The intervention team is not masked to allocation. The data collection team and analyses are masked to allocation. This is evaluation is led at two centres: Ekjut (India) and University College London (UK).

The intervention’s impact will be assessed using a non-randomised controlled design in six districts purposively selected with the Jharkhand State Health Mission. The districts were allocated to receiving the intervention early or being waitlisted to start later on the basis of government scale up plans. Within these six districts, the trialists have purposively select 20 blocks, and five data collection clusters of around 10,000 population each per block. They have sought cluster-level consent from village leaders to collect data in their areas and created 100 data collection clusters of around 10,000 population each. Three districts will receive the intervention in 2017, while the remaining three will begin in in 2019. This allocation has been

decided purposively by the National Health Mission and is therefore non-random. The delayed intervention area clusters will serve as control clusters in the evaluation period of 2017-2019. The trialists will collect quantitative data in our 100 surveillance clusters from 1st March 2017 until the 31st of August 2017 for the baseline period (6 months), and then from the 1st September 2017 till 31st August 2019 for the evaluation period (24 months).

The intervention being evaluated is a cycle of women's group meetings using a facilitated participatory learning and action approach to improve maternal and newborn health. Groups usually have around 20 members. Meetings are open to all community members but facilitators and members deliberately seek to attract pregnant women and new mothers. The participatory learning and action cycle consists of around 20 meetings divided into four phases. In the first phase, groups identify and prioritise problems commonly faced by women during pregnancy and the postnatal period. In the second phase, they analyse the immediate and underlying causes of their prioritised problems, then identify and prioritise locally feasible strategies to address these. In the third phase the groups implement their strategies, and in the fourth phase they evaluate the process. The intervention seeks to improve birth outcomes (reduce neonatal deaths, maternal deaths, perinatal deaths and stillbirths) by increasing the use of preventive practices at home, and appropriate care-seeking.

The intervention was introduced in three 'early' districts in 2017, and will be introduced in another three districts in 2019.

Intervention Type
Behavioural

Primary outcome measure
Neonatal mortality measured via a questionnaire survey for all women who gave birth in the study areas during the study period (1st March 2017-30th August 2017 for the baseline period, and 1st September 2017-30th August 2019 for the evaluation period)

Secondary outcome measures
All secondary outcomes are measured via a questionnaire survey for all women who gave birth in the study areas between 1st March 2017 and 30th August 2019. They include:
1. Stillbirth rate (per 1000 births)
2. Perinatal deaths (per 1000 births)
3. Neonatal mortality among mothers in the most socio-economically deprived, defined as mothers belonging to the two poorest wealth quintiles and who cannot read
4. Maternal deaths
5, % Mothers who received three ANC consultations by a skilled provider
6. % Mothers who made plans for birth (transport, location, money) in pregnancy
7. % Mothers who sought skilled care for a problem in pregnancy
8. % Births with a skilled attendant
9. % Births in a health facility
10. % Home births where a clean delivery kit was used
11. % Infants wiped within 30 mins of birth
12. % Infants wrapped within 30 mins of birth
13. % Infants not given a bath in 1st 24 hours
14. % Infants given breastmilk within one hour
15. % Infants exclusively breastfed

16. % Mothers visited by ASHA three times in the first week
17. % Infants for whom skilled care is sought for a newborn health problems
18. % Mothers who receive a postpartum check-up from a skilled provider

Overall study start date
01/12/2015

Completion date
30/08/2020

Eligibility

Key inclusion criteria
Two types of respondents will be eligible to participate in the questionnaire survey that will be administered in the study area:
1. Women aged 15 and above residing in the study area and who have delivered an infant, or experienced a stillbirth or neonatal death between the 1st March 2017 and 30th August 2019
2. Relatives of women who have died as a result of complications of pregnancy and childbirth (maternal deaths) during the study period

Participant type(s)
All

Age group
Mixed

Sex
Female

Target number of participants
50,000

Total final enrolment
48589

Key exclusion criteria
Women who are not found within 120 days of being identified as having delivered an infant, and are therefore considered migrated

Date of first enrolment
01/03/2017

Date of final enrolment
30/08/2019

Locations

Countries of recruitment
England

India

United Kingdom

Study participating centre
Ekjut
1A, Ashok Nagar Ranchi
Ranchi
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Study participating centre
Institute for Global Health - University College London
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Funder(s)

Funder type
Charity

Funder Name
Children's Investment Fund Foundation

Alternative Name(s)
CIFF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 04/02/2020:
The study protocol has been registered with RIDIE: https://ridie.3ieimpact.org/index.php?r=search/detailView&id=542 . This registration includes the study protocol. The data analysis plan is included with this registration.

The trialists plan to disseminate results of the baseline study (i.e. the first 6 months of data collection) to policy-makers through training events and at National Health Mission review meetings in Jharkhand. The data will be anonymised (it will not identify the villages or study participants).

At the end of the evaluation, the trialists will organise community-level dissemination meetings using 'traffic light signs' to show which preventive and care-seeking practices have improved, and which have not, and graphs to show trends in mortality. They also intend to produce at least two open access publications:
1. The impact of the intervention on preventive and care-seeking practices, neonatal deaths and maternal deaths
2. Impact of the intervention among the most socioeconomically deprived households

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

Previous publication and dissemination plan:
The study protocol has been registered with RIDIE: RIDIE-STUDY-ID-595f13a090784: http://ridie.3ieimpact.org/index.php?r=search/detailView&id=542. This registration includes the study protocol and will soon include the data analysis plan (to be submitted by end of February 2019).

The trialists plan to disseminate results of the baseline study (i.e. the first six months of data collection) to policy-makers through training events and at National Health Mission review meetings in Jharkhand. The data will be anonymised (it will not identify the villages or study participants).

At the end of the evaluation, the trialists will organise community-level dissemination meetings using 'traffic light signs' to show which preventive and care-seeking practices have improved, and which have not, and graphs to show trends in mortality. They also intend to produce at least two open access publications:
1. The impact of the intervention on preventive and care-seeking practices, neonatal deaths and maternal deaths
2. Impact of the intervention among the most socioeconomically deprived households

IPD sharing statement
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version v1.5	20/01/2020	04/02/2020	No	No
Results article		03/11/2021	05/11/2021	Yes	No