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Implementing knowledge into practice for improved neonatal survival: a community-based trial in Quang Ninh province, Vietnam

Submission date	Recruitment status	[_] Prospectively registered
07/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2019	Neonatal Diseases	

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
N/A

Study information

Scientific Title
Implementing knowledge into practice for improved neonatal survival: a cluster-randomised, community-based trial in Quang Ninh province, Vietnam

Acronym
NeoKIP

Study objectives
The overall objective of this project is to evaluate if facilitation on the community level results in effective improvement of perinatal health and survival. Specifically, we hypothesise:
1. That a cluster-randomised intervention using a facilitation approach targeting primary health care staff and key community members reduces the risk for neonatal death, and
2. That the facilitation intervention will result in increased knowledge and use of evidence-based practice related to maternal and perinatal health among health care staff in intervention as compared to the control clusters

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Ministry of Health (Vietnam), 12/10/2007, ref: 3934/QD-BYT
2. The Provincial Health Bureau in Quang Ninh (Vietnam)
3. The Research Ethics Committee at Uppsala University (Sweden), 25/01/2006, ref: 2005:319

Study design
Single-centre cluster-randomised population-based community intervention trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Neonatal health and survival

Interventions

The facilitation intervention targets CHC staff and key persons at the community level. Each CHC is accountable for the health care in the community, including all villages. For each village the CHC has one Village Health Worker (VHW) who is responsible for the basic health care. At each CHC, there are 3 - 6 staff working, of whom a midwife or a medical doctor provides perinatal care. Key persons in the community are the vice chairman and the Women Union leader, who both are in decision-making positions. The basic feature of the study intervention is that individuals from the Women Union are acting as facilitators in supporting CHC staff and key persons in their efforts to improve health care practice. Individuals from local Women Union organisations have been recruited and trained for one week to be able to act as facilitators. A locally recruited person act as supervisor of the facilitators; i.e., supporting the facilitators, assisting and coordinating in the facilitation process, and report back to the research team.

A facilitation manual was developed to guide the work of the facilitators. Each facilitator operates within the same communities for the whole intervention period and meet with each community group monthly. Such a group, called the Maternal-Newborn-Health-Group (MNHG), normally consists of three CHC staff, a village health worker, the vice chairman in the community and two women union representatives (community and village level). The facilitator uses a problem solving, participatory and enabling approach (instead of prescribing and directing a set of actions). Basing the discussions on individual and common experiences, the facilitator support critical reflection, problem identification, finding solutions, setting up and accomplish change strategies, using the PLAN-DO-STUDY-ACT cycle. This intervention implies a strong local ownership and 'bottom-up' approach in empowering health care staff to improve practice. As an ingredient in the facilitation strategy, the recommendations in the National Guidelines are highlighted. Practically the work process entails the development of an action plan at one meeting to be fully or partial implemented until next meeting, where the process proceeds.

The unit of intervention (and thus randomisation) is the community with its Community Health Centre, and will be proportional to the number of deliveries in the communities. Approximately 44 communities will be allocated to the intervention arm of the study.

Controls are communities without intervention.

The total duration of the intervention will be two years. Follow-up will be done three years after the end of intervention.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Neonatal mortality, measured one year after intervention start and at the end of intervention (two years)

Secondary outcome measures
1. Effects on home visits by midwifes
2. Exclusive breast-feeding
3. Temperature control

4. Knowledge among health staff
5. Care-seeking behaviour
6. Other indicators for neonatal health

Outcomes will be measured one year after intervention start and at the end of intervention (two years).

Overall study start date
02/06/2008

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Districts in Quang Ninh province in Northern Vietnam with a neonatal mortality rate (NMR) higher than 15/1000 have been selected for the intervention, resulting in a study involving eight districts composed by 87 communities with a corresponding community health centre (CHC). In 2005 there were 6227 births and 150 neonatal deaths in these districts resulting in a NMR of 24 /1000.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
300000

Key exclusion criteria
Districts in Quang Ninh province with a NMR less than 15/1000 were excluded.

Date of first enrolment
02/06/2008

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Sweden

Viet Nam

Study participating centre
University Hospital
Uppsala
Sweden
75185

Sponsor information

Organisation
Swedish Agency for International Development Cooperation (Sida)/Department for Research Cooperation (SAREC) (Sweden)

Sponsor details
Valhallavägen 199
Stockholm
Sweden
10525

Sponsor type
Government

Website
http://www.sida.se

ROR
https://ror.org/01fn7me06

Funder(s)

Funder type
Government

Funder Name
Swedish Agency for International Development Cooperation (Sida)/Department for Research Cooperation (SAREC) (Sweden)

Funder Name
Uppsala Universitet

Alternative Name(s)

Uppsala University, UU_University, Uppsala Universitet, Sweden, UU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

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	28/03/2008		Yes	No
Results article	results	01/03/2011		Yes	No
Other publications	study design	27/09/2011		Yes	No
Results article	results	01/04/2012		Yes	No
Results article	results	01/12/2012		Yes	No
Results article	results	01/12/2013		Yes	No
Results article	results	29/12/2015		Yes	No
Results article	results	13/01/2016		Yes	No
Results article	results	01/09/2018	18/12/2019	Yes	No