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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
07/05/2008		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

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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).

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

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

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
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
Other publications	study design	27/09/2011	Yes	No
Participant information sh	eet Participant information s	heet 11/11/2025	11/11/2025 No	Yes